VRMIND– Virtual Reality Based Evaluation of Mental Disorders
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D5.9 – Independent Report on the performance of DIMEMO on North American population

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1. EXECUTIVE SUMMARY

VRMIND-DIMEMO (Nesplora Suite from now on) is a neuropsychological test for memory function in people from 16 to 90 years old. It is a test designed to evaluate the main memory processes to support the diagnosis and severity of any clinical condition which course memory impairment. This assessment is carried out through the performance of the person within a virtual furniture store. The proper assessment of memory function is a crucial issue in many conditions as different types of dementia, the natural ageing process, 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 Suite 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 Suite 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 Suite 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 USA 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 USA.

2. RELATION WITH OTHER WPS AND DELIVERABLES

This deliverable is closely related with D5.7 (Independent report on the performance of Suite on European population) and D5.8 (Independent report on the performance of Suite on Latam population).

3. COLLABORATOR'S STUDIES

Since the moment we received the approval of the VRMIND project we started looking for North American 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 Suite. 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. At this point, we started focusing on USA and Canada and in general, in other regions where we thought that it would be interesting to have studies as a first step to start the commercialization of our products there. These unsuccessful contacts are shown in table 1.

Most of these contacts were made proactively by us. That is to say, seeing that few centres contacted us and those that did were "lost" along the way, mainly for reasons of access to the sample, not being able to commit to a specific time for the study, no time /resources for the studies or for not wanting to comply with the ethical requirements that we asked from Nesplora, we decided to start contacting different centres that we saw experts in neuropsychology. So we conducted an internet search for collaborators in the USA who met the following requirements:

- Interested in doing evaluations with Ice Cream and/or Suite. Ideally they could also do evaluation with Aquarium and Aula.

- Belong to a medium/large clinic or a university. This requirement was due to the fact that a collaborator from a medium or large centre has easier access to the sample, and to an ethics committee and also more research experience in comparison with collaborators from small centres.

- Have a nearby/accessible ethics committee and availability to fulfil the different ethics requirements.

We sent an e-mail about the VRMIND project, the collaboration in the studies, the benefits for the collaborators, etc., and we sent it to the contacts we had identified. Some of them responded by asking a specific question or even

accepted the invitation to have a teleconference with us to clarify participation in the study. But even after that clarification or teleconference no one agreed to participate.

As a contingency plan, and as it was also an impediment by the collaborators not having personnel to carry out the tests due to the high workload in the centre, we were interested in the procedures to be carried out so that a researcher from Nesplora could go to a specific centre in the USA to carry out a stay and she would be the one to carry out the evaluations with our tools, thus removing the workload from the collaborator there. But we found that in USA it is needed to have a specific license to practice psychology within the state in which the centre is located. This is a long and arduous process that also did not ensure that it is finally achieved.

During this process, we were contacted by Professor Alexander de Foe of RMIT University in Melbourne who was very interested in collaborating. Since we did not have Ice Cream and Suite studies outside Europe and Latin America, we decided to accept this collaboration because Australia, although we did not mention it in the VRMIND DoA in principle, is an interesting market for us because of the number of potential clients, and because it is a receptive market for the use of new technologies in practices and clinics.

And on the other hand, thanks to the meeting we had with the psychiatrist Luis Rojas Marcos, who exercises his profession in the PAGNY Health & Research Foundation, we have managed to contact pediatricians of this association and they are interested in doing a study which aims to detect the sensitivity of the test Nesplora Aula to detect differences between Attention Deficit Hyperactivity Disorders (ADHD), Learning Disabilities without ADHD (LD) and Healthy controls between 6 to 16 years old.

However, since they are pediatricians they would use the Nesplora Aula tool in the study given the age of the study participants. We are currently in conversations with this collaborator and may soon sign the collaboration agreement and start the study. Even if it is a study outside of the VRMIND Project we will continue with it in 2019.

3.1 RMIT University, Melbourne.

Collaborator's description: RMIT University (officially the Royal Melbourne Institute of Technology, informally RMIT) is an Australian public research university located in Melbourne, Victoria. RMIT is driven by impact and, as the world economy transforms, the University has a responsibility to make the resulting changes work for the whole of society. In support of this, RMIT has created a cohesive and supportive environment for entrepreneurship and innovation activity within RMIT's research network of enabling capability platforms (ECPs), research centres, groups and research collaborations. Unlike traditional discipline-based research structures, ECPs connect researchers from multiple disciplines and from across all RMIT colleges under a thematic umbrella. This provides a vehicle that allows RMIT to deploy its areas of research excellence to comprehensively address critical local, national, regional and global challenges and capture emerging opportunities. Dr Alexander De Foe is a Melbourne-based writer, neurophilosopher and experimental researcher with an interest in global states of consciousness and the perceptual binding problem. The collaborator agreement signed with this collaborator can be found in Annex 1 in this deliverable.

Location: Melbourne (Australia).

Sample's commitment: 90 adults over 16 years old with anxiety disorder diagnose and 10 adults over 16 years old without any mental condition.

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 Suite: Nesplora Suite (Climent 2018) is a neuropsychological test for the evaluation of memory function in people from 16 to 90 years old. It is a test designed to evaluate the main components of memory as working memory, short term and long term memory, recognition and visoespatial memory to support the diagnosis and severity of any clinical condition which course with memory impairment. This assessment is carried out through the performance of the person within a furniture store. Our tool target crucial cognitive functions 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.
- STAI inventory: The State-Trait Anxiety Inventory (STAI) is a commonly used measure of trait and state anxiety (Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983). It can be used in clinical settings to diagnose

anxiety and to distinguish it from depressive syndromes. It also is often used in research as an indicator of caregiver distress

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 explore if there are any neuropsychological impairment in people suffering from anxiety disorders, and also how this impairment is and how can affect to the daily life of the patient. The control group of this study will be useful to compare Australian vs Spanish population and test the reliability of our norms.

This collaborator will also use the Nesplora Ice Cream tool in this study.

Next steps:

After receiving the data at the end of December, we will perform mean differences analysis between clinical and control groups. The results will be disseminated in scientific journals publications.

4. CONCLUSIONS

For different reasons accessing partners in this geographical area has been a very difficult task within the proposed timeline for this project. We have found that, even the collaboration project awoke the motivation of the researchers we have contacted; several issues blocked the process after a good first contact. Lack of funding for research activities during the data collection process has been a problem for some of the collaborators, especially in USA. On the other hand, some collaborators working on a clinical setting didn't want to use a tool which, even it has CE marking and it is approved as medical device, doesn't counts with the FDA approval. Nevertheless, we are keeping contact with some institutions in the territory which can carry on collaboration in the near future, out of this project's framework.

Although the collaborator included in this document is out of the region targeted, we think it presents a great opportunity to open a new market for our assessment tools; due it is a reference institution in the region.

The clinical validation study presented in this document is tackling different issues for a new neuropsychological test. First, collecting data of normative population in other regions can provide scientific evidence about the validity

of the norms already created for Nesplora Suite to be used in other regions populations.

Also, we want to test the sensitivity of our tool to detect cognitive impairment in clinical population, in this case, anxiety disorders, which are one of the most prevalent mental issues around the world.

Besides, we have a collaborator in the North Carolina State University from USA, who is going to collaborate for the Nesplora Ice Cream and Nesplora Suite normative studies (see D4.1 and D4.2 for more information). He wanted to start the collaboration with us by means of a normative study since the ethical committee management is easier for this type of studies. But he has expressed in several teleconferences his interest in participating in clinical studies in the future.

In any case, we will continue with the studies with these collaborators and with their publication and diffusion through different scientific means.
However, we consider that we have fulfilled the objective that we had with these studies because we have products that can be marketed today and although the results of clinical studies from other countries arrive a little later, that does not delay us in our marketing.