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GAMIFICATION IN STROKE REHABILITATION

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Abstract

Stroke has a high incidence in the population and it is one of the leading causes of functional impairments among adults. Brain damage rehabilitation is still a relatively undeveloped field and some research lines are following functional motor recovery. Brain-Computer Interface (BCI) provides new techniques to overcome stroke-related motor impairments. Recent studies present the brain's capacity in order to promote the brain plasticity. The use of the BCI for rehabilitation tries to foster three mechanisms of neuropsychology that have proven to be of radical impact in brain function recovery: Motor Imagery, Mirror Neuron and Sensorimotor loop. In this project, we present a pilot study with a rehabilitation session based on BCI system combined with gamification. We try to demonstrate that including gamification in the rehabilitation sessions the performance is the same as the base avatar, but the engagement and entertainment of patients increase. In this pilot study is explained the whole design and development of the gamification session as well as the intervention with real patients.

Contents

Acknowledgments	vi
1 Introduction	2
1.1 Motivation	2
1.2 Purpose	3
1.3 Scope	3
1.4 Planning	3
1.5 Document structure	5
2 Background	6
2.1 Stroke	6
2.2 Stroke rehabilitation	7
2.3 Brain-Computer Interface (BCI) for rehabilitation	8
2.4 Gamification	9
3 Brain-Computer Interface (BCI)	11
3.1 BCI operation	11
3.1.1 Signal acquisition	11
3.1.2 Control model	11
3.1.3 Acquisition techniques	12
3.1.4 Signal processing	14
3.1.5 Signal classification	14
4 Game Development	16
4.1 Methodology	16
4.2 RecoveriX	17
4.3 BCI method in recoveriX rehabilitation	17

4.4	Game development tools	19
4.5	Game development process	19
4.5.1	Narrative	20
4.5.2	Interaction model	20
4.5.3	Modelling and graphic environment	22
4.5.4	Animations	23
4.5.5	Game sound	24
4.5.6	Game compilation	25
5	Pilot Study	28
5.1	Hypothesis	28
5.2	Methods and materials	28
5.2.1	Recoverix system	28
5.2.2	Game	29
5.2.3	Test	29
5.2.4	Experimental design	29
5.3	Subject profiles	30
6	Results	32
6.1	Discussion	35
7	Conclusions	44
A	Questionnaire	46
B	Informed consent	51
	Bibliography	55

List of Figures

1.1	Timing of the project in a GANTT diagram	4
2.1	Scheme of the BCI-system control loop of painball game machine	10
3.1	Brain waves sorted by frequency	13
4.1	<i>Left:</i> General process of the technology development <i>Right:</i> Iterative process of the game creation	16
4.2	Electrodes distribution according to international 10/10 system	18
4.3	<i>Left:</i> Example of control user stroke rehabilitation session using the recoverix system. <i>Right:</i> Exampe of patient stroke rehabilitation session using the recoverix system	18
4.4	Schematic representation of the BCI communication	22
4.5	A full view of Jasper model	24
4.6	A full view of the rat model	25
4.7	Rat animation states	25
4.8	<i>Left:</i> Right response of the video-game. Jasper shoos the rat. <i>Right:</i> Wrong response of the video-game. The rat steal a piece of cheese from the stack	26
4.9	<i>Left:</i> Performance of jasper movement; <i>Right:</i> State machine of Jasper's animation	27
4.10	<i>Left:</i> Performance of the smelling rat movement; <i>Right:</i> State machine of rat's animation . . .	27
A.1	Illustration of the questionnaire answers of control users and patients	50

List of Tables

6.1	Control users max accuracy	32
6.2	Control users mean accuracy	32
6.3	Control users significance	33
6.4	Patient max accuracy	33
6.5	Patient mean accuracy	33
6.6	Patient significance	34
6.7	Comparison of the max accuracy results amongst control users and patients (<i>1st session</i>) . . .	34
6.8	Average of the max accuracy results amongst control users and patients (<i>1st session</i>)	34
6.9	Comparison of the max accuracy results amongst control users and patients (<i>2nd session</i>) . .	35
6.10	Average of the max accuracy results amongst control users and patients (<i>2nd session</i>)	35
6.11	Comparison of the mean accuracy results amongst control users and patients (<i>1st session</i>) . .	35
6.12	Average of the mean accuracy results amongst control users and patients (<i>1st session</i>)	36
6.13	Comparison of the mean accuracy results amongst control users and patients (<i>2nd session</i>) . .	36
6.14	Average of the mean accuracy results amongst control users and patients (<i>2nd session</i>)	36
6.15	Comparison of the max accuracy results amongst the base avatar and rat game in calibration	37
6.16	Average of the max accuracy results amongst the base avatar and rat game in calibration . .	37
6.17	Comparison of the mean accuracy results amongst the base avatar and rat game in calibration	38
6.18	Average of the mean accuracy results amongst the base avatar and rat game in calibration . .	38
6.19	Comparison of the max accuracy results amongst the base avatar and the rat game in training 1	39
6.20	Average of the max accuracy results amongst the base avatar and the rat game in training 1 .	39
6.21	Comparison of the mean accuracy results amongst the base avatar and the rat game in training 1	40
6.22	Average of the mean accuracy results amongst the base avatar and the rat game in training 1	40
6.23	Comparison of the max accuracy result in Training 2, both with the rat game	40

6.24 Average of the max accuracy result in Training 2, both with the rat game	40
6.25 Comparison of the mean accuracy result in Training 2, both with the rat game	41
6.26 Average of the mean accuracy result in Training 2, both with the rat game	41
6.27 Comparison of the max accuracy results amongst the base avatar and the rat game in visual feedback	41
6.28 Average of the max accuracy results amongst the base avatar and the rat game in visual feedback	41
6.29 Comparison of the mean accuracy results amongst the base avatar and the rat game in visual feedback	42
6.30 Average of the mean accuracy results using the base avatar and the rat game in visual feedback	42
6.31 Results of the questions related to the videogame development. See the whole questionnaire's answers with its questions attached in Appendix A	42
6.32 Average of each questionnaire answers	42
6.33 Test of the max accuracy results amongst control users and patients (<i>1st session</i>)	42
6.34 Test of the max accuracy results amongst control users and patients (<i>2nd session</i>)	43
6.35 Test of the mean accuracy results amongst control users and patients (<i>1st session</i>)	43
6.36 Test of the mean accuracy results amongst control users and patients (<i>2nd session</i>)	43
6.37 Test of the max / mean accuracy results amongst the base avatar and rat game in calibration	43
6.38 Test of the max / mean accuracy results amongst the base avatar and rat game in training ₁ .	43
6.39 Test of the max / mean accuracy results amongst the base avatar and rat game in visual feedback	43

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Chapter 1

Introduction

1.1 Motivation

Stroke is the main cause of impairment and the second of cognitive injuries. In average, one in six people suffer the disease and nowadays, there are around 17 millions of people affected. In addition, it is the second major cause of death responsible of 6 millions deaths per year; it is the first cause of death in women and the third in men [1].

In Catalonia, more than 1300 people younger than 55 years are affected by stroke and more than 900 children live with this impairment. Moreover, 45 % of the people with stroke have physical disabilities.

Rehabilitation is essential after stroke because is the moment when functional injuries are recovered. Thus, it is important to understand this process as part of the treatment. The rehabilitation intervention is done by multidisciplinary and qualified teams, the patient and the family as well, and it can be long, repetitive and boring. This is why, some research has been done in adding new methodologies such as virtual reality or videogames to enhance patients motivation.

Brain-Controller Interface (BCI) is a direct connection between the neural signals and an external device. BCI translates brain patterns, according to local neural activity, and is able to understand from actions the neural activity response. Preliminary research and development of this technology were focused on neuroprosthetic applications in order to reduce motor, visual and auditory injuries [2]. Now, this technology has been used for many other applications, for instance, in stroke rehabilitation.

The master thesis presented herein is framed within academical agreement with the company GTEC medical engineering. This company focuses on the development and marketing of real-time bio-signal analysis software and hardware. GTEC is developing multidisciplinary technological projects requiring a huge experience in neuroscience, psychology, signal processing in real time and deep knowledge in engineering (including hardware, software, biomedicine and robotics). This experience covers a wide diversity of biosignals including EEG, EMG, GSR, ECG, EOG and respiratory signals.

GTEC has focused mainly and for a long time in the academic and research sector, and the company is currently widely recognised as the leading provider of high quality products in universities and research centres around the world. In the last years, GTEC has become increasingly active in the medical sector. New products have already been developed for different clinical applications, such as mindBeagle for evaluation and communication with people diagnosed with disorders of consciousness (DOC) and recoveriX,

which facilitates motor recovery secondary to stroke by using the BCI technology. These systems have been used with patients in clinical practice in hospitals and other health centres.

The motivation of this thesis is to contribute to the improvement of the user experience in BCI rehabilitation by adding game elements to the session. Its aim is to provide insights about the impact of gamification in BCI rehabilitation with recoveriX.

1.2 Purpose

The main aim of this project is to design and realise a pilot study on the impact of gamification in the BCI-based stroke rehabilitation of the upper limb.

Thereby, the specific project objectives are:

- To develop a videogame and incorporate it in a stroke rehabilitation session
- To connect the videogame with the BCI technology
- To hitch the videogame with Functional Electrical Stimulation (FES)
- To validate the videogame with both control users and patients in a pilot study
- To assess the impact of the gamification in the rehabilitation with this pilot study
- To evaluate patients motivation and distraction with gamification in this pilot study
- To present the state of art of the technology used

1.3 Scope

The project encompasses the design of the gamification, the implementation of the game, the design of the pilot study and its realisation. Therefore, the project is not only theoretical: in addition to the technological development, it covers the design of the pilot study as well as its realisation, with an important part of intervention with real patients and control users.

The pilot study brings important elements of reflection, but it cannot be considered as a full validation experiment since the number of patients is small (five control user and nine patients) and the number of sessions is low (only two sessions are done). A complete validation study should be done with at least ten patients and control users in ten sessions. This limitation is due to time restrictions, since a complete study should take between six month or a year more.

1.4 Planning

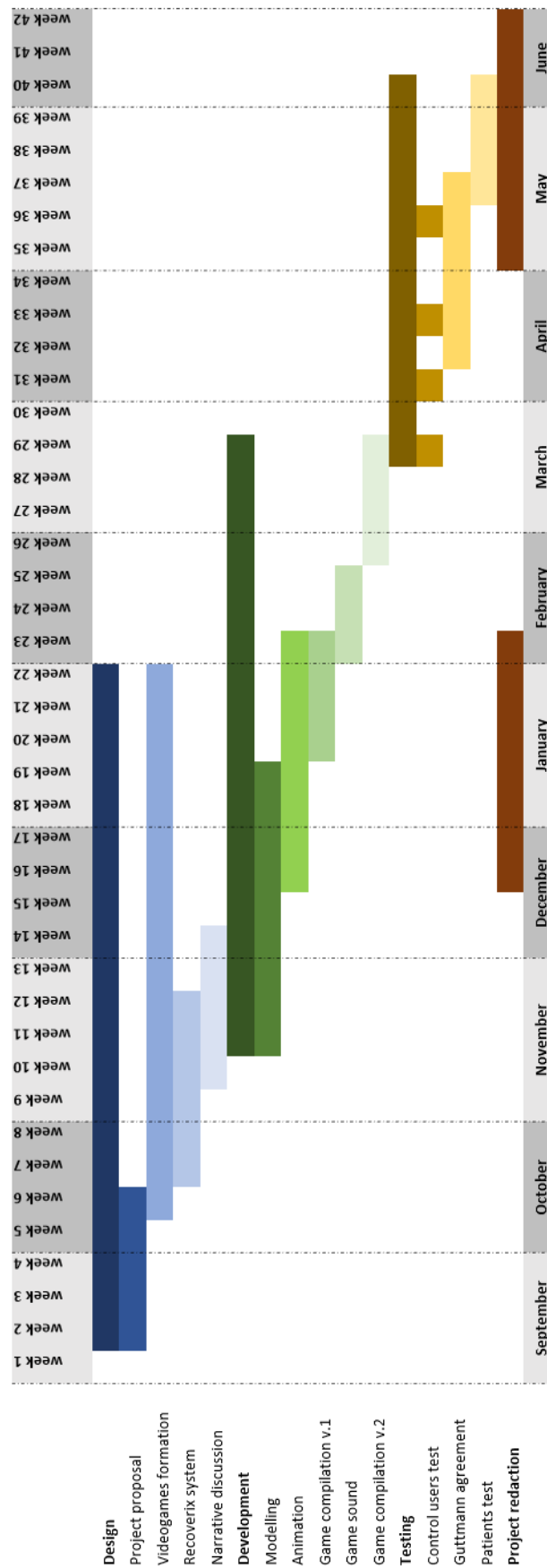


Figure 1.1: Timing of the project in a GANTT diagram

Figure 1.1 shows the time it has taken to develop the whole project. The project begun the second week of September and it lasted until the third week of June with part-time dedication.

1.5 Document structure

The first part of the project consists of an introduction describing the stroke injury, the functional and cognitive effects and some remedies and disease prevention. The second part is a technical one where the technology used is explained together with its state of the art. Then, the development of the game is presented with illustrative pictures of all the project. Afterwards, the results are shown and discussed.

Chapter 2

Background

2.1 Stroke

Stroke is caused by a sudden alteration in blood circulation, either because of a lack of flow or because of bleeding that produces serious damage in the brain [3]. Stroke is also called embolism, thrombosis, apoplexy and cerebrovascular accident.

There are two types of strokes: ischemic, or cerebral infarct, and hemorrhagic, or cerebral hemorrhage. The first one is caused by an arterial block reducing the blood flow that arrives to the brain; the second, is a corruption of the central nervous system because of blood bleeding either in the brain (intracerebral hemorrhage) or out of the brain, but in the skull (subarachnoid hemorrhage).

The main symptoms are:

- Physical weakness or a part of the body paralysed
- Loss of vision in one eye or partly in both
- Loss or difficulty when speaking
- Loss of body or face sensibility
- Instability, imbalance and inability to walk
- Unusual hard headache

The effects of the stroke are different and depend on the affected location and infarct volume. The differential trait of these symptoms is the severity with which they are expressed. Reasons can be very different even though the symptoms are similar. Thus, the cause must be identified in order to determine the treatment and therapeutic planning to ensure maximum functional motor recovery.

The causes of stroke are classified regarding its type, either ischemic or hemorrhagic. For an **ischemic stroke**:

- **Arteriosclerosis:** Chronic inflammation of the arteries that causes a hardening and accumulation of cholesterol plaques on walls favouring the thrombus or obstruction formation.
- **Cardioembolism stroke:** A blood clot formed by a disruption of the cardiac rhythm, the cavity dilation or an alteration of the cardiac valves, can travel through arteries as far as the brain and produces an obstruction.

- **Unusual stroke causes:** A blood clot can also be formed as a consequence of an arterial dissection. This stops the blood flows and produces the disease.
- **Brain venous thrombosis:** It can also be due to a venous thrombosis. It does not allow the blood going back to brain and this flow reduction makes the irrigation difficult.
- **Undetermined stroke cause:** There are some cases for which, even after a full study, the specific cause is not determined.

For an **hemorrhagic stroke:**

- **High arterial pressure:** The arterial hyperpressure can produce either an obstruction or an arterial rupture.
- **Degenerative process:** This happens when *amyloids* are placed to the arterial walls. This produces cerebral hemorrhages.
- **Secondary hemorrhages of cerebral vascular malformations:** It is because of an abnormal vessels breakdown. This reason is the less frequent.

There are some risk factors that increase the possibility of suffering this disease. They can be classified as controllable and uncontrollable. The controllable factors are directly related with persons lifestyle: diet and nutrition, physical activity, tobacco smoking, alcohol drinking... among others. These factors are harmful to arterial pressure, arterial fibrillation, cholesterol, diabetes and blood circulation problems.

Uncontrollable factors are people intrinsic, and they are important to know for determining the overall risk: the age, the genre, race and ethnicity, family history, previous strokes, fibromuscular dysplasia (FMD)¹, patent foramen ovale (PFO)² and transient ischemic attack (TIA)³.

Various treatments can be applied after a stroke and they are planned after an initial diagnosis [4]. However, there are some general steps common to all therapeutic approaches in order to reduce the unforeseen and avoid further damage in the early hours. The overall treatment consists of monitoring the arterial pressure, the fever, the oxygenation and the glucose. In addition, for those people who loss the consciousness, swallowing must be observed with specific techniques, and sometimes respiratory supply is also given. These cares are applied to all the patients regardless of stroke type.

More specific treatments are also applied considering the stroke type. For an ischemic ictus or thrombosis, basically, drug administration is to break up the clot formed in order to restore the blood flow and try to recover the damaged cerebral tissue. This administration only can be done in the early hours and under specific health conditions.

Finally, a preventive drug can be supplied to reduce the risk of the injury reproduction, mostly anticoagulation and antiplatelet drugs. In addition, more specific drugs can be supplied regarding the infarct circumstances.

2.2 Stroke rehabilitation

When the disease diagnosis has been done, the treatment is properly applied and the clinical stabilisation is achieved, the next step is to begin the functional motor rehabilitation. Rehabilitation (RHB) is a process

¹ The FMD is a medical disorder where some arteries are not developed as they should. This can cause a blood flow diminution

² PFO is a heart "hole". There are not symptoms of this medical condition, thus many PFO-related strokes are called cryptogenic, i.e. undetermined stroke cause

³ TIA is a brief episode of stroke-like symptoms that can last from few minutes to 24 hours. Usually, it is a serious warning sign of a possible future stroke

centred in recovering as much as possible the functional, cognitive and social level, giving patients tools to change their lives. A multidisciplinary team takes part in this process: emergency service, neurology department, rehabilitation team, physiotherapists, nurses... together with a disease specialised doctor.

The diseases does not only affect a single aspect, it has to be seen as a whole. Hence, the main aim is to treat the physical disability to gain as much motor physical activity as possible, help with patient autonomy and reintegration to familiar, social and labour environment.

The RHB has to begin as soon as possible, once the diagnosis is done, and when the control of the vital state is insured, because the sooner RHB starts, the larger the improvements on functional recovery and patients life quality [5].

The rehabilitation process has evolved thanks to new research findings; new methodologies and new technology have been developed in the last decades. One example is the *Brain-Computer Interface (BCI)*, that is addressed in the next section.

2.3 Brain-Computer Interface (BCI) for rehabilitation

Brain-Computer Interface (BCI), also known as Neural-Control Interface (NCI), are electrode-computer constructs that extract and decode information from the nervous system to generate functional outputs. They are able to detect the neuronal signal of the patients while they are moving or imagining a functional motor movement. These devices have been developed to bypass motor lesions and, more recently, to boost neural plasticity and motor learning to enhance recovery after injury (rehabilitative BCI) [6].

BCI's capture of brain activity helps experts to understand better the neurological injury and plan a more accurate and customized rehabilitation therapy. Thereby, it is becoming a useful tool for brain injuries rehabilitation [7].

The use of BCI for RHB tries to foster three mechanisms of neuropsychology that have proven to be of radical impact in brain function recovery: *motor imagery*(MI), *mirror neuron* and *sensorimotor loop*. These phenomena, that will be described later, are part of a general concept called *brain plasticity*. Brain plasticity - also called neuroplasticity - is the ability of the brain to modify its connections and reorganise itself. Hence, it describes the potential ability to adapt and learn in an experience-dependent manner in health and disease [8].

Motor Imagery

Motor Imagery (MI) rehabilitation is based on patient imagination. It states that simulating a movement is the same thing as actually realising it, except that execution is blocked [9]. The influence of mental training using MI on motor performance has been confirmed by several experiments [10]. It has been shown that mental training affects not only global motor performance such as muscular strength [11]), but also aspects of the performance normally thought to be more specific outcomes of training, such as reduction of variability and increase in temporal consistency [12]. An explanation of this phenomenon is that increasing traffic in neural circuits can be responsible for improving synaptic efficacy in critical parts of the system.

Nowadays, there are non-invasive methods that are able to capture the neural activity and thus, assess MI. These methods are BCI [13], electroencephalography (EEG), magnetoencephalography (MEG), functional near-infrared spectroscopy (fNRI) and functional magnetic resonance imaging (fMRI)... amongst others.

Neuron Mirror

The Neuron Mirror (NM) phenomenon consists of mirroring an observed motor act inside the brain, i.e. reflecting the behaviour of another, as if the observer was himself acting [14]. This phenomenon has been used in stroke rehabilitation to foster MI by the observation of somebody else's action. It has been seen that the mirror neuron system are found to be active from the time of the observation of the model until actual execution of the actions. Moreover, since the mirror neuron system is bilateral, this strategy should apply regardless of the lesion site [15]. BCI can be coupled with the display of virtual environments to foster MI of the patient in imagining the movement performance thanks to the NM phenomenon. The display can show a virtual avatar moving accordingly to the patient's MI or more complex virtual environments and actions. Virtual reality (VR) brings 3D stereoscopic perception of these environments [16] that can also been shown in conventional displays.

Closed sensorimotor loop rehabilitation (CL)

Closed sensorimotor rehabilitation loop aims to compensate the lost function by controlling external devices which assist or actually perform the action that the patient has imagined and is not able to do. It has been shown that closing the loop of MI with motor practice has positive impact on rehabilitation [17]. The assistance can be provided with robot devices [18]. When couple with BCI, these systems are called Brain Robot Interfaces (BRI) [19].

Functional electrical stimulators (FES) are an alternative tool to robots to close the sensorimotor loop [20,21]. They consists of an electrical boost trying to reproduce the muscle force when the movement is performed. FES can be combined to MI and NM: when the MI is correct, the stimulation is effectively applied to the patient, and, at the same time, the virtual avatar moves.

The combination of the three phenomena (MI, NM and CL) have been exploited not only for rehabilitation but also to better understand the brain connections after the neurological injury in order to strengthen or to quantify the patient neural activity.

2.4 Gamification

Gamification consists of using game elements and game dynamics in non-game contexts in order to improve motivation and guide people's behaviour to achieve specific goals [22]. Serious games are a step further in gamification: they consist of a complete video-game that is specifically designed for learning, training or for rehabilitation [23]. Gamification and serious games can be applied in very diverse areas from education to marketing, business and health [24–26].

Games have been traditionally used for stroke rehabilitation in order to improve both the psychological and motor behaviour of the patient. For instance the Smart PegBoard toolkit (<https://unlimbited.com/products/item/rapae-smart-pegboard>) is aimed at training grasping, dexterity and hand/eye coordination by proposing at patients a series of games consisting of inserting pegs in a digital board with audio and light effects.

Serious computer games have also been used for the same purpose. The principle in these games is to use patient's motor intention or real actions to control complex interactions in the virtual environment. Specific interfaces have been developed for this purpose like the Cyber Glove. Games are generally simple, for instance MindBalance or Bacteria Hunt [27]. Their narration simulates daily life activities such as

placing objects on a table, sports and other activities such as piano playing ??.

Several studies have shown that BCI signals can be used to provide physical input in games with healthy people. As an example, Michael W. Tangermann et al. showed that it was possible to control a pinball game using non-invasive BCI [28]. The aim of the game is to prevent a ball falling down from a board using two paddles. In this study, the control signals of the paddles are connected to a BCI system that contains the signal recorded in the previous 500ms. By using a low-level control mechanism, the signal is continuously classified into three-class signals (left flipper, idle, right flipper). Thus, the "imagined" paddle is brain-activated. Moreover, the system is able to translate a very long lasting control signal for the left or right class into a hold-and-shoot mechanism. An illustration of the control loop of the physical input is shown in Figure 2.1. Another example of a complex game that has been controlled through EEG is the well-known World of Warcrafts (WOW) ??.

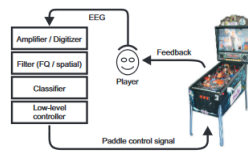


Figure 2.1: Scheme of the BCI-system control loop of pinball game machine

The use of BCI for rehabilitation games has also been addressed, for instance coupling a BCI controlled basketball game ??.

Chapter 3

Brain-Computer Interface (BCI)

In the medical field, BCI has been applied for stroke rehabilitation in different stages of disease, during the stroke rehabilitation for functional recovery as well as post-stroke rehabilitation [29]. This technology has not only used in stroke rehabilitation, it has also been used in other field such as videogames for mind reading and remote communication. This chapter describes this technique and some of its application areas.

3.1 BCI operation

BCI is intended at decoding the brain signals function. To achieve this goal, there are four steps that BCI must work on before decoding the signal: signal acquisition, signal pre-processing, feature extraction and signal classification. Afterwards, the BCI interprets the user intentions and gives a program response.

3.1.1 Signal acquisition

The human brain is a complex system with billions of nerve cells interconnected. This nerves cells, called neurons, communicate each other through electrical impulses that travel from one to others. When all these neurons are activated, they generate a synchronised electrical activity that can be measured. This section is extended in the next two sections, control model and acquisition techniques.

3.1.2 Control model

The control model is the technique used to decode the user neurological activity from the BCI signal. These techniques can be classified in 3 types: active, reactive or passive.

Active BCI

The user must generate continuously neurological activity. This means that the user has an active task to accomplish, and all the attention is centred on executing this action. Then, by using a discriminatory method, the parts of the brain that are activated are determined while this task was carried out.

Some active BCI lecture use MI. The user is asked to imagine the movement of a specific action, therefore he activates the corresponding part of the brain. Section 2.4 shows an example of an active BCI device working with a videogame. In such a case, the user must think in what is the paddle that need to be move in order to control the ball.

Reactive BCI

As opposed to active BCI, in reactive BCI the stimulation is not generated by the user itself but it is provided by an external agent, such as a screen displaying images. The brain activity of the user is registered after visual stimulation, and it can be used to many purposes: to study what part of the brain is used in visual stimulation (any other kind of stimulation can also be done); or to accomplish a task. The most common techniques to register this neurological activity are evoked potential (or evoked response) and P300. Evoked Potential (EP) is neural response time-locked recorded from nervous system to some stimulus [30]. P300 is a positive wave deflection of the human Event-Related Potential (ERP) [31]. ERP is a brain response from a sensory, cognitive or motor event.

One kind of evoked potentials is the visual evoked potential (VEP). VEP is a measurement of the electrical neural response to a light stimulus. Danhua Zhu et al. proposes a study where the VEP is monitored [32]. P300 is an evoked potential component, that can be recorded by electroencephalography (EEG), which appears approximately with a latency of 300 ms after a stimulus. The presence, magnitude, topography and timing of this signal are often used as metrics of cognitive function in decision making processes. It is considered to be endogenous potential, it seems to be linked to person's reaction. It is a common choice for psychological test in both clinic and laboratory.

Passive BCI

The passive operation expects to capture the brain state of the user. In this case, the user does not have to imagine the performance of an action, but the BCI registers the rest neural state. The passive BCI application is mainly to make easier the interaction between system and user because it quantifies relevant insights such as mental and emotional states. It is difficult to integrate this technology in many daily life applications because there are some factors that could impair this usability. However, some have been tested in laboratories, especially for real-time mental state evaluation in operational environments, evaluation of team resources, training and expertise assessment, gaming and neuromarketing applications [33].

3.1.3 Acquisition techniques

Different patterns of neurological activity can be recognised by their amplitude and frequencies [34]. The main five types are:

- Gamma: 31 - 100Hz. This brainwave is the fastest measurable wave and it has been linked to mechanism of consciousness i.e. heightened perception, problem-solving task and learning.
- Beta: 13 - 30Hz. This wave is characteristic for its easy detection when the user is busy actively thinking. It is also associated to alert.
- Alpha: 8 - 13Hz. It corresponds to a physical and mental relaxed state. It was the first to discover and can be detected before falling sleep, performing some relaxed activities such as yoga and in a creative or artistic task.
- Theta: 4 - 8Hz. This brain wave is detected when dreaming. It is associated to automatic task that the mind can be disengage from it. In research, it is also classified as memory, creativity and psychological well-being wave [35].

In order to detect and classify these frequencies many techniques have been developed [36]. They can be classified as invasive, partially invasive and non-invasive BCI.

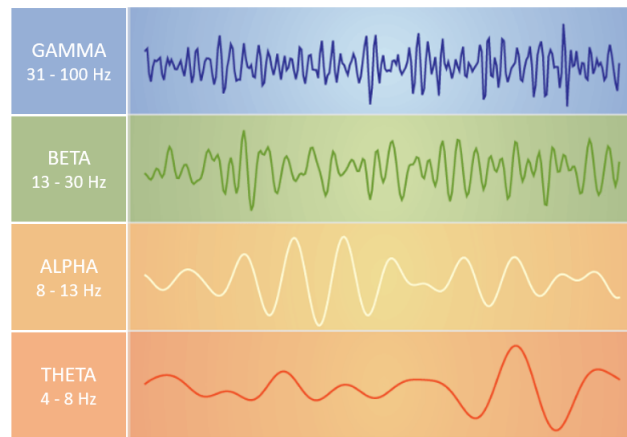


Figure 3.1: Brain waves sorted by frequency

Invasive techniques

Invasive BCI consists of implanting electrodes under the scalp, more precisely the implant is done *intracortical*, to capture the electrical communications. The main advantage is that the signal provided has high temporal and spatial resolution, hence the signal-noise ratio is of good quality. However, there are some issues. Apart from the need of a surgical procedure to implant electrodes and all its medical complications (stability and protection from infection can arise and the body must adapt to the new technology), problems related to system output can occur. For instance, neural signals can get weaker. In addition, they cannot be shifted to measure different location brain signals. Due to these complications, this procedure has been restricted, and it is mostly used to experiment with animals such as monkeys and rats [37].

Partially invasive techniques

Partially invasive implanting also requires surgery. Nevertheless, it is said that is partially invasive because the electrodes are implanted over the cortex surface, so they are not directly implanted on the brain. This technique tries to preserve the advantage of invasive approach but making it more safe. It is seen that it offers a higher temporal and spatial resolution than non-invasive techniques and it is also less affected by the noise artefacts generated by muscles engagement. Partially invasive technique has been used to some epilepsy patients before surgery [38].

Non-invasive techniques

This approach captures the neural signals by using a recording device without surgery. This is the method with less temporal and spatial resolution; the frequencies that can be used are limited by the skull because, at a high frequencies, the signal is diminished, scattered and distorted. However, as the safer recording method, many techniques has been developed to measure the neurological activity. They are functional magnetic resonance (fMRI), functional nearinfrared spectroscopy (fNIRS), magnetoencephalography (MEG) and electroencephalogram (EEG). Every method uses different methodology to approximate the brainwaves.

- **MRI:** It captures the magnetic field generated by the brain electrical activity [39]. It is sensitive to other magnetic signals such as the earth's magnetic field, so this recording must be configured with specific equipment. This method present less distortion but it does not lead to huge improvement either in performance or in training times in comparison with electrical methods.
- **fMRI:** It maps the brain activity by detecting the changes in the blood flow. When a brain part is activated, it requires an increase of incoming blood flow. To detect the changes it uses the blood-

oxygen-level-dependent (BOLD) which is sensitive to hemodynamic response [39]. It has a low temporal resolution but it provides a high spatial resolution and captures information from deep parts that cannot be gathered by either electrical or magnetic methods

- fNIRS: This is similar to fMRI but instead of measuring the blood flow, it measures the blood dynamics of the brain by using infrared light. Compared to magnetic methods, it is less effective considering the temporal resolution but it is more portable and less expensive
- EEG: It records the electrical activity by measuring the voltage fluctuations. This device looks like a swimming cap where the electrodes are attached. It provides good temporal resolution but the signal to noise ratio represents a limitation compared to other methods. It is one of the most usable methods due to its ease of use, portability and low cost.

3.1.4 Signal processing

Signal processing is mainly based on two parts: signal pre-processing and feature extraction. Pre-processing is basically data filtering to properly detect and remove artifacts and noise in the signals. Feature extraction consists of determining what are the properties of the captured signals that differentiate itself amongst others.

Pre-processing signal

It is an important step in the BCI capturing procedure to obtain a quality data. Signals registered by any of the methods mentioned above are affected by different kind of noise such as environmental noise or artefacts generated by any muscle movement. To prevent distortion, it is needed to efficiently detect and remove them. This step includes signal filtering, signal cutting, amplitude scaling and verification of expert marks, artefacts detection and signal segmentation.

In order to determine what signals belong to each type, a feature extraction must be performed. The data obtained can be captured in either time or frequency domain. Different set of techniques have been developed in both domains.

Feature Extraction

Features are needed in order to determine and differentiate the different neural signals. A feature can be defined as a singular signal trait. The signal can be measured by time domain, frequency domain or a combination of both. But, according to Heisenberg uncertainty principle, it is difficult to measure the signal in both time and frequency domain simultaneously i.e. increasing the accuracy in time domain leads to decrease accuracy in frequency domain, and vice-versa. Thus, many techniques have been developed based on both. Several examples are shown in [40] for both time and frequency domain and also for linear and non-linear methods. In this paper there are some pre-processing examples as well.

3.1.5 Signal classification

Classification consists of finding the label of each signal by using a mapping obtained from a training set. After performing all steps explained before, the main objective is to be able to determine to which signal belongs to every signal measured from the signal acquisition method used. Based on the examples above, in this case, the classifier encodes the action that is performing the user using the BCI quantifying the emotional and neural state. Several algorithms have been developed to classify properly the neural signals according to certain criteria [40, 41].

At the end, when the signal is classified, the applicability depend on its use. If the signal is properly captured and filtered and also well classified, the user can control any proposed action. Some application have been proposed for video-games and also, it has seen as a chance in neurorehabilitation [42].

Chapter 4

Game Development

In this chapter GTEC company is presented, the software developed by them, recoveriX and how they use BCI technology to help in stroke rehabilitation. It is also explained how the video-game has been created and how it is linked to GTEC technology.

4.1 Methodology

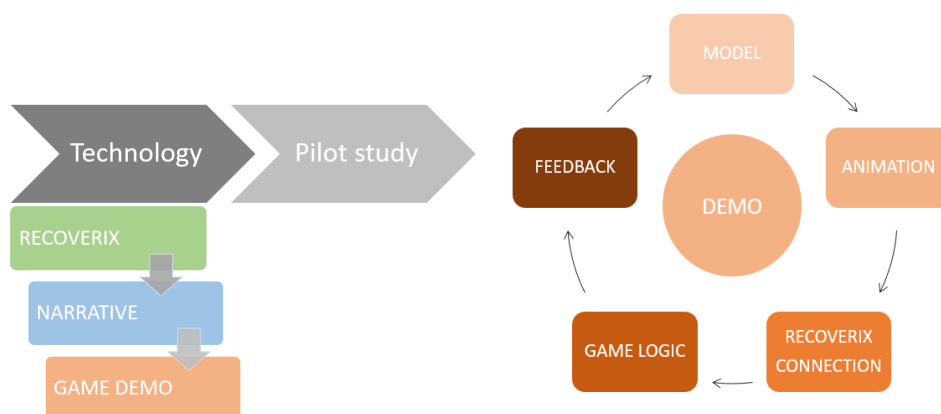


Figure 4.1: *Left*: General process of the technology development *Right*: Iterative process of the game creation

There are two main blocks in the realisation of the project: a technological development and an experimentation. The experimental part is the pilot study done with real patients that is detailed in chapter 5. The technological process is the tools developed to create the game and its implementation in the recoverix. As it is shown in Figure 4.1, it is divided in three parts: recoverix, narrative and game demo.

Recoverix

Recoverix is the technology developed by GTEC company that allows users interacting with a virtual environment by using the BCI method. The first step of the project was to understand how it works and how the connection with the virtual world was done in order to adapt it later to the videogame. Recoverix is the responsible of recording the brain wave, processing the signals and sending the order to interact with the virtual environment.

Narrative

The second step was to discuss about the story of the game. The story had to be easy enough to be comprehensible for all users but complex enough to challenge them, as well. Many proposals have done to the company and, at the end, the rat fight was selected.

Game demo

The last step was to develop the videogame; an iterative process was done by following an agile methodology. The agile methodology is a project management method that consist of releasing small parts of the whole project and assessing it in a continuous way. In this case, the process is shown on the right side of the figure 4.1. Firstly, a preliminary version of the graphical models was created with their animations. Secondly, the properly connection of their functionality was done with the recoverX and finally, the compilation result was presented to the company to receive some feedback and redo the parts that needed enhancements and keep working on the whole videogame.

4.2 RecoveriX

RecoveriX is a new form of therapy specifically developed for the rehabilitation of hand and foot movement after a stroke. This method can be used for treatment in the acute phase as well as in the chronic phase. The rehabilitation procedure consists of registering the intention of the movement through BCI, applying electrostimulation to effectively do the movement and, at the same time, showing the movement in a virtual avatar in a screen.

A stroke impairs the movement of some parts of the body, but it does not disable your ability to think about the movement. The imagination of the movement produces a brain activity similar to the performance of it, so recoverix uses this therapy for stroke rehabilitation.

The therapy uses three concepts: functional electrical stimulation, to produce the movement of the wrist; mirror neuron, by observing the movement of a virtual body parts on a computer screen; Motor imagination to increase the activity of the motor regions in the brain. This paired associative stimulation (PAS) is an important factor for motor recovery [43–46]. Neural networks are facilitated when the presynaptic and postsynaptic neurons are both active. recoveriX is a complete hardware and software platform which can record, analyse, and utilise EEG activity in real-time to “close the sensorimotor loop” for rehabilitation [47].

4.3 BCI method in recoveriX rehabilitation

The patients’ EEG is recorded by using 16 electrodes placed over the sensorimotor area of the cortex according to international 10/10 system (extended 10/20 system): FC5, FC1, FCz, FC2, FC6, C5 C3, C1, Cz, C2, C4, C6, Cp5, Cp1, Cp2, Cp6. A reference electrode was located on the right earlobe and a ground electrode was at FPz. Figure 4.2 shows the whole system distribution.

Throughout the procedure, patients sat in a comfortable chair and placed their forearms on a table, as shown in Figure 4.3. Before recording, the cap was mounted on the patient’s head, and FES parameters were adjusted to find the individual current amplitude to induce wrist dorsiflexion in each session without causing discomfort. Two FES electrodes were placed on the wrist extensor muscles of the left and right forearms, respectively. The FES stimulation was set to a frequency of 50 Hz with a pulse width of 300 μ s. The therapist increased the intensity of stimulation until smooth movement of wrist was observed in patients with mild and moderate impairment, or until muscle contraction was observed in the target muscle

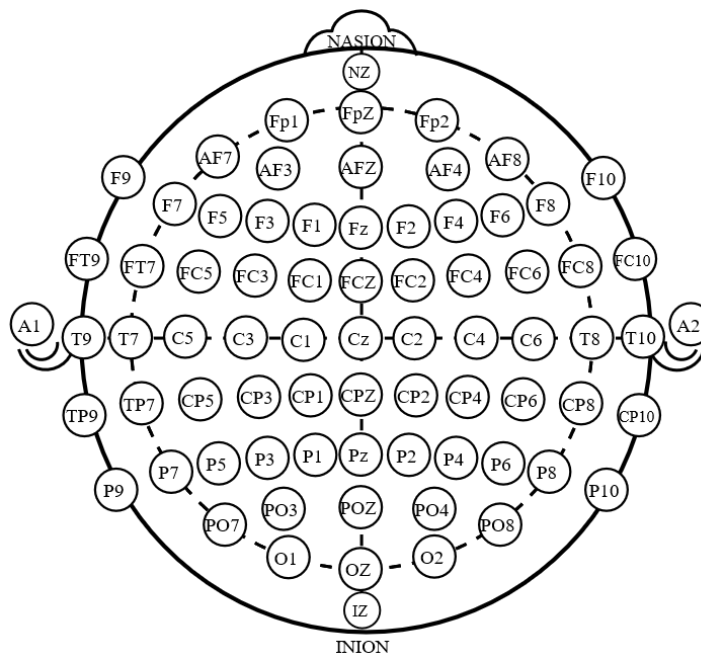


Figure 4.2: Electrodes distribution according to international 10/10 system

of their paretic side for patients with severe impairment. Patients were asked to imagine left or right wrist

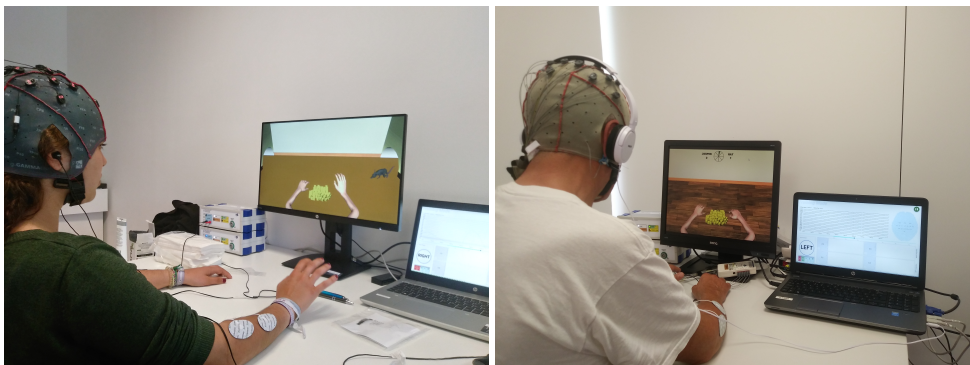


Figure 4.3: *Left*: Example of control user stroke rehabilitation session using the recoverix system. *Right*: Exampe of patient stroke rehabilitation session using the recoverix system

dorsiflexion according to visual and auditory cues from the BCI system. The sequence of motor imagery tasks was specified in pseudo random order with randomized inter-trial intervals. A beep was played to start each trial. An animated green arrow and spotlight to either the left or right hand visually instructed the patient to imagine left or right-hand movement. The patient also received an auditory instruction, which was a recorded voice that said “left” or “right” in Spanish. When the system classified the correct side of movement from the EEG during feedback phase (3.5–8 second), the FES and avatar were activated. This decision was updated every 200 ms.

The BCI system used (recoveriX, g.tec Medical Engineering GmbH) captured and amplifies the EEG data by using a biosignal amplifier (gUSBamp, g.tec Medical Engineering GmbH). The first preprocessing approach is done by applying a Common Spatial Patter (CSP), obtaining a matrix where two classes are shown: the one with the higher variance and another with the less. Both belong to the EEG signals cor-

responding to right and left wrist dorsiflexion, respectively. To determine if patient is imagining correctly the corresponding wrist movement, a Linear Discriminant Analysis (LDA) is performed [47]. The classifier accuracy is computed at the end by using a cross-validation method. For each repetition, signal features are captured every 0.5 seconds from the 1.5 second of the exercise to the end; 14 classification measures are obtained from 0% to 100%. Then, an average is done regarding features of the other repetitions. The accuracy of each exercise is computed by getting the maximum classification precision (MCP) obtained during each repetition phase.

Linear discriminant analysis (LDA), normal discriminant analysis (NDA), or discriminant function analysis is a generalisation of Fisher's linear discriminant, a method used in statistics, pattern recognition and machine learning to find a linear combination of features that characterises or separates two or more classes of objects or events. The resulting combination may be used as a linear classifier, or, more commonly, for dimensional reduction before later classification.

4.4 Game development tools

Unity is a cross-platform developed by Unity Technologies that is used to create three-dimensional, two-dimensional, virtual reality and augmented reality games, as well as simulations and other experiences. In this project, Unity has been the main tool that helps to develop the simulation for the rehabilitation purpose. Thanks of unity, it has been easy to implement the video-game with the recoverix technology and also to generate all dynamics of the game. Nevertheless, it is not the only software used, some others have been used to create the models and the animations of each character.

Maya is an animation, modelling, simulation and 3D rendering software with powerful integrated tools. It can be use for animation, environment description scenes, movement graphics, virtual reality and characters modelling. This software has been used in our project to develop some of the models implemented in the same way as to create all video-game animations.

Sketchup is a premier 3D design software that, because of its easy use, anyone can make their 3D models with its tools. It is used in a wide range of applications such as architectural, interior design, civil and mechanic engineering... And also for films and game modelling. It takes part in this project as a useful 3D modelling tool for the first draft models.

Mixamo is a 3D computer graphics technology company that has created a web-based service to help 3D characters animation. It uses a sophisticated technology to make easy the process from 3D modelling to rigging and animation.

GIMP is a cross-platform image editor with many useful tools to enhance your graphics or illustrations. It is a free software distributed with GNU general public license. In this case, GIMP has been a useful tool for this project for texture creation.

4.5 Game development process

The whole creation process has been divided in four phases: the narrative, modelling and graphic environment, the animations and game compilation. The next section present thoroughly the process in each phase.

4.5.1 Narrative

This was one of the most discussed section of the project. The narrative is important for the game development, moreover, it adds a new dimension to the game. Therefore, there are some elements that are related to the history that must be considered.

- Story itself: characters, settings, genre, plot
- Visual style: Visual coherence amongst the story course
- Game controls: How the play is played
- Game sound: How it helps to users to immerse themselves to the game

Besides, in this project there were some aspects that needed to be considered, as well. On one hand, this project did not have entertainment as a primary purpose, so the history could not be either very sophisticated or complicated to understand. The history had to be enjoyable enough for the people who had to play the game. Likewise, it had to be challenging enough to keep user attention and concentration during the whole game.

On the other hand, regarding the main aim behind the game, the neurological issue rehabilitation, the game dynamics was fixed beforehand. In this case, the rehabilitation was about a upper extremity i.e. the right/left wrist. So, it had to be a repetitive movement using the corresponding affected hand.

Hence, two options were proposed as thematic thread for the game: bird's releasing and rat catching. Bird's releasing consists of freeing birds from a small cage to their natural environment. Rat catching consists of avoiding a rat catching a piece of cheese. Both are simple games with simple rules regarding the restrictions mentioned before.

The one chosen is rat catching. Further explained, rat catching thread is about to protect a cheese stack avoiding that the rat could eat any of them. There are two possible options in this story, that the rat steals a piece of cheese from the stack, or that the user shoos the rat from the stack. One or the other of these two possibility is chosen depending on how good is the user MI performance with BCI technology.

This thread was chosen because the user can be defeated, unlike the bird thread. If the user is not concentrated enough, the rat will eat more pieces of cheese than the ones the user could keep. Therefore, it adds an extra value making the game more challenging and entertaining.

4.5.2 Interaction model

In video-games there is an important feature that is how the user is able to communicate and interact with the virtual world, it is known as physical input. There are many devices that have been developed to achieve this purpose and they have been improved thanks of technology improvement and research. The most common way to do that is by using a controller device and a sequentially combination of buttons. In this case, two different interaction models have been created, the first one was by using the keyboard (for the development stage) and the second, by using a BCI method (for the rehabilitation stage).

Keyboard physical input

Keyboard physical input was programmed in order to simulate BCI signals and observe the game behaviour. The messages that can be sent by the BCI are:

- textitcues. Depending on what upper limb side has to work, the system sends a right cue or a left cue;

- *feedback on*, the recoverix starts to register the neural signals generated by the user using the EEG hat. At the same time, the recoverix tries to identify if the signal received fits with the movement that the user must imagine. As a result, two possible signals are released:
 - *positive response*, if the user's imagery fits with the working hand movement;
 - *negative response*, if the user's imagery does not fit with the working hand movement;
- *feedback off*, when the time runs out.

Some extra features have also been created in order to make easier to interact with the game.

- 0: Cue right
- 1: Cue left
- 2: Feedback on
- 3: Positive response
- 4: Negative response
- 5: Feedback off
- 6: Reset the game as default
- ESC: Show detailed statics of the game
- TAB: Show extra information, the timer and the score
- Q: Quit the game

ESC function is barely used but it was created in order to watch the game course, and to make easier some game development parts. **TAB** function is used to assess some objectives of the game. It has two phases, the first time the TAB is pressed the timer and the score are shown promptly, one every ten times. If it pressed again, the timer and the score are shown permanently. Finally, another press makes the timer and the score disappear and the sequence restarts.

BCI method

This is the main physical input of the game. BCI method needs a two steps to set up: a connection between the device and the computer and the data interpretation. For connection, two different methods have been used to connect the BCI and the video-game: UDP client and Zeus client. For interpretation, the same methodology for both is used, unity events.

Every time that the recoverix is started, a new server is created and receives candidates as a *RecoverixDevice*. If they are properly identified, these are appended to a *ConnectedDevices* list. The changes from the recoverix are published in this server and all connected device receive them. This is the way how the devices are able to interact with the recoverix messages and consequently, to the EEG hat.

The first connection done was by using User Datagram Protocol (UDP) that is a simple message-oriented transport layer protocol. With UDP, any computer application can send messages to a host on an internet protocol (IP) network. In this case, recoverix is the computer application and FES and the video-game are the host. This was the first way how the recoverix connection was made but nowadays it is unused. Otherwise, Zeus client was developed by GTEC company to make easier the connection with the recoverix

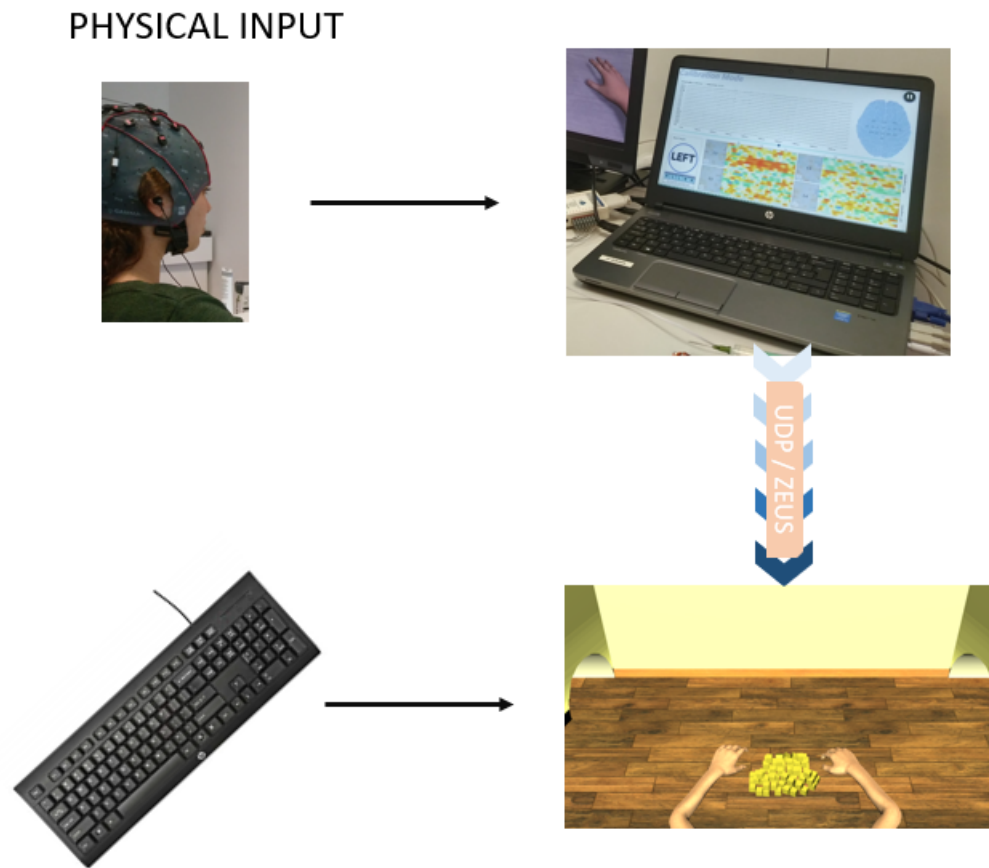


Figure 4.4: Schematic representation of the BCI communication

and the different devices that are used in the whole system. It follows the same connection structure explained before but it is done in a TCP protocol. A handicap of the Zeus client is that messages are sent as asynchronous signals, thus a buffer is needed to process them sequentially and regarding the unity update function. This is the current connection used.

The received data is interpreted by unity events. Unity events are a way of allowing user driven callbacks to persist from edit time to run time without the need of additional programming and script configuration. Hence, the message can be treated as a function argument and can perform the corresponding action according to the game flow. Each message corresponds to a unity event, and it makes the changes in the virtual world.

4.5.3 Modelling and graphic environment

Sketchup, Maya and GIMP are the software used to create or customise the models that appear in the game. Not all the models are created from scratch, actually only the environment models, but all of them have been modified to fit the game. The models of the game are an humanoid and a rat and, for the environment, interior walls of a house and the stack of cheese pieces. These two types are differentiated because models are animated while graphic environment objects remain static.

So, the first question to answer was, where is the right place to develop the action?

At the beginning, the first environment approach was to perform the action in an outdoor and disgraceful environment i.e. performing a dirty place. This first approach wanted to represent a common place where rats are used to live, thus it was easy to imagine and to understand the story coherence. However, it was seen that it was not a good environment because a lot of facts could distract the users, thereby, the rehabilitation will not had the expected results. Hence, the second option was to perform the action in a plain place and without distraction i.e. in indoor place.

The interior walls of the house were made from scratch using the sketchup software. Thanks to its easy tools it was not difficult to build them. Two types of walls were made, the front wall with a plain texture and without any shape or relief; the side walls with also the same plain texture but with a hole representing the rat lair. The texture was also created from scratch by using GIMP. Finally, a simple plane was created with wooden floor texture.

In order to make the wall and floor textures more real, a normal map was also applied. Normal map is a technique used for faking the bumps and dents lightning and it adds more detail without introducing new polygons.

Stack of cheese pieces were much simple to create. Each piece of cheese is a simple small cube where cheese textures and the corresponding normal map are applied to make it more real. Then, many of them were grouped correctly forming the stack. This model was created using the unity creation tools.

Modelling is not an easy task and usually, it takes a lot of time. Thus, both the humanoid and rat models were obtained from Mixamo and turbosquid ¹ web-page [48] and afterwards, they were customized to fit the game composition.

For the humanoid model, Jasper's character was chosen from Mixamo resources, shown in Figure 4.5. Humanoid is the main character in the game, he is the one that reproduces the movement to be done by the user or patient and, at the same time, he is the one that fixes the main point of view of the scene. The model modification, basically, was to adjust the jasper dimension in order to fit correctly the main camera of the game. The final result is just keeping Jasper's body and placing the camera at his head. These changes were done in Maya.

For the rat model, as said before, it was obtained from turbosquid web-page. The rat model looked like a mutation rat with big claws and fang. So, basically, the modification was to erase these parts from the model and make it more pleasant. The modified rat is shown in Figure 4.6.

4.5.4 Animations

Animation is a technique that creates a sequence of images corresponding to successive instants of time and such that projected at enough speed they give the impression of continuous movement. Traditional animations were done by drawing or painting all images sequence in a celluloid sheet. Nowadays, with technology improvement, animation uses computer-generated imagery (CGI)

In this project, animation is used to give life to all characters mentioned in modelling i.e. the main character, Jasper and the rat.

To animate every model, the first step that must be done is rigging. Rigging consists of creating the digital controls of the model and linking them with the 3D model. Thus, rigging generates a digital skeleton for each model. To complete this task the software used was Maya in both cases.

Jasper model that, as mentioned above, was obtained from Mixamo had already a predefined skeleton. However, fingers of this skeleton did not have all phalanges joint and, therefore, they were created from

¹Turbosquid is a digital media company that sells 3D models used in 3D graphics to a variety of industries.

scratch. The skeleton consists of a set of joints in ankles, knees, rip, chest, shoulders, elbows and wrists, and also, in all phalanges of both hands and toes fingers.

To make easier the character animation, controllers and inverse kinematics (IK) for the joints were created. Each controller is linked with a joint, and if the controller is moved, the joint follows its movement. At the same time, when the controller is created, a rest position is set to 0. This means that when the animation has finished, it is easy to return the character to the rest position to start a new animation procedure.

IK is a mathematical process that reproduces the movement of an object in the world by defining the final position. It is very used in robotics and in characters animation. In this case, IK is used for upper extremities. By defining where the hand should be placed, all the arm movement follows the hand movement as a real person. So, the IK has used in the Jasper model, mainly, to define the desired position of the arms.

Rat model was more complicated to rig because of two main reasons: firstly, it has not a common person

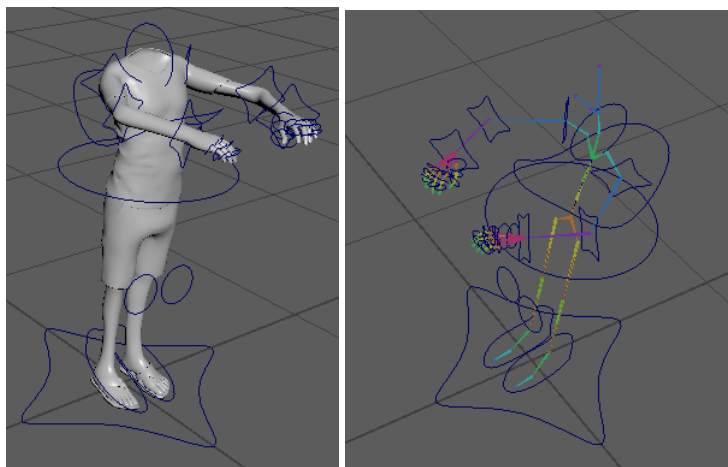


Figure 4.5: A full view of Jasper model

skeleton, so the skeleton was invented and created according to the movements that should be perform. Secondly, the rat model is curved body, so it is not an standard skeleton. Moreover, the joint weights ² are different from a human skeleton and had to be defined from scratch.

For the rat rigging, the following joints were done: seven tail joints, one for the hip, five for each leg, three for the back, four for each arm, three for each finger phalanges, and finally, three for neck and mouth. The resulting skeleton is shown in the right side of Figure 4.6. In the figure, the controllers are also shown as a blue shape around the models/skeleton. They were created in order to make easier the rat's animation.

There are five rat animation states: to walk position, smelling, walk, stand up and idle. Both *to walk position* and *stand up* are transitional states. Since other states could not be consecutive states, these were made to make the animation more versatile. Thereby, *to walk position* is the movement of the rat bending down as he wants to start walking and *stand up* is the rat rising to both feet. *Smelling* is a rat nose movement searching for the cheese smell and *idle* is a rest position of the rat. Both are performed when the user is imagining the wrist movement. Finally, *walk* is displayed when the rat is moving.

4.5.5 Game sound

The game sound in video-games is an important feature because it improves the game functionality. Usually, the sound displayed in the game, no matter if the user likes it or not. It provides sensory cues such

²Joint Weights consist of the part of the body in what the skeleton is bind to and, when its joint is moved, how the model texture is also moved accordingly

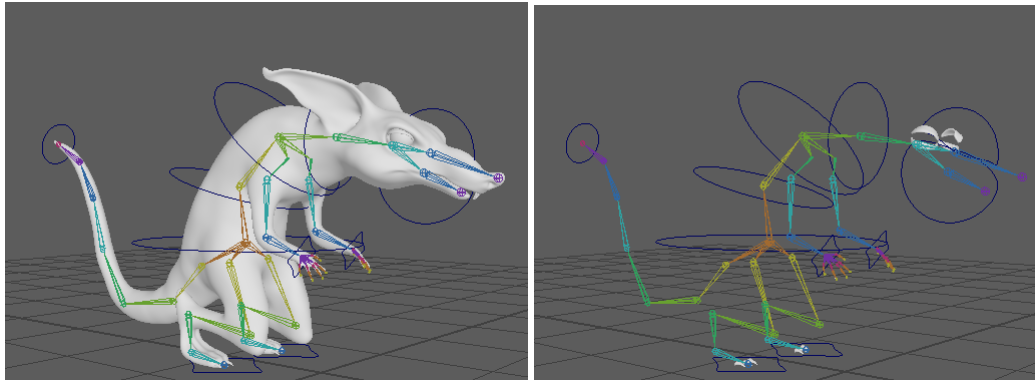


Figure 4.6: A full view of the rat model

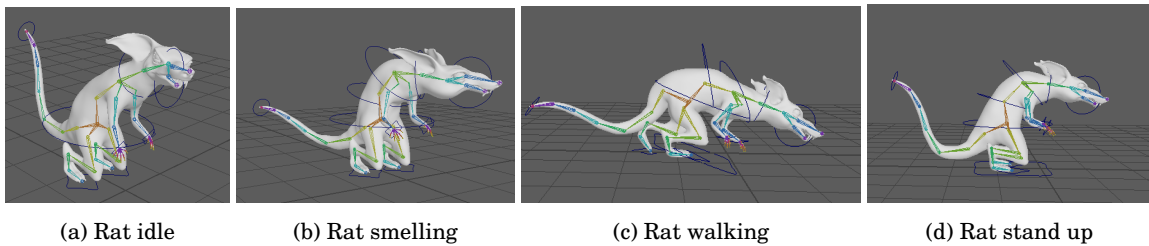


Figure 4.7: Rat animation states

as warning, hints, comments for proper moves... In this project, sound is used to help users to understand the performance, to stimulate users for what is going on in the scene and, finally, to help user's immersion. Thus, two main sounds types are differentiated: game instructions and sound effects.

Game instructions is fundamentally, a narrator that tells to the user what is the action to perform next. There is a sound that indicates when to start imagining the movement, after the narrator tells what hand is working and, at the end, there is a final message to stop imagining until the next cue is released. So, game instructions help users to understand what to do and when and what is happening along the scene course.

Sound effects is sound displayed according to what the scene is showing. In this case, there are three sound effects related to the two possible options explained in the narrative. If the rat has been able to steal a piece of cheese from the stack, there is a rat laugh sound while it is going back to its lair. The rat laugh at the user performance and it is a soft way of challenging a bit more the user.

Quite the opposite, the other sound effect is when the rat cannot steal a piece of cheese from the stack and then, the user shoos the rat. The sound effects displayed are, one corresponding to a blow on the ground and another corresponding to rat strike. With these sound effects the intention is make more real the simulation and also, to immerse the user to the game.

4.5.6 Game compilation

Game compilation includes basically the distribution of the different objects in the scene, the game dynamics regarding the animation of each character and the game sound. As mentioned in Section 4.1, this was not done by stages, if not in agile method. As the models and the different elements were built, the scene was constructed, presented and remade.

The construction of the scene takes not much time because when the models were been available, they were

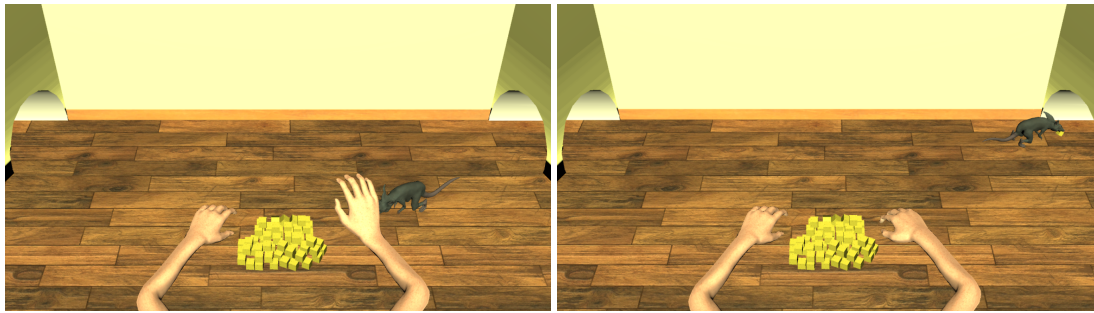


Figure 4.8: *Left*: Right response of the video-game. Jasper shoos the rat. *Right*: Wrong response of the video-game. The rat steal a piece of cheese from the stack

located in order to obtain a comprehensive and consistent virtual environment. The part that takes more time was the game dynamics. Regarding the limitation of some users, game dynamics must be flexible and easy to understand. Thus, two dynamics were introduced regarding the messages sent by the recoverix, for the right response and for the wrong response.

The game action happens along 8 seconds. During this period of time the recoverix send positive or negative messages to video-game, that are stored and process, and acts consequently. Messages sent by the recoverix depends on how well the software is able to identify the movement of the wrist that is working and the imagery intention of the user. The two action that can be perform after this signal processing are either right or wrong response.

As said before, if recoverix is able to correctly associate the movement of the wrist that is working with the imagery intention of the patient, a positive signal is sent to the video-game. If along the 8 seconds, three of this positive signals are sent, it is treated as a right response. The consequently action of a positive answer is that the rat is no able to steal a piece of cheese from the stack and Jasper (the user) is able to shoo the rat. An example is shown on the left side of figure 4.8. Otherwise, if less than three messages are sent to the video-game and the time is up, it is treated as a wrong response. When this happens, Jasper (the user) is not able to shoo the rat and a piece of cheese is stolen from the stack. An illustration is shown in on the right side of the figure 4.8.

A state machine has been created to implement the video-game dynamics regarding the message sent by the recoverix. When the state is updated, the corresponding action (right or wrong) is performed.

In a similar way, a state machine has been used to combine the character animations with the game dynamics. Every character has its own state machine and depending on the messages sent and the currently situation of the virtual world, the characters do the properly movement.

Jasper has basically two actions to perform, as it is shown in Figure 4.9, hence he only has two animation. They depend on the limb side that is working and the messages sent by the recoverix. While positive messages are sent by the recoverix, Jasper raise up his working hand (right or left) showing the movement that the user must imagine. However, if messages sent by the recoverix are negative, he stops his movement until either a new positive message is received or until the time is up. Then, after processing the whole information for this 8 seconds, a correct or a wrong answer is returned.

As explained in Section 4.5.4, the rat has more animation than jasper but it uses the same methodology. In Figure 4.10 is shown the possible movement of the rat. At the beginning, the rat walks to its first destination while the user is working on imagining the ordered hand movement. Then, the smelling and idle animations are played until the 8 seconds have passed and the data is processed. Depending on the

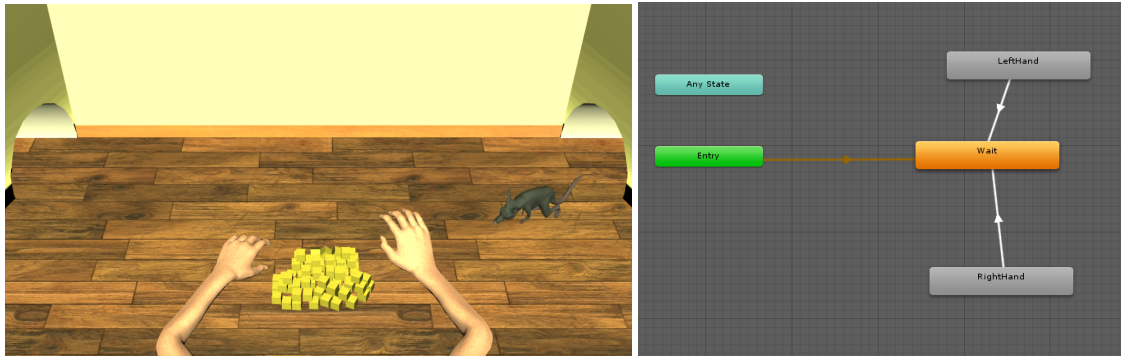


Figure 4.9: *Left*: Performance of Jasper movement; *Right*: State machine of Jasper's animation

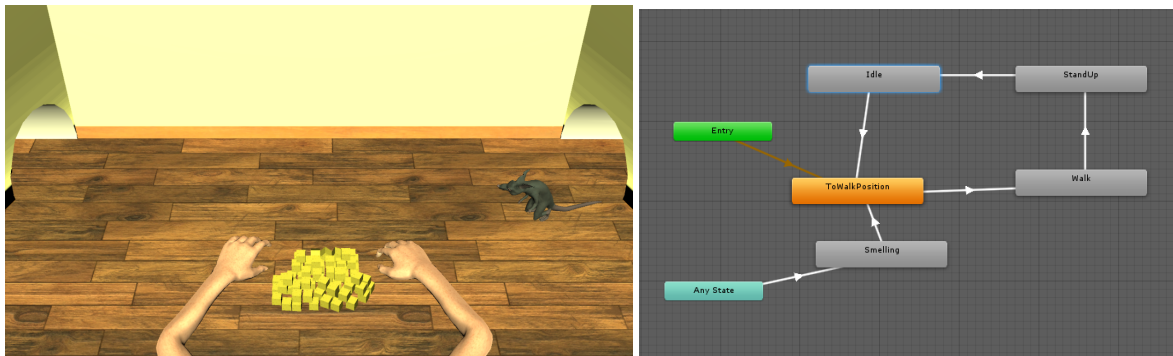


Figure 4.10: *Left*: Performance of the smelling rat movement; *Right*: State machine of rat's animation

user results, the rat has different destinations, if the answer is positive, the rat goes in straight line to the piece of cheese stack and Jasper shoos her. However, if the answer is wrong, the rat dodges Jasper's hand and steals a piece of cheese. This both action are shown before in Figure 4.8. Finally, the game sound must also fit the game dynamics and flow. The orders are displayed in voice-over and are attached to the corresponding flow moment i.e orders has temporal dependency, they do not depend on whats happening in the game world. However, the sound effect could not be done in that way because they are heavily related to the character action. Hence, the sounds effect are linked with its corresponding action.

Chapter 5

Pilot Study

The pilot study studies patients that have suffer a stroke and they have muscular weakness in half part of the body and, at the same time, they are doing an upper limb rehabilitation. The aim of the study is to analyse the effect of the gamification in the BCI rehabilitation, to assess if the game influences the results of the therapy and the user experience.

5.1 Hypothesis

The recoverix therapy, as it is explained in the Section 4.2, is based in three concepts: functional electrical stimulation, mirror neuron and motor imagination. The aim of this project is to include the gamification in the BCI rehabilitation by using a videogame instead of the avatar simulation for the mirror neuron therapy. The hypothesis of the pilot study is that including the gamification in the visual feedback of the BCI rehabilitation with recoverix has a neutral or positive effect in patient's performance and it diminishes the patient's feeling of monotony and boredom. The algorithm based the recoverix computes the significance of the captured signals with BCI in relation to the motor intention. Thus, the principal hypothesis can be described as:

1. The significance level is not modified significantly in the calibration part for both the control users (without therapeutic purpose) and patients
2. The significance level is not modifies significantly in the training part for both the control users (without therapeutic purpose) and patients
3. The kindness of the session with the game is major for both the control users and the patients.
4. The frequency of the visual feedback of the score modifies the significance level of cerebral activation
5. In a scale from 1 to 5, the majority of the patients grade with favourable (4) or more favourable (5) to introduce gamification in the rehabilitation.

5.2 Methods and materials

5.2.1 Recoverix system

The BCI method is used with the recoverix for rehabilitation the upper limb. In the rehabilitation with this method the patients wear a BCI device (hat), electrical stimulation in both arms and headphones.

The patient is in front of a screen where it is displayed wrist dorsiflexion in an avatar simulation. Every session is done repetitively following the same pattern: the patient receive an order of rising the arm (auditory stimulus), then the patient imagine the motor movement and receive an electrical stimulation (sensory stimulus) to rise the corresponding arm as well as the movement is displayed in the screen by a virtual avatar (visual stimulus).

5.2.2 Game

A videogame has been created regarding some requirements:

- Virtual environment where the avatar is centred and only the upper limb are shown
- Unique interaction mechanism by registering the brain activity with the intention of moving one of the upper limbs
- Display the same frequency and intensity in each rehabilitation exercises

Regarding these requirements an story line is proposed that help in the movement realisation: the user moves the arm with the aim of pushing aside an intruder to protect their belongings. With this story line, two of the four primary instincts are develop: protection (related to with the fight and defence instincts) and wealth (belongings acquisition related to nutrition instinct). Hence, the game shows the user belongings as a cheese stack in between the two avatar arms. A rat (intruder) comes from either right or left and she tries to steal a piece of cheese from the stack. If the movement intention is well performed according to the recoverix analysis the user moves the arm and shoos the rat. Otherwise, the rat eats a piece of cheese. By including a competition point of view, the game is strengthened. The score is shown in different moments: at the end of the exercise, at the end of each session or permanently.

The game has been connected with the recoverix system and it captures continuously the number of coincidence between the movement and the game intentions and it fits the narrative.

5.2.3 Test

To test the patient's performance, two rehabilitation sessions has been programmed using both the avatar simulation and the videogame. To test the patient's motivation and concentration, a questionnaire has been developed based on ten questions and inspired by SUSE. It is passed to all users to assess qualitatively the game interest.

5.2.4 Experimental design

Two sessions are done with each user. Each session consists of three different parts: calibration, training 1 and training 2. It takes 15 minutes each part and regarding the initial preparation, it takes around an hour per session.

Calibration aims to understand the patterns of the user's brain when the functional movement is realised, the first training test the patterns obtained in the calibration and enhance its performance and finally, the second training test the patterns obtained in the two previous parts.

The purpose of the first session is to familiarise the user with the technology and evaluate the gamification without score feedback. The calibration and the first training are done without using gamification whereas the second, it is used.

The intention of the second session is to assess the impact of the gamification in the calibration part and also, the relevance of the score feedback. The whole session is done with the gamification but the score feedback is only shown in the training parts. The first training shows it punctually since the second part it is shown permanently.

5.3 Subject profiles

Control users involved in the study have voluntarily decided to participate on it. They are randomly chosen in the range between 18 and 80 years old and regarding both genders. The volunteers that have suffered a cerebrovascular injury with spastic hemiparesis are chosen regarding the following specifications.

Inclusion criteria:

Patients involved in the pilot study must be/have:

1. Enough cognitive capacity to understand correctly the game instructions in Spanish
2. Be elder than 18 years old
3. A cerebrovascular injury with residual spastic hemiparesis
4. Stroke that happened at least a week ago
5. Impairment in the upper limb, defined as a disability for realising daily life activities
6. A stable neurological state
7. The choice to participate in the pilot study
8. Availability to come to the Institut Guttmann facilities for rehabilitation sessions
9. Be able to understand and execute the task required in the protocol

Exclusion criteria:

1. Pregnancy
2. Medical devices implemented, active or passive, that does not allow FES usage
3. Metallic fragments implemented to the upper limb that does not allow FES usage
4. Cerebellum injuries
5. High intracranial pressure
6. History of disordered aneurysm
7. Epilepsy records that are not controlled with correctly treatment
8. Under anaesthetic or similar drug
9. With severe mental impairment that the patient cannot understand the task to realise
10. Do not understand properly the given instructions such as the informed consent
11. Without upper limb injuries

12. Pulmonary illness, infections, renal failure, hepatic damage, risk of heart disease
13. Pusher syndrome
14. Significant circulation problems in the upper limb
15. Incapacity of being in sat position without help for 60 minutes
16. Sensory alterations that significantly affect of feeling pain and reacting inappropriately to proprioceptive stimulus
17. Diseases of the peripheral nervous system that affect the upper limb (paralysis of brachial plexus, cervical disease, root or trunk syndromes)
18. Botulinum toxin treatment of the paretic upper limb during the pilot study

Chapter 6

Results

After the experimentation, the results obtained are shown:

Table 6.1: Control users max accuracy

Control Users ID	1st session			2nd session		
	Calibration	Training 1	Training 2	Calibration	Training 1	Training 2
ADCC	-	-	97.8	-	95.5	94.3
DT	68.1	69.4	73	90.3	95	90.5
G	-	-	55.9	74.1	64.1	68.8
JRS	95.3	97.6	97.6	94.7	96.7	97.8
MB	81.1	78.1	82	65.2	69.3	81.3
MCB	94.6	97.7	95.8	92.3	97.9	97.8
TEST	87.5	88.9	-	-	-	-

Table 6.2: Control users mean accuracy

Control Users ID	1st session			2nd session		
	Calibration	Training 1	Training 2	Calibration	Training 1	Training 2
ADCC	-	-	91.615	-	89.796	89.421
DT	59.92	65.783	69.181	85.912	89.524	86.486
G	-	-	48.026	67.98	61.801	65.119
JRS	91.74	94.331	95.035	92.857	93.703	95.69
MB	-	73.938	72.286	61.472	65.26	73.774
MCB	89.541	93.407	90.923	79.487	91.468	92.1556
proves	81.439	77.579	-	-	-	-

Table 6.1, table 6.2, table 6.4 and table 6.5 show the accuracy of each exercise in each session for both, control users and patients while table 6.3 and table 6.6 show its significance. The significance is an statistical indicator that, regarding the sample (N) show which should be the minimum score to accept user performance. Hence, to obtain quality data, the accuracy value must be higher than the significance value. This is not what happens in all cases; the cells marked in red are accuracy values lower than its corresponding significance value, that are also marked in red in its corresponding significance table. For the statistical test, the data that does not accomplish this requirement has not been taken into account. There are also some missing value displayed as a '-'. These have also erased for data statistics.

Below are shown the table that have been used to calculate the differences between groups and to validate

Table 6.3: Control users significance

Control Users ID	1st session			2nd session		
	Calibration	Training 1	Training 2	Calibration	Training 1	Training 2
ADCC	-	-	65.1	-	59.5	58
DT	62	59.1	57.5	62	63.2	61.9
G	-	-	58.2	63.4	60.6	58.6
JRS	62.8	59	57.9	61.7	58.2	56.6
MB	61.9	59.5	58.2	62.6	60.9	58.7
MCB	63.7	58.8	57.3	61.5	58.4	56.7
TEST	61.4	62	-	-	-	-

Table 6.4: Patient max accuracy

Patient ID	1st session			2nd session		
	Calibration	Training 1	Training 2	Calibration	Training 1	Training 2
AOB	73.8	71.5	70.8	64.1	71.1	74.8
CVC	83.8	75.7	75.2	82.9	88.7	89.6
FFM	82.1	73.4	81.9	83.8	86.5	80
JBF	76.9	74.4	67.5	82.9	82.9	75
JCZ	76.9	82.9	79.4	79.5	80	80.2
MBB	97.4	96.9	93.3	91.3	91.3	91.3
MCB	57.4	59.2	57.5	64.3	58.8	55.9
MCM	78.8	70.9	73.8	83.3	76.7	78.7
PG	75	76.3	-	81.4	76	75.2
TPB	80	80	75.8	69.7	-	-

the previous null hypothesis. The table are sorted by the comparison of the performance between the control users and the patients for each exercise in each session and then, the comparison between three different aspects: the calibration using either the base avatar or the rat game, the result accuracy using either the base avatar or the rat game, and finally, the result accuracy by including visual element in the game. The last table 6.31 shows the qualitative answers of the questionnaire.

The table 6.31 shows the answers of the questionnaire,

In the table 6.31 is also shown the mean of each control user and patient regarding all answers of the questionnaire, whereas the mean that is displayed in Table 6.32 is the average of each exercise answer.

Table 6.5: Patient mean accuracy

Patient ID	1st session			2nd session		
	Calibration	Training 1	Training 2	Calibration	Training 1	Training 2
AOB	65.179	67.993	67.857	59.158	66.447	68.635
CVC	68.34	73.616	59.255	74.248	79.074	78.639
FFM	76.374	69.078	78.752	76.25	80.311	78.82
JBF	69.78	67.321	65.536	75.376	76.854	70.763
JCZ	72.161	78.477	77.071	72.894	75.429	77.155
MBB	90.293	89.643	88.929	81.964	82.321	82.976
MCB	48.529	54.527	53	59.184	51.158	53.797
MCM	66.607	63.837	67.143	70.513	71.81	63.416
PG	60.536	72.894	-	68.57	66.438	69.884
TPB	70.893	75.268	71.368	62.03	-	-

Table 6.6: Patient significance

Patient ID	1st session			2nd session		
	Calibration	Training 1	Training 2	Calibration	Training 1	Training 2
AOB	61.4	58	56.5	61.5	58.2	56.6
CVC	61.9	58.2	56.6	61.7	58.5	56.9
FFM	61.5	58	56.5	61.4	58.1	56.6
JBF	61.5	58	56.5	61.7	58	56.6
JCZ	61.5	58.2	56.5	61.5	58.2	56.6
MBB	61.5	58	56.5	61.4	58	56.5
MCB	62.4	58.5	57.1	62.2	58.3	56.7
MCM	61.4	58	56.5	61.5	58.2	56.6
PG	61.4	58.1	-	62.2	58.3	56.7
TPB	61.4	58	56.5	61.7	-	-

Table 6.7: Comparison of the max accuracy results amongst control users and patients (*1st session*)

Calibration_A		Training 1_A		Training 2_A	
users	patients	users	patients	users	patients
68.1	73.8	69.4	71.5	97.8	70.8
95.3	83.8	97.6	75.7	73	75.2
81.1	82.1	78.1	73.4	97.6	81.9
94.6	76.9	97.7	74.4	82	67.5
87.5	76.9	88.9	82.9	95.8	79.4
	97.4		96.9		93.3
	78.8		59.2		57.5
	75		70.9		73.8
	80		76.3		75.8
			80		

In order to prove the hypothesis two test's have been used: the Student's t-test and Mann-Whitney test. Student's t-test is statistical hypothesis test in which, under a null hypothesis, the test statistic follows a Student's t-distribution. The Man-Whitney test is a similar to Student's t-test but it uses a non-parametric test i.e. the data does not follow an specific distribution. The most common usage of this tests is to determine the heterogeneity of two sample, the null hypothesis is that both samples are homogeneous. By regarding the p-value obtained on both tests, can be determined if there are enough reasons to reject the null hypothesis or not.

Tests are done regarding two different kind of groups: the first four tables show the differences between the control users and the patients, whereas the last three tables show the differences amongst base avatar and rat game overall accuracy.

The cells marked in green in the Table 6.33 and in the Table 6.35 show that the p-value of the test is lower than 0.05, what means that exist differences between the two groups. The differences found are between the control users and patients in the calibration part using the base avatar and also, in the

Table 6.8: Average of the max accuracy results amongst control users and patients (*1st session*)

	Calibration_A		Training 1_A		Training 2_A	
	users	patients	users	patients	users	patients
Average	85.32	80.52	86.34	76.12	89.24	75.02
Std	11.234	7.100	12.422	9.651	11.207	9.900

Table 6.9: Comparison of the max accuracy results amongst control users and patients (2nd session)

Calibration_G		Training 1_G		Training 2_G	
users	patients	users	patients	users	patients
90.3	64.1	95.5	71.1	94.3	74.8
74.1	82.9	95	88.7	90.5	89.6
94.7	83.8	64.1	86.5	68.8	80
65.2	82.9	96.7	82.9	97.8	75
92.3	79.5	69.3	80	81.3	80.2
	91.3	97.9	91.3	97.8	91.3
	64.3		58.8		78.7
	83.3		76.7		75.2
	81.4		76		
	69.7				

Table 6.10: Average of the max accuracy results amongst control users and patients (2nd session)

	Calibration_G		Training 1_G		Training 2_G	
	users	patients	users	patients	users	patients
Average	83.32	78.32	86.42	79.11	88.42	80.60
Std	12.963	9.124	15.394	10.015	11.406	6.478

training 2 of the first session. The average of the calibration part for the base game and the rat game in both control users and patients are (87.57, 72.45) and (81.56, 72.73) respectively. The average of the training 2 for both control users and patients are (83.808 and 71.989) respectively.

6.1 Discussion

The first observation that can be done from the results exposed in Section 6 is that the calibration of BCI is not affected by the the game. Table 6.15 and Table 6.17 for the values and Table 6.16 and Table 6.18 for the average values show that the accuracy of calibration is slightly lower with the game, but the difference is not significant, neither with t-student nor with Mann-Whitney as shown in 6.37. Thus, introducing a game does not suppose a disturbance in the setup of the training. Thus, the first hypothesis is true for these sample data.

When analysing the differences between control and test users in the calibration, control users has a higher mean and max accuracy than patients, for the first (Table 6.7 and Table 6.11) as well as the second

Table 6.11: Comparison of the mean accuracy results amongst control users and patients (1st session)

Calibration_A		Training 1_A		Training 2_A	
users	patients	users	patients	users	patients
91.74	65.179	65.783	67.993	91.615	67.857
89.541	68.34	94.331	73.616	69.181	59.255
81.439	76.374	73.938	69.078	95.035	78.752
	69.78	93.407	67.321	72.286	65.536
	72.161	77.579	78.477	90.923	77.071
	90.293		89.643		88.929
	66.607		63.837		67.143
	70.893		72.894		71.368
			75.268		

Table 6.12: Average of the mean accuracy results amongst control users and patients (*1st session*)

	Calibration_A		Training 1_A		Training 2_A	
	users	patients	users	patients	users	patients
Average	87.57	72.45	81.01	73.13	83.81	71.99
Std	5.425	7.994	12.498	7.657	12.086	9.283

Table 6.13: Comparison of the mean accuracy results amongst control users and patients (*2nd session*)

	Calibration_G		Training 1_G		Training 2_G	
	users	patients	users	patients	users	patients
	85.912	74.248	89.796	66.447	89.421	68.635
	67.98	76.25	89.524	79.074	86.486	78.639
	92.857	75.376	61.801	80.311	65.119	78.82
	79.487	72.894	93.703	76.854	95.69	70.763
		81.964	65.26	75.429	73.774	77.155
		70.513	91.468	82.321	92.1556	82.976
		68.57		71.81		63.416
		62.03		66.438		69.884

session (Table 6.9 and Table 6.13). The difference is significant only for the mean accuracy in the first session (Table 6.35), i.e. without the game. However, this result could be due to the fact that the number of control users was small in this session, because, as mentioned in Section 6, two control users did not reach the minimum significance and had to be drop down, and results of two users were lost. In any case, this result is concordant with the fact that control users have always higher accuracy than patients, in calibration as well as in training session, with and without game.

In order to address the impact of the game in the accuracy, we first compare the results of Session 1 Training 1 (without game) and Session 2 Training 1 (with game) (Table 6.19 and Table 6.21 and average values in Table 6.20 and Table 6.22). The accuracy is always higher in Session 2, with the game than in Session 1, globally and for patients and control. However the differences are not significant (Table 6.38). Thus, we can conclude that the game does not worsen the training, which was the major concern. Therefore, these sample data verify hypothesis 2.

When comparing this result between control and patients, we can see in Table 6.7, Table 6.9, Table 6.11 and Table 6.13, that the accuracy with the game is higher for control than for patients. Again, just as in the calibration, this difference is not significant (Table 6.33 and Table 6.35).

Furthermore, when comparing the results of the two sessions in Training 2, both with the game, we can see that the accuracy is higher in the second session than in the first one (Table 6.23 and Table 6.25 and for the average, Table 6.24 and Table 6.26). Thus, it seems that the second session gives better results than the first one, independently from the fact that they have or not a game. The average difference is much higher for the max accuracy (5.96 vs 2.51) than the difference observed in Training 1 (Table 6.24 and Table 6.20), but it is approximately the same in mean (1.53 vs 1.58) (Table 6.26 and Table 6.22). A possible

Table 6.14: Average of the mean accuracy results amongst control users and patients (*2nd session*)

	Calibration_G		Training 1_G		Training 2_G	
	users	patients	users	patients	users	patients
Average	81.56	72.73	81.93	74.84	83.77	73.79
Std	10.572	5.900	14.368	6.076	11.828	6.581

Table 6.15: Comparison of the max accuracy results amongst the base avatar and rat game in calibration

Base avatar	Rat game
68.1	90.3
95.3	74.1
81.1	94.7
94.6	65.2
73.8	92.3
83.8	64.1
82.1	82.9
76.9	83.8
76.9	82.9
97.4	79.5
57.4	91.3
78.8	64.3
75	83.3
80	81.4
	69.7

Table 6.16: Average of the max accuracy results amongst the base avatar and rat game in calibration

	Base avatar	Rat game
Average	82.24	79.99
Std	8.691	10.367

explanation of the lower level of improvement in accuracy in Session 2 versus Session 1 in Training 1 is that the novelty introduced by the game could have had a small impact in control and patients.

Again in Training 2, the results are better globally in Session 2 for control as well as for patients (see Table 6.7, Table 6.11 and for the average, Table 6.8 Table 6.12). It seems that in the second training users understand better what they have to do and focus better on the exercise. Similarly to what happens in Training 1, the results are better for control than patients in both sessions. This difference is significant in the first session for the max accuracy (Table 6.33), but in not in the second one (Table 6.34). For the mean accuracy, however, the difference is significant in the first session, but according to Mann-Whitney test only (Table 6.35). This difference can be explained by the fact that in Session 1, the change between the first training and the second (no game vs game) was unexpected, and in patients could yield to a lower performance than for control users.

For patients, in Session 1 the maximum accuracy decays along training (it is lower in training 2 than in training 1), but it increases in session 2 (with game) (training2 has a higher accuracy than training 1) (Table 6.33 and Table 6.35). However, again for patients, the mean accuracy decays along time in both sessions. By opposite, the maximum and mean accuracy of control users increase in the two sessions. Thus, it seems that the game introduced abruptly in session 1 may have add a negative impact on patients, but not in control users. This "surprise" effect does not happen in session 2 and the behaviour of the patients is similar to that of control users. Another interesting issue arisen by the results of session 2 is that introducing visual stimuli in training 2 does not affect the performance of users (neither control not patients), because, as just explained, the maximum accuracy increases in both types of users and the mean decreases only for patients, but following the same tendency observed in Session 1 and without significant differences (Table 6.27 and Table 6.29 and for the average Table 6.28 and Table 6.30). Thus, the hypothesis that the presence of visual feedback on the score would not affect the training applies with these sample

Table 6.17: Comparison of the mean accuracy results amongst the base avatar and rat game in calibration

Base avatar	Rat game
59.92	85.912
91.74	67.98
89.541	92.857
81.439	61.472
65.179	79.487
68.34	59.158
76.374	74.248
69.78	76.25
72.161	75.376
90.293	72.894
48.529	81.964
66.607	59.184
60.536	70.513
70.893	68.57
	62.03

Table 6.18: Average of the mean accuracy results amongst the base avatar and rat game in calibration

	Base avatar	Rat game
Average	76.57	75.67
Std	10.025	8.457

data.

Finally, concerning the results of the questionnaire, users have evaluated the quality and interest of the game. The interest of the game has been evaluated regarding the game entertainment, the different devices used to play the game, the level of concentration and boredom of the user and finally, the idea of introducing videogames in stroke rehabilitation. The game entertainment has been well punctured (3.3125 over 5 in average) even is the worst obtained result. The different techniques used to play the game, basically external stimulation to immerse the user in the video-game, have also been well evaluated (3.75 over 5 in average). Surprisingly, the result for both the level of concentration and boredom have obtained the same score (4.25 over 5 in average) and the idea of introducing more entertainment in the stroke rehabilitation has also been very well punctured for both control users and patients obtaining a 4.5 over 5 in average. The quality of the game has been evaluated regarding the visual feedback of the game, the easiness of use, the game rules and the narrative. All of them are above an score of 4 except the visual feedback that has a punctuation of 3.75. The easiness of use, the game rules and the narrative have been well evaluated (4.4375, 4.6875, 4.375 over 5 in average, respectively).

Users were gratified with the game but there were some requirements repeatedly suggested. The first requirement was, especially from patients, a soundless place where to do the session. Patients did the exercise in the middle of a common rehabilitation gym isolated only by a curtain, thus they mentioned that it would be helpful being isolated for game concentration. The rat movement, after 240 times, was exactly the same when the user lost. Some of them suggested that changing the rat movement will enhance the visual feedback and the game entertainment. The stimulation regardless the feedback was also important for the users. The last requirement was about improving the other sensory channel of the game: the electrical stimulation and the sound.

The game is not only a rehabilitation session for the patients, it also can be understood as a tool for

Table 6.19: Comparison of the max accuracy results amongst the base avatar and the rat game in training 1

Base avatar	Rat game
69.4	95.5
97.6	95
78.1	64.1
97.7	96.7
88.9	69.3
71.5	97.9
75.7	71.1
73.4	88.7
74.4	86.5
82.9	82.9
96.9	80
59.2	91.3
70.9	58.8
76.3	76.7
80	76

Table 6.20: Average of the max accuracy results amongst the base avatar and the rat game in training 1

	Base avatar	Rat game
Average	79.53	82.03
Std	11.351	12.477

the therapist. The therapists were present during the whole rehabilitation session and the most common opinion amongst them was that it would be a useful tool for them to work in a different manner diverse aspects of the disease. In addition, they mentioned that, with the EEG of the patient, they would be able to understand a little bit better the patients brain behaviour.

Table 6.21: Comparison of the mean accuracy results amongst the base avatar and the rat game in training 1

Base avatar	Rat game
65.783	89.796
94.331	89.524
73.938	61.801
93.407	93.703
77.579	65.26
67.993	91.468
73.616	66.447
69.078	79.074
67.321	80.311
78.477	76.854
89.643	75.429
54.527	82.321
72.894	71.81
75.268	66.438

Table 6.22: Average of the mean accuracy results amongst the base avatar and the rat game in training 1

	Base avatar	Rat game
Average	75.94	77.87
Std	9.975	10.608

Table 6.23: Comparison of the max accuracy result in Training 2, both with the rat game

Training 2_A	Training 2_G
70.8	94.3
75.2	90.5
81.9	68.8
67.5	97.8
79.4	81.3
93.3	97.8
57.5	74.8
73.8	89.6
75.8	80
90.3	75
74.1	80.2
94.7	91.3
65.2	78.7
92.3	75.2

Table 6.24: Average of the max accuracy result in Training 2, both with the rat game

	Training 2_A	Training 2_G
Average	77.99	83.95
Std	11.360	9.421

Table 6.25: Comparison of the mean accuracy result in Training 2, both with the rat game

Training 2_A	Training 2_G
91.615	89.421
69.181	86.486
95.035	65.119
72.286	95.69
90.923	73.774
67.857	92.1556
59.255	68.635
78.752	78.639
65.536	78.82
77.071	70.763
88.929	77.155
67.143	82.976
71.368	63.416
	69.884

Table 6.26: Average of the mean accuracy result in Training 2, both with the rat game

Training 2_A	Training 2_G	
Average	76.535	78.067
Std	11.610	10.170

Table 6.27: Comparison of the max accuracy results amongst the base avatar and the rat game in visual feedback

Training 1	Training 2
95.5	94.3
95	90.5
64.1	68.8
96.7	97.8
69.3	81.3
97.9	97.8
71.1	74.8
88.7	89.6
86.5	80
82.9	75
80	80.2
91.3	91.3
76.7	78.7
76	75.2

Table 6.28: Average of the max accuracy results amongst the base avatar and the rat game in visual feedback

	Base avatar	Rat game
Average	82.03	83.95
Std	12.477	9.421

Table 6.29: Comparison of the mean accuracy results amongst the base avatar and the rat game in visual feedback

Training 1	Training 2
89.796	89.421
89.524	86.486
61.801	65.119
93.703	95.69
65.26	73.774
91.468	92.1556
66.447	68.635
79.074	78.639
80.311	78.82
76.854	70.763
75.429	77.155
82.321	82.976
71.81	63.416
66.438	69.884

Table 6.30: Average of the mean accuracy results using the base avatar and the rat game in visual feedback

	Base avatar	Rat game
Average	77.87	78.07
Std	10.608	10.170

Table 6.31: Results of the questions related to the videogame development. See the whole questionnaire's answers with its questions attached in Appendix A

q1	q2	q3	q4	q5	q6	q7	q8	q9	Mean
3	4	4	4	4	5	3	2	4	3.67
4	4	2	5	5	4	3	4	5	4
2	4	4	5	5	5	5	5	5	4.44
2	3	4	5	5	4	4	4	5	4
2	3	3	5	5	3	3	4	4	3.55
4	5	5	5	5	5	5	5	5	4.89
4	4	4	5	5	5	5	5	5	4.67
3	3	4	4	5	3	4	4	3	3.67
5	5	5	5	5	5	5	5	5	5
5	5	5	5	5	5	5	5	5	5
4	5	4	5	5	5	4	4	5	4.55
3	2	5	4	4	3	5	4	5	3.89
3	2	4	2	4	4	3	4	3	3.22
4	5	5	4	5	4	5	5	5	4.67
3	2	2	3	3	5	4	3	3	3.11
2	4	5	5	5	5	5	5	5	4.55

Table 6.32: Average of each questionnaire answers

	GE	VF	ES	Easy usage	Game rules	Narrative	CL	BL	Game in RHB
Average	3.3125	3.75	4.0625	4.4375	4.6875	4.375	4.25	4.25	4.5

Table 6.33: Test of the max accuracy results amongst control users and patients (*1st session*)

Test	Calibration	Training 1	Training 2
Student's t-test	0.421	0.151	0.045
Mann-Whitney test	0.175	0.079	0.023

Table 6.34: Test of the max accuracy results amongst control users and patients (*2nd session*)

Test	Calibration	Training 1	Training 2
Student's t-test	0.469	0.335	0.175
Mann-Whitney test	0.149	0.108	0.058

Table 6.35: Test of the mean accuracy results amongst control users and patients (*1st session*)

Test	Calibration	Training 1	Training 2
Student's t-test	0.012	0.247	0.104
Mann-Whitney test	0.026	0.115	0.034

Table 6.36: Test of the mean accuracy results amongst control users and patients (*2nd session*)

Test	Calibration	Training 1	Training 2
Student's t-test	0.195	0.300	0.105
Mann-Whitney test	0.101	0.166	0.053

Table 6.37: Test of the max / mean accuracy results amongst the base avatar and rat game in calibration

Test	Calibration (<i>max</i>)	Calibration (<i>mean</i>)
Student's t-test	0.980	0.946
Mann-Whitney test	0.397	0.488

Table 6.38: Test of the max / mean accuracy results amongst the base avatar and rat game in training₁

Test	Training 1 (<i>max</i>)	Training 1 (<i>mean</i>)
Student's t-test	0.570	0.715
Mann-Whitney test	0.309	0.315

Table 6.39: Test of the max / mean accuracy results amongst the base avatar and rat game in visual feedback

Test	Training 12_G <i>max</i>	Training 12_G (<i>mean</i>)
Student's t-test	0.992	0.936
Mann-Whitney test	0.422	0.491

Chapter 7

Conclusions

After a whole year working on this project all the purposes fixed at the beginning have been accomplished. In the project a game-based rehabilitation instrument has been developed as an improvement of the existing recoveriX system of post-stroke upper limb rehabilitation. The instrument is a game driven through Motor Imagery registered with BCI and coupled with external stimuli such as FES and sound. A pilot study have been realised to test the impact of the game component of this instrument in the rehabilitation process with both control users and real stroke patients.

The results obtained validate the hypothesis of the pilot study, discussed in Section 5.1. The first hypothesis was that the calibration results would not be affected by the game neither for control users nor for patients. Results (see Table 6.37) show that there are not significant differences between the calibration part, thus the game does not introduce disturbances in the calibration for the sample data. The second hypothesis was that there were not significant differences between the training with and without game. As in the first hypothesis, results (Table 6.38) show this hypothesis was true. The third hypothesis was about the rehabilitation entertainment, i.e. users find more pleasant the rehabilitation session by using the game. This was measured through a questionnaire (Table ??). Results show that in average, the score is above 2.5, half way between the entertainment and the boredom. Also regarding the questions related to the interest of the game, as it is shown in the Section 6 scores are almost all above the value 4. Hence, the hypothesis has be also validated for the sample data. In the fourth hypothesis, another aspect has been taken into account that is the concentration and the distraction of the patient performance with more visual feedback. In this case, as explained in the Section 5, users receive extra visual feedback to assess their performance. Table 6.39, once again, does not show significant differences with and without feedback. Finally, about the interest of gamifying stroke rehabilitation session, as it is shown in Table 6.31, almost all users scored it with a value equal or higher than 4, and in average (Table 6.32) a value of 4.5. It seems that it can a good practice to keep on for rehabilitating sessions.

The evaluation the performance between groups arises interesting findings. Control user have a better performance than patients in all cases. This difference is more significant in the calibration of the first session using the base avatar, and in the first training session with the rat game.

Rat game improvement as well as future research lines can be followed from this seminal work. According to rat game improvements, the game could adapt its difficulty by modifying the threshold mention in Section 4.5.6. As better the results of the user are, as higher the right response threshold should be (initialised in 3). This will induce either an extra challenge to well performance users making them to pay more attention to the game in order to maintain high score, or extra motivation by adapting its value in

a low one making easier to win the rat. This will help users to do not reject the game for being bored or frustrated. According to future research, firstly, a larger study could be done with more sessions and more patients. Then, other narrative threads could be tested and stratified into levels in order to increase the motivation.

Appendix A

Questionnaire

This appendix shows the questionnaire that was passed to users after the second rehabilitation session. This is the way how we were able to assess, in a subjective point of view, how users feel about the game and the opinion about the game.

Encuesta de valoración de la rehabilitación con BCI

Esta encuesta está dividida en dos partes. La primera, se pide información relevante del usuario y la segunda, se valora de forma subjetiva la rehabilitación con BCI

* **Necessari**

Encuesta demográfica

Estado del sujeto

1. Fecha de nacimiento *

Exemple: 15 desembre, 2012

2. Sexo *

Maqueu només un oval.

☐ Hombre

☐ Mujer

3. ¿Ha sufrido un ictus? En qué lado? *

Maqueu només un oval.

☐ Sí

☐ No

4. En caso afirmativo, ¿en qué lado?

Maqueu només un oval.

☐ Lado izquierdo

☐ Lado derecho

5. Fecha del ictus

Exemple: 15 desembre, 2012

6. Localización del ictus

Maqueu només un oval.

☐ Cortical

☐ Subcortical

☐ Cortical y Subcortical (mixto)

☐ Desconocido

Encuesta de valoración

Valoración de la rehabilitación con BCI

14. Las reglas del juego eran *

Maqueu només un oval.

	1	2	3	4	5	
Nada claras	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Muy claras

15. Con respecto a la narrativa (la lucha contra el ratón para proteger el queso), te ha parecido *

Maqueu només un oval.

	1	2	3	4	5	
Nada adecuada	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Muy adecuada

16. Con respecto al nivel de concentración necesario para realizar el ejercicio, en tu opinión, añadir el juego a la sesión de rehabilitación ha contribuido a *

Maqueu només un oval.

	1	2	3	4	5	
Despistarse mucho	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Concentrarse mucho

17. Con respecto a la posible sensación de aburrimiento al realizar el ejercicio, en tu opinión, añadir el juego a la sesión de rehabilitación ha contribuido a *

Maqueu només un oval.

	1	2	3	4	5	
Aburrirse mucho	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Animarse mucho

18. En general, la idea de introducir un juego (no necesariamente éste) en la terapia de rehabilitación, te parece *

Maqueu només un oval.

	1	2	3	4	5	
Nada acertado	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Muy acertado

19. Comentarios y contribucione

¿Ha sufrido un ictus? En qué lado?	¿Es caso definitivo, con qué lado?	Fecha del ictus	Localización del ictus	¿Ha utilizado con frecuencia un dispositivo BCI?	¿Es caso definitivo, con qué facilidad?	¿Juega a algún videojuego?	¿Le gustaría entrenar/leer el juego?	¿Cuánto volumen de juego en total del juego? (q8)	¿Y los entornos físicos (casas, parques, etc.)? (q9)	¿Cuál es la facilidad de uso del juego (q4)	¿Le gusta jugar el juego en su propia casa? (q5)	Con respecto a la herramienta (la idea contra la herramienta, la idea para la herramienta), ¿cuánto le gusta jugar el juego en su propia casa? (q6)	Con respecto al nivel de dificultad, ¿cuánto le gusta jugar el juego en su propia casa? (q7)	Con respecto a la posibilidad de jugar el juego en su propia casa, ¿cuánto le gusta jugar el juego en su propia casa? (q8)	En general, la idea de introducir un juego en la herramienta, ¿cuánto le gusta jugar el juego en su propia casa? (q9)
No	No			No	No	Algunos veces	3	4	4	4	5	3	3	2	4
No	No			No	No	Frecuentemente	4	4	2	5	5	4	4	4	5
No	No			No	No	Frecuentemente	2	4	4	4	5	5	5	5	5
No	No			No	No	Algunas veces	2	3	3	5	5	3	3	4	4
No	No			No	No	Frecuentemente	4	5	5	5	5	5	5	5	5
Sí	Lado derecho	28/02/2016	Desconocido	No	No	Nunca	4	5	4	5	5	5	5	5	5
Sí	Lado izquierdo	28/07/2015	Desconocido	No	No	Nunca	3	3	4	5	5	3	3	4	4
Sí	Lado izquierdo	30/03/2018	Desconocido	No	No	Nunca	5	5	5	5	5	5	5	5	5
Sí	Lado izquierdo	15/05/2016	Desconocido	Sí	reciente	Nunca	4	5	4	5	5	5	5	5	5
Sí	Lado derecho	28/03/2016	Desconocido	Sí	reciente	Frecuentemente	3	2	5	4	4	3	4	4	5
Sí	Lado izquierdo	6/11/2012	Desconocido	No	No	Casi nunca	3	4	4	4	4	4	4	4	5
Sí	Lado derecho	28/03/2018	Desconocido	No	No	Algunas veces	4	5	5	5	5	4	4	5	5
Sí	Lado izquierdo	15/05/2016	Desconocido	Sí	reciente	Algunas veces	3	4	5	5	5	5	5	5	5
Sí	Lado derecho	28/03/2016	Desconocido	Sí	reciente	Algunas veces	2	4	5	5	5	5	5	5	5

Figure A.1: Illustration of the questionnaire answers of control users and patients

Appendix B

Informed consent

The informed consent is an explanatory document where appears all the explanation about the game protocol, how the different session are programmed, a further explanation on what the study is about and the risk factors that exists in the study. This is a mandatory documentation that must be shown to each control user or patient in order to publish the results obtained of the study. There are three documents that must be shown: an information document, where all the specifications mention above must be explained; a questionnaire, this is to ensure that any of the requirements explained in the information document have been understood; and finally, the informed consents, in this document the user signs in agreement on the study requirements.

INFORMACIÓ AL PARTICIPANT			
Tipus de document		Àrea de Responsabilitat	
FULL INFORMATIU		INVESTIGACIÓ	
CODI JCI:	CODI ACH:	Versió: 1	Pàg. 1/6

NIP: _____

2017269_RECOVERIX: BRAIN COMPUTER INTERFACE-FUNCTIONAL ELECTRICAL STIMULATION SYSTEM FOR UPPER-LIMB REHABILITATION THERAPY WITH STROKE PATIENTS - recoveriXGAME

Investigador Principal: Montserrat Bernabeu

Investigadors: Anna Morales, Ignasi Soriano, Narda Murillo, Eloy Opisso, Cristina Silvestre, Raquel Lezcano, Loreto García, Josep Medina, Manel Ochoa

DOCUMENT D'INFORMACIÓ PER AL PARTICIPANT

1.1. EL QUE VOSTÈ HA DE SABER

EN QUÈ CONSISTEIX:

En aquest estudi estem estudiant a persones que han sofert un ictus i tenen un costat del cos amb debilitat muscular, i que a la vegada estan realitzant rehabilitació de l'extremitat superior.

La rehabilitació funcional amb interfícies cervell-computador consisteix en identificar i enregistrar l'activitat del cervell (electroencefalografia, EEG) mentre s'imagina el moviment de la mà o el braç. Per tal d'ajudar-vos, s'incorpora un sistema d'estimulació elèctrica (FES), que genera petits impulsos elèctrics per estimular els músculs i induir moviment funcional, i una simulació d'un avatar que realitza de forma virtual el moviment en qüestió. El sistema que es fa servir es coneix amb el nom de *recoveriX*.

Aquesta rehabilitació es fa repetint el moviment funcional i, per tant, es pot tornar monòtona i avorrida. El que es pretén és incorporar elements de jocs a la simulació per tal de millorar l'atenció, la motivació i l'entreteniment. Així doncs, l'estudi consisteix en avaluar de forma quantitativa i qualitativa quin és l'impacte de la gamificació en la rehabilitació de l'ictus.

La seva participació en aquest estudi és totalment **voluntària**. Si decideix participar li sol·licitarem que signi un document de consentiment informat, expressant el seu desig de participar. És molt important que vostè sàpiga que pot negar-se a participar o retirar el seu consentiment en qualsevol moment posterior a la signatura, sense haver d'explicar els motius i sense que això repercuteixi de cap manera en l'assistència mèdica que rep o pugui rebre en el futur.

Aquest estudi ha estat avaluat pel **Comitè de Recerca i Innovació** de l'Institut Guttmann, que ha valorat els beneficis esperats en relació als riscos previsibles i l'adequació de la proposta al Codi Ètic de la Institució. Així mateix, aquest document ha estat avaluat pel **Comitè d'Ètica Assistencial** de l'Institut Guttmann, que ha aprovat l'adequació de la informació que conté.

PER A QUÈ SERVEIX:

L'objectiu principal de l'estudi és analitzar l'efecte del joc en la teràpia rehabilitadora de les extremitats superiors fent ús del recoveriX. Es pretén avaluar si el joc té un impacte en els resultats de la teràpia (si millora, si no té efecte o si empitjora) i també, l'experiència de l'usuari (acceptació i entreteniment per part dels pacients).

A més, si vostè participa en aquest estudi col·laborarà en investigar sobre l'eficàcia que proporciona el tractament que combina l'ús d'interfícies cervell ordinador i l'estimulació elèctrica funcional aplicada a la rehabilitació de pacients que han patit un ictus.

COM ES REALITZA:

Si vostè decideix participar en aquest estudi, li demanarem fer les següents coses:

- Utilitzar un gorro d'electroencefalografia (EEG) per tal de registrar els senyals elèctrics produïts en el cervell - presents en el cuir cabellut. L'electroencefalografia o EEG és un terme clínic que descriu l'enregistrament no invasiu de senyals elèctrics del cervell presents a la superfície de la pell. El gorro d'EEG és molt similar a un gorro d'un nedador amb elèctrodes de disc petits a l'interior disposats en un patró específic. Es posarà una petita quantitat de gel sota cada elèctrode per proporcionar una millor connexió elèctrica entre el cuir cabellut i l'elèctrode. Aquest gel és a base d'aigua i marxa amb un simple rentat.
- Mentre dura l'entrenament i es proven els algorismes del recoveriX per les seves ones cerebrals específiques, se li demanarà que imagini el moviment de la mà o el braç per controlar un braç avatar virtual a la pantalla de l'ordinador durant els exercicis posteriors.
- Les seves ones cerebrals registrades per EEG donaran indicacions a un dispositiu d'estimulació elèctrica funcional (FES) que produeix petits impulsos elèctrics al braç i al canell. Li demanem que permeti que el dispositiu li mogui lliurement el braç, i que no es resisteixi als moviments.
- Com a part d'aquest estudi li demanem que es comprometi a un número de dues sessions d'una hora. Abans de començar, se li explicarà degudament tots els detalls de la sessió i es resoldran tots els dubtes que puguin sorgir. Després, començaran les sessions de recuperació que inclouran:
 - 15 minuts d'instruccions, muntatge del gorro de l'EEG, i la col·locació del elèctrodes de FES.
 - 40 – 45 minuts d'exercicis específics gamificats amb pauses de dos minuts entre exercicis.
 - Primers 15 minuts: Fase de calibració
 - 15 – 30 minuts: Primera fase d'entrenament
 - 30 – 45 minuts: Segona fase d'entrenament
 - Finalment, haurà de realitzar un qüestionari d'avaluació relacionat amb l'estudi que s'està duent a terme

Es recolliran i emmagatzemaran les següents dades durant el programa recoveriX:

1. Senyals neurofisiològiques de l'electroencefalografia (EEG)
2. Resultats provinents dels algorismes del recoveriX i del joc
3. Dades demogràfiques i clíniques
4. Informació de la història clínica, així com d'imatges mèdiques
5. Fotografies de les diferents sessions

La seva informació serà recollida únicament amb finalitats relacionades amb aquest estudi i es farà tot el possible per protegir la seva privacitat. Per tant, durant la realització de l'estudi s'utilitzarà un codi d'identificació en lloc del seu nom en qualsevol còpia dels seus registres de l'estudi, i els resultats de les investigacions que s'envien fora de la institució de recerca local per a la seva revisió o prova. Vostè tindrà l'opció d'indicar una adreça de correu electrònic que mantindrem en el nostre arxius durant 10 anys per notificar de publicacions d'investigació, si és el cas, que surten d'aquest projecte. Els registres de l'activitat cerebral s'emmagatzemen en un ordinador amb un codi investigació de manera que no pot ser identificat a partir de les dades.

QUINS EFECTES LI PRODUIRÀ:

La realització de moviments repetits controlats per la imaginació del moviment millora la funcionalitat del sistema muscular. Més important encara, aquest mètode pot estimular la plasticitat cerebral, el que condueix a millores en la funció motora de les extremitats.

L'associació de les imatges motores i l'estimulació elèctrica funcional és similar a una recuperació intensiva i s'espera que augmenti l'impacte en el procés de rehabilitació, tot generant beneficis complementaris.

EN QUÈ EL BENEFICIARÀ:

El tractament, pot fer que vostè tingui una millora en la debilitat muscular o paràlisi que tingui en una part del cos (p.e. un braç), de totes maneres, això no li podem garantir.

Els resultats d'aquest estudi podrien, així mateix, beneficiar a d'altres persones amb problemes similars al de vostè.

QUINS RISCOS TÉ:

Aquest estudi no té conseqüències negatives que es coneguin, no obstant, sí que en coneixem alguns riscos lleus. Nosaltres li aplicarem el protocol dels sistemes d'interfície cervell ordinador i d'estimulació elèctrica funcional seguint les pautes estàndards, que minimitzen molt aquests riscos. De totes formes, li detallem a continuació per a què els conegui.

- ELS MÉS FREQUENTS:
 - L'estimulació elèctrica funcional (FES) pot produir una sensació de formigueig o sensació de picada sota els elèctrodes.
 - El FES també pot produir una mica de fatiga muscular o rigidesa, que desapareixerà amb repòs
 - Lesions o irritació de la pell sota els elèctrodes de FES.
- ELS DERIVATS DELS SEUS PROBLEMES DE SALUT:
 - Risc 1: Crisi Adrenèrgica
 - Risc 2: Crisi Comicial
- EN CAS QUE APAREGUIN, APLICARÍEM LES SEGÜENTS MESURES PER A CADASCUN DELS MATEIXOS:
 - Finalitzar la sessió.
 - Avisar al metge en cas de crisi.
 - Finalitzar el tractament en cas d'intolerància (per exemple, si el pacient té molèsties en totes les ocasions)

INFORMACIÓ PER AL TRACTAMENT DE DADES DE CARÀCTER PERSONAL

En virtut del què disposa el Reglament General de Protecció de Dades (UE)2016/679 del Parlament Europeu (RGPD) i la Llei Orgànica 3/2018, de 5 de desembre, de Protecció de Dades Personals i garantia dels Drets Digitals, la Fundació Institut Guttmann posa en el seu coneixement que el fet de signar el present document implica el coneixement i acceptació per part seva que l'entitat disposa d'un fitxer amb dades de caràcter personal denominat *FITXER D'INVESTIGACIÓ*.

La finalitat de la seva creació és la de gestionar les dades necessàries per la investigació que duu a terme la Fundació Institut Guttmann, garantint el registre i seguiment de la prestació assistencial que requeriran els usuaris durant l'estudi, i obtenir informació per complimentar la Historia Clínica dels usuaris.

Els destinataris de la informació són tots els departaments en què s'organitza la Fundació Institut Guttmann, així com els estaments oficials públics o privats que, per obligació legal o necessitat material, hagin d'accedir a les dades als efectes del correcte desenvolupament del projecte d'investigació, d'acord amb les bones pràctiques científiques.

La Fundació Institut Guttmann és responsable del tractament de les seves dades i es compromet a complir amb la normativa de protecció de dades en vigor. Les dades recollides per a l'estudi estaran identificades mitjançant un codi, de manera que no s'inclogui informació que pugui identificar-lo, i només l'investigador i els col·laboradors podrà relacionar aquestes dades amb vostè i amb la seva història clínica. Per tant, la seva identitat no serà revelada a cap altra persona excepte a les autoritats sanitàries, quan així ho requereixin o en casos d'urgència mèdica. Els Comitès d'Ètica de la Investigació, els representants de l'autoritat sanitària en matèria d'inspecció i el personal investigador autoritzat, únicament podran accedir per comprovar les dades personals, els procediments de l'estudi i el compliment de les normes de bona pràctica (sempre mantenint la confidencialitat de la informació).

En tot cas, té dret a exercitar els drets d'oposició, accés, rectificació i cancel·lació en l'àmbit reconegut pel RGPD. També pot limitar el tractament de dades que siguin incorrectes, sol·licitar una còpia o que es traslladin a un tercer (portabilitat) les dades que vostè ha facilitat per a l'estudi.

L'Investigador està obligat a conservar les dades recollides per a l'estudi com a mínim fins a 25 anys després de la seva finalització. Posteriorment, la seva informació personal només es conservarà pel centre per a la cura de la seva salut i per a d'altres fins d'investigació científica si vostè hagués atorgat el seu consentiment per a això, i si així ho permet la llei i els requisits ètics aplicables.

Si féssim transferència de les seves dades codificades fora de la UE a les entitats del nostre grup, a prestadors de serveis o a investigadors científics que col·laboren amb nosaltres, les dades del participant quedaran protegides amb salvaguardes com ara contractes o altres mecanismes per les autoritats de protecció de dades. Si el participant vol saber més sobre aquest tema, pot contactar el/la Delegat/da de Protecció de Dades.

Li recordem que les dades no es poden eliminar encara que deixi de participar en l'estudi per garantir la validesa de la investigació i complir amb els deures legals i els requisits d'autorització de medicaments. Així mateix, té dret a dirigir-se a l'Agència de Protecció de Dades si no quedés satisfet.

Per exercir els seus drets, o si li sorgeix qualsevol dubte o pregunta sobre l'estudi, estem sempre a la seva disposició i pot posar-se en contacte directament amb l'Investigador Principal, **la Dra. Montserrat Bernabeu**, en el telèfon 934977700; o amb el Delegat de Protecció de Dades de l'Institut de Guttmann, en el correu electrònic protecciodedades@guttmann.com.

IMATGES EXPLICATIVES:



Imatge d'una sessió d'un subjecte de control. Sistema recoveriX®

QÜESTIONARI CONSENTIMENT INFORMAT SOBRE TRACTAMENT			
Tipus de document		Àrea de responsabilitat	
QÜESTIONARI		RECERCA	
CODI - JCI: PFR.7	CODI - ACH: 5d-14 (D) E01	Versió: 2	Pàg. 1/2

**2017269_RECOVERIX: BRAIN COMPUTER INTERFACE-FUNCTIONAL
ELECTRICAL STIMULATION SYSTEM FOR UPPER-LIMB REHABILITATION
THERAPY WITH STROKE PATIENTS - recoveriXGAME**

Investigador Principal: Montserrat Bernabeu

Investigadors: Anna Morales, Ignasi Soriano, Narda Murillo, Eloy Opisso, Cristina Silvestre, Raquel Lezcano, Loreto García, Josep Medina, Manel Ochoa

QÜESTIONARI SOBRE EL CONSENTIMENT INFORMAT

- Entén que es sotmetrà a un estudi de recerca que ajudarà a conèixer més sobre les possibilitats de tractament en **persones que tenen debilitat muscular en un braç**, en pacients que han patit **un ictus**?
Sí ☐ No ☐
- Entén que encara que els procediments es realitzen seguint totes les recomanacions i les normes de seguretat conegudes, no estan exempts de riscos?
Sí ☐ No ☐
- Entén que participant en aquest estudi pot **NO OBTENIR** una milloria dels seus problemes, però que la informació que se'n obtingui potser podrà ajudar a entendre millor la seva malaltia i ajudar d'aquesta manera a vostè i a d'altres persones?
Sí ☐ No ☐
- Entén que l'estudi en què participa no modifica la possibilitat de rebre cap altre tractament que vostè necessiti?
Sí ☐ No ☐
- Entén que ens comprometem a que tota la informació relacionada amb la seva persona s'arxivarà i es processarà de manera que en cap moment quedi compromesa la seva intimitat?
Sí ☐ No ☐
- Ha entès totes les possibles complicacions que poden relacionar-se amb l'estudi?
Ha entès en quina manera se li prestarà atenció i ajuda en cas de que apareguin
Sí ☐ No ☐
- Creu que si no participa en aquest estudi això afectarà d'alguna manera a l'atenció clínica o al tractament que rep en el nostre Hospital?
Sí ☐ No ☐

8. Sap a qui ha de contactar en cas de necessitar més informació sobre qualsevol aspecte relacionat amb l'estudi, o en cas de que tingui qualsevol dubte durant la seva participació en el mateix

Sí ☐ No ☐

9. Entén que en qualsevol moment i per qualsevol raó pot decidir no seguir participant en l'estudi?

Sí ☐ No ☐

Número d'Identificació del Participant:

Nom:

Signatura:

Data: __/____/__

Investigador principal:

Nom:

Signatura:

Data: __/____/__

IMPORTANT: Aquest document conté informació confidencial i ha de ser custodiat a l'arxiu de la Oficina d'Investigació, juntament a la informació relativa al participant

CONSENTIMENT INFORMAT			
Tipus de document		Àrea de responsabilitat	
CONSENTIMENT INFORMAT		INVESTIGACIÓ	
CODI JCI:	CODI ACH:	Versió: 1	Pàg. 1/3

NIP: _____

**2017269_RECOVERIX: BRAIN COMPUTER INTERFACE-FUNCTIONAL
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Aquest document serveix per a què vostè, o qui el representi, doni el seu consentiment per a participar en aquest estudi. Això significa que ens autoritza a realitzar aquesta intervenció.

Vostè pot retirar aquest consentiment quan ho desitgi. Signar-lo no l'obliga a participar en l'estudi. Del seu rebuig no se'n derivarà cap conseqüència adversa respecte a la qualitat de la resta de l'atenció mèdica rebuda. Abans de signar, és important que hagi llegit atentament la informació continguda en el **full informatiu** de l'estudi, que ha rebut juntament amb aquest consentiment.

Si té algun dubte o necessita més informació no dubti en dir-nos-ho, l'atendrem amb molt de gust.

Consentiment informat:

(En el cas **d'incapacitat o presumpta incapacitat i/o minoria d'edat** del/de la pacient serà necessari el consentiment del seu representant o tutor/a)

DADES DEL PACIENT I DEL SEU REPRESENTANT O TUTOR/A (en cas de ser necessari)

Cognoms i nom del/de la pacient:

D.N.I.:

Cognoms i nom del/de la representant o tutor/a del pacient:

D.N.I.:

CONSENTIMENT INFORMAT

PROFESSIONAL QUE INTERVÉ EN EL PROCÈS D'INFORMACIÓ I/O CONSENTIMENT:

Cognoms i nom:

Signatura:

Data:

Consentiment:

Jo, En/Na _____, manifesto que estic conforme amb l'estudi que se m'ha proposat. He llegit i comprès la informació continguda en el **full informatiu** que se m'ha proporcionat. He pogut preguntar i aclarir tots els meus dubtes. Per això he pres conscientment i lliurement la decisió de participar. També sé que puc retirar el meu consentiment quan ho estimi oportú.

A Badalona, el _____ de _____ de _____

El/La PACIENT

Consentiment/vistiplau del/de la
REPRESENTANT o TUTOR/A

Signat:

Signat:

Revocació del consentiment:

Jo, En/Na _____, de forma conscient i lliure he decidit retirar el meu consentiment a participar en aquest estudi.

A Badalona, el _____ de _____ de _____

El/La PACIENT

Consentiment/vistiplau del/de la
REPRESENTANT o TUTOR/A

Signat:

Signat:

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