D2.4

WORK PACKAGE 2 – Gaming System and Pilot Design

DISSEMINATION LEVEL: Public ■ Confidential □

This document was prepared by FSJD and HSJD
with the valuable contribution of NCSRD

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## Project Information

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|  | José Ángel Alda (HSJD)  
|  | Carlota Saumell (FSJD) |
| **Contributor(s):** | Adam Doulgerakis (NCSRD)  
|  | Tassos Kanellos (NCSRD) |
| **Reviewer(s):** | Maria Bessa (NCSRD) |
| **Ethical advisor(s):** | Dimitris Kyriazanos (NCSRD) |
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Executive Summary

This deliverable documents the results of task T2.5 Pilot Definition, Evaluation Metrics & Criteria and it defines all key aspects of the FocusLocus Pilot implementation to be organised at the premises of HSDJ in Barcelona, Spain. It describes the exact start date, duration, involved stages and relevant pilot activities determined on the basis of the plan outlined in Section 1.3.4.2 (FocusLocus Testing, Evaluation and Documentation - Pilot Study Deployment). It also contains the evaluation metrics and KPIs for the assessment of FocusLocus in the pilot study in terms of meeting intended technological and social aspect specifications.
# List of Acronyms and Abbreviations

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Explanation</th>
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<tbody>
<tr>
<td>ADHD</td>
<td>Attention Deficit and Hyperactivity Disorder</td>
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<td>AEPD</td>
<td>Asociación Española Protección de Datos</td>
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<td>API</td>
<td>Application Programming Interface</td>
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<td>AR</td>
<td>Augmented Reality</td>
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<tr>
<td>CORT</td>
<td>Cortechs Connect Limited</td>
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<tr>
<td>DoA</td>
<td>Description of Action</td>
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<td>EB</td>
<td>Executive Board</td>
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<td>EC</td>
<td>European Commission</td>
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<td>EEG</td>
<td>Electroencephalography</td>
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<td>EMC</td>
<td>Ethics Monitoring Committee</td>
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<td>Fundació Sant Joan de Déu</td>
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<td>GA</td>
<td>General Assembly</td>
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<td>HDPA</td>
<td>Hellenic Data Protection Authority</td>
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<td>Health Service Executive</td>
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<tr>
<td>TAU</td>
<td>Treatment as Usual</td>
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<tr>
<td>VWG</td>
<td>Virtualware 2007 SA</td>
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<td>WP</td>
<td>Work Package</td>
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<td>WPL</td>
<td>Work Package Leader</td>
</tr>
</tbody>
</table>
Table of Contents

Project Information ......................................................................................................................................... 2
Document Information .................................................................................................................................... 3
Document Version History ............................................................................................................................... 4
Disclaimer ....................................................................................................................................................... 5
Executive Summary ......................................................................................................................................... 6
List of Acronyms and Abbreviations ................................................................................................................. 7
Table of Contents ............................................................................................................................................ 8
List of Tables .................................................................................................................................................. 10

1. Introduction........................................................................................................................................... 11
   1.1. Objectives - Aim of this report ................................................................................................................ 11
   1.2. Document structure ................................................................................................................................ 11

2. Ethical Clearance Authorisation .............................................................................................................. 12
   2.1. Research and Ethical Commissions’ Approval ............................................................................................ 12
   2.2. Informed consent procedures .................................................................................................................... 12
   2.3. Data Protection ........................................................................................................................................... 14
       2.3.1. The collection of personal, and/or sensitive data within the FocusLocus field tests and pilot study 14
       2.3.2. Written and Audio/Visual documentation of the FocusLocus field test pilot ................................. 15
       2.3.3. Notification to/Authorization from the National Data Authorities .................................................... 16

3. Implementation Dates ............................................................................................................................ 17
   3.1. Preliminary Integration Testing Implementation Dates (10 participants) ................................................. 17
   3.2. Pilot Test Implementation Dates (80 participants) .................................................................................... 17

4. Participant Population Inclusion Criteria ................................................................................................. 18
   4.1. ADHD Diagnosis and previous treatment ................................................................................................... 18
   4.2. Age .............................................................................................................................................................. 18
   4.3. Gender ........................................................................................................................................................ 18
   4.4. IQ Range ...................................................................................................................................................... 18
   4.5. Other deficits and disorders ....................................................................................................................... 19
   4.6. Group distribution ...................................................................................................................................... 19
       4.6.1. Preliminary Integration Testing Group Distribution ........................................................................... 19
       4.6.2. Pilot test Group Distribution ............................................................................................................. 19

Even though ADHD is more prevalent in males than females (4:1 to 9:1), the FocusLocus gaming system aims to be gender-neutral and equally attract audiences from both genders. Every effort will be made to ensure that the pilot male to female ratio in the pilot participants does not exceed the mean statistical ratio (6:1 – 7:1). Both males and females will be equally distributed among the four groups for the pilot.
4.6.3. Internet connection

4.7. Withdrawal

5. **Recruitment**

5.1. Recruitment period

5.2. Recruitment phases

5.3. Medical centers involved

5.4. Tests and procedures

6. **FocusLocus Game Sessions**

6.1. FL VWM UX mode game sessions (Group A and C)

   6.1.1. FL VWM UX mode game sessions duration (Group A and C)

   6.1.2. FL VWM UX mode game sessions equipment and location (Group A and C)

6.2. FL MMR UX mode game sessions (Group B and C)

   6.2.1. FL MMR UX mode game sessions duration (Group B and C)

   6.2.2. FL MMR UX mode game sessions equipment and location (Group B and C)

6.3. FL VWM and MMR UX mode game sessions pre- and post- interviews

6.4. Time of day monitoring

7. **Evaluation Metrics and KPIs**

7.1. Pre-evaluation

7.2. Post-evaluation and KPIs

   7.2.1. Clinical post-evaluation

   7.2.2. User satisfaction post-evaluation

8. **Pilot Implementation Risk Management and Mitigation Measures**

Annex A: Research Commission of Parc Sanitari Sant Joan de Déu approval

Annex B: Clinical Research Ethics Committee (CEIC) revision

Annex C: Informed Consent preparation documents
List of Tables

Table 1. Risks and Mitigation Measures.......................................................................................................................................................... 27
1. Introduction

1.1. Objectives - Aim of this report

The aim of this report is to document the results in Task 2.5 Pilot Definition, Evaluation Metrics & Criteria and to provide details of the action plan for all key aspects of the FocusLocus Pilot implementation to be organised at the premises of HSDJ in Barcelona. Specifically, the Ethical Clearance Authorisation Process will be reviewed, the participant population inclusion criteria will be defined and the exact start date, duration, involved stages and relevant pilot activities will be determined. The report is also meant to be a guide for the evaluation metrics and KPI’s for the assessment of FocusLocus in the pilot study in terms of meeting intended technological and social aspect specifications (T2.2, T2.4).

1.2. Document structure

The deliverable presents guidelines and procedures for the efficient management implementation of the pilot. It contains the following sections:

- **Section 1. Introduction**
  Includes the aim of this report and the deliverable structure description.

- **Section 2. Ethical Clearance Authorisation**
  Reviews the status of FocusLocus Ethical Clearance Authorization process.

- **Section 3. Implementation dates**
  Establishes the integration testing and the pilot implementation dates.

- **Section 4. Participant Population Inclusion Criteria**
  Defines the participant population inclusion criteria.

- **Section 5. Recruitment**
  Details the recruitment plan to achieve the target of ten naive participants for the integration testing, eighty naive participants for the pilot, and twelve spare participants to anticipate possible withdrawals.

- **Section 6. Gaming sessions**
  Defines the structure of the gaming sessions.

- **Section 7. Evaluation Metrics and KPIs**
  Lists the pre- and post- evaluation tests.

- **Section 8. Pilot Implementation Risk management and mitigation measures**
  Assesses potential risks and describes mitigation measures.

- **Annexes**
  Includes ethical clearance documents.
2. Ethical Clearance Authorisation

2.1. Research and Ethical Commissions’ Approval

The FocusLocus Ethical Monitoring Committee (EMC) submitted all of the necessary documents for ethical clearance authorization to the two research ethics committees that supervise the studies that are conducted at the premises of Hospital Sant Joan de Déu; the Research Commission of Parc Sanitari Sant Joan de Déu and The Clinical Research Ethics Committee at Hospital Sant Joan de Déu. The documents contained a summary of the project as well as the informed consent forms to be signed by the parents of the volunteers and the volunteers of twelve years of age and older.

- The Research Commission of Parc Sanitari Sant Joan de Déu approved the project on September 12th (see Annex A).
- The Clinical Research Ethics Committee reviewed the project, for the first time, on September 28th and requested minor clarifications. The Committee requested clarifications on the TAU and whether the 3 non-TAU groups of pilot participants will be receiving TAU during the pilot or not. FSJD updated the summary of the project to include the clarifications and updated the information sheet and the informed consent forms to include explicit consent for audiovisual recording of the gaming sessions. The updated documents were submitted on October 19th and the Clinical Research Ethics Committee reviewed them on October 26th (see documents submitted in Annex B). The submitted documents (also attached in Annex B) are preliminary and may be subject to changes in order to comply with the requirements of the Clinical Research Ethics Committee. Furthermore, these documents do not reflect some of the issues that are described in the main body of this current deliverable D2.4, which were the result of the FocusLocus Ethics Monitoring Committee meeting that took place on October 26th.

2.2. Informed consent procedures

Informed Consent requires three elements: (i) voluntary participation, (ii) competence and (iii) comprehension. In order to conform to the requirements set in place by the Nuremberg Code, the Declaration of Helsinki, the APA Ethics Code and the pertinent EU legislation, the Informed Consent forms include, at minimum, the following information:

- A statement that FocusLocus involves the participation of volunteers and an explanation of the main purpose,
- The expected duration of the subject’s participation in the pilot activity,
- A description of the procedures to be followed with focus on the experimental procedures,
- A statement that participation is voluntary,
- Information about who is organising and funding the research,
- A description of any reasonably foreseeable risk, discomfort or disadvantages. (First Aid and medical care will be available during the pilot testing),
- A description of any possible benefits to the participants or to others, which may reasonably be expected from
the research, thus avoiding inappropriate expectations,

- A statement describing the procedures adopted for ensuring data protection/confidentiality/privacy including duration of storage of personal data and curation procedures,

- A description of handling of incidental findings,

- A reference to whom to contact for answers to pertinent questions about the research and research subjects’ rights, and whom to contact in the event of a research-related injury to the subject,

- A statement offering the subject the opportunity to ask questions and to withdraw from the research at any time, without consequences,

- An explanation of what will happen with the data or samples at the end of the research period and if the data/samples are retained or sent/sold to a third party for further research,

- Information about the possible research outcome in terms of scientific dissemination and product commercialization.

Finally, the participants’ parents/legal guardian will have to date and sign the form, declaring that: they understand the purpose of the pilot, they have been given all the information that they have asked for, they agree for their child(ren) to participate in the pilot test, and that they understand that their child(ren) reserve the right to ask for clarifications during the pilot and that the child(ren) can withdraw from the study at any given time. Children over twelve years old will also have to date and sign the form.

To be valid, consent must be informed, voluntary, and competent.

To ensure that consent is informed, FocusLocus will prepare information sheets written in lay terms prior to the commencement of the pilot study. The information sheet will be carefully developed and piloted with a few parents/guardians of children with ADHD to ensure that it is ‘user friendly’ and that it will meet the information needs of potential participants. (See Annex C)

To ensure that consent is voluntary, FocusLocus will use procedures that require that participants ‘opt in’ to the study. Potential participants will be asked by their clinician if they would be willing to participate. This request will be accompanied with an information sheet and telephone and email addresses that allow potential participants to request further information. When willingness to consider participation is stated, further information will be provided verbally and an opportunity will also be provided for the potential participant to ask questions before their parent/legal guardian being asked to sign the consent form. In addition, the team will also ensure that participation is entirely voluntary throughout the study and that should legal guardians wish to withdraw their children from the study without penalty at any time. Throughout the pilot, the parents/guardians of the participants will be regularly asked if they wish to continue. Any distress that children may show during the study will be handled sensitively.

To ensure that consent is competent, the team will discuss the project with all study volunteers and check for any signs suggesting that the potential parents/guardians of the participant do not have the capacity to consent (e.g. due to sleep-deprivation or intoxication). In addition, although young children with ADHD may be unable to give informed consent, an effort to explain basic issues of this study to the participants in very lay terms will be made.
Prior to the pilot study, participants and their legal guardian will be guided through the consent form and pilot procedures by qualified research staff. FSJD will provide the appropriate consent forms for minors’ legal guardians’ involvement in FocusLocus’ activities and they will be properly guided through the form and procedure (see Annex C). The signed consent forms for the FocusLocus pilots will be collected in the final report on ethics (D1.6 Ethical Monitoring Annual Reports –M27), and copies of the forms will be included in the deliverable D6.1 POPD-Requirement No. 1 (WP6, M16).

2.3. Data Protection

A considerable part of FocusLocus research will include human participants and process of their personal and/or sensitive data. “Personal data” are defined as information that relates to and identifies a living individual. Anonymous information, however does not qualify as personal data because it cannot be used to identify living persons individually. Information processing in terms of this project is defined as obtaining, using, maintaining or holding personal information. As described in Deliverable D1.2: Data Management Plan (M9), participants have vested rights in relation to their personal information. This includes the right of access to their data; in certain situations, the right to prevent further data processing; and the “right to be forgotten”.

All FocusLocus researchers should be fully aware of the following requirements and need to comply with them:

- Researchers should always assume that the personal information of participants is confidential, especially if it touches on private or sensitive matters, which generally will be the case in most FocusLocus research.
- Researchers have the duty to ensure that personal confidential information remains secure.

All data collection activities that will be performed within FocusLocus, will strictly adhere to EC regulation as well as the legislation of individual Member States and Associated Countries.

2.3.1. The collection of personal, and/or sensitive data within the FocusLocus field tests and pilot study

With regards to the Data Storage and communication, a secure yet effective methodology will be followed in compliance with the privacy-by-design approach, the established standards and the ethics requirements. The FocusLocus data storage and communication system will ensure that FSJD will be able to monitor and control the data flow and particularly the access level granted to the FocusLocus system components and users, regarding the FocusLocus data sets. It is noted that FSJD is the Partner that will be responsible for the organisation and the deployment of the pilot study, with ethical clearance for handling personal and/or sensitive data in the context of the FocusLocus pilot study.

To that end, the data that will be collected during the FocusLocus pilot study will be separated into two distinct data sets as described below:

a) The personal and sensitive data that will be collected by the FSJD personnel. They will be encrypted and stored in a database on a server located at the premises of HSJD.

b) The anonymised gameplay, performance and usage-related data that will be collected by the FocusLocus gaming applications during the gaming sessions. These anonymized data will be encrypted and stored in a cloud-based...
database so as to be accessible by the FocusLocus applications. They will also be tagged with a unique identifier that will be used for associating them to the person they correspond to, on an on-demand basis, when requested by a user with appropriate security credentials through a FocusLocus authorized application.

These databases will feature an API that will allow the system’s components (i.e. VWM and MMR Game Clients, CPPM and Cloud Analytics Service) to communicate with the databases in order to read and write collected user-related data. As far as security is concerned, the databases will use encryption for both ‘in-flight’ and ‘at-rest’ occasions. Additionally, the databases’ APIs will feature an access permissions interface that will allow the FSJD personnel to remotely monitor and control the data that can be accessed by the FocusLocus components, also depending on each user’s access level (children, parents, doctors). Thus apart from FSJD, the FocusLocus partners will only have access to anonymised data.

In the context of the FocusLocus system and pilot study, there are three cases where personal and anonymised data from the aforementioned datasets will be correlated:

a) Authorised intermediaries (parent, teacher, psychologist etc.) will be able to monitor the user’s performance and manage the gameplay settings through the Control Panel and Performance Monitoring Web Portal. In order to ensure that only authorised individuals (i.e. FSJD personnel and parents for the pilot study) will have access to personal and sensitive data, it is foreseen that the correlation of the two distinct data-sets will occur in a non-permanent manner and on an on-demand basis, and that the portal will visualise data that will be retrieved on-the-fly from two different databases using two separate authentication procedures.

b) Once allowed by FSJD via the access permissions interface, the Cloud Analytics Service will have access on both datasets for performing post-analytics calculations on the available data. The cloud analytics service will process either individual user data or will analyse the entire FocusLocus user base data. This can occur on an automated schedule or on an on-demand basis.

c) Once allowed by FSJD via the access permissions interface, the gaming application clients (VWM and MMR) will be able to access some of the user’s personal data during gaming sessions (such as Age, Gender, Language, ADHD diagnosed type and severity ranking, etc.) for personalisation and gameplay adaptation purposes.

Throughout the pilot study, the FSJD will be able to control the data exchange (allow, restrict, allow with data abstraction) according to the ethical considerations that will arise from the user groups that will participate in the pilot study, ensuring that the participants will not be directly or indirectly identified.

The proposed data privacy scheme aims at ensuring the confidentiality and integrity of sensitive information as provided by the FSJD.

2.3.2. Written and Audio/Visual documentation of the FocusLocus field test pilot

(Relevant tasks: Task 4.2 Pilot Deployment and Testing and Task 4.3 Gaming System Validation)

Apart from the data collection activities performed within the FocusLocus system, the FocusLocus field test and pilot will be extensively documented by means of collecting written and photographic evidence, as well as audio/video capture. As previously stated, the participants of the project’s pilot and field test will be debriefed and fully notified of all the pilot-related activities, including the documentation activities. Consent forms will be made available to the participants. Volunteers will be able to withdraw from these activities at any given time. The
audiovisual material as well as the photographic evidence will be recorded in a specific manner to protect the identity of the participant (no faces will be shown).

2.3.3. Notification to/Authorization from the National Data Authorities

The relevant national and/or local Data Protection Authorities competent to provide FocusLocus with the necessary instructions, authorizations and notifications for the pilot study are the following:

- The Spanish Data Protection Agency¹ (Agencia Española de Protección de Datos, AEPD)
  - The Hellenic Data Protection Authority² (HDPA)

In the case of personal, non-sensitive data, Data Controllers (NCSRD researchers) who have been registered with the HDPA, are authorized to collect and anonymise data. A data Controller registered already to the HDPA is Dimitris Kyriazanos, appointed member of the FocusLocus Ethics Monitoring Committee and a Privacy and Data Protection expert. With the supply of informed consent forms for the collection of personal data during the FocusLocus tests, there is currently no foreseen risk in terms of legal compliance.

FSJD is already authorised (by the AEPD) to collect, access and handle sensitive data as long as the guidelines of the Ley Orgánica (Organic Law) 15/1999, of December 13, for the Protection of Personal Information are followed.

FSJD will be responsible for the collection of personal and sensitive data throughout the project as well as all process of anonymization.

¹ http://www.agpd.es/
² http://www.dpa.gr/
3. Implementation Dates

The FocusLocus approach will be formally demonstrated, thoroughly tested and evaluated through the implementation of pilot study experiments at HSJD, Barcelona, Spain.

3.1. Preliminary Integration Testing Implementation Dates (10 participants)

The preliminary integration testing was scheduled to take place within a 3-month time frame:

M19 (01/05/18) – M21 (31/07/18). This test will allow FocusLocus to correct minor issues both in the software and in the testing set up and methods.

Taking into account that children in Barcelona finish school at the end of June (M20), the preliminary integration testing will take place during **the first two weeks of June starting on Monday June 3rd 2018.**

3.2. Pilot Test Implementation Dates (80 participants)

According to the work plan the official testing was scheduled to run within a 3-month time frame: from M22 (01/08/18) to M24 (31/10/18) and have a duration of 2 months. M22 (i.e. August) is a difficult month to test in Spain as it falls in the middle of the summer vacation and the families might be outside of Barcelona. Therefore, the pilot is scheduled to be conducted during a 2-month period (8 weeks) during M23 and M24.

**The pilot will start on Monday September 3rd 2018 and it will last 8 weeks.**
4. Participant Population Inclusion Criteria

The FocusLocus pilot at HSJD will involve 80 patients in total with a diagnosis of ADHD. Ten patients will first participate in the preliminary integration testing. Together with 70 more patients, they will participate in the final pilot.

The Consortium will not discriminate among volunteers on basis of their race, ethnicity, religious or political beliefs etc. but will exercise caution in order to maintain demographic diversity in terms of age and gender balance among volunteers. Children that are in high risk of injury as well as children whose legal guardian is not capable of giving consent (e.g. showing signs of being intoxicated, sleep-deprived, under high stress, suffering from mental illness such as PTSD) will be excluded from participating in the FocusLocus pilot and/or field tests.

4.1. ADHD Diagnosis and previous treatment

HSJD will initially recruit naive patients. A naive patient is defined, in the context of FocusLocus as well as in previous studies conducted at HSJD, as a patient that has been diagnosed with ADHD by a specialist three months prior to joining the study. A naive patient must have never taken any drug approved in Spain to treat ADHD in children and teenagers before joining the study. Absence of pharmacological treatment is defined as not having taken any dose of stimulants during two consecutive days or more than six consecutive days for any pharmacological treatment for ADHD throughout the patient’s life. In the event that the target of 80 naive participants cannot be reached for the pilot test, the recruitment will include non-naive participants that have abstained from medication or other treatments during August (holiday season in Spain) so that their ADHD symptoms are present during the pilot. If non-naive participants are finally included in the sample, they will be equally distributed across the 4 groups.

Participants might have varying types of ADHD and the severity of ADHD might range between 28 and 45 in the ADHD RS Du Paul test.

4.2. Age

Participants will range from 8 to 15 years old.

4.3. Gender

Even though ADHD is more prevalent in males than females (4:1 to 9:1), the FocusLocus gaming system aims to be gender-neutral and equally attract audiences from both genders. Every effort will be made to ensure that the pilot male to female ratio in the pilot participants does not exceed the mean statistical ratio (6:1 – 7:1). Both males and females will be equally distributed among the four groups for the pilot.

4.4. IQ Range

Participants must have an average IQ range.
4.5. Other deficits and disorders

Participants will show no presence of neurological deficit, neurodevelopmental disorder, and will not have a comorbid diagnosis (e.g. Autism spectrum disorder, depression, bipolar disorder).

4.6. Group distribution

4.6.1. Preliminary Integration Testing Group Distribution

The preliminary integration test will involve 10 patients that will test both modes twice over a period of two weeks. The patient will come to the HSJD facilities and will test the VWM mode for 30 minutes and then the MMR mode for 30 minutes.

4.6.2. Pilot test Group Distribution

The FocusLocus pilot test will involve 80 patients (including the ten patients that will have participated in the preliminary integration testing). Three active treatment groups (A,B,C) and one Treatment As Usual (TAU) control group (D), each comprising of 20 patients, will be formed for testing the efficacy of (A) exclusive use of the VWM UX mode, (B) exclusive use of the FocusLocus MMR UX mode and (C) combined use of FocusLocus VWM and MMR UX modes. The active treatment group participants will be compared to the TAU control group.

TAU is defined, in the context of the FocusLocus pilot, as a multimodal treatment following the guidelines of the usual clinical practice guides for ADHD treatment (SING 2009, NICE 2009, SNS 2010). The TAU includes psychological and psychopedagogic treatment (at school and outside of school), psychoeducational treatment for the parents/legal tutors of the patients and pharmacological treatment on the most severe cases. The pharmacological treatment might include stimulants (Methylphenidate, Lisdexamfetamine) or non-stimulants (Guanfacine, Atomoxetine).

Patients will be assigned to each of the four groups pseudo-randomly, thus preserving an equivalent number of participants of the same age and gender in each group. There should be no significant cognitive, educational or social differences between the profiles of each subgroup (i.e. no significant variations in IQ. Pre- and post-intervention assessments of this variables (e.g., of IQ) will be applied and introduced in covariate analyses of the data). A trained clinician will conduct these assessments and all data will be stored on an encrypted laptop and will be backed up to an encrypted server.

4.6.3. Internet connection

The recruiting team will need to ensure that participants in group A and C will have an internet connection available at their homes that will allow the game to connect to the FL server. Participants that do not have an internet connection will be allocated to group B or D.

4.7. Withdrawal

Participants will have the right to withdraw at any time. This will be explained and respected throughout the research process. Researchers will not pressure any participants to re-engage with the research. It will also be made
clear on all Information Sheets that the right to withdrawal extends beyond actual participation (to cover research data) and that researchers will make it clear at what point withdrawal of data is no longer possible (give a cut-off date).

Should the participant with their legal guardian’s consent or the legal guardian themselves wish to withdraw participation, then a request will be made to FSJD and/or NCSRD to comply with the request. All personal and/or sensitive data that FSJD estimates that could possibly lead to the participant’s identification will be removed irretrievably.
5. Recruitment

5.1. Recruitment period

The recruitment will take place from M18 through M22.

5.2. Recruitment phases

Ten patients will be recruited for the preliminary integration testing, 70 more patients will be recruited for the pilot test (80 in total, counting the patients that participate in the preliminary integration testing), and 12 spare patients will be recruited in case participants withdraw from the study.

5.3. Medical centers involved

HSJD will collaborate with two other Mental Health centres (CSMIJ Vilanova and CSMIJ Mollet) that are part of the SJD network to ensure that the recruitment goal is met.

Parking or public transportation will be covered for participants that live outside Barcelona.

5.4. Tests and procedures

During the recruitment period, an expert clinician will evaluate potential participants, both at HSJD and at CSMIJ Vilanova and CSMIJ Mollet, through the evaluation tests described in Section 7. Once the patients have been diagnosed with ADHD, the clinician will offer them the opportunity to join the pilot if the criteria for doing so are met (see section 4).
6. FocusLocus Game Sessions

Three groups (A,B,C) will receive the FocusLocus treatment during the pilot. Group A will receive the VWM UX mode, group B will receive the MMR UX mode and group C will receive a combined use of VMX and MMR UX modes.

6.1. FL VWM UX mode game sessions (Group A and C)

The participants will have 2-3 unsupervised VWM gaming sessions per week at home.

6.1.1. FL VWM UX mode game sessions duration (Group A and C)

VWM gaming sessions are ideally expected to have a duration of about 45 minutes. However, considering that 20 patients will be receiving the double treatment (FL VWM UX mode and MMR UX mode), the consortium recommends sessions of thirty minutes. The game session will end automatically after thirty minutes to be able to control for duration of play.

6.1.2. FL VWM UX mode game sessions equipment and location (Group A and C)

HSJD will provide each participant in Group A and C with a tablet device. There will be forty active tablet devices and Electroencephalography (EEG) headsets and there will be five-ten spare tablet devices and EEG headsets. The participants that receive the tablet device will be asked to sign a form agreeing to return the tablet device and EEG headset at the end of the eight weeks or at the time of their withdrawal.

6.2. FL MMR UX mode game sessions (Group B and C)

The participants will have one supervised session per week (total of eight sessions).

6.2.1. FL MMR UX mode game sessions duration (Group B and C)

MMR gaming sessions are ideally expected to have a duration of about 45 minutes. However, in order to hold forty supervised sessions a week (Group B and C) within a working schedule in only one MMR room, the sessions will need to be shortened to 30 minutes.

6.2.2. FL MMR UX mode game sessions equipment and location (Group B and C)

The spatial requirements for the MMR gaming mode is:

- A room sized approximately five by five meters, without natural light. A researcher will monitor the MMR gaming sessions.
- The room where the game will be played will be suitably prepared by mounting printed markers at several locations to enable AR functionalities
- An interactive touchscreen table will be present
- Five to ten small-sized RFID-enabled base stations will be present
Physical objects to be used as tangible interface media will be available.

Each participant will play the game individually and will wear a lightweight Augmented Reality (AR) headset and a lightweight Electroencephalography (EEG) headset. An authorised FSJD/HSDJ researcher will monitor the MMR gaming sessions.

6.3. FL VWM and MMR UX mode game sessions pre- and post- interviews

Pre- and post- interviews with pilot participants will be conducted after each gaming session to obtain some basic information on the patients pre- and post- general experience (considering both psychological and “gaming usability” variables). The per-session surveys will be limited to a few questions and will be integrated within the game. Below follow some indicative questions that will be used:

- Pre- and post-: How focused do you feel right now? Rate from 1-10 (10 being the most focused)
- Pre- and post-: How tired do you feel right now? Rate from 1-10 (10 being the most tired)
- Post-: Did you enjoy the game session today? Rate from 1-10 (10 being the most enjoyment)
- Post-: Would you want to keep playing? Rate from 1-10

In addition, a trained staff member will supervise the game sessions and will write notes to document potential relevant information.

6.4. Time of day monitoring

The ideal procedure would be to hold the MMR UX gaming sessions only during the morning hours as children with ADHD tend to be very tired by the end of the day, with an associated drop of concentration and arousal levels.

Timing constraints will not allow exclusive morning sessions as there will only be one room available and 40 children a week will individually spend an average of 40 minutes in it.

Morning sessions and afternoon sessions will be counterbalanced for each participant through the eight sessions.

If a patient's availability does not allow for a balanced mix of morning and afternoon sessions, there will be a control measured added: the time of day at which the participant plays the game will be recorded for posterior covariate analysis of the possible impact of this variable on other variables included in the study.
7. Evaluation Metrics and KPIs

7.1. Pre-evaluation

A balanced mix of the following testing and evaluation methods and approaches will be included in the FocusLocus assessment activities, following their careful consideration for suitability (Tasks T2.3, 2.4, 2.5).

Non-clinical qualitative measures such as school and parent reports and the following clinical instruments will be employed to evaluate the effectiveness of FocusLocus pre- and post-intervention for ADHD management skill acquisition and symptom de-escalation.

The evaluation tests were initially listed in Section 1.3.4.2 (FocusLocus Testing, Evaluation and Documentation - Pilot Study Deployment) of the GA Description of Action (DoA) by the former consortium partner HSE. There have been some changes on the repertoire of evaluation tests to better match the capabilities and modus operandi of HSJD and the changes are highlighted below:

(i) Neuropsychological test (Conners CPT Visual and Auditory), this test provides a quantitative measure of sustained attention, inattentiveness, vigilance and impulsivity.

(ii) Parent and teacher ratings using the Swanson, Nolan and Pelham Questionnaire (SNAP-IV), this questionnaire measures the core symptoms according to DSM-IV. HSJD recommends replacing this questionnaire with ADHD RS DuPaul. It is validated in Catalan language and HSJD has standardized scales, validated in Spanish population.

(iii) The Strengths and Difficulties Questionnaire (SDQ) gives a well-validated measure of child behaviour in a number of clinically relevant domains e.g. emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems, pro-social behaviours. HSJD recommends replacing with Achenbach System of Empirically Based Assessment. HSJD believes this test provides a better estimate of the aforementioned and the hospital has already set-up an automated correction.

(iv) The Clinical Assessment of Attention Deficit-Child (CAT-C) provides self-rating, parent and teacher questionnaires, measuring Inattention, Impulsivity, Hyperactivity, Personal, Academic/Occupational, Social and Internal, External locus. All three CAT-C Rating questionnaire are comprehensive, highly reliable, and sensitive to the symptomatology of attention deficits, with and without hyperactivity, in children and adolescents. HSJD recommends replacing this test with Conners 3. The hospital staff has no previous experience with CAT C and Conners 3 tackles the same variables.

(v) Add SCQ (Social Communication Questionnaire). HSJD believes it is important to discard a comorbid diagnosis with autism (ASD) and SCQ is a reliable and fast tool.

(vi) Add K-SADS (Kiddie Schedule for Affective Disorders and Schizophrenia). HSJD believes K-SADS is a basic test to evaluate comorbidity with affective and psychotic disorders. It is also nearly indispensable to publish in clinical journals.

(vii) Add CGI (Clinical Global Impression). HSJD believes it is an efficient tool to measure possible improvements in a variety of ADHD symptoms.
(viii) Add CGAS (Children's Global Assessment Scale). HSJD believes it is a fast tool to measure the patient’s functioning, as it coincides with Axis 5 of DSM IV measures.

7.2. Post-evaluation and KPIs

7.2.1. Clinical post-evaluation

The HSJD clinician will evaluate the participants after the period of eight weeks through the same tests described in section 7.1. The results will be compared to the original diagnosis information. The goal of improvement for each test is the following:

(i) Conners CPT Visual and Auditory: score below 60 or no positive symptoms.

(ii) ADHD RS Du Paul: score below 20 or decrease of 30%.

(iii) Achenbach System of Empirically Based Assessment: less than 65% in the subscales.

(iv) Conners 3: less than 65% in the subscales.

(v) SCQ: no comparison, screening test.

(vi) K-SADS: no comparison, screening test.

(vii) CGI: score below 2.

(viii) CGAS: score below 70.

7.2.2. User satisfaction post-evaluation

FocusLocus considers user satisfaction amongst the top priorities of the project and aims in assessing them thoroughly. User satisfaction will be evaluated based on information collected in two stages throughout the FocusLocus pilot study. At a first stage, quick feedback will be requested from the participants after each gaming session through a set of a few questions integrated within the FocusLocus game app. At the end of the FocusLocus pilot study, thorough feedback will be requested through questionnaires. Questions will be designed for the assessment of perceived usability of children taking into consideration standardized usability questionnaires and other questionnaires developed under European funded projects. Questionnaires to be considered are the following:

Standardized Usability Questionnaires. They are designed for the assessment of perceived usability, typically with a specific set of questions presented in a specified order using a specified format with specific rules for producing scores based on the answers of respondents. For usability testing, standardized questionnaires are available for assessment of a product at the end of a study (post-study – for example, QUIS, SUMI, PSSUQ, SUS, and, most recently, UMUX and UMUX-LITE) and after each task in a study (post-task – for example, ASQ, SEQ, SMEQ). All of these questionnaires have undergone psychometric qualification, including assessment of reliability, validity, sensitivity.

GeQ: The Game Experience Questionnaire. It was developed by the Eindhoven University of Technology during the FUGA project funded by the European Commission under the FP6 programme. The questionnaire consists of three...
different parts: 1) Core module - assesses game experience as scores on seven components: Immersion, Flow, Competence, Positive and Negative Affect, Tension, and Challenge 2) social presence module - investigates psychological and behavioural involvement of the player with other social entities 3) post game module - assesses how players felt after they had stopped playing
8. Pilot Implementation Risk Management and Mitigation Measures

Table 1. Risks and Mitigation Measures.

<table>
<thead>
<tr>
<th>Description of risk</th>
<th>Proposed risk-mitigation measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethical compliance delays testing</td>
<td>Clearance expected to be received between M13-M15 of the project (T4.1), well in advance of the testing start date.</td>
</tr>
<tr>
<td>Prospective participant recruitment. Not enough volunteers for pilot testing are secured.</td>
<td>Recruitment preparations will start from Month 18 through T2.5 and will be concluded before pilot testing (M22). FSJD/HSJD will collaborate with two other Mental Health centres (CSMIJ Vilanova and CSMIJ Mollet) that are part of the SJD network to ensure that the recruitment target is met.</td>
</tr>
<tr>
<td>Participant withdrawal</td>
<td>FSJD/HSJD will recruit a pool of twelve spare participants (three for each group). If a patient withdraws during the first two-three weeks of the pilot study a spare patient will join the study. Withdrawals that take place after three weeks will not be replaced with a new participant as there would not be enough data from the new volunteer to compare it to the rest.</td>
</tr>
<tr>
<td>HSJD is unable to provide a suitable room for the set-up of the MMR UX mode within the hospital facilities</td>
<td>HSJD will find a suitable room for the set-up of the MMR UX mode at another health center (within the HSJD network) in the city of Barcelona</td>
</tr>
<tr>
<td>Game prototypes fail to achieve sufficient functionality</td>
<td>There will be a preliminary integration testing phase in June to ensure that the game prototypes achieve complete operational functionality</td>
</tr>
<tr>
<td>Receiving parents’ complains because children spend too much time playing the game on a tablet device</td>
<td>Game sessions will be limited to 30 minutes and the application will automatically end the game session when reaching the time limit</td>
</tr>
<tr>
<td>The family of the participant fails to return the tablet device and EEG headset when the pilot test ends</td>
<td>The family of the participant will sign a form agreeing to return the tablet device and EEG headset at the end of the pilot test</td>
</tr>
</tbody>
</table>
Annex A: Research Commission of Parc Sanitari Sant Joan de Déu approval

The Research Commission of Parc Sanitari Sant Joan de Déu revised and approved the project titled “FocusLocus: ADHD management Gaming System for educational achievement and social inclusion” cofounded by the Horizon 2020 Framework Programme of the European Union Grant Agreement No. 732375, and coordinated by Dr. Jordi Navarra at Hospital Sant Joan de Déu in Barcelona.

The project has the support of the Research Commission. The topic is in line with the Institution’s research interests and the protocol can be carried on within the stipulated terms. The professional and research experience as well as the academic background of the researchers ensure, in our opinion, an adequate development of the project.

12nd September 2017

Josep Maria Haro Abad
Annex B: Clinical Research Ethics Committee (CEIC) revision

The current document is provided in Spanish, as submitted to the CEIC. The CEIC will write their final approval in English.

Informe Solicitud Aclaraciones
Proyecto Investigación Biomédica
CP. - C1. PPC-105-17
3 de octubre de 2017

CEIC Fundació Sant Joan de Déu

Dr. Pau Ferrer Salvans
Secretario del CEIC Fundació Sant Joan de Déu

HACE CONSTAR QUE:

El CEIC Fundació Sant Joan de Déu en su reunión del día 28/09/2017, ha evaluado la propuesta del promotor referida al estudio:

Título: “FocusLocus ADHD management gaming system for educational achievement and social inclusion”
Código Interno: PIC-105-17
Investigador Principal: Sr. Jordi Navarro Ordoñez

El CEIC ha evaluado el proyecto “Focus Locus” y considera que es susceptible de aprobación si se añaden las siguientes aclaraciones y/o modificaciones:

a) La hoja informativa para padres y pacientes contiene un error en el primer párrafo del apartado 2 “METODOLOGÍA”. El punto (3) se halla repetido, y en la primera vez se refiere al grupo 3, que combinará dos entornos, y la segunda vez se refiere al grupo que recibirá el tratamiento habitual.

b) Falta en la documentación recibida y en la hoja de información la descripción de en qué consiste el tratamiento habitual, especialmente si incluye tratamiento farmacológico y cual.

c) Falta explicar si el tratamiento habitual se dará sólo al grupo 4 o se dará a todos los grupos en forma “add on”.

d) En el texto descriptivo del proyecto se menciona el WP6 con los requerimientos éticos del proyecto y unos informes anuales sobre las condiciones éticas del proyecto. (D1.4 a D1.6). Se solicita enviar información al respecto o cuando menos un resumen.

Quedando a la espera de la información solicitada, le saluda atentamente.

Lo que firma en Esplugues de Llobregat, a 3 de octubre de 2017

Fdo:

Dr. Pau Ferrer Salvans
Secretario del CEIC Fundació Sant Joan de Déu
Annex C: Informed Consent preparation documents

1. FocusLocus Project Summary (Spanish)

Resumen (en castellano) del proyecto “FocusLocus: ADHD management Gaming System for educational achievement and social inclusion”

Proyecto concedido por la Unión Europea, multicéntrico
Código: H2020-ICT-2016-1

Investigador: Jordi Navarra Ordoño (partner)

Centro coordinador (IP): National Center For Scientific Research “Demokritos” (Grecia)

El Trastorno de Déficit de Atención con Hiperactividad (TDHAH) afecta a una parte significativa de la población y causa considerables problemas de comportamiento, limitaciones de aprendizaje en el contexto del sistema de educación formal, aumentando la probabilidad de exclusión social. Los enfoques de tratamiento actuales inducen altos costos para los sistemas de bienestar y los individuos, mientras que el uso generalizado de medicación estimulante sigue siendo objeto de una gran controversia debido a determinados efectos secundarios indeseables.

FocusLocus reúne un consorcio multidisciplinario, que incluye centros de distintos países de la Unión Europea, con el objetivo de diseñar y producir productos y servicios orientados al mercado para la gestión del TDHAH mediante el aprovechamiento del conocimiento y la tecnología de las actividades de investigación e innovación anteriores. FocusLocus propone una intervención altamente innovadora basada en juegos de videoconsola (de estrategia, completamente no-violentos). La mecánica de juego se apoya en el uso de habilidades cognitivas (de atención, planificación, inhibición de impulsos, el manejo de información multisensorial, etc.) y motoras que son muy susceptibles de mejorar, sobre todo si se tiene en cuenta que el aprendizaje y entrenamiento se lleva a cabo en un entorno lúdico muy atractivo para los niños y adolescentes.

A pesar de que FocusLocus será diseñado, probado y evaluado específicamente en niños con TDHAH, se espera que también será beneficioso como complemento a la terapia psicológica en diversos trastornos mentales que impliquen déficits en las habilidades que se ponen en práctica en el entorno FocusLocus, generándose así un elevado potencial de comercialización.

Las actividades de FocusLocus incluirán la puesta en marcha de un estudio piloto, en el que se recultarán noventa niños y adolescentes diagnosticados con TDHAH para la evaluación extensiva del sistema de juego propuesto, la generación de evidencia con respecto a su desempeño, la documentación de los resultados para otros propósitos de investigación del TDHAH y la creación de bases sólidas para un producto comercializable.

Dentro de la muestra de 90 participantes, 10 participarán en una prueba inicial de los primeros diseños del juego; 20 (Grupo A) formarán parte de un grupo en el que se probará el juego en formato tablet, en sus casas, 20 (Grupo B) acudirán al hospital para participar en sesiones de juego interactivo en la sala de juego "multisensorial"; 20 (Grupo C) tendrán experiencia con las dos intervenciones y 20 (Grupo D) participantes recibirán el tratamiento habitual que recibirían según su diagnóstico. Su desempeño en distintas habilidades cognitivas se medirá a través de una batería de tests psicológicos y neuropsicológicos.
Aclaraciones al protocolo

- Definición del tratamiento habitual:
Únicamente el grupo D recibirá el tratamiento habitual durante el piloto. Los tres grupos restantes recibirán exclusivamente las diferentes versiones del tratamiento FocusLocus.

El tratamiento habitual del paciente con TDAH es multimodal y se rige por las directrices de las guías de prácticas habituales SING 2009, NICE 2009, SNS 2010.

Consiste en tratamiento psicológico y psicopedagógico (tratamiento de refuerzo escolar y extraescolar), tratamiento psicoeducativo a los padres de los pacientes y tratamiento farmacológico en los casos más graves. El tratamiento farmacológico puede ser estimulante (Metifenidato, Lisdamphetamine) o no estimulante (Guanfacina, Atomoxetina).

- Criterios de inclusión:

• Los pacientes deberán ser naïve; carecerán de diagnóstico previo para el mismo, es decir, deben tener un nuevo diagnóstico para el TDAH (según el DSM IV-TR o DSM-5) realizado por un especialista (pediatra, psiquiatra infantil, neuropsiquiatra o psicólogo clínico) durante los 3 meses previos a entrar en el estudio.

• Los pacientes no deben haber tomado ningún tipo de fármaco aprobado en España para el tratamiento del TDAH en niños y adolescentes antes de iniciar el estudio. Se define por ausencia de tratamiento farmacológico el no haber tomado más de 2 días consecutivos cualquier dosis de estimulantes o más de 6 días consecutivos cualquier tratamiento farmacológico para el TDAH a lo largo de la vida del paciente.

• A los efectos del estudio el diagnóstico de TDAH y la presencia de comorbilidad se confirmará aplicando la entrevista semiestructurada K-SADS PL.

• Así mismo se exigirá que la puntuación del ADHD-RS IV versión padres sea superior a 1,5 desviaciones estándar de la norma de edad para la puntuación total.

• Los pacientes deberán tener un CI estimado superior o igual a 70.

• Los pacientes no podrán presentar comorbilidad con trastornos del espectro autista, psicosis o trastorno bipolar.

En el caso que no se llegue a reclutar la muestra de 90 pacientes naïve (teniendo en cuenta el elevado número y las limitaciones de tiempo), se admitirá en el piloto a pacientes que durante el verano no hayan seguido un tratamiento por motivo de vacaciones terapéuticas.

- Recrutación adicional:
Se reclutarán 12 pacientes adicionales para anticipar el abandono habitual (10%) en esta tipología de estudios.

- Protección de datos personales:
  • Las sesiones en el entorno multisensorial con estimulación 3D en la sala del Hospital Sant Joan de Déu (Esplugues de Llobregat,
Barcelona) se grabarán audiovisualmente y el material grabado se utilizará exclusivamente para el presente estudio y se destruirá una vez analizado. En el caso de que aparezca la cara del participante en la grabación se difuminará para proteger la identidad del menor. En ningún caso se emplearán estas imágenes para otros fines o usos y en ningún caso se les dará un uso público. En caso de utilizarlas para uso docente se solicitaría de los padres o tutores una nueva autorización específica y en cualquier caso se preservará la identidad del menor.

- El material audiovisual servirá para: 1. Documentar el funcionamiento del piloto. 2. Investigar problemas técnicos. 3. Ayudar a entender los patrones de comportamiento durante el juego. 4. Material de diseminación en los canales propios del proyecto.

- Se adjunta a esta solicitud el documento D1.2 Data Management Plan que contiene el plan de gestión y protección de datos elaborado por un grupo miembro del consorcio H2020.

- Se informa asimismo que el equipo se reunirá con el Sr. Domèneç Cardona la semana del 23 de octubre para establecer las directrices en cuanto a la protección y la gestión de los datos personales y los datos generados en el estudio.
2. FocusLocus Project Summary (English)

**Project Summary** *FocusLocus: ADHD management Gaming System for educational achievement and social inclusion*

Project funded by the European Union, multicentric
Código: H2020-ICT-2016-1

Researcher: Jordi Navarra Ordoño (partner)

Coordinating center (PI): National Center For Scientific Research “Demokritos” (Grecia)

Attention Deficit Disorder with Hyperactivity (ADHD) affects a significant part of the population and causes considerable behavioral problems, learning limitations in the context of the formal education system, increasing the probability of social exclusion. Current treatment approaches induce high costs for wellness systems and individuals, while widespread use of stimulant medication continues to be highly controversial due to undesirable side effects.

FocusLocus brings together a multidisciplinary consortium, which includes centers from different European Union countries, with the objective of designing and producing market-oriented products and services for the management of ADHD by harnessing the knowledge and technology of research and innovation activities above. FocusLocus proposes a highly innovative intervention based on game consoles (strategy, completely non-violent). The game mechanic is based on the use of cognitive abilities (attention, planning, inhibition of impulses, management of multisensory information, etc.) and motor skills that are very susceptible to improvement, especially considering that learning and training takes place in a playful environment very attractive for children and adolescents.

Although FocusLocus will be designed, tested and evaluated specifically in children with ADHD, it is expected that it will also be beneficial as a complement to psychological therapy in various mental disorders involving deficits in the skills that are implemented in the FocusLocus environment, it thus have a high marketing potential.

FocusLocus activities will include the launching of a pilot study, which will recruit ninety children and adolescents diagnosed with ADHD for the extensive evaluation of the proposed game system, the generation of evidence regarding their performance, the documentation of the results for other research purposes of ADHD and the creation of solid bases for a marketable product.

Within the sample of 90 participants, 10 will participate in an initial test of the first designs of the game, 20 (Group A) will form part of a group that will test the game in tablet format, at home, 20 (Group B) will go to the hospital to participate in interactive gaming sessions in the “multi-sensorial” game room, 20 (Group C) will have experience with the two interventions and 20 (Group D) participants will receive the usual treatment that they would receive according to their diagnosis. Their performance in different cognitive abilities will be measured through a battery of psychological and neuropsychological tests.
Protocol clarifications

- Definition of TAU (treatment as usual):

Only group D will receive the usual treatment during the pilot. The remaining three groups will receive the different versions of the FocusLocus treatment.

The usual treatment of patients with ADHD is multimodal and is governed by the guidelines of the usual practice guidelines SING 2009, NICE 2009, SNS 2010.

It consists of psychological and psychopedagogical treatment (treatment in school and extracurricular reinforcement), psychoeducational treatment to the parents of the patients and pharmacological treatment in the most serious cases. The pharmacological treatment may be stimulant (Methylphenidate, Lisdexamfetamine) or non-stimulant (Guanfacine, Atomoxetine).

- Inclusion criteria:

  - Patients should be naive; they will not have a previous diagnosis for it, that is, they must have a new diagnosis for ADHD (according to the DSM IV-TR or DSM-5) made by a specialist (pediatrician, child psychiatrist, neuropsychiatric or clinical psychologist) during the previous 3 months before joining the study.

  - Patients should not have taken any type of drug approved in Spain for the treatment of ADHD in children and adolescents before starting the study. Absence of pharmacological treatment is defined by not having taken any dose of stimulants for more than 2 consecutive days or having taken any pharmacological treatment for ADHD for more than 6 consecutive days throughout the life of the patient.

  - For the purposes of the study, the diagnosis of ADHD and the presence of comorbidity will be confirmed by applying the semi-structured interview K-SADS PL.

  - It will also be required that the score of the ADHD-RS IV parent version is greater than 1.5 standard deviations from the age standard for the total score.

  - Patients must have an estimated IQ greater than or equal to 70.

  - Patients will not be able to present comorbidity with autism spectrum disorders, psychosis or bipolar disorder.

In case the sample of 90 naïve patients is not recruited (taking into account the high number and time limitations), the pilot will admit patients who during the summer did not follow a treatment due to therapeutic vacations.

- Spare recruitment:

Twelve additional patients will be recruited to anticipate the usual abandonment (10%) in this typology of studies.

- Personal data protection:
The sessions in the multi-sensory environment with 3D stimulation in the room of the Hospital Sant Joan de Déu (Esplugues de Llobregat, Barcelona) will be audiovisually recorded and the recorded material will be used exclusively for the present study and will be destroyed once analyzed. In case the participant’s face appears on the recording, it will be blurred to protect the identity of the child. In no case will these images be used for other purposes or uses and in no case, will be given a public use. In case of using them for educational use, a new authorization will be requested from the parents or guardians and in any case the identity of the minor will be preserved.

The audiovisual material will serve to: 1. Document the operation of the pilot. 2. Investigate technical problems. 3. Help understand patterns of behavior during play. 4. Dissemination material in the project’s own channels.

Attached to this application is document D1.2 Data Management Plan containing the data protection and management plan developed by the members of the H2020 consortium.

It is also reported that the team will meet with Mr. Domènec Cardona the week of October 23 to establish guidelines regarding the protection and management of personal data and data generated in the study.
3. FocusLocus Participant Information Sheet (Spanish)

HOJA INFORMATIVA - Proyecto “FocusLocus: Sistema de manejo de juego para el logro educativo y la inclusión social en el TDAH”

Este documento es para su información. Por favor léalo detenidamente, y pregunte cualquier duda que le surja, sin que por ello esté obligado a participar en el estudio.

1. OBJETIVO DEL ESTUDIO

Usted ha mostrado interés en (o ha sido seleccionado para) que su hijo/a participe voluntariamente en un estudio sobre entrenamientos de habilidades cognitivas mediante el juego en TDAH. Este proyecto está financiado por la Unión Europea y se realiza en colaboración con distintos centros de varios países.

FocusLocus propone una intervención altamente innovadora basada en juegos de videoconsola (de estrategia, completamente no-violentos) para entrenar determinadas habilidades cognitivas (mentales) en niños y adolescentes con TDAH. La mecánica de juego se apoya en el uso de estas habilidades (de atención, planificación, inhibición de impulsos, manejo de información multisensorial, etc.) y motoras. Estas son susceptibles de mejorar, sobre todo si se tiene en cuenta que el aprendizaje y entrenamiento se lleva a cabo en un entorno lúdico muy atractivo para los niños y adolescentes.

Las conclusiones de este estudio nos permitirán diseñar un entorno de juego que permita, tanto dentro como fuera del entorno asistencial (hospitales, centros de psicología, etc.), trabajar estas habilidades de una forma atractiva para el niño/adolescente, posiblemente reduciendo la necesidad de terapias farmacológicas.

2. METODOLOGÍA:

Los participantes en el estudio serán asignados a uno de los siguientes grupos: (1) Grupo A, que utilizará el entorno de juego FocusLocus en casa, mediante una tablet; (2) Grupo B, que utilizará el juego diseñado por el equipo de FocusLocus en un entorno multisensorial con estimulación 3D en una sala preparada para ello en el Hospital Sant Joan de Déu (Espelgués de Llobregat, Barcelona); (3) Grupo C, que combinará ambos entornos lúdicos y (4) Grupo D, que recibirá la intervención habitual según el diagnóstico.

El entorno lúdico se basa, fundamentalmente, en juegos de estrategia en los que el niño/adolescente aprende a desarrollar y expandir un ecosistema natural (por ejemplo, un arrecife de coral) con todos sus seres vivos que se necesitan para ello. El desempeño del niño/adolescente en distintas habilidades cognitivas se medirá mediante tests psicológicos estándar diseñados para ello.

La duración del estudio será de ocho semanas. Los participantes que formen parte de los grupos B y C deberán acudir al Hospital Sant Joan de Déu durante una hora cada semana (ocho sesiones en total).

3. INCOMODIDADES Y RIESGOS:

Su participación en este estudio no entraña riesgo alguno, puesto que se están utilizando medidas y técnicas de registro no invasivas.

4. CARÁCTER VOLUNTARIO DE SU PARTICIPACIÓN Y TERMINACIÓN DEL ESTUDIO:

Su participación en el estudio tiene un carácter totalmente voluntario. Si deciden participar, recibirán esta hoja de información para que la conserven y se le pedirá que firme un formulario de consentimiento.
Tanto usted como su hijo/a pueden negarse a participar en cualquier momento y puede retirarse del estudio sin necesidad de explicar sus motivos, y sin que por ello se altere la relación con su médico o el investigador principal ni se produzca perjuicio en su tratamiento. Si usted decide interrumpir su participación en el estudio puede hacerlo notificando su decisión al profesional que le atiende.

El equipo asistencial que le atiende, por su parte, también podrá interrumpir su participación en el estudio si, una vez efectuada la exploración inicial, no se considerara un candidato apropiado para poder ser incluido en el mismo, en función de los criterios de inclusión/exclusión.

5. TRATAMIENTO DE LOS DATOS:
Las sesiones en el entorno multisensorial con estimulación 3D en la sala del Hospital Sant Joan de Déu (Esplugues de Llobregat, Barcelona) se grabarán audiovisualmente y el material grabado se utilizará exclusivamente para el presente estudio y se destruirá una vez analizado. En el caso de que aparezca la cara del participante en la grabación se difuminará para proteger la identidad del menor. En ningún caso se emplearán estas imágenes para otros fines o usos y en ningún caso se les dará un uso público. En caso de utilizarlas para uso docente se solicitará a los padres o tutores una nueva autorización específica y en cualquier caso se preservará la identidad del menor.

Los datos obtenidos a lo largo del estudio serán confidenciales y únicamente estarán a disposición de los grupos de investigadores del mismo. En las listas de trabajo no constará el nombre de su hijo/a y sólo constará el número que se le haya asignado en el estudio. Según la Ley Orgánica 15/1999, del 13 de diciembre, el consentimiento para el tratamiento de sus datos personales y para su cesión es revocable. Usted puede ejercer el derecho de acceso, rectificación y cancelación dirigiéndose a los investigadores que están a cargo del estudio.

Por favor, no dude en preguntar a al investigador cualquier duda o pregunta que tenga.

Si usted decide participar en el estudio, firme el formulario facilitado por el experimentador/a, en el que se dice que se le ha proporcionado toda la información necesaria sobre el estudio (puntos 1-5) y que usted la entiende.
4. FocusLocus Participant Information Sheet (English)

INFORMATION SHEET - Project “FocusLocus: ADHD Management Gaming System for Educational Achievement and Social Inclusion”

This document is for your information. Please read it carefully and ask any questions that arise without being bound to participate in the study.

1. PURPOSE OF THE STUDY

You have shown interest in (or been selected for) your child to participate voluntarily in a study on cognitive skills training through play for ADHD. This project is funded by the European Union and is carried out in collaboration with different centers in several countries.

FocusLocus proposes a highly innovative intervention based on game consoles (strategy, completely non-violent) to train certain cognitive (mental) abilities in children and adolescents with ADHD. The game mechanics rely on the use of these abilities (attention, planning, inhibition of impulses, handling of multisensory information, etc.) and motor skills. These are likely to improve, especially if you take into account that learning and training is carried out in a playful environment very attractive for children and adolescents.

The conclusions of this study will allow us to design a play environment that allows, within and outside the healthcare facilities (hospitals, psychology centers, etc.), to work these skills in an attractive way for the child / adolescent, possibly reducing the need of pharmacological treatment.

2. METHODOLOGY:

Participants in the study will be assigned to one of the following groups: (1) Group A, which will use the FocusLocus game at home, using a tablet, (2) Group B, which will use the game designed by the FocusLocus Consortium in a multisensory environment with 3D stimulation in a room prepared for it in the Hospital Sant Joan de Déu (Esplugues de Llobregat, Barcelona), (3) Group C, which will combine both play environments and (4) Group D, who will receive the treatment as usual according to the diagnosis.

The ludic environment is fundamentally based on strategy games in which the child / adolescent learns to develop and expand a natural ecosystem (e.g., a coral reef) with all the living elements that are needed for it. The performance of the child / adolescent in different cognitive abilities will be measured by standard psychological tests designed for it.

The duration of the study will be eight weeks. Participants who are part of groups B and C must go to the Sant Joan de Déu Hospital for one hour each week (eight sessions in total).

3. RISKS OR INCONVENIENCES:

Your participation in this study does not involve any risk, since non-invasive registry measures and techniques are being used.

4. VOLUNTARY CHARACTER OF YOUR PARTICIPATION AND TERMINATION OF THE STUDY:
Your participation in the study is completely voluntary. If you decide to participate, you will be given this information sheet for your records and will be asked to sign a consent form.

Both you and your child may refuse to participate at any time and may withdraw from the study without explaining your reasons, and without thereby altering the relationship with your doctor or the principal investigator or causing harm to your treatment. If you decide to discontinue your participation in the study you can do so by notifying your professional to your decision.

The care team that attends to you, on the other hand, may also interrupt your participation in the study if, after the initial screening, your child is not considered to be an appropriate candidate to be included in it, depending on the inclusion-exclusion criteria.

5. DATA MANAGEMENT:

The sessions in the multi-sensory environment with 3D stimulation in the room of the Hospital Sant Joan de Déu (Esplugues de Llobregat, Barcelona) will be audiovisually recorded and the recorded material will be used exclusively for the present study and will be destroyed once analyzed. In case the participant’s face appears on the recording, it will be blurred to protect the identity of the child. In no case will these images be used for other purposes or uses and in no case will be given a public use. In case of using them for educational use, a new authorization will be requested from the parents or guardians and in any case the identity of the minor will be preserved.

The data obtained throughout the study will be confidential and will only be available to the research groups. In the work lists, the name of your child will not be included and only the number assigned in the study will be included. According to the Organic Law 15/1999, of December 13, the consent for the processing of your personal data and for its assignment is revocable. You can exercise the right of access, rectification and cancellation by contacting the researchers who are in charge of the study.

Please, do not hesitate to ask the researcher any questions or doubts you might have.

If you decide to participate in the study, sign the form provided by the experimenter, which says that you have been provided with all the necessary information about the study (points 1-5) and that you understand it.
5. FocusLocus Informed Consent (Spanish)

CONSENSIEMIENTO INFORMADO

Título del estudio: "FocusLocus: Sistema de manejo de juego para el logro educativo y la inclusión social en el TDAH"

Yo, ........................................................................................................................................ (padre, madre, tutor legal)
   (nombre y apellidos)
   de .................................................................................................................................... (hijo/a)
   (nombre y apellidos)

   - he hablado con la persona a cargo del estudio, que me ha facilitado la hoja informativa del estudio,
   - he leído la hoja de información que se me ha entregado,
   - he (o mi hijo/a ha) podido hacer preguntas sobre el estudio y
   - hemos recibido suficiente información al respecto.

Comprendo que la participación de mi hijo/a es voluntaria.

Comprendo que las sesiones en el entorno multisensorial con estimulación 3D en una sala preparada para ello en el Hospital Sant Joan de Déu (Esplugues de Llobregat, Barcelona) serán grabadas audiovisualmente.

Comprendo que los datos obtenidos a lo largo del estudio, así como el historial clínico de mi hijo/a, serán confidenciales y únicamente estarán a disposición de los investigadores del estudio.

Comprendo que mi hijo/a puede retirarse del estudio:
   - cuando quiera
   - sin tener que dar explicaciones
   - sin que esto repercuta en nuestra relación con el equipo de investigación ni otros miembros de la institución.

Soy consciente de que, al dar mi permiso para la participación de mi hijo/a en el estudio, se recogerán y procesarán datos de mi persona. Estos datos son totalmente confidenciales y estarán protegidos según lo establecido en la Ley Orgánica 15/1999 de 13 de Diciembre de Protección de Datos de Carácter Personal.

Presto libremente mi conformidad para la participación de mi hijo/a en el estudio.

Firma del padre/madre/tutor: ____________ Firma del participante (mayor de 12 años): ____________
Fecha: ______________

Firma del investigador (Jordi Navarra) Fecha: 6 de julio de 2017.
6. FocusLocus Informed Consent (English)

INFORMED CONSENT FORM

Name of the project: “FocusLocus: ADHD Management Gaming System for Educational Achievement and Social Inclusion”

I, ........................................................................................................ (parent or legal tutor)
(name and surnames)

of ........................................................................................................ (volunteer)
(name and surnames)

- have spoken to the researcher in charge of the study, who provided me with the study information sheet,
- have read and understood the information about the project, as provided in the information sheet,
- have been given the opportunity to ask questions about the project,
- have received enough information about the pilot.

I understand that my child’s participation in the study is voluntary.

I understand that the gaming sessions in the multi-sensory environment with 3D stimulation in a room prepared for this in the Hospital Sant Joan de Déu (Esplugues de Llobregat, Barcelona) will be recorded audiovisually.

I understand that the data collected throughout the study, as well as my child’s medical history, will remain confidential and will only be available to the researchers of the study.

I understand that my child is free to withdraw:
- at any time
- without giving a reason
- without affecting my present or future relationship with the research team and other members of the institution.

I am aware that, by giving permission for my child’s participation in the study, personal and sensitive data will be collected and processed. These data are completely confidential and will be protected according to the provisions of the Organic Law 15/1999 of December 13 on the Protection of Personal Data.

I freely agree to the participation of my child in the study.

Parent/legal tutor signature: _______________ Volunteer signature (12yo and above): _______________

Date: _______________

Researcher signature (Jordi Navarra) Date: April, 16th 2018