



D5.4 – Independent Report on the performance of ICSTEST on European 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 or 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 Europe 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 Europe.

2. RELATION WITH OTHER WPS AND DELIVERABLES

This deliverable is closely related with D5.5 (Independent report on the performance of Ice Cream on Latam 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 and ADHD field. At this point, we mainly focused on France, Germany and Italy, since they are really interesting countries for us for business reasons. These unsuccessful contacts are shown in table 1.

We have also contacted with **AMEN, Older adults home** in Cyprus which also has a Day Care Centre for Dementia patients and offers a range of rehabilitation services. They are also one of the members of the CAPTAIN project (<https://www.captain-eu.org/>), which aims to develop friendly and usable interfaces for smart technologies to help elder people to maintain their autonomy.

Currently we are close to sign a collaboration agreement with them. The objective of this agreement is to developed and study with 30 adults from 60 to 75 years old with Mild Cognitive Impairment (MCI) diagnosis and 30 adults from 60 to 75 years old without cognitive impairment.

The aim of the 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 test widely used in the evaluation and diagnosis of MCI) 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 usefulness of our norms to be applied in Cyprus population.

Collaborator's description: Oviedo University is a public university placed at Asturias, Spain which counts with 25.601 students. Dr. Celestino Rodríguez is head of the research group of scholar learning impairments and academic performance of the Psychology Department. He has wide expertise on the research of learning disabilities, as well as ADHD or Autism spectrum disorder, and he has work with many technological innovative tools in different projects. The collaborator agreement signed with this collaborator can be found in Annex 1 in this deliverable.

Location: Oviedo (Spain)

Sample's commitment: 50 young adults from 16 to 23 years old.

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

- **CANTAB® [Cognitive assessment software]:** CANTAB test are widely used in the research field, and their tasks have proven sensitivity in the diagnosis of many mental conditions. It is a neuropsychological battery with different task which run in an iPad. For this study, a battery aiming to assess executive functions has been designed. The battery specifically developed for this study consists on the following tests:
 - CANTAB - Paired Associates Learning
 - CANTAB - Spatial Working Memory
 - CANTAB - One Touch Stockings of Cambridge

- o CANTAB - Spatial Span
- o CANTAB - Rapid Visual Información Processing

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

The sample goals for this collaborator have been established according to the data estimation for the normative study of Nesplora Ice Cream:

Age	Age N	Gender	Gender N	Education Level	EL N
16-19	19	Female	9	Low	6
				Medium	3
				High	0
		Male	10	Low	7
				Medium	2
				High	0
20-24	26	Female	13	Low	3
				Medium	7
				High	3
		Male	13	Low	4
				Medium	7
				High	2

Objectives of the study:

The aim of this study is to test convergent validity between Nesplora Ice Cream and the CANTAB executive functions tasks in non pathologic population. 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. This study also aims to complete the normative sample of Nesplora Ice Cream for the age ranges between 16 to 24 years old, as specified in D4.1.

For the study each participant is participating in two sessions of approximately 1.5 hours each. In the first session, the Nesplora tests (Ice

Cream and Suite) will be administered in a counterbalanced manner, to avoid fatigue effects. In the second session, the CANTAB tests will be administered.

Next steps:

After receiving the data at the end of March, we will perform Spearman correlation analysis between Ice Cream scores and the ones from the CANTAB battery. The results will be disseminated in congress publications.

3.2 University Francisco de Vitoria

Collaborator's description: University Francisco de Vitoria is a private University placed at Pozuelo de Alarcon, Madrid. According to a study of the Industrial and Financial Analysis Institute (IAIF), this institution is ranked the 4th private university in teaching quality in Spain. The collaborator agreement signed with this collaborator can be found in Annex 2 in this deliverable.

María García Arias is neuropsychologist and she is director of the Orientation and Education Research group.

Location: Madrid (Spain)

Sample's commitment: 50 young adults from 16 to 23 years old.

Sociodemographic 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.

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.

- **WAIS-IV:** is an Intelligence Quotient (IQ) test designed to measure intelligence and cognitive ability in adults and older adolescents. [1] The original WAIS (Form I) was published in February 1955 by David Wechsler, as a revision of the Wechsler-Bellevue Intelligence Scale, released in 1939. [2] It is currently in its fourth edition (WAIS-IV) released in 2008 by Pearson, and is the most widely used IQ test, for both adults and older adolescents, in the world.

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 convergent validity between Nesplora Ice Cream and the WISC-IV test in non pathologic population. 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. This study also aims to complete the normative sample of Nesplora Ice Cream for the age ranges between 16 to 24 years old.

Next steps:

After receiving the data at the end of June, we will perform Spearman correlation analysis between Ice Cream scores and the ones from the WISC-IV. The results will be disseminated in congress publications.

3.3 Dr. José Camacho Conde Psychology Clinic

Collaborator's description: José Antonio Camacho is Psychologist and Ph.D. in Neuroscience by the University of Granada. He's psychotherapy European specialist. He's also specialist on Clinical Neuropsychology and has expertise in cognitive rehabilitation and ADHD intervention. The collaborator agreement signed with this collaborator can be found in Annex 3 in this deliverable.

Location: Algeciras (Spain)

Sample's commitment: 20 young adults from 16 to 18 years old.

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.
- **CEFI:** The Comprehensive Executive Function Inventory™ (CEFI®) is a comprehensive behavior rating scale of executive function strengths and weaknesses in children and youth aged 5 to 18 years. Executive function is important for problem solving and reasoning, and difficulties with executive function can often make simple tasks challenging. Assessing a child or adolescent's executive function is an important step to formulate a diagnosis and treatment plan.

Descriptive 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.

Objectives of the study:

The aim of this study is to test the effect of Mindfulness intervention on the Executive Functions (EEFF). Participants will be assessed with Nesplora Ice Cream and the CEFI test before and after a 2 weeks Mindfulness program to test if this intervention generates changes in the EEFF of the participants.

Next steps:

After receiving the data at the end of July, we will perform Mann-Whitney U test in order to analyse differences between pre and post treatment measures. Results will be disseminated in congress publications.

3.4 Psicotogether

Collaborator's description: Psicotogether is the Psychopedagogy Unit of La Paloma Hospital, the center works with learning disabilities helping the patients to acquire the necessary tools to face the challenges and needs that studies and their own lives present to them. Dr. Zaira Santana Amador has a Humanities Phd by the International University of Catalonia, a Master degree in educational processes and she's psycho-pedagogist. The collaborator agreement signed with this collaborator can be found in Annex 4 in this deliverable.

Location: Las Palmas de Gran Canaria (Spain).

Sample's commitment: 25 young adults from 16 to 50 years old.

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 habilities, 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.

- **CANTAB® [Cognitive assessment software]:** CANTAB test are widely used in the research field, and their tasks have proven sensitivity in the diagnosis of many mental conditions. It is a neuropsychological battery with different task which run in an iPad. For this study, a battery aiming to assess executive functions has been designed. The battery specifically developed for this study consists on the following tests:
 - CANTAB - Paired Associates Learning
 - CANTAB - Spatial Working Memory
 - CANTAB - One Touch Stockings of Cambridge
 - CANTAB - Spatial Span

- o CANTAB - Rapid Visual Información Processing

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

Objectives of the study:

The aim of this study is to test convergent validity between Nesplora Ice Cream and the CANTAB executive functions tasks in non pathologic population. Specifically, the objective of this study is to compare the discriminant value of the executive function variables provided by the CANTAB test with the Ice Cream test.

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. This study also aims to complete the normative sample of Nesplora Ice Cream for the age ranges between 16 to 24 years old.

Next steps:

After receiving the data on December, we will perform Spearman correlation analysis between Ice Cream scores and the ones from the CANTAB battery. Since this study has a protocol similar to the study carried out by the collaborator University of Oviedo (section 3.1 of this deliverable), the data from both studies will be gathered so that the study of Psychotogether represents the clinical group of the study and that of the University of Oviedo has the participants of the control group of said study. The results will be disseminated in congress publications.

3.5 Andalusian Institute of Pediatric Neurology (INANP).

Collaborator's description: The INANP is a private medical center in Sevilla. They provide medical attention to kids and teenagers with neurodevelopmental issues as well as high IQ children. Manuel Fernández is Neuropediatrician and he works with a multidisciplinary team to provide an integral intervention for each case. He's one of the earliest adopters of the Nesplora's assessment systems. The collaborator agreement signed with this collaborator can be found in Annex 5 in this deliverable.

Location: Seville (Spain)

Sample's commitment: 75 kids from 13 to 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 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.

Descriptive 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.

Objectives of the study:

The aim of this study is to test the reliability of Nesplora Ice Cream to be applied in clinical teenage population. The results of this study could establish the concrete age to implement Nesplora Ice Cream, potentially extending the application age of the test to the early adolescence.

Next steps:

After receiving the data at the end of July, we will carry out difficulty rate analysis, as well as analyse floor effect of the variables in order to establish reliability of our test in this population. Results will be disseminated in congress publications.

3.6 AGREDACE

Collaborator's description: The Granada Association of Families for the Rehabilitation of Acquired Brain Injury, AGREDACE, is a non-profit mutual aid entity born in 2003 from the need to support those affected by acquired

brain injury (DCA) and their families, to face with more and better resources the changes that have suffered their lives. The collaborator agreement signed with this collaborator can be found in Annex 6 in this deliverable.

Location: Granada (Spain).

Sample's commitment: 50 people over age 16 with a diagnosis of Acquired Brain Damage.

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

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

Objectives of the study:

The aim of this study is to characterize the cognitive profile of the Acquired Brain Damage population using Nesplora Ice Cream.

Next steps:

After receiving the data, Mann-Whitney U test will be carried out to analyse differences in the Ice Cream scores between Acquired Brain Damage group and the control group. Depending on the results, additional analysis will be also carried out to complement the data and the cognitive profile. Results will be disseminated in congress publications.

4. COLLABORATOR'S STUDIES

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. Specifically, studies with the Ice Cream tool that are currently planned or started help us:

- 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 chosen 2 widely used tools for the assessment of EEFF as are the CANTAB battery and the WAIS-IV. Other of the objectives of the studies performed is to increase the age range of the test, analysing the reliability of the test in a young clinical population.
- ADHD is a pathology to which Nesplora has always paid close attention since the beginning. For this reason, specific studies in this pathology are also going to be carried out with Nesplora Ice Cream, since it has been widely found in the literature that executive functions are damaged in it. If we find interesting results, the portfolio of our tools for ADHD would also be increased with Ice Cream.
- The study that is proposed with Dr. José Camacho Conde Psychology Clinic is a study that will help us to measure the reliability of Ice Cream after a non-pharmacological treatment, in this case the Mindfulness. This study would open the doors to be able to use Ice Cream as a monitoring tool after pharmacological or non-pharmacological interventions.
- 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. 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.

- And finally we also want to test sensitivity in Acquired Brain Damage, a very numerous and heterogeneous group for which there are currently no validated tools.

Although we have actively tried to obtain data from these studies by the time this deliverable is presented, we have only obtained data from the AGREPLACE collaborator but we are still waiting for the remaining data so we cannot draw up solid conclusions with the data shared up to now.

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 6 agreements to make studies with an estimated sample of 270 people. 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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