Escola Superior de Saùde Atlàntica

Diploma in Physiotherapy

Research project

4th year

Academic year 2018/2019

Final project:

THE ALLYANE PROCESS EFFECT IN THE TREATMENT OF PATIENTS SUFFERING FROM INCOMPLETE SPINAL CORD INJURY OF THE 12th THORACIC VERTEBRA LEVEL

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Barcarena, 2018-2019

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ACKNOWLEDGMENTS

The achievement of this research project would not have been possible without support of numerous people we would like to thank here.

We thank Dr. Geronimi and our memory tutor Mrs. Pennamen, who guided and mentored us throughout this project. They showed patience, availability, kindness and provided us with expert advices to carry out our work.

We thank the teaching staff of ESSATLA for all the knowledge transmitted during these four years of study.

We thank the entire ALLYANE® project team for their investment, and for the necessary documents they provided.

We would also like to express our gratitude to Mrs. Zennou-Azogui, from the Sensory and Cognitive Neuroscience Laboratory from Aix-Marseille University, for her help throughout the progress of our manuscript.

Our thanks also extend to our respective families and friends whose support and encouragement were essential during this four-year study.

Finally, we would like to thank all those who, directly or indirectly, contributed to the completion of this work.

ABTRACT

Introduction: Incomplete spinal cord injuries affect the conduction of sensory and motor signals, inducing sensorimotor deficits that impact patients' life quality. Recent advances in the field of neuroscience have underlined importance of early rehabilitation after a cerebral damage. Traditional rehabilitation is based primarily on compensatory strategies aimed at maximizing patient' independence in his activities on daily life. An innovative process, the ALLYANE® process, combining low frequency sounds and specific rehabilitation involving visual and proprioceptive imaging, has been developed to improve post-injury functional restoration and quality of life.

Objective: The main objective is to show the effects of the ALLYANE® process associated with traditional rehabilitation on patients with incomplete spinal cord injury at the 12th thoracic vertebra level. More specifically, purpose is to evaluate the impact of this process on the articular amplitude, muscle strength, plasticity, balance, walking and quality of life.

Methodology: This study is an « experimental » type. This is a prospective cohort study. It is controlled and randomized. The selected sample consisted of 50 patients who met specific criteria for inclusion and exclusion and which were randomly divided into two groups: the control group submitted to a traditional rehabilitation protocol five times a week during a five–week period, and the experimental group submitted a five-week traditional rehabilitation protocol four times a week combined with the ALLYANE® process once a week. Variables measured are articular amplitude, muscle strength, spasticity, balance, walking and quality of life. Using instruments (goniometer, dynamometer) and evaluation scales (modified Ashworth scale, Berg scale, WISCI scale, SF-36), these variables are collected at the end of each week, and three months after the end of rehabilitation process, in both groups of patients. After verifying that distribution of the collected data follows a normal distribution, they will be compared between the two groups by an analysis of variance using the software Statistica.

Conclusion: Purpose of this study is to determine whether beneficial effects of the ALLYANE® process exist in rehabilitation of patients with incomplete traumatic spinal cord injury at 12th thoracic vertebra level, thus highlighting the major importance of mental imagery associated with low frequency sounds in the improvement of functional deficits and the quality of life.

Key Words: Rehabilitation; Spinal cord injury; Low frequency sounds; ALLYANE® process; Alphabox®.

RESUMO

Introdutivo: Lesões incompletas da medula espinhal afetam a condução de sinais sensoriais e motores, induzindo deficits sensório-motores que impactam na qualidade de vida dos pacientes. Progressos recentes no campo da neurociência têm sublinhado a importância primordial da reabilitação precoce após o dano nervoso. A reabilitação convencional baseia-se principalmente em estratégias compensatórias que visam maximizar a independência do paciente em suas atividades de vida diária. Um processo inovador, o processo ALLYANE®, que combina sons de baixa frequência e reabilitação específica envolvendo imagens visuais e proprioceptivas, foi desenvolvido para melhorar a restauração funcional pós-lesão e a qualidade de vida.

Objetivo: O objetivo principal deste estudo é mostrar os efeitos do processo ALLYANE®, combinado com a reabilitação convencional em pacientes com lesão medular incompleta na 12ª vértebra torácica. Mais especificamente, os objetivos são avaliar o impacto desse processo na amplitude de movimento, força muscular, espasticidade, equilíbrio, marcha e qualidade de vida.

Metodologia: Este estudo é do tipo "experimental". És é um estudo prospectivo de coorte. É controlado e randomizado. A amostra selecionada é de 50 pacientes que preenchem os critérios precisos de inclusão e exclusão e divididos aleatoriamente entre dois grupos: o grupo controle submetido a um protocolo de reabilitação convencional, cinco vezes por semana, e o grupo experimental submetido a um protocolo de reabilitação convencional quatro vezes por semana, combinado com o processo ALLYANE® uma vez por semana durante cinco semanas. As variáveis medidas são amplitude de movimento, força muscular, espasticidade, equilíbrio, marcha e qualidade de vida. Com a ajuda de instrumentos (goniômetro, dinamômetro) e escalas de avaliação (escala de Ashworth modificada, escala de Berg, escala WISCI, SF-36), estas variáveis são coletadas no final de cada semana, e três meses após o término do procedimento de reabilitação, em ambos os grupos de pacientes. Após verificar que a distribuição dos dados obtidos segue uma distribuição normal, eles serão comparados entre os dois grupos por uma análise de variância usando o software Statistica.

Conclusão: Este estudo deve ressaltar os efeitos benéficos do processo ALLYANE® na reabilitação de pacientes com lesão traumática incompleta da 12ª vértebra torácica, evidenciando a grande importância da imagem mental associada aos sons de baixa frequência na melhora dos deficits funcionais e qualidade de vida.

Palavras-chave: Reabilitação; Lesão medular; Sons de baixa frequência; Processo ALLYANE®; Alphabox®.

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LIST OF ABBREVIATIONS

ASIA: American Spinal Injury Association

CNS: Central Nervous System

EBP: Evidence Based Practice

EEG: Electroencephalogram

ESSATLA: Escola Superior de Saùde Atlàntica

fMRI: functional Magnetic Resonance Imaging

HAH: High Authority of Health

Hz: Hertz

LFS: Low Frequency Sounds

MI: Mental Imagery

PNS: Peripheral Nervous System

SC: Spinal Cord

SCI: Spinal Cord Injury

WHO: World Health Organization

WISCI: Walking Index for Spinal Cord Injury

I. INTRODUCTION

This research project was carried out as part of our fourth year of Bachelor in Physiotherapy at ESSATLA.

During our four years of studies, we noticed that management of patients with spinal cord injury (SCI) often involves lengthy, tedious and sometimes discouraging rehabilitation techniques, with people whose autonomy, for most of the time, remains very limited.

SCIs represent a major public health problem. Doctor Margaret Chan (2013), Director of the World Health Organization (WHO) between 2007 and 2017, refers to the SCI in 2013 as « particularly devastating » because it occurs unexpectedly and results in premature mortality or, at best, social exclusion.

SCI refers to damage caused on the spinal cord (SC) that is part of the central nervous system (CNS). SC provides with the conduction of motor and sensory messages between brain and peripheral nerves (Kirshblum et al, 2011). International journal Clinical Epidemiology describes LM as « an event that disrupts normal sensory, motor, or autonomic function that ultimately affects the patient's physical, psychological, and social well-being » (Singh et al, 2014).

According to the High Authority of Health (HAH, 2007), causes of SCI can be traumatic, vascular, tumoral, infectious, malformative and metabolic. A study of the HAH in 2007 reports the incidence of SCI in France and it estimates 1,200 new traumatic cases per year (about 19.4 new cases per million inhabitants), which represents between 70 and 80% of the total SCI (Desert, 2002). In addition, injuries at the 12^{th} thoracic vertebra level are the most frequent (Lonjon et al, 2012).

In its report on international SCI perspectives, a 2013 WHO guideline highlights importance of the management of SCI patients and emits as first recommendation « to improve health sector responses to spinal cord injury » (Officer, Shakespeare & Groote, 2013).

Our interest for patients with spinal injuries has led us to take an interest in their management including process presented as innovative by its designers, the ALLYANE® process. Relevance of our study is justified by the fact that the ALLYANE® process is more and more used in the practice of some physiotherapists whereas its efficiency has never been scientifically demonstrated. Completion of our study would allow physiotherapists to suggest an evidence-based protocol. The proposed technique is the neuromotor reprogramming allowing the modification or the acquisition of a movement in a fast and durable way. It combines multi-sensory stimulation, namely proprioceptive imaging, associated with visual imagery and specific sequences of low frequency sounds (LFS). Although the application of this method is very wide, neuromotor pathologies have proven to be very receptive to this treatment, according to ALLYANE® team.

The ALLYANE® process is included in some health journals as a breakthrough innovation in the world of neuromotor rehabilitation. However, some concepts used in untraditional medicine seem to approach it. Thus, we could mention the concept of Bioresonance, widely used in quantum medicine. It is based on the ability of living beings to emit and capture radiation. Some devices used in this field allow emission of electromagnetic radiation (including low frequency waves) intended to rebalance the body energy.

We know that there are two types of neuro-motor lesions described by the American Spinal Injury Association (ASIA) scale: incomplete lesions, described as lesions B, C, D, E which, unlike complete lesions (A lesions), benefit from preservation of sensation in the S4-S5 territory (Kirshblum et al, 2011). Only the lesions C, D, E show a preservation of motricity below the lesioned level, which is necessary for the application of the ALLYANE® process.

Therefore, we have been led, through our bibliographic research, to see the interest of the implementation of the ALLYANE® process, on the patient suffering from an incomplete spinal cord injury of C, D, E type.

The main objective of our study is to show the effects of the ALLYANE® process on patients with incomplete traumatic SCI injury at the 12th thoracic vertebra level. We will compare the evolution of the deficits of patients who have been rehabilitated by the ALLYANE® process associated with a traditional rehabilitation, to those who were inserted only in traditional rehabilitation protocol. More specifically, our purpose is to compare impact of this process on articular amplitude, muscle strength, plasticity, balance and walking, and on the quality of life often altered on patients with SCI.

Regarding methodology, this experimental study is qualified as a randomized-controlled prospective study. As a result of our bibliographic research, we selected a sample of 50 patients from the targeted population (Lee, Dudley-Javoroski & Shields, 2019, Pira et al, 2019) with SCI and meeting criteria for inclusion and accurate exclusion. The sample will be randomly divided into two groups of equal size. Group 1, the control group (traditional rehabilitation) and the group 2 will be the experimental group (traditional rehabilitation associated with the ALLYANE® process).

In this manuscript, we will first review the literature. This will concern the anatomical and functional organization of the SC, the functional deficits associated with its lesion and their assessment. We will also describe the traditional physiotherapy treatment of patients with SCI and the ALLYANE® process. At the second stage, we will present the protocol that we set to achieve our goals.

II. THEORETICAL FRAMEWORK

1. The spinal cord

A. Anatomy

In order to better understand the functional deficits associated with spinal injuries and the major challenge of effective management, it is necessary to make a reminder of the anatomical organization of the SC and its primary functional role.

« The spinal cord is the main way of transferring information from the skin, joints and muscles to the brain and vice versa » (Bear, Connors & Paradiso, 2007 ; p.176).

The SC is protected by a bone envelope called the vertebral column (Netter, 2011). This bone structure consists of 7 cervical vertebrae, 12 thoracic vertebrae, 5 lumbar vertebrae, 5 sacral vertebrae and 4 coccygeal vertebrae (ANNEX I). The juxtaposition of the arches of each vertebra forms the spinal canal which occupies the entire length of the vertebral column. Inside is the SC and its envelopes, as well as the cerebrospinal fluid, fat, cell tissue and vessels (Tortora & Derrickson, 2009).

The SC is protected by the meninges, which consist of three layers of connective tissue: the dura mater, the arachnoid mater and the pia mater. The dura, the outermost layer, envelops and protects the SC. The arachnoid, an intermediate envelope, is avascular and serves as a sheath for the roots of the nerves. Finally, the pia mater, the innermost envelope, adheres intimately to the SC and contains many blood vessels that supply the spinal cord with oxygen and nutrients (Tortora & Derrickson, 2009).

B. Motricity and sensitivity

The nervous system comprises two major subsystems: the CNS and the Peripheral Nervous System (PNS). The SC forms with the brain the CNS (ANNEX II). The SC is a cord of nervous tissue of 43 to 45 cm long (Bican, Minagar & Pruitt, 2013).

SC give birth to spinal nerves that belong to PNS and arises in pairs between each vertebra. There are 8 cervical pairs, 12 dorsal pairs, 5 lumbar pairs and 6 sacred pairs (Ross, 2007) (ANNEX III). Each spinal nerve is attached to the SC by two branches forming the ventral root and the dorsal root. These nerves innervate and provide information transfer between the whole body and SC (Bear, Connors & Paradiso, 2007).

The SC is located in the upper two-thirds of the vertebral canal. In adults, it starts at the foramen magnum and ends at the first and second lumbar vertebrae. A conical structure called medullary cone is the sign of termination (Paulsen & Waschkle, 2013).

The SC presents two depressions: the ventral medial fissure and the dorsal medial fissure dividing it into two sides, right and left. It is formed of gray and white substances (ANNEX IV).

- The gray substance is in the form of a capital H. It is mainly composed of neuronal cell bodies that integrate information that enters and leaves the SC. The two large bars of the H form the anterior and posterior horns. The cells of the anterior horns are motor cells. The cells of the posterior horns integrate sensory information and are called sensory.
- The white substance surrounds the gray substance. It is composed of nerve fibers covered with their myelin sheath and grouped into bundles. The bundles and tractus carry the potential actions from the sensory receptors to the brain (sensory pathways) and the potential actions from the brain to the effectors (motor pathways (Marieb & Hoehn, 2018).

The cells in the dorsal horn receive sensory information (tactile, thermal, nociceptive, and proprioceptive) from the skin, muscles and tendons, and the cells of the ventral horn send their axons in the ventral roots and innervate the muscles (Bear, Connors & Paradiso, 2007).

The SC is therefore a place of passage of the motor and sensory pathways that connect the body to the cerebral cortex. We talk about ascending bundles and tractus conducting sensory impulses to the somatosensory cortex and about descending bundles and tractus leading motor impulses from the motor cortex to the effector organs.

For sensitivity, there are two systems with different purposes: the lemniscal system in which are conveyed information on the epicritic touch (fine) and proprioception; and the extra lemniscal system leading information on protopathic (coarse) touch as well as thermal and nociceptive information (ANNEX V).

For motricity two systems are involved. The first one is the pyramidal system with its major component, the corticospinal tractus coming from the cortex. Its components control the fine movements of the arms and fingers. The second one is the extrapyramidal system consisting of four descending bundles (vestibulospinal, tectospinal of pontic origin, reticulospinal of bulbar origin and rubrospinal resulting from the red nucleus located in the midbrain) which influence the spinal interneurons preferentially controlling the proximal and axial musculature on the basis of sensory information related to the sense of balance, the position of the body and the visual environment (Bear, Connors & Paradiso, 2007) (ANNEX VI).

C. Injury

C.1 Definition

An impairment of the SC affects the conduction of sensory and motor signals and may give rise to a variety of symptoms and functional deficits, the severity of which will be determined by the level of lesions.

SC damage can cause loss of sensation and muscle paralysis below the neurological level of the lesion. Thus, damages to the spinal cord are particularly serious as they are located higher.

If the spinal section is located between the first thoracic vertebra and the first lumbar vertebra, the two lower limbs are affected : it is paraplegia (complete paralysis) or its less important form in case of partial damage to the SC, paraparesis, which is a weakest form of paralysis of the lower extremities accompanied by muscular weakness. In any case, this does not mean that the muscles cannot function; rather they stop receiving control commands from the brain (Bear, Connors & Paradiso, 2007).

It can be noted that a lesion at the level of the 12th thoracic vertebra leads to motor and sensory deficits, the severity of which is different for each patient. The muscles that can be affected are those of the abdominal wall, innervated by nerve roots from T7 to T12, as well as the psoas, adductors and gluteal muscles, innervated by nerve roots from T12 at L3 (Valerius & Beauthier, 2013). In addition, all the innervated muscles by the nerve roots below the lesion (thus from the root T12 to S5) are affected. The involved muscles include the gluteal muscles and those of the perineum and the lower limbs.

C.2 Assessment

Spinal nerves leave the SC through the foramina. The SC is shorter than the spinal canal which explains a difference between the vertebral level and the spinal metameric level (Paulsen & Waschkle, 2013).

To be able to understand how the sensory and motor evaluation is carried out, two terms might be defined:

- The dermatome, which corresponds to a region of the skin innervated by the dorsal roots of a single spinal segment. There is a correspondence between the segmental organization of the spinal nerves and the one of the cutaneous sensory innervation. All spinal nerves, except C1, delineate dermatomes (ANNEX VII) (Bear, Connors, & Paradiso, 2007).
- The myotome is a group of muscles innervated by a single nerve root (Kirshblum et al, 2011).

Through the examination of dermatomes and myotomes, it is possible to define sections of the SCs which are affected (Bear, Connors & Paradiso, 2007 ; Marieb et al, 2018).

Sensitivity assessment of the dermatomes is carried out bilaterally. Sensitivity is tested for a light touch and pinprick. A score of 0 indicates no sensation, a score of 1 indicates an impaired sensation, and a score of 2 indicates a normal feeling.

The motor evaluation concerns five specific muscle groups in the upper extremities and five others in the lower limbs. These are the main lumbar and cervical myotomes. For the driving force, the assessment will be done using a universal six-point scale (rated from 0 to 5) (ANNEX VIII) (Roberts, Leonard & Cepela, 2017).

C.3 Types of injury

ASIA classifies the different injuries in order to determine whether they are complete or not (Maynard-Jr et al., 1997) :

A = Complete. No sensory or motor function is preserved in the sacral segment S4-S5.

B = Incomplete. The sensory function and not the motor function is preserved below the level of injury and includes the sacral segment S4-S5.

C = Incomplete. Motor function is preserved below the neurological level of injury, and more than half of the tested muscles located below this level have a muscle level less than 3.

D = Incomplete. The motor function is preserved below the neurological level of the injury and at least half of the tested muscles located below this level have a muscular level higher or equal to 3.

E = Normal. Sensory function and motor function are normal.

According to the ASIA scale, incomplete lesions, lesions B, C, D and E, unlike the complete lesions (lesions A), induce preservation of sensation in the S4-S5 territory and only the lesions C, D, E, induce preservation of motricity below the level of injury (Kirshblum et al, 2011). This preservation of motricity is mandatory to apply for the ALLYANE® process.

SC injuries have two causes (Désert, 2002) :

- Traumatic, with road accidents, sports accidents, suicide attempts …

- Medical, which may be of vascular, tumoral, infectious, malformative and metabolic origins.

We chose to focus on patients suffering from traumatic and incomplete injury at the 12th thoracic vertebra level. As we have seen in the introduction, traumatic causes account for more than half of the etiologies (HAH, 2007) and for 70 to 80% (Désert, 2002) of the spinal cord injuries. Moreover, lesions at the 12th vertebra thoracic level are the most common (Lonjon et al, 2012).

C.4 Specific consequences for patients affected in T12

Many symptoms appear upon an injury to the SC. Patients who are part of our study have an injury at the 12th thoracic vertebra level, which leads to the following deficits:

- Motor disorders (articular amplitude, muscle strength, spasticity, balance, and walking)
- Sensory disorders
- Sphincter dysfunction, bladder, bowel and sexual disorders
- Pain
- Circulatory disorders characterized by an impaired venous return and which may lead to edema, skin fragility and thrombophlebitis.
- Other disorders may be associated such as bedsores and urinary tract infections (World Health Organization, & International Spinal Cord Society, 2013).

It is important to understand that the motor deficits are due to the lesion of the pyramidal tract (responsible for the voluntary motricity). This pyramidal tract, monosynaptic, consists of two neurons. A SC lesion causes damage of the first neuron also called central neuron, and results in a central paralysis causing the spasticity. Plasticity corresponds to an increase in the tonic stretching reflex associated with an exaggeration of secondary tendon reflexes and hyperexcitability of the stretching reflex. The muscle tone is increased in this case (Smail, Kiefer & Brussel, 2003).

All these deficits lead us to definition of the concept of quality of life. This complex concept was defined by WHO in 1948 as « a full state of physical, mental and social well-being ». The various disorders caused by SCI affect the quality of life which is important to evaluate with the SF-36 scale described in the methodology section.

2. Conventional rehabilitation for patients with SCI

Conventional rehabilitation uses physiotherapy techniques combining a passive and active work. More specifically, the rehabilitative management of a patient with SCI includes several stages described by the HAH in 2007:

- Pain relief: circulatory massage, analgesic physiotherapy, cryotherapy and thermotherapy
- Soft passive and progressive mobilizations in the total amplitude of the movement
- Strengthening upper limbs and torso
- Progressive verticalization (from cardiopulmonary rehabilitation to orthostatism)
- Solicitation of the sub-lesional motricity preserved
- Working balance of the torso
- Work on the transfers and all the necessary techniques for autonomy in all activities of the daily life (eating, bathing, dressing...) and learning how to use the wheelchair
- Cardiorespiratory exercise training
- Walking rehabilitation.

Some techniques, such as mental imagery (MI) previously used for other neurological diseases, appear in the traditional rehabilitation of patients with SCI (Thomschewski et al, 2017).

3. The ALLYANE® process

The ALLYANE® process is a neuro-motor reprogramming that combines LFS-specific sequences emitted by a generator (Alphabox®) with visual imaging and proprioceptive imaging.

A. Historical

Two approaches induce existence of the ALLYANE® process:

- The first is a scientific approach, led by a doctor in neurophysiology, Mr. Jean FEIJOO who studied the role of LFS and helped to understand their involvement in the system of memorization of automatic gestures.

- The second was conducted by Mr. Bernard GASQUET, coach and mental trainer for elite sport and former top athlete. Its purpose was to find a sound sensory stimulus which, together with the neurological components of the sporting gesture, was intended to accelerate the acquisition of automatic motricity abilities.

The ALLYANE® process has thus developed empirically in collaboration with a doctor, a personal trainer and some physiotherapists who are experts in neuroscience.

B. The Alphabox®

The Alphabox® (APPENDICES I & II) is recognized as a medical device by the following definition:

> « Any instrument, equipment (...) intended by the manufacturer to be used in humans for medical purposes and whose principal intended action is not obtained by pharmacological, immunological or metabolic means, but whose function can be assisted by such means » (National Agency for Medicines and Health Products, 2018).

As such, the Alphabox® enters the classification of medical devices and belongs to Class IIa « moderate and measured potential risk » which includes, for example, contact lenses, ultrasound devices or dental crowns (Ministry of Solidarity and Health, 2019). This box has also been the subject of electrical testing and electromagnetic compatibility ensuring reliability, reproducibility of its signals and the safety of its users.

This generator using headphones emits specific frequency sounds of about 400 Hertz (Hz). The range of audible sounds for the human ear ranges from 20 to 20,000 Hz, this device emits in the LFS area. These sounds are emitted with different sequences and modes during the rehabilitation period. Alphabox® allows to emit two types of sounds: pulsed sounds and associated sounds. Impulsed sounds can create a state of advanced concentration by influencing brain rhythms and their combination with associated sounds is used to mark the proprioception during movements (Friggeri and Le Blay, 2018).

C. The rhythms of the brain

The human organism, in all its functions, is subject to rhythms. As for the brain, sleep and wakefulness are the most striking periodic behaviors. However, other are other much faster rhythms exist (Bear, Connors & Paradiso, 2007): « At any moment, brain neurons produce millions of action potentials. Together, these electrical signals form brain waves» (Tortora & Derrickson, 2009, p 305). These brain waves can be recorded by placing detectors, called electrodes, at specific parts of the forehead and scalp. The recording thus obtained is an electroencephalogram (EEG). Activation of brain neurons has been shown to generate four types of waves that differ in their rhythm. These waves are dependent of our activity (awakening, learning, light and deep sleep). They are distinguished according to their frequency band and are called by a Greek letter:

- Beta (β) waves, the fastest, have a frequency greater than 13 Hz. They indicate an overall activation of the cortex and correspond to a period of sensory stimulation and mental activity, when we learn, think or read as you do now.

- Alpha (α) waves, from 8 to 13 Hz, normally appear in individuals with closed eyes. They are associated with quiet wakefulness.
- Thêta (θ) waves, from 4 to 7 Hz correspond to a state from deep relaxation to some slight sleep states.
- Delta (δ) waves with frequencies below to 4 Hz correspond to deep sleep. At this frequency band, only vital functions are controlled by the brain.

These are the Alpha waves that interest us for the use of the ALLYANE® process. When we operate at Alpha rhythm, our mental state is calm. This state is called *«hypovigilance»* and our concentration is increased (Mathewson et al, 2009). In this rhythm, the two cerebral hemispheres work perfectly synchronized (Marieb & Hoehn, 2018).

Synchronization of brain waves is a not very well known concept that states that people can independently synchronize the waves independently emitted by both brain hemispheres. This would allow, thanks to an external stimulus, a synergistic work of the areas devoted to logic, creativity and learning. In the other rhythms, when this synchronization does not exist, the activity of one hemisphere would always be privileged to the detriment of the other with, as a repercussion, reduced mental and intellectual performances. Therefore, synchronization would promote the well-being of the individual and improve its performances.

This theory helps to understand the beneficial effects of Alpha rhythm in the different processes that are: memorization (Başar et al, 2000), attention (Wolfgang, 2012, Mazaheri, 2014), concentration (Park et al, 2018), vision (Zhan et al, 2014), and anxiety (Isik et al, 2017).

As we saw above, the synchronization of brain waves and therefore their passage in Alpha mode is possible due to an external stimulus. Some therapeutic practices suggest the possibility of promoting the passage through Alpha rhythm thanks to the use of cardiac coherence (O'Hare, 2012). It is a relaxation technique to regulate the variability of the heart rhythm.

It is in this alpha mode that ALLYANE® seeks to place the patient in a rehabilitation session. The patient is then installed in a dark and quiet room, in a comfortable supine position. After a general relaxation protocol that approximates cardiac coherence techniques, he listens for SBF emitted by Alphabox®.

A large number of websites evoke the supposedly harmful effects of LFS emitted by vehicles or household appliances. However, these are very low frequency sounds (some Hz) which are different to that emitted by the Alphabox®.

More generally, LFS are associated with meditation and relaxation and are ancestrally recognized for their soothing virtue such as Tibetan singing bowls, tuning forks or drum rolls. Clinical data has not yet been obtained, however, according to some authors, listening to these sounds allows the brain to become alpha-rhythmic (Friggeri & Le Blay, 2018).

Among the few experimental studies about LFB, one was conducted on 90 students of the University of Medical Sciences in Iran. Its purpose was to investigate the effects of these sounds on the mental performance of subjects. It was concluded that LFS improved accuracy and the speed of execution during the test (Alimohammadi, Sandrock & Gohari, 2013).

D. Mental imagery

MI « is a conscious process in which subjects simulate internally a motor action without actually realizing it, without apparent movement or apparent muscular contraction » (Papaxanthis et al, 2002).

There are different types of mental images. Some are created from external sensory information: visual images. Others are created from internal sensory information: proprioceptive images.

- Visual imagery consist in imagining oneself moving as an external observer of one's own action.

- Proprioceptive imagery or proprioceptive identification can be defined as « the mental evocation of the sensations of contraction, relaxation and stretching generated and felt during the realization of a movement » (Robin & Flochlay, 2017). It corresponds to the perception of the musculo-articular sensations, usually generated from the actual execution of a movement (tension, limits, pain, compensations, muscular weakness) whereas this one is non-existent.

Currently numerous studies conducted in Functional Magnetic Resonance Imaging (fMRI) have shown that the mental imagery of a movement activates similar cerebral areas to those activated during the realization of the movement (ANNEXE IX) (Hanakawa et al, 2008).

In patients with SCI, MI is based on previous experiences (memory images).

From a practical point of view, numerous studies have highlighted the benefits of MI on motor performance: improvement in the speed of movement, increased joint movement amplitude (Williams et al, 2004), increased motivation (Guillot, & Collet, 2008), increased strength and muscle activation (Ranganathan, 2004), as well as an optimal solicitation of the muscles (Papaxanthis et al, 2002).

It has been shown that in the motor cortex, size of the representation areas of the muscles involved in the movement increases with either physical or mental training (Pascual-Leone et al, 1995). This last result involves phenomenon of cerebral plasticity or neuroplasticity. This is the amazing ability of the brain to reorganize itself.

After a SCI, there is a reorganization of cortical areas involved in motor control. Indeed, the cortical areas at the origin of the impaired movements are invaded by the neighboring cortical areas. In a study performed in 2008 in amputees, Maclver et al. showed that MI reversed post-lesion cortical reorganization which is believed to cause neuropathic pain in amputees. Indeed, the MI of the movement of the missing limb reverses the cortical remodeling (cortical areas of the hand invaded by the adjacent areas of the face) and thus the motor representation of this limb is restored (ANNEX X).

Using fMRI, Sabbah et al. in 2002, studied the residual activation of the cortex of nine patients with a SCI between T6 and L1, at lesional levels including the patients of our study (T12). They showed that activation of the cortical networks, activating the body parts through a spinal segment below the injury, are preserved. « Therefore, spinal cord injured patients keep, despite the post-lesional cortical reorganization, the ability to have a representation of the movements of their limbs which no longer receive motor commands » (Grangeon et al, 2009). Grangeon, Guillot and Collet evoked in 2009, in a review of the literature on the role of MI in the recovery of motor functions after SCI, the need to integrate MI in rehabilitation protocols following a central or peripheral injury.

III. METHODOLOGY

1. Study question

Our study aims to answer the question: what is the therapeutic value of ALLYANE® process in the patient with an incomplete SCI at the 12th thoracic vertebra level ? We are particularly interested in the effect of this method, in combination with conventional functional rehabilitation, on the myo-articular, locomotor and postural balance deficits as well as on spasticity caused by the SCI. These deficits also have implications for health, physical, psychological and social well-being of the patient (Pili et al, 2018). They also create activity limitations and participation restrictions because of disabling physical alterations resulting from trauma. We can then ask ourselves what are the effects of the ALLYANE® process on the patients' quality of life.

2. Objectives

The main goal of our study is to establish that the use of the ALLYANE® method improves the traditional management of patients with SCI. Our specific objectives are to demonstrate that the ALLYANE® process induces on the lower limbs:

- a maintenance of joint range,
- an increase in muscle strength,
- a decrease in spasticity,
- a recovery of balance,
- a walking progress,
- an improvement in the quality of life.

Through this study, we seek to put forward an innovative approach to neuromuscular rehabilitation, especially for traumatic SC injured patients.

3. Assumption

The assumption that we formulate here is that, with the ALLYANE® process, the combination of LFS provided by Alphabox®, combined with visual and proprioceptive imaging, would improve traditional management.

4. Type of study

Among the various research methods, we chose an experimental research method which includes manipulation of independent and dependent quantitative variables. This allows us to generate the analyzed data with appropriate statistical processing. Our research is quantitative, including numerical data such as myo-articular, spasticity, postural balance, locomotion and quality of life data.

Participants are randomly assigned to the control group and the experimental group. Therefore, this project is classified as controlled-randomized studies (Rohrig et al, 2009).

Our research is a cohort study: it includes a set of patients with the same inclusion criteria, exposed or not to ALLYANE® process. It is also a prospective study (Rohrig et al, 2009) since it examines the effect of this therapy over time and up to 120 days after the end of the treatment.

5. Population

In research, a population is a well-defined set of individuals who are the subject of the study and have the same characteristics. In our study, these are patients with incomplete SCI at the level of the 12th thoracic vertebra, responding to well-defined inclusion criteria (Table 1).

A sampling of the population is carried out which permits to have a representative sample. We have chosen a simple random sampling technique in which each member of the population has an equal chance to be selected as a subject, independently of other members (Setia, 2016).

We selected several inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Age : 18 – 35 years	Deafness and uncorrected hearing problems
Traumatic spinal cord injury	Uncorrected visual disturbances
Incomplete SCI at the 12th thoracic vertebra	Cognitive and psychiatric disorders
ASIA C, D, E	Support > 1 year after injury
Have read, understood and signed the informed consent	Contraindication according to the ALLYANE® process (major mechanical injuries, epilepsy, severe arterial hypertension)

Table 1: Inclusion and exclusion criteria for the study

On the basis of recent studies, we selected a sample of 50 patients (Lee, Dudley-Javoroski & Shields, 2019, Pira et al, 2019) who met these criteria. We randomly divided this sample into two groups of the same size drawing lots of sealed envelopes containing a ballot in group No. 1 or No. 2.

Group 1: experimental group of 25 patients receiving specific rehabilitation according to the ALLYANE® method associated with a conventional rehabilitation.

Group 2: control group of 25 patients receiving conventional rehabilitation.

6. Variables: independent and dependent

As a rule, we will use here two categories of variables, independent and dependent variables.

An independent variable is defined as « a variable at the origin of certain observed effects, directly controlled and manipulated by the researcher during the study » (Vetter, 2017). In this case in our study, it concerns the use (experimental group) of the ALLYANE® process (control group) and will be called « therapy ». Indications for use of the ALLYANE® procedure indicate a weekly application of the process for five weeks, with a visible benefit from the first rehabilitation session. Therefore, we propose to study the effects of this therapy after each of the five sessions, as well as three months after in order to measure its long-term effects.

Regarding the dependent variables, we can define them as « variables that are directly affected by the various independent variables and directly measured by the researcher during the study » (Vetter, 2017). As part of our research, the dependent variables assessed are: articular amplitude, muscle strength, spasticity, balance, walking, and quality of life. We chose these variables for several reasons:

First, SCI can cause periods of inactivity leading to joint stiffness and muscle atrophy (Dionyssotis et al, 2015). For this reason, we used **joint amplitude** and **muscle strength** as dependent variables.

We also chose **spasticity** as a dependent variable, which is known to be a long-term complication of SCI (Sadeghi et al, 2016). This is a common motor disorder with an impact on the voluntary muscular activity of the lower limbs, walking and also daily activities (Bravo et al, 2013).

Many patients with incomplete SCI have problems with postural balance and locomotion, with an ability to relearn how to walk limited by proprioceptive deficits (Chrisholm et al, 2019). It is for these reasons that we have chosen **balance** and **walking** as other dependent variables.

As already mentioned, a patient with SCI is likely to experience deficits such as a decreased in the articular amplitude of the joints, a decreased in muscle strength, and increased spasticity (Charlifue et al, 2012). We can also indicate that psychological damage is often present. Such deficits are likely to be permanent and may also result in activity limitations and participation restrictions. (Charlifue et al, 2012). Therefore, it seems appropriate to evaluate in our study the effects of the ALLYANE® process on the **quality of life** of patients.

Conventional rehabilitation will be carried out for five weeks from Monday to Thursday in all patients (experimental group and control group). On Fridays of each week of the rehabilitation, the experimental group will have a session with the ALLYANE® process and the control group will continue its conventional rehabilitation.

Thus, the dependent variables we have chosen (except quality of life) will be assessed for both groups weekly at the end of each week of rehabilitation. All patients will also be tested three months after the end of the fifth week to study the long-term effects of the ALLYANE® process that we will compare to those of the conventional procedure (APPENDIX III): Day 0 (date of the first session), Day 5, Day 12, Day 19, Day 26, Day 33 (date of the last session), and at Day 120 (3 months after the end of the rehabilitation process).

Quality of life will be assessed only three times, before (Day 0), at the end (Day 33) and 3 months after (Day 120) the rehabilitation for both control and experimental groups.

7. Equipment used

The ALLYANE® device, Alphabox®

According to the ALLYANE® process, the session should take place in a treatment room including the Alphabox®, a massage table, cameras and a computer (APPENDIX IV). These cameras allow the patient to become aware of his motor pattern as well as the visualization of the patient's progress by the physiotherapist during the sessions. As already mentioned, the Alphabox® is a generator specially designed and patented by the creators of the ALLYANE® process, which provides LFS through headphones.

The Alphabox® is composed of a case of about 70 x 30 centimeters together with a headphone and a remote control. The case and its accessories are inserted in a trunk allowing transport from one room to another. A dial on the case allows modulating the number of decibels to adapt sounds to the patient. Sound transmission is via stereo headphones specially created for their emission. These sounds are emitted according to different sequences and modes. The Alphabox® can indeed be operated in two different modes: manual and automatic. While the automatic mode allows the emission of pulsed sounds, the manual mode allows the associated sound emission.

So, there are two types of sounds:

- Pulsed sounds allow the patient to switch to a state of hypo-vigilance (state of rest or Alpha rhythm) allowing optimal concentration of the patient. The sounds are launched automatically by the box on several intervals.
- The associated sounds, allow the modification of the motricity during the phases of erasure and reprogramming (see Protocol). They must be manually launched by the manipulator. The associated sounds are themselves broken down into five categories of sounds, ranging from the low-pitched sound to the high-pitched sound, at the convenience of the patient.

Equipment used during traditional rehabilitation

The equipment needed to practice conventional rehabilitation includes: dumbbells, elastics, weight machines, Klein ball, gym ladder, parallel bars (...).

8. Instruments and assessment tests

Tests are conducted at the same time (Day 0, Day 5, Day 12, Day 19, Day 26, Day 33 and Day 120) in the subjects of the experimental group and control group. Appropriate assessment tools are used to measure articular amplitude, muscle strength, and tests for spasticity, balance, and walking. A test to determine the quality of life will be done on D0, D33 and D120 for both groups.

- **Measurement of the articular amplitude: the goniometer**

Joint amplitudes are usually measured by the goniometer (Gajdoskik & Bohannon, 1987). In our study, given the level of the lesion, we measure only the articular amplitudes of the lower limbs:

- Hip : flexion, extension, abduction, adduction, internal and external rotation
- Knee : flexion and extension
- Ankle (Tibio-tarsal) : dorsal and plantar flexion, inversion and eversion

➢ **Measurement of muscle strength : the dynamometer**

A dynamometer is a device that measures muscle strength. It is known for its ease of use, accurate and low cost of purchase (Chamorro et al, 2017).

People with SCI have a strength deficiency that can limit their functional ability to perform daily activities. Muscle strength tests are used to assess recovery or loss of motor function (Sisto & Dyson, 2007). The involved muscles in our study are all pelvic girdle muscles as well as the legs.

➢ **Scale of Spasticity : Modified Ashworth scale**

The Ashworth scale is considered providing a reliable measure of spasticity (Bohannon and Smith 1987) (ANNEX XI). It measures the increase in muscle tone associated with reinforced osteo-tendinous reflexes, muscle spasms and clonus (Meseguer et al, 2018). It was also shown that this scale is reliably used in spasticity measurements of the lower limbs of people with SCI (Akpinar et al, 2017).

The Ashworth scale evaluates the resistance to stretching, with six different ratings ranging from 0 to 5: 0, when there is no increase in tone and 5, when the joint concerned is put in flexion, extension, abduction or adduction. Only spasticity of the lower limbs is evaluated in our study.

➢ **Scale of balance : Berg scale**

The purpose of the Berg scale is to quantify static and dynamic equilibrium (ANNEX XII). It was developed in 1989 to measure the risk of falls among the elderly (Downs, 2015). It is now recognized and verified in patients with SCI (Datta, Lorenz, & Harkema, 2012). That's why we decided to use this scale in our study.

The Berg scale has 14 items with five different scores: a score of 0 indicates an « inability to perform a task autonomously », and a score of 4 indicates « no difficulty in completing the task ». The final score varies from 0 to 56.

- **The scale of walk: Walking Index for Spinal Cord Injury II (WISCI II)**

WISCI II is a scale for the analysis of locomotor disorders (ANNEX XIII). It allows more specific assessment of walking ability in patients with SCI (Burns et al, 2011).

Patients with incomplete SCI may have difficulties in walking. These disorders result in a pace, a length and symmetry of steps that differ from the healthy patient. Let's also note a slow execution of the walk. These difficulties have a negative impact on the overall effectiveness of walking (Perez et al, 2017).

The WISCI II scale is in the form of a 21-point classification, from the most severe impairment level (0: the patient is unable to stand or participate in walking) to the least severe level (20: the patient walks 10 meters unaided and without physical assistance). The scale takes into account the use of appliances, braces and physical assistance of one or more persons (Dittuno & Dittuno, 2001).

- **The scale of the quality of life : Short Form 36 Health Survey (SF-36)**

People with SCI have several sequelae such as decreased locomotor function, reduced autonomy, reduced spasticity that may impact quality of life (Andressen et al, 2016). A study targeting these patients with SCI has shown a decrease in their quality of life (Aquarone & Faro, 2014).

The measurement of a patient standard of health will be evaluated in our study by the standardized questionnaire SF-36 (Ware & Sherborne, 1992). This questionnaire will be submitted and completed by the patient. This self-assessment scale consists of 36 items to assess eight dimensions of quality of life : 1) limitations of physical activity because of health problems; 2) limitations of social activities because of emotional or health problems; 3) limitations of activities in daily life due to physical health problems; 4) physical pain, 5) general mental health (psychological distress and well-being); 6) limitations in everyday activities due to emotional problems; 7) vitality (energy and fatigue) and 8) general perception of one's health (Ware & Sherborne, 1992) (ANNEX XIV). The items in this questionnaire are on a scale of 3 or 5 categories. Each score is standardized from 0 to 100, with 100 representing an optimal level of quality of life.

9. Data processing plan

Our experimental data are initially formatted before being processed. Thus, the data obtained for each patient at each rehabilitation period are normalized with respect to his initial data, before treatment of the patients.

This data will then be statistically processed by the Statistica software 13.2 (Statsoft, France) traditionally used in research. Before doing this analysis, the software will allow us to verify beforehand that the distribution of our data follows a normal distribution (symmetric distribution), a major condition for performing our statistical analysis. The normality test used is the Shapiro test (Henderson, 2006).

In order to analyze our data and thus to confirm or reject our research hypothesis regarding the effects of the ALLYANE® process, we will use an analysis of variance (ANOVA) or factorial analysis which allows us to find out if one or more of our dependent variables are related to the independent variable. ANOVA thus highlights the influence of a factor (independent variable) on a variable of interest (dependent variable), by comparing the averages of each group of patients (experimental group and control group) while taking into account the intra-group variability. Analysis of variance will be repeated measures ANOVA as the dependent variables will be obtained in the same subject at different times or after rehabilitation. ANOVA will allow us to validate for each of the dependent variables analyzed the null hypothesis (H0) : « there is no difference between the experimental group and the control group » or to validate the alternative hypothesis (H1) « There is a significant difference between the experimental group and the control group ».

In case of rejection of the null hypothesis (there is a difference between the 2 groups), ANOVA will be followed by the use of a post-hoc test, such as the Neuman-Keuls test, which will indicate at which rehabilitation day the dependent variables differ between the experimental group and the control group.

10. Experimental protocol

The control group will be subject to traditional rehabilitation with five sessions per week of two hours, from Monday to Friday.

The experimental group will undergo a conventional rehabilitation four days a week, Monday to Thursday, followed by the fifth day with a rehabilitation session with ALLYANE® protocol. Indeed, the procedure recommended by the designers of ALLYANE® indicate the use of five weekly sessions lasting two hours for the improvement the deficits of patients with SCI.

On the first Monday of the treatment, we inform each patient of the experimental and control groups of the general objective of the study and detail the progress of the experimental protocol. This information, which defines and presents the protocol and the material used, must be clear because it is on the basis of this exchange that the patient must give and sign his free and informed consent (ANNEX XV) to participate in the study (Rohrig et al, 2009). During this first session, we also track the patient's medical history and complaint history (anamnesis). Then we take pictures and videos of patients to follow their evolution. At the end of this first stage, patients are subjected to the first conventional rehabilitation protocol.

The conventional rehabilitation

The conventional rehabilitation to which the patients of our two experimental groups will be subjected follows the directives of the HAH in 2007 and those of the Vade

Mecum of Physiotherapy and Functional Reeducation (Xhardez, 2016). However, this rehabilitation will have to be adapted to each patient, according to his specific deficits.

It consists in :

- A circulatory massage of the lower limbs
- Soft and progressive passive mobilizations in the total amplitude of the movement with, more specifically, mobilizations of the pelvic girdle, the knee and the foot
- Verticalizations and progressive loading using a verticalizer depending on the patient
- Transfer work: flips, push-ups, transfers bed to the chair
- Solicitation of the sub-lesional motricity with a work of different muscular areas of the lower limbs using particular weights, elastics and exercise balls
- Upper limb strengthening with more specific reinforcement of the scapular girdle, biceps and triceps and supinator and pronator muscles using weight machines, dumbbells, and elastics
- A muscle strengthening core muscles including a work of the latissimus dorsi and abdomen muscles
- Balance exercises in sitting and standing up position
- A training in walking, progressive work with the use of parallel bars, a walker and crutches

Therapy by the ALLYANE® process

As already indicated, we performe a first individual anamnesis session. Thereafter, each Friday, patients in the experimental group will benefit from ALLYANE® rehabilitation (APPENDIX V) which is performed in 9 steps.

Step 1: Negative proprioceptive imaging

This involves identifying negative proprioceptive sensations. This phase of the process consists in making the patient aware of proprioceptive sensations related to the movement whose schema is modified (Friggeri & Le Blay, 2018). This step helps the patient to become aware of the myo-articular deficits, locomotion and spasticity of the lower limbs.

Step 2: Negative visual imaging.

Numerous experimental data have shown the positive impact of the practice of visual imaging in patients with neurological disorders following strokes or SCI (Dickstein & Deutsh, 2007). Visual images are « the mental representation of an action without executing it physically. It stimulates the brain's motor networks and promotes motor learning after a spinal cord injury » (Di Rienzo et al, 2015). Patients can imagine that they perform a movement without actually performing it (Ehrsson, Geyer & Naito, 2003).
During this stage, the patient is asked to imagine performing the movement without executing it physically. The mental representation is focused on the movement, which for the moment is still altered, hence the name of this step « Negative visual imaging ».

Step 3: General relaxation

This stage consists in a general relaxation protocol performed by ALLYANE® after installing the Alphabox® (ANNEX XVI). From this step, the pulsed sounds emitted by the Alphabox® aims at placing him in a state of hypo-vigilance. This state is also made possible through the silence, the supine position and the dark atmosphere of the room.

The relaxation protocol is inspired by Jacobson's progressive relaxation method (Jacobson, 1980), Schultz's autogenic training (Schultz, 1960), and certain methods of cardiac coherence.

Step 4: Positive proprioceptive imaging

As indicated in the first step, the proprioceptive sensations allow to be aware of the position and movement of each body segment. Pulsed sounds are still issued. The patient is completely relaxed and his attention is focused on his feelings, and he will become aware of the altered movement to modify it with the help of the physiotherapist. Specifically, the patient with traumatic SCI at the level of the 12th lumbar vertebra is encouraged to perform appropriate contractions of the less activated muscles since the trauma. During these contractions, it is important for the patient to become aware of the proprioceptive sensations that would be most appropriate (Friggeri & Le Blay, 2018). To do so, the patient uses his previous memories, during which his motor functions were optimal.

Step 5: Positive visual imaging

The patient having experienced appropriate proprioceptive sensations, he is then asked to imagine the proper movement of the segment of each of the lower limbs in order to be able to integrate them into the motor pattern (Friggeri et Le Blay, 2018).

The emission of pulsed sounds is always present. This phase is called « positive » because this visual imagery concerns the « right movements to perform ».

Step 6: Erasure

It is important to « erase » the patient's negative motor pattern. To facilitate the completion of this phase, he is asked to watch the videos or pictures taken at the first session. So, we ask the patient to « erase » the motor pattern of the affected lower limbs. The physiotherapist adds to the pulsed sounds (already put previously), the associated sounds chosen previously by the patient to allow « erasure » of the old motor pattern. This step is reproduced three to six times, depending on the patient.

Step 7: Reprogramming using sounds

At this step, we will ask the patient to return to step five, « Positive Visual Imaging ». This allows finding the mental image of the new desired motor pattern. Once this mental image is well integrated by the patient, the physiotherapist re-launches the associated sounds allowing the reprogramming of the new motor pattern. This step is repeated three to six times depending on the patient.

Step 8: Integration

This step helps to maintain the results of reprogramming in the long run. To integrate the different proprioceptive information acquired during visual and proprioceptive imaging, pulsed sounds and associated sounds are issued together during this step. The patient is left alone in the room, still in a decubitus position, with a calm atmosphere and dark lighting. The duration of this step is about 10 minutes.

Step 9: Modified motor function

At the end of these eight steps, the patient is expected to have found the expected motor pattern. Therefore, it is important to reassess the various dependent variables seen previously in order to observe and evaluate the progress of patients. To help us in this process, we make new photos and videos.

The data is analyzed and interpreted to answer the problem of our study, namely what is the therapeutic value of ALLYANE® process in the patient with an incomplete SCI at the 12th thoracic vertebra level and its effect on the standard of health.

IV. CRITICAL CONSIDERATIONS AND CONCLUSION

In this last part, we will present the expected results in order to provide a critical consideration on the research protocol we propose in this manuscript.

The main objective of our study was to highlight the effects of the ALLYANE® process, associated with a conventional rehabilitation in patients with incomplete traumatic SCI at the level of the 12th thoracic vertebra compared to conventional rehabilitation. More specifically, our aim was to evaluate the impact of this process on articular amplitude, muscle strength, spasticity, balance and walking, and quality of life.

The theoretical framework we presented argues in favor of the assumption that the combination of the LFS issued by Alphabox®, together with the visual and proprioceptive imaging, will improve the conventional support of the patients.

The relevance of our study is related to the emergence of the use of the ALLYANE® by many physiotherapists. However, the number of scientific evidence of its effectiveness remains limited. Our study is therefore motivated by the need to provide additional scientific arguments justifying the benefit provided by this process to patients.

It is important to point out that an impairment of the SC affects the conduction of sensory and motor signals between effectors and the brain and can give rise to a number of deficits and symptoms whose severity depends on the level of injury (Bear, Connors & Paradiso, 2007).

We have seen that many studies have highlighted the benefits of MI in motor performance: improvement of the speed of a movement, increased articular amplitude (Williams et al, 2004), increased motivation (Guillot , & Collet, 2008), increased strength and muscle activation (Ranganathan, 2004), as well as optimal solicitation of the muscles (Papaxanthis et al, 2002).

We have also seen that despite the cortical reorganization following to the spinal injury, patients retain the ability to represent movement with their member which no longer receives motor commands (Grangeon et al, 2009). MI can therefore be considered as an effective therapeutic approach in the recovery of motor functions after SCI (Guillot & Collet, 2009).

In addition, according to some authors, listening to LFS allows the brain to bring Alpha into rhythmic activity (Friggeri & Le Blay, 2018). As we have seen, this rhythmic state puts the patient in a state of advanced concentration. This state was shown to have effects in different processes such as memorization (Başar et al, 2000), attention (Wolfgang, 2012; Mazaheri, 2014), concentration (Park et al, 2018), vision (Zhan et al. , 2014), anxiety (Isik et al, 2017).

In order to meet our main objective, we created an experimental research methodology that compares two groups randomly distributed. The control group benefits from a conventional rehabilitation and the experimental group benefits from a conventional rehabilitation associated with the ALLYANE® procedure.

This study is a prospective cohort study. It is controlled and randomized. The studied variables are articular amplitude, muscle strength, spasticity, balance, walking and quality of life. Throughout our project, these variables are measured using several assessing instruments such as the goniometer, the dynamometer and evaluation scales such as the modified Ashworth scale, the Berg scale and the WISCI scale II.

However, it is important to highlight some of the limitations of our study. Although some studies devoted to the ALLYANE® process in various pathologies, including neurological disorders, are in progress, there is today a lack of scientific literature about it. We are also the first to realize a thesis on this physiotherapy procedure.

A limitation of our study is the difficulty of recruiting our sample size (50 patients). Indeed, our inclusion and exclusion criteria are highly selective and restrict the opportunities for participation to a large number of patients with SCI.
Another limitation is the need for a strong attention and concentration of the patient, resulting in a greater mental fatigue during the rehabilitation with ALLYANE® procedure. This aspect could discourage some patients. However, we can note that this

process is, according to its designers, effective after only five sessions; which limits the potential risks of abandonment from patients.

The analysis of variance will allow in our study to reject or not the null hypothesis for each of the dependent variables analyzed. The interpretation of the results after this statistical analysis will allows us to determine if the rehabilitation procedure is significantly different between the experimental and the control group.

If the null hypothesis (H0) is confirmed, it will be concluded that the ALLYANE® process associated with traditional rehabilitation does not significantly show higher efficiency compared to conventional rehabilitation. In this case, the exploration of the effects of the ALLYANE® process could be pursued by increasing, for example, the frequency of the sessions that use this process.

If the alternative hypothesis (H1) is validated, it will be deduced that the ALLYANE® method associated with conventional rehabilitation has a significantly higher efficiency compared to the conventional rehabilitation alone. In this case, the ALLYANE® process will constitute a therapeutic strategy for neuromotor reprogramming of Evidence Based Practice (EBP). This will provide physiotherapy with a new tool whose effectiveness would be scientifically confirmed. It would give patients with incomplete SCI at the 12th thoracic vertebra level, an additional chance to recover good locomotor function and a better quality of life. Moreover, this rehabilitation can also be applied to patients with partial lesions at other levels of the SC.

It would be interesting and relevant not to limit the rehabilitation ALLYANE® to patients with SCI, and to practice it in other neurological domains, such as patients with stroke or Parkinson's disease, but also in patients with other non-neurological pathologies such as adhesive capsulitis, low back pain, sciatica or ankle instability.

Our study should provide scientific arguments for the use of this innovative process, which could then constitute a major therapeutic approach in the field of neuro-motor rehabilitation.

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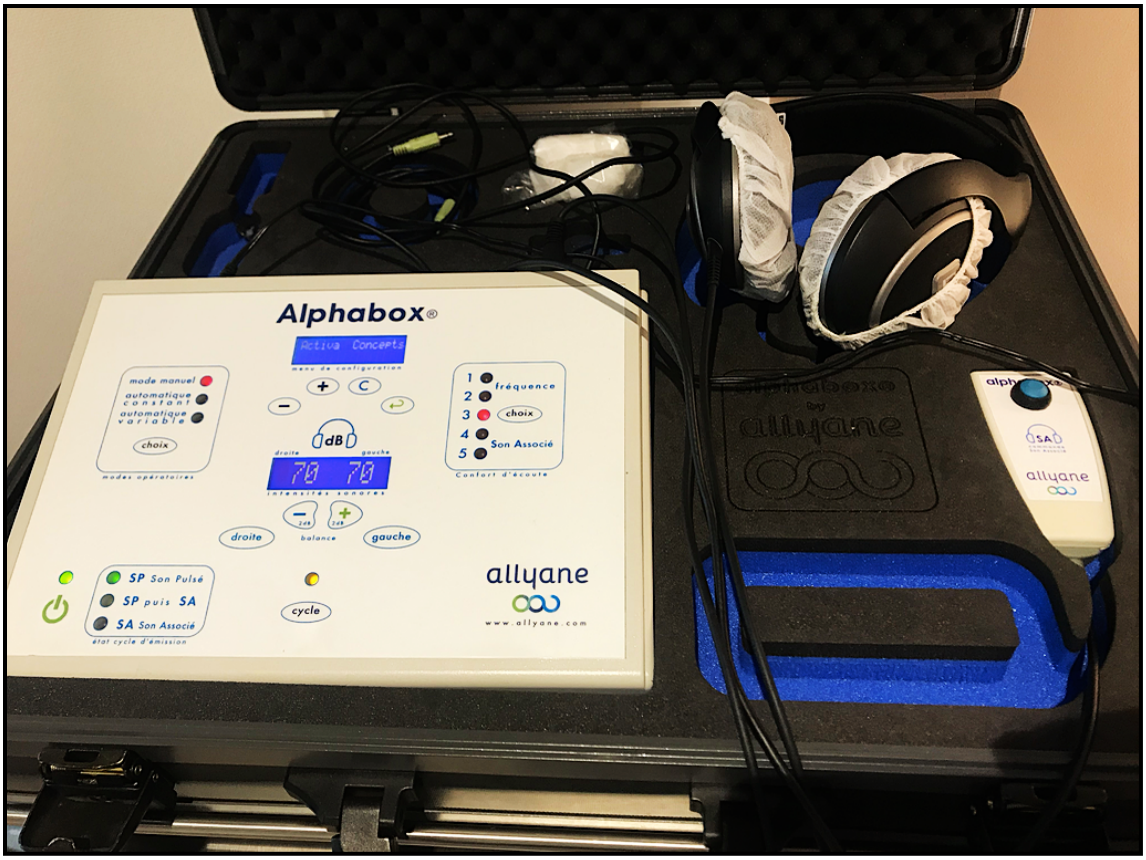
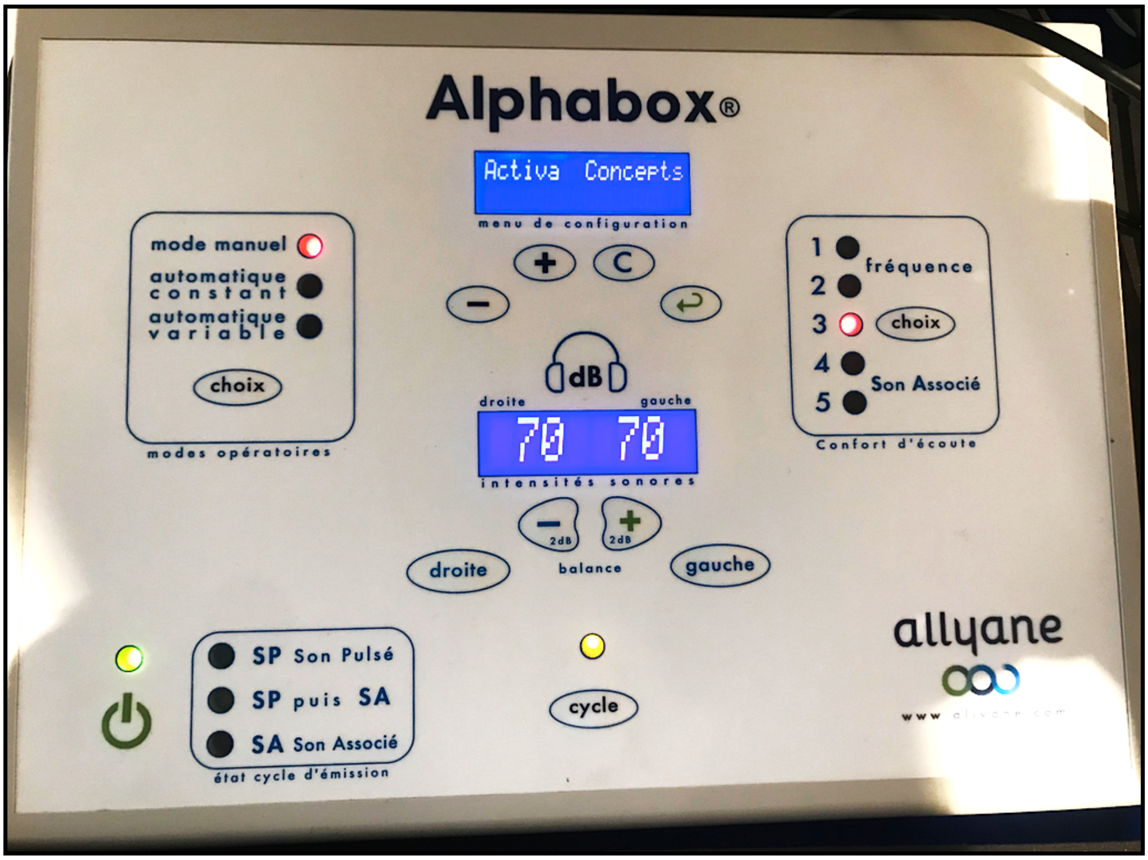
APPENDICES

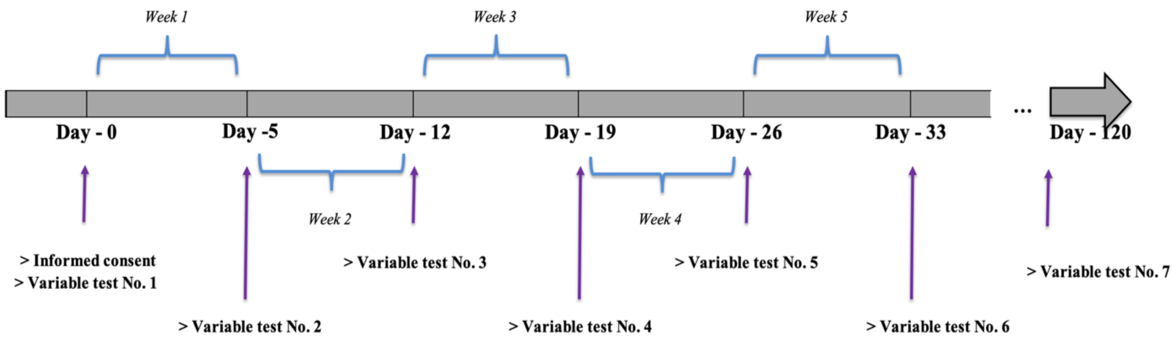
APPENDIX I: The Alphabox®



APPENDIX II: Table controle of the Alphabox®



APPENDIX III: Test of variables in function of time



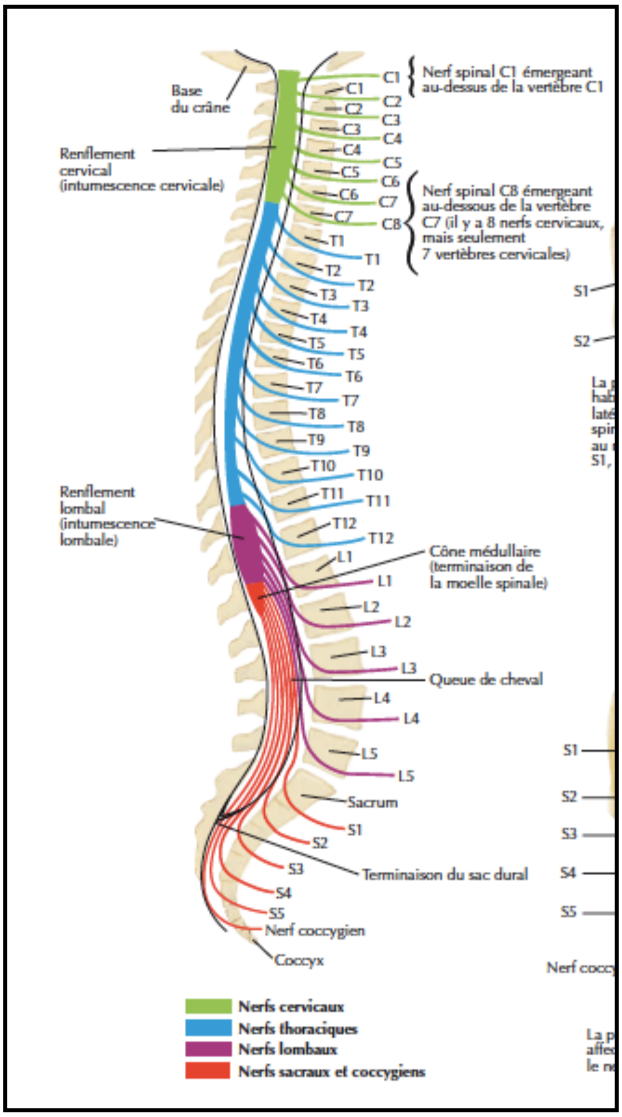
APPENDIX IV: Example of a treatment room

APPENDIX V: Summary of two types of rehabilitation

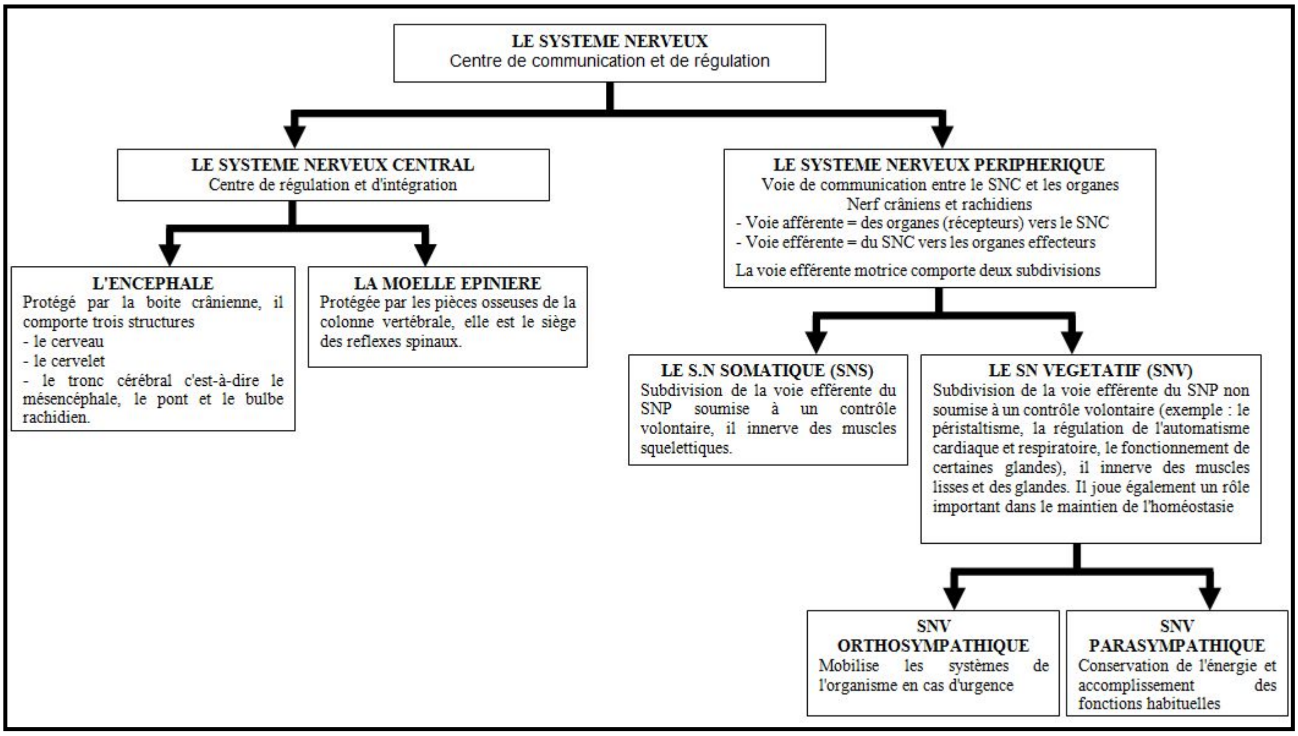
	Traditional process	**ALLYANE process and traditional method**	
Number of sessions	5 sessions / week	ALLYANE : 1 session / week Traditional method : 4 sessions / week	
Duration of the session	2 hours	2 hours	
Steps of the process	Anamnesis - Diagnosis - Appraisal - Goal	Anamnesis - Diagnosis - Appraisal - Goal	
	Circulatory massage of the lower limbs	Negative proprioceptive imaging	
	Passive mobilizations	Negative mental imaging	
			Implementation of Alphabox with impulsed sounds
	Vertical integration	Skip to hypovigilance	*Pulsed sounds*
	Work transfers	Positive proprioceptive imaging	*Pulsed sounds*
	Solicitation of the sub-lesioned motricity	Positive mental imaging	*Pulsed sounds*
	Strengthening the upper limbs	Erasure	*Pulsed sounds*; *Associated sounds*
	Strengthening of the core muscles	Reprogramming (3 times)	*Pulsed sounds*; *Associated sounds*
	Work Balance	Implementation	*Pulsed sounds*; *Associated sounds*
	Walking	Modified motricity	

ANNEXES

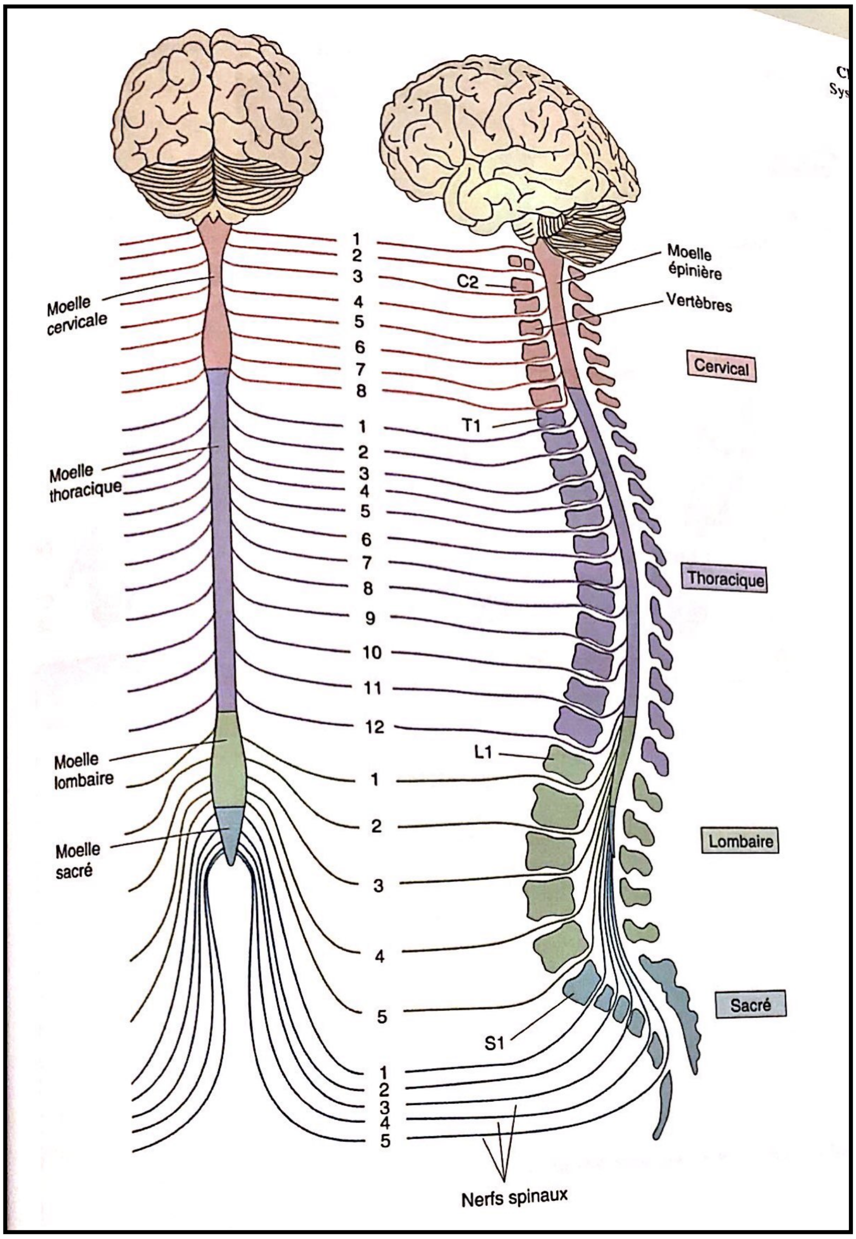
ANNEX I: Bone protection of the SC: The spine (Netter, 2011).



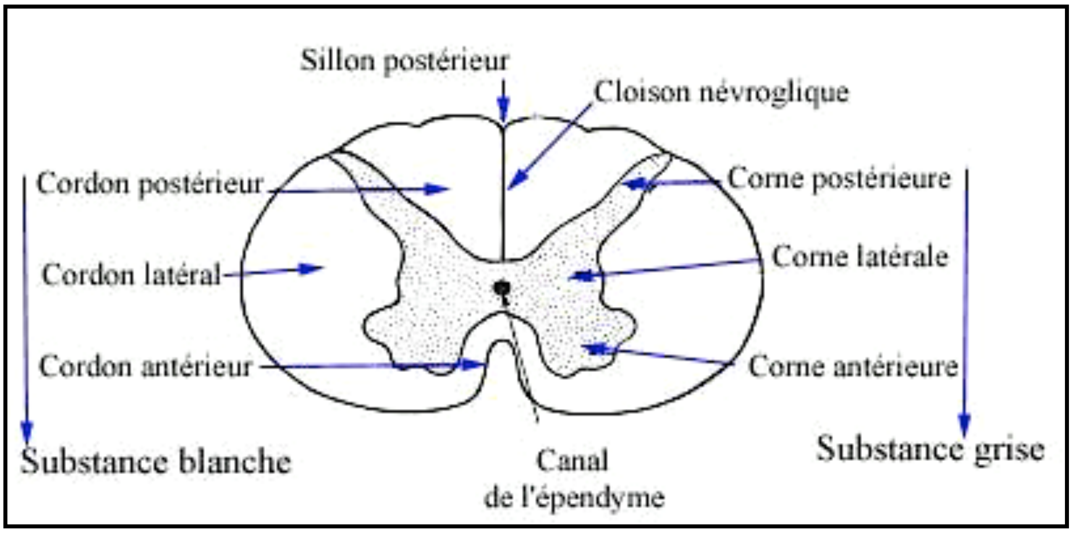
ANNEX II: Organization chart SNC-SNP (Ecole Normale Supérieure Lyon, 2019).



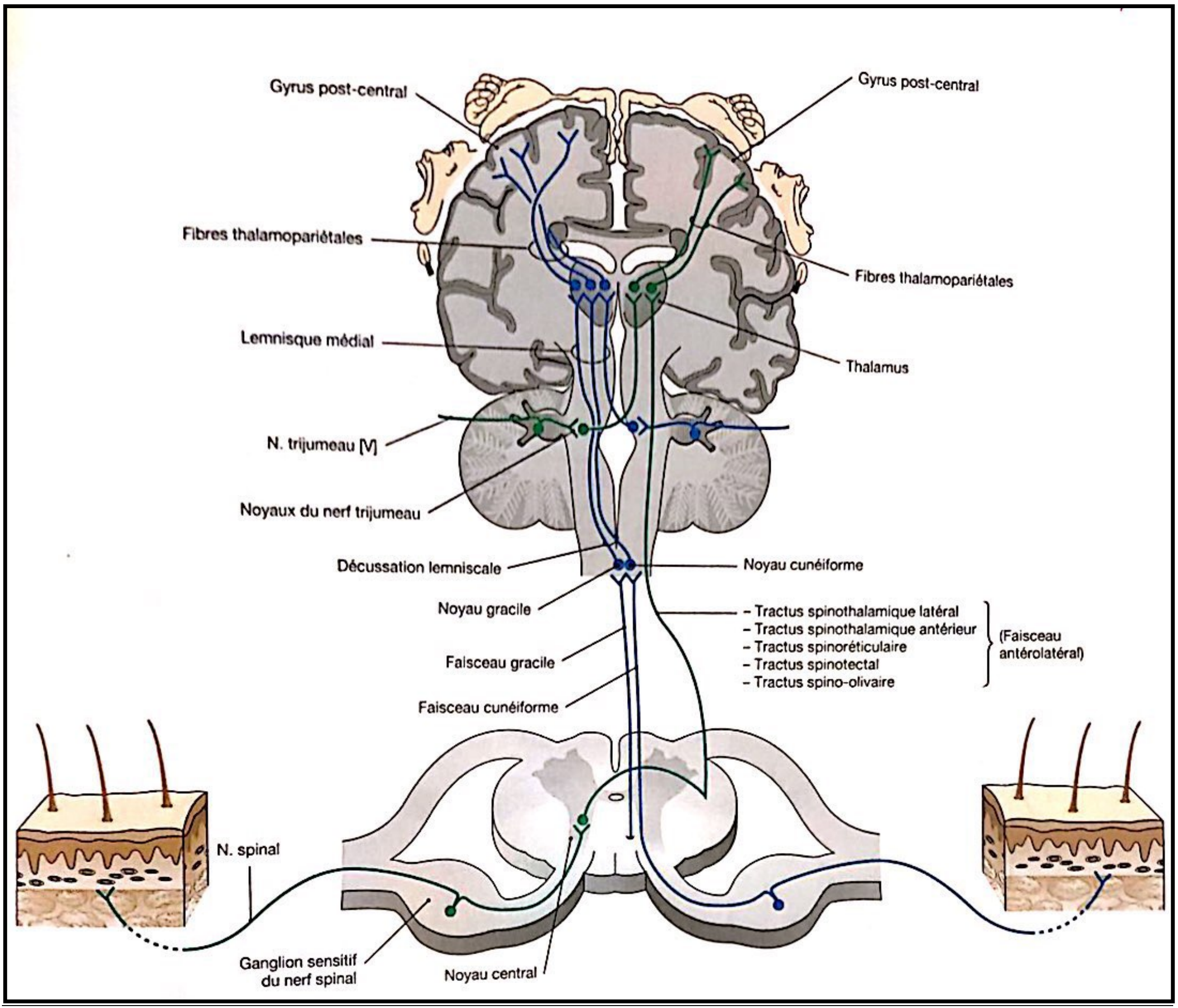
ANNEX III: Segmental organization of the spinal cord and spinal nerves (Bear, Connors & Pradiso, 2007)



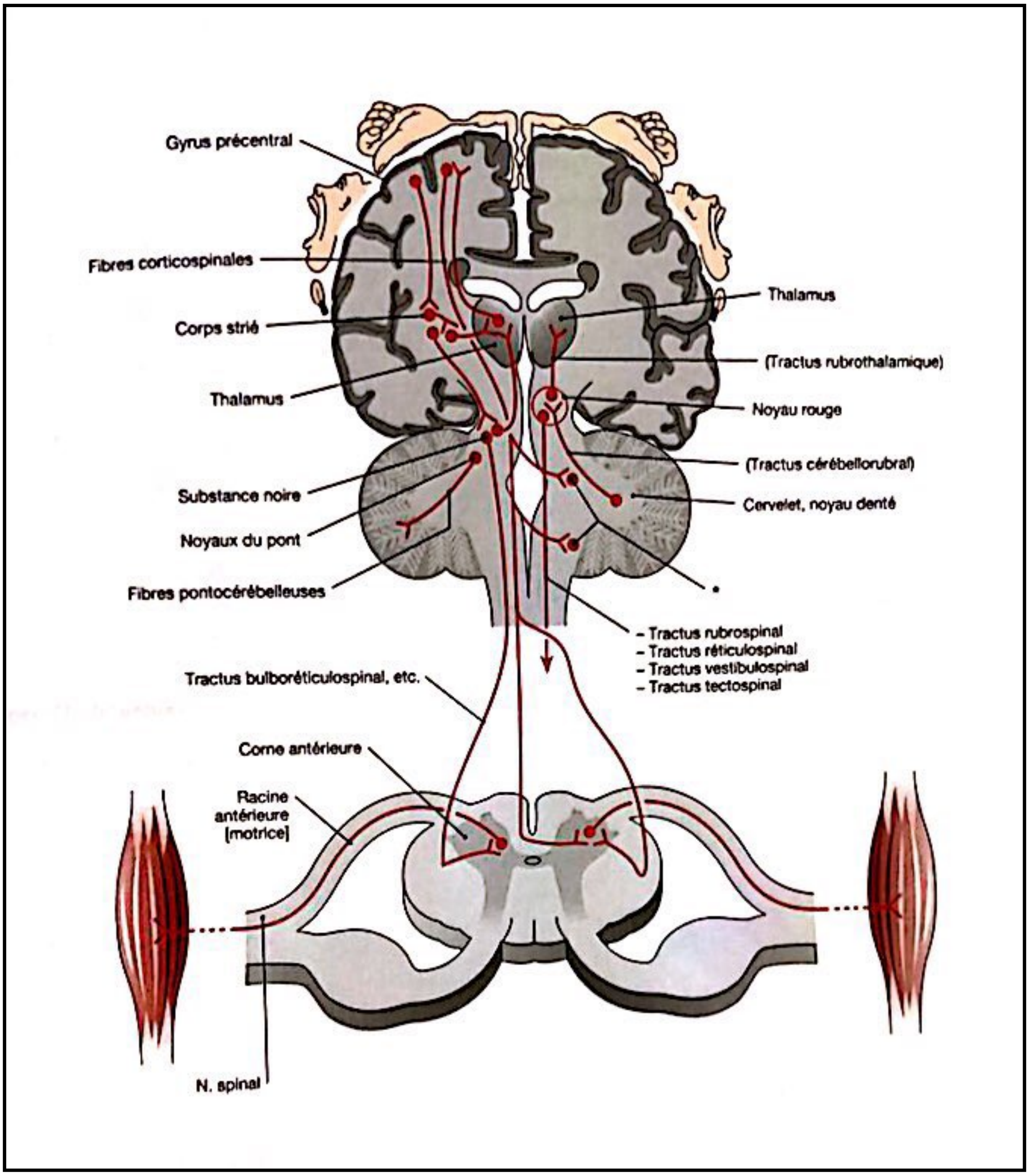
ANNEX IV: Cross section of the spinal cord (Netter, 2011)



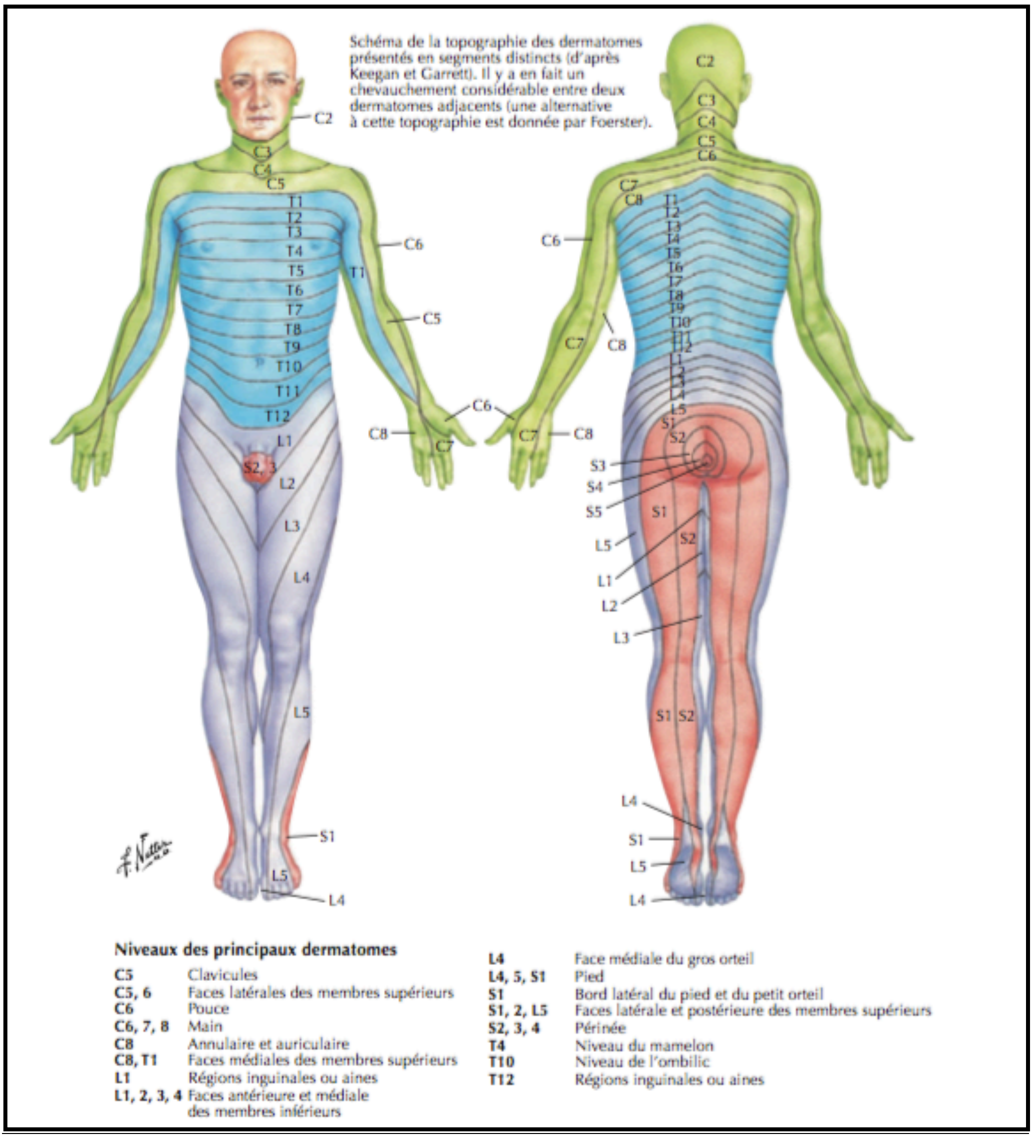
ANNEX V: Path of epicritic (blue) and protopathic (green) sensitivity (Paulsen & Waschke, 2018).



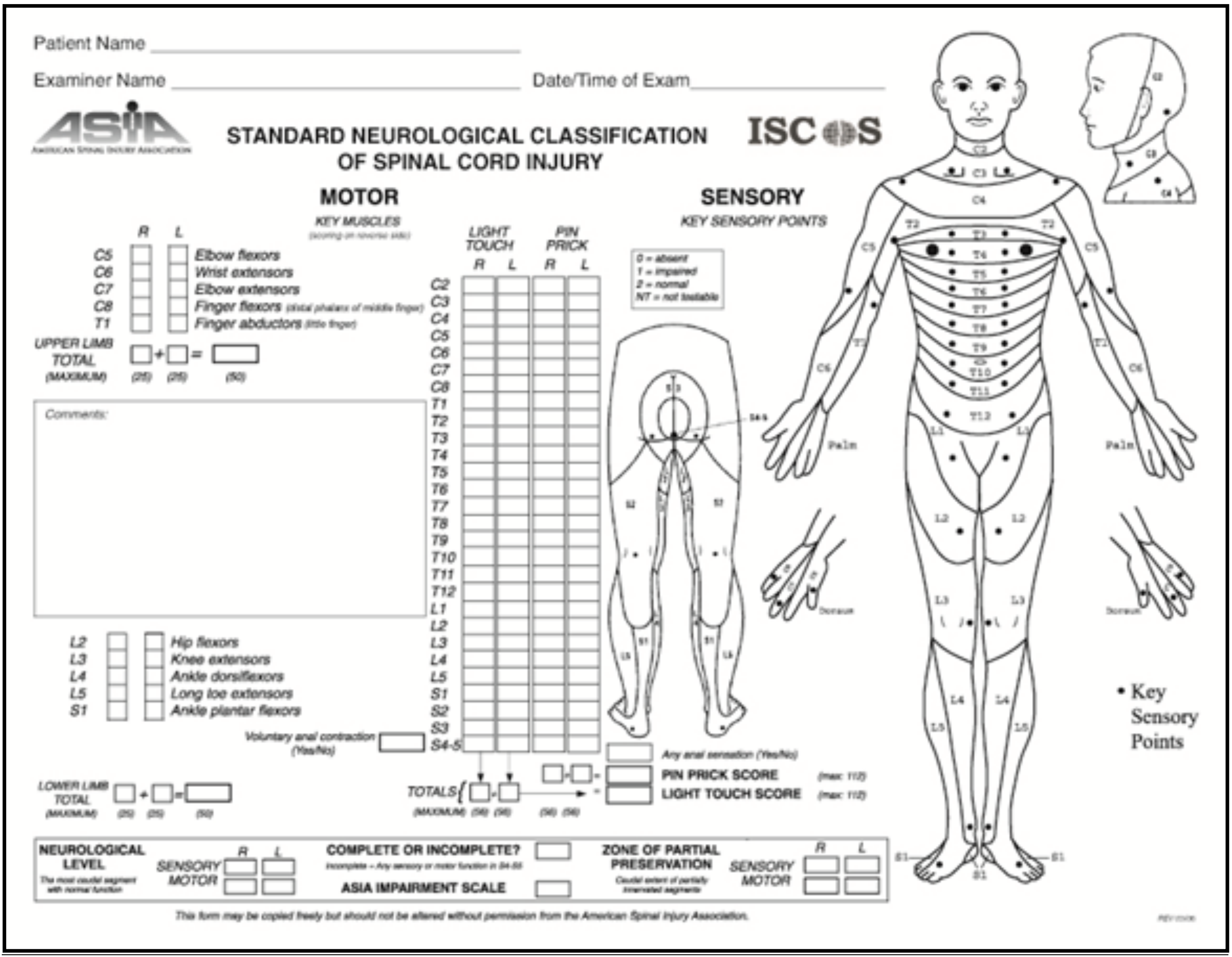
ANNEX VI: Motorways (Paulsen & Waschke, 2018).



ANNEX VII: Dermatomes (Netter, 2011)



ANNEX VIII: ASIA scale (Roberts, Leonard & Cepela, 2017)



Patient Name ____________________

Examiner Name ____________________ Date/Time of Exam ____________________

AMERICAN SPINAL INJURY ASSOCIATION

STANDARD NEUROLOGICAL CLASSIFICATION OF SPINAL CORD INJURY

ISCOS

MOTOR

KEY MUSCLES (scoring on reverse side)

	R	L	
C5			Elbow flexors
C6			Wrist extensors
C7			Elbow extensors
C8			Finger flexors (distal phalanx of middle finger)
T1			Finger abductors (little finger)

UPPER LIMB TOTAL (MAXIMUM) ☐ + ☐ = ☐ (25) (25) (50)

Comments:

	R	L	
L2			Hip flexors
L3			Knee extensors
L4			Ankle dorsiflexors
L5			Long toe extensors
S1			Ankle plantar flexors

Voluntary anal contraction (Yes/No) ☐

LOWER LIMB TOTAL (MAXIMUM) ☐ + ☐ = ☐ (25) (25) (50)

SENSORY

KEY SENSORY POINTS

	LIGHT TOUCH R	LIGHT TOUCH L	PIN PRICK R	PIN PRICK L
C2				
C3				
C4				
C5				
C6				
C7				
C8				
T1				
T2				
T3				
T4				
T5				
T6				
T7				
T8				
T9				
T10				
T11				
T12				
L1				
L2				
L3				
L4				
L5				
S1				
S2				
S3				
S4-5				

TOTALS { ☐ + ☐ (MAXIMUM) (56) (56) (56) (56)

0 = absent
1 = impaired
2 = normal
NT = not testable

Any anal sensation (Yes/No) ☐

☐ + ☐ = ☐ PIN PRICK SCORE (max: 112)

☐ LIGHT TOUCH SCORE (max: 112)

NEUROLOGICAL LEVEL (The most caudal segment with normal function) R L SENSORY ☐ ☐ MOTOR ☐ ☐

COMPLETE OR INCOMPLETE? ☐ (Incomplete = Any sensory or motor function in S4-S5)

ASIA IMPAIRMENT SCALE ☐

ZONE OF PARTIAL PRESERVATION (Caudal extent of partially innervated segments) R L SENSORY ☐ ☐ MOTOR ☐ ☐

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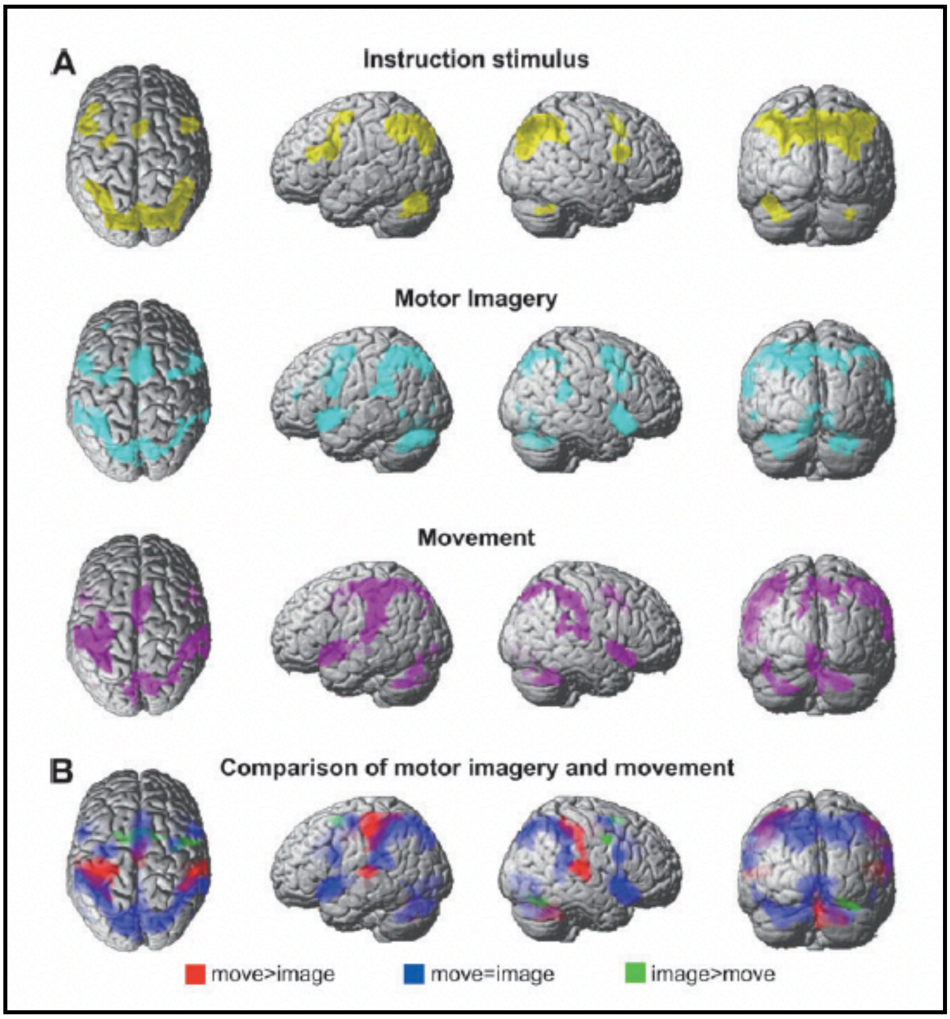
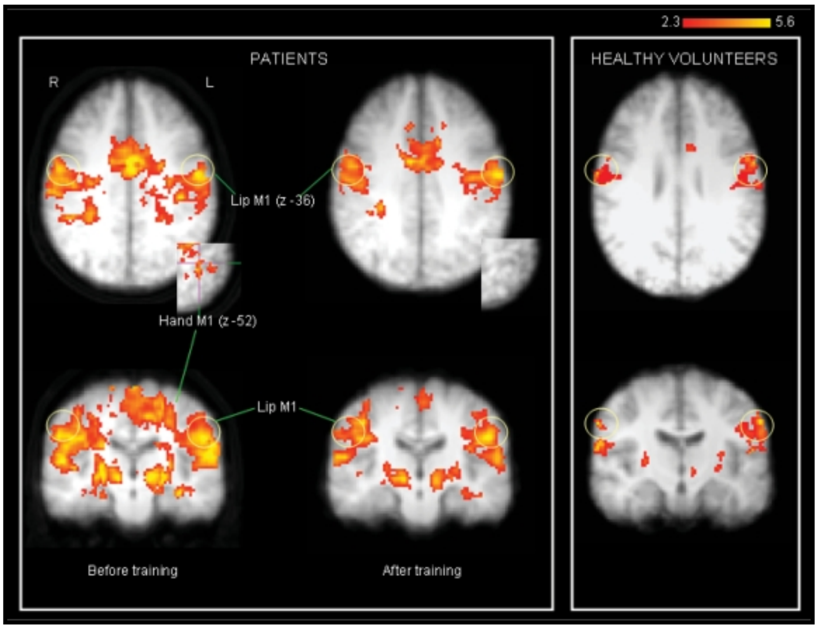
ANNEX IX: Similar activation of the cortical areas in MI and during the actual execution of a movement (Hanakawa, Dimyan, & Hallett 2008).



ANNEX X: Reorganization of the cortex after mental training (Maclver et al, 2008).



ANNEX XI: Modified Ashworth scale (Bohannon & Smith, 1987).

Modified Ashworth Scale

The Modified Ashworth Scale (MAS) measures resistance during passive soft-tissue stretching. It is a quick and easy measure that can help assess the efficacy of treatment. The following conventions prevail:

- The MAS is performed in the supine position (this will garner the most accurate and the lowest score as any tension anywhere in the body will increase spasticity)
- Because spasticity is "velocity dependent" (the faster the limb is moved, the more spasticity is encountered), the MAS is performed while moving the limb at the "speed of gravity"; this is defined as the same speed at which a non-spastic limb would naturally drop (fairly fast)
- The test is performed a maximum of three times for each joint; if more than three times, the short-term effect of a stretch can influence the score
- The MAS is performed prior to goniometric testing; goniometric testing provides a stretch, and the short-term effect of a stretch can influence the score

Scoring

0 = Normal tone, no increase in tone
1 = Slight increase in muscle tone, manifested by a catch and release or minimal resistance at the end of the range of motion (ROM) when the affected part(s) is moved in flexion or extension
1+ = Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the ROM
2 = More marked increase in muscle tone through most of the ROM, but affected part(s) easily moved
3 = Considerable increase in muscle tone, passive movement difficult
4 = Affected part(s) rigid in flexion or extension

Positions

The positions used for an MAS assessment are as follows:

Score______Elbow. *Start position:* Elbow fully flexed, forearm neutral. Movement: Extend elbow from maximum possible flexion to maximum possible extension. (Triceps would be in the same position, opposite direction.)

Score______Wrist. *Start position:* Elbow as straight as possible, forearm pronated. Movement: Extend the patient's wrist from maximum possible flexion to maximum possible extension.

Score______Fingers. *Start position:* Elbow as straight as possible, forearm neutral. All fingers are done at once. Movement: Extend the patient's fingers from maximum possible flexion to maximum possible extension.

Score______Thumb. *Start position:* Elbow as straight as possible, forearm neutral, wrist neutral. Movement: Extend the thumb from maximum possible flexion (thumb against index finger) to maximum possible extension (in anatomical position, "abducted").

Score______Hamstrings. *Start position:* Prone so that ankle falls beyond end of the plinth, hip in neutral rotation. Movement: Extend the patient's knee from maximum possible flexion to maximum possible extension

Score______Quadriceps. *Start position:* Prone so that ankle falls beyond end of the plinth, hip in neutral rotation. Movement: Flex the patient's limb from maximum possible flexion to maximum possible extension

Score______Gastrocnemius. *Start position:* Supine, ankle plantarflexed, hip in neutral rotation and flexion. Movement: Dorsiflex the patient's ankle from maximum possible plantarflexion to maximum possible dorsiflexion not more than three consecutive times and rate the muscle tone.

Score______Soleus. *Start position:* Supine, ankle plantarflexed, hip in neutral rotation and flexion and with the knee flexed to ~15°. Movement: Dorsiflex the patient's ankle from maximum possible plantarflexion to maximum possible dorsiflexion.

Reprinted with permission from Peter G. Levine. Testing spasticity: the Modified Ashworth Scale. June 2, 2009. http://physical-therapy.advanceweb.com/Article/Testing-Spasticity-The-Modified-Ashworth-Scale.aspx. and Bohannon R, et al. Interrater reliability of a Modified Ashworth Scale of muscle spasticity. *Phys Ther.* 1987;67(7):206-207.

ANNEX XII: Berg scale (Downs, 2015)

BERG BALANCE TESTS AND RATING SCALE

Patient Name ____________________
Date ____________________
Location ____________________
Rater ____________________

ITEM DESCRIPTION SCORE (0-4) Sitting to standing _____ Standing unsupported _____ Sitting unsupported _____ Standing to sitting _____ Transfers _____ Standing with eyes closed _____ Standing with feet together _____ Reaching forward with outstretched arm _____ Retrieving object from floor _____ Turning to look behind _____ Turning 360 degrees _____ Placing alternate foot on stool _____ Standing with one foot in front _____ Standing on one foot _____ TOTAL _____

GENERAL INSTRUCTIONS
Please demonstrate each task and/or give instructions as written. When scoring, please record the lowest response category that applies for each item.

In most items, the subject is asked to maintain a given position for a specific time. Progressively more points are deducted if the time or distance requirements are not met, if the subject's performance warrants supervision, or if the subject touches an external support or receives assistance from the examiner. Subjects should understand that they must maintain their balance while attempting the tasks. The choices of which leg to stand on or how far to reach are left to the subject. Poor judgment will adversely influence the performance and the scoring.

Equipment required for testing are a stopwatch or watch with a second hand, and a ruler or other indicator of 2, 5 and 10 inches (5, 12 and 25 cm). Chairs used during testing should be of reasonable height. Either a step or a stool (of average step height) may be used for item #12.

1. SITTING TO STANDING
INSTRUCTIONS: Please stand up. Try not to use your hands for support.
( ) 4 able to stand without using hands and stabilize independently
( ) 3 able to stand independently using hands
( ) 2 able to stand using hands after several tries
( ) 1 needs minimal aid to stand or to stabilize
( ) 0 needs moderate or maximal assist to stand

2. STANDING UNSUPPORTED
INSTRUCTIONS: Please stand for two minutes without holding.
( ) 4 able to stand safely 2 minutes
( ) 3 able to stand 2 minutes with supervision
( ) 2 able to stand 30 seconds unsupported
( ) 1 needs several tries to stand 30 seconds unsupported
( ) 0 unable to stand 30 seconds unassisted

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4.

3. SITTING WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL
INSTRUCTIONS: Please sit with arms folded for 2 minutes.
( ) 4 able to sit safely and securely 2 minutes
( ) 3 able to sit 2 minutes under supervision
( ) 2 able to sit 30 seconds
( ) 1 able to sit 10 seconds
( ) 0 unable to sit without support 10 seconds

4. STANDING TO SITTING
INSTRUCTIONS: Please sit down.
( ) 4 sits safely with minimal use of hands
( ) 3 controls descent by using hands
( ) 2 uses back of legs against chair to control descent
( ) 1 sits independently but has uncontrolled descent
( ) 0 needs assistance to sit

5. TRANSFERS
INSTRUCTIONS: Arrange chairs(s) for a pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.
( ) 4 able to transfer safely with minor use of hands
( ) 3 able to transfer safely definite need of hands
( ) 2 able to transfer with verbal cueing and/or supervision
( ) 1 needs one person to assist
( ) 0 needs two people to assist or supervise to be safe

6. STANDING UNSUPPORTED WITH EYES CLOSED
INSTRUCTIONS: Please close your eyes and stand still for 10 seconds.
( ) 4 able to stand 10 seconds safely
( ) 3 able to stand 10 seconds with supervision
( ) 2 able to stand 3 seconds
( ) 1 unable to keep eyes closed 3 seconds but stays steady
( ) 0 needs help to keep from falling

7. STANDING UNSUPPORTED WITH FEET TOGETHER
INSTRUCTIONS: Place your feet together and stand without holding.
( ) 4 able to place feet together independently and stand 1 minute safely
( ) 3 able to place feet together independently and stand for 1 minute with supervision
( ) 2 able to place feet together independently but unable to hold for 30 seconds
( ) 1 needs help to attain position but able to stand 15 seconds with feet together
( ) 0 needs help to attain position and unable to hold for 15 seconds

8. REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING
INSTRUCTIONS: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the finger reaches while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.)
( ) 4 can reach forward confidently >25 cm (10 inches)
( ) 3 can reach forward >12 cm safely (5 inches)
( ) 2 can reach forward >5 cm safely (2 inches)
( ) 1 reaches forward but needs supervision
( ) 0 loses balance while trying/requires external support

9. PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION
INSTRUCTIONS: Pick up the shoe/slipper which is placed in front of your feet.
( ) 4 able to pick up slipper safely and easily
( ) 3 able to pick up slipper but needs supervision
( ) 2 unable to pick up but reaches 2-5cm (1-2 inches) from slipper and keeps balance independently
( ) 1 unable to pick up and needs supervision while trying
( ) 0 unable to try/needs assist to keep from losing balance or falling

10. TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING
INSTRUCTIONS: Turn to look directly behind you over toward left shoulder. Repeat to the right. Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.
( ) 4 looks behind from both sides and weight shifts well
( ) 3 looks behind one side only other side shows less weight shift
( ) 2 turns sideways only but maintains balance
( ) 1 needs supervision when turning
( ) 0 needs assist to keep from losing balance or falling

11. TURN 360 DEGREES
INSTRUCTIONS: Turn completely around in a full circle. Pause. Then turn a full circle in the other direction.
( ) 4 able to turn 360 degrees safely in 4 seconds or less
( ) 3 able to turn 360 degrees safely one side only in 4 seconds or less
( ) 2 able to turn 360 degrees safely but slowly
( ) 1 needs close supervision or verbal cueing
( ) 0 needs assistance while turning

12. PLACING ALTERNATE FOOT ON STEP OR STOOL WHILE STANDING UNSUPPORTED
INSTRUCTIONS: Place each foot alternately on the step/stool. Continue until each foot has touched the step/stool four times.
( ) 4 able to stand independently and safely and complete 8 steps in 20 seconds
( ) 3 able to stand independently and complete 8 steps in >20 seconds
( ) 2 able to complete 4 steps without aid with supervision
( ) 1 able to complete >2 steps needs minimal assist
( ) 0 needs assistance to keep from falling/unable to try

13. STANDING UNSUPPORTED ONE FOOT IN FRONT

INSTRUCTIONS: (DEMONSTRATE TO SUBJECT) Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width)

( ) 4 able to place foot tandem independently and hold 30 seconds
( ) 3 able to place foot ahead of other independently and hold 30 seconds
( ) 2 able to take small step independently and hold 30 seconds
( ) 1 needs help to step but can hold 15 seconds
( ) 0 loses balance while stepping or standing

14. STANDING ON ONE LEG

INSTRUCTIONS: Stand on one leg as long as you can without holding.

( ) 4 able to lift leg independently and hold >10 seconds
( ) 3 able to lift leg independently and hold 5-10 seconds
( ) 2 able to lift leg independently and hold = or >3 seconds
( ) 1 tries to lift leg unable to hold 3 seconds but remains standing independently
( ) 0 unable to try or needs assist to prevent fall

TOTAL SCORE (Maximum = 56: _______

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ANNEX XIII: WISCI II scale (Dittuno & Dittuno, 2001)

Instructions for the Use of the Walking Index for Spinal Cord Injury II (WISCI II) – March 2005

Instructions for the Use of the Walking Index for Spinal Cord Injury II (WISCI II)
(see attached scale and scoring sheet)

The information in this manual is based on current observations in clinical studies and recent publications[1,2,3]. This manual will require ongoing modifications based on knowledge gained from future clinical trials as they occur.

Subject Selection
The purpose of this scale is for use in clinical trials to measure improvements in walking in persons with spinal cord injury. The following outline describes subjects for whom the scale is most commonly utilized.

1. Spinal cord injury subjects who are capable of standing and walking in the parallel bars will be eligible for assessment. Only a reciprocal gait is to be considered in scoring the WISCI scale. Additional inclusion/exclusion criteria may be necessary.
2. Most often ASIA A below T10 and ASIA B, C, and D subjects may qualify[3]. (Ditunno 2004).
3. Individuals with tetraplegia would require motor strength in triceps of at least grade 3 or be able to support their body weight[3,4]. (Ditunno 2004, Dobkin 2003).

Standardized Physical Environment and Distance
This is a functional limitation scale, NOT a disability scale. It must be used in a standardized environment with standardized equipment and definitions, which are observed and recorded by professional staff that are trained. The following requirements are necessary:

1. A flat, smooth, non-slippery surface of 10 meters will be utilized.
2. Individuals walk at their own speed and the 10 meters should not be timed.

Standardized Equipment
1. Walkers should be conventional, but if a rolling walker is used, it should be coded as a walker and identified in the descriptors.
2. Use of a platform walker is equivalent to a walker.
3. Crutches can be Lofstrand (Canadian) or axillary.
4. Braces means one or two braces, either long or short, and should be identified in the descriptors. Other devices used for bracing such as ace wraps or splints should be coded as a brace and described under "other".
5. Whether long leg braces are locked or unlocked at the knees should be identified in the descriptors.
6. Clothing should not cover braces to allow therapists and other professional staff to make a visual determination that the patient has a brace.

Standardized Assistance
1. Any physical contact with the subject, including "contact guard" is considered physical assistance.
2. Supervision should not be regarded as physical assistance.

Instructions for the Use of the Walking Index for Spinal Cord Injury II (WISCI II) – March 2005

Scoring (See attached scoring sheet)
The Walking Index for Spinal Cord Injury Scale (WISCI 2) has demonstrated a response to change in the Spinal Cord Injury Locomotion Trial[5] (ISCOS 2004) and in clinical validation studies[1,6] (Ditunno 2003, 2004). In scoring the WISCI, check the descriptors that apply to current walking performance, and then assign the highest level of walking performance. In scoring one level, one should choose the level at which the patient is safe as judged by the therapist, with patient's comfort level described. If devices other than those stated in the standard definitions are used, they should be documented as descriptors. If there is a discrepancy between two observers, the higher level should be chosen.

The subject is observed by the trained personnel and the WISCI level is recorded on the scale of 0 to 20 at baseline (Baseline WISCI). The subject is observed again at the defined interval (Interval WISCI). The change in score is calculated by subtracting the baseline WISCI from the Interval WISCI, which equals the change in WISCI (Changed WISCI). If a group of subjects are enrolled, medians and means may be calculated.

References:

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2. Ditunno PL, Ditunno JF. Walking index for spinal cord injury (WISCI II): scale revision. *Spinal Cord* 2001;39:654-656.

3. Morganti B, Scivoletto G, Ditunno P, Ditunno JF, Molinari M. Walking index for spinal cord injury (WISCI): criterion validation. *Spinal Cord* 2005; 43(1): 27-33.

4. Ditunno JF, West C, Schmidt M, Patrick M. Validation and refinement of the Walking Index for Spinal Cord Injury (WISCI) in a clinical setting. 30th Annual Scientific Meeting of the American Spinal Injury Association, Denver, CO, May 14 – 16, 2004.

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6. Ditunno JF, Dobkin BH. Walking index for spinal cord injury (WISCI): response to change in a clinical trial (SCILT) and setting (TJU). Inaugural International Campaign for Cures of spinal cord injury Paralysis (ICCP) Clinical Trials Workshop, Vancouver, Canada, February 20-21, 2004.

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Instructions for the Use of the Walking Index for Spinal Cord Injury II (WISCI II) – March 2005

Walking Index for Spinal Cord Injury (WISCI II) Descriptors

Physical Limitation for walking secondary to impairment is defined at the person level and indicates the ability of a person to walk after spinal cord injury. The development of this assessment index required a rank ordering along a dimension of impairment, from the level of most severe impairment (0) to least severe impairment (20) based on the use of devices, braces and physical assistance of one or more persons. The order of the levels suggests each successive level is a less impaired level than the former. The ranking of severity is based on the severity or the impairment and not on functional independence in the environment. The following definitions standardize the terms used in each item:

Physical assistance: 'Physical assistance of two persons' is moderate to maximum assistance. 'Physical assistance of one person' is minimal to moderate assistance.

Braces: 'Braces' means one or two braces, either short or long leg. (Splinting of lower extremities for standing is considered long leg bracing). 'No braces' means no braces on either leg.

Walker: 'Walker' is a conventional rigid walker without wheels.

Crutches: 'Crutches' can be Lofstrand (Canadian) or axillary.

Cane: 'Cane' is a conventional straight cane.

Level	Description
0	Client is unable to stand and/or participate in assisted walking.
1	Ambulates in parallel bars, with braces and physical assistance of two persons, less than 10 meters
2	Ambulates in parallel bars, with braces and physical assistance of two persons, 10 meters.
3	Ambulates in parallel bars, with braces and physical assistance of one person, 10 meters.
4	Ambulates in parallel bars, no braces and physical assistance of one person, 10 meters
5	Ambulates in parallel bars, with no braces and no physical assistance, 10 meters.
6	Ambulates with walker, with braces and physical assistance of one person, 10 meters.
7	Ambulates with two crutches, with braces and physical assistance of one person, 10 meters.
8	Ambulates with walker, no braces and physical assistance of one person, 10 meters.
9	Ambulates with walker, with braces and no physical assistance, 10 meters.
10	Ambulates with one cane/crutch, with braces and physical assistance of one person, 10 meters.
11	Ambulates with two crutches, no braces and physical assistance of one person, 10 meters.
12	Ambulates with two crutches, with braces and no physical assistance, 10 meters.
13	Ambulates with walker, no braces and no physical assistance, 10 meters.
14	Ambulates with one cane/crutch, no braces and physical assistance of one person, 10 meters.
15	Ambulates with one cane/crutch, with braces and no physical assistance, 10 meters.
16	Ambulates with two crutches, no braces and no physical assistance, 10 meters.
17	Ambulates with on devices, no braces and physical assistance of one person, 10 meters.
18	Ambulates with on devices, with braces and no physical assistance, 10 meters.
19	Ambulates with one cane/crutch, no braces and no physical assistance, 10 meters.
20	Ambulates with no devices, no braces and no physical assistance, 10 meters.

Instructions for the Use of the Walking Index for Spinal Cord Injury II (WISCI II) – March 2005

Scoring Sheet for the Walking Index for Spinal Cord Injury (WISCI II)

Name___________________________________ Date____________________

Check descriptors that apply to current walking performance, and then assign the highest level of walking performance. (In scoring a level, one should choose the level at which the patient is safe as judged by the therapist, with patient's comfort level described. If devices other than those stated in the standard definitions are used, they should be documented as descriptors. If there is a discrepancy between two observers, the higher level should be chosen.)

Gait: reciprocal _______ ; swing through _______

Descriptors

Devices		Braces		Assistance	Patient reported Comfort level
//bars < 10 meters		Long Leg Braces- Uses 2 Uses 1		Max Assist x 2 people	Very comfortable
//bars 10 meters		Short Leg Braces- Uses 2 Uses 1		Min/Mod assist x 2 people	Slightly comfortable
Walker- Standard Rolling Platform		Locked at knee _____ Unlocked at knee _____		Min/mod assist x 1 person	Neither comfortable nor uncomfortable
Crutches- Uses 2 Uses 1		Other: _______________			Slightly uncomfortable
Canes- Quad Uses 2 Uses 1					Very uncomfortable
No devices		No braces		No assistance	

WISCI Levels

Level	Devices	Braces	Assistance	Distance
0				Unable
1	Parallel bars	Braces	2 persons	Less than 10 meters
2	Parallel bars	Braces	2 persons	10 meters
3	Parallel bars	Braces	1 person	10 meters
4	Parallel bars	No braces	1 person	10 meters
5	Parallel bars	Braces	No assistance	10 meters
6	Walker	Braces	1 person	10 meters
7	Two crutches	Braces	1 person	10 meters
8	Walker	No braces	1 person	10 meters
9	Walker	Braces	No assistance	10 meters
10	One cane/crutch	Braces	1 person	10 meters
11	Two crutches	No braces	1 person	10 meters
12	Two crutches	Braces	No assistance	10 meters
13	Walker	No braces	No assistance	10 meters
14	One cane/crutch	No braces	1 person	10 meters
15	One cane/crutch	Braces	No assistance	10 meters
16	Two crutches	No braces	No assistance	10 meters
17	No devices	No braces	1 person	10 meters
18	No devices	Braces	No assistance	10 meters
19	One cane/crutch	No braces	No assistance	10 meters
20	No devices	No braces	No assistance	10 meters

Level assigned____________

Revised 3/19/2002

ANNEX XIV: SF-36

SF-36 QUESTIONNAIRE

Name:____________________ **Ref. Dr:**___________________ **Date:** _______

ID#: _______________ **Age:** _______ **Gender: M / F**

Please answer the 36 questions of the **Health Survey** completely, honestly, and without interruptions.

GENERAL HEALTH:
In general, would you say your health is:
- Excellent
- Very Good
- Good
- Fair
- Poor

Compared to one year ago, how would you rate your health in general now?
- Much better now than one year ago
- Somewhat better now than one year ago
- About the same
- Somewhat worse now than one year ago
- Much worse than one year ago

LIMITATIONS OF ACTIVITIES:
The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.
- Yes, Limited a lot
- Yes, Limited a Little
- No, Not Limited at all

Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf
- Yes, Limited a Lot
- Yes, Limited a Little
- No, Not Limited at all

Lifting or carrying groceries
- Yes, Limited a Lot
- Yes, Limited a Little
- No, Not Limited at all

Climbing several flights of stairs
- Yes, Limited a Lot
- Yes, Limited a Little
- No, Not Limited at all

Climbing one flight of stairs
- Yes, Limited a Lot
- Yes, Limited a Little
- No, Not Limited at all

Bending, kneeling, or stooping
- Yes, Limited a Lot
- Yes, Limited a Little
- No, Not Limited at all

Walking more than a mile
- Yes, Limited a Lot
- Yes, Limited a Little
- No, Not Limited at all

Walking several blocks
- Yes, Limited a Lot
- Yes, Limited a Little
- No, Not Limited at all

Walking one block
- Yes, Limited a Lot
- Yes, Limited a Little
- No, Not Limited at all

Bathing or dressing yourself
◯Yes, Limited a Lot ◯Yes, Limited a Little ◯No, Not Limited at all

PHYSICAL HEALTH PROBLEMS:
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

Cut down the amount of time you spent on work or other activities
◯Yes ◯No

Accomplished less than you would like
◯Yes ◯No

Were limited in the kind of work or other activities
◯Yes ◯No

Had difficulty performing the work or other activities (for example, it took extra effort)
◯Yes ◯No

EMOTIONAL HEALTH PROBLEMS:
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

Cut down the amount of time you spent on work or other activities
◯Yes ◯No

Accomplished less than you would like
◯Yes ◯No

Didn't do work or other activities as carefully as usual
◯Yes ◯No

SOCIAL ACTIVITIES:
Emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

◯Not at all ◯Slightly ◯Moderately ◯Severe ◯Very Severe

PAIN:
How much bodily pain have you had during the past 4 weeks?

◯None ◯Very Mild ◯Mild ◯Moderate ◯Severe ◯Very Severe

During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

◯Not at all ◯A little bit ◯Moderately ◯Quite a bit ◯Extremely

ENERGY AND EMOTIONS:
These questions are about how you feel and how things have been with you during the last 4 weeks. For each question, please give the answer that comes closest to the way you have been feeling.

Did you feel full of pep?
- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Have you been a very nervous person?
- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Have you felt so down in the dumps that nothing could cheer you up?
- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Have you felt calm and peaceful?
- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Did you have a lot of energy?
- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

ANNEX XV: Informed ALLYANE® consent.

CENTRE EXPERT DU MOUVEMENT

Autorisation d'utilisation de l'image d'une personne

Je soussigné(e)
____

Demeurant : ____

Autorise la société Allyane à utiliser et diffuser à titre gratuit et non exclusif des photographies ou vidéos me représentant, réalisées à l'occasion d'une séance Allyane, ainsi qu'à exploiter ces clichés, en partie ou en totalité, à des fins d'enseignement et de recherche ou d'exploitation commerciale.

Les photographies et vidéos susmentionnées sont susceptibles d'être reproduites sur les supports suivants :

- Publication dans une revue, ouvrage ou journal
- Publication pour une publicité
- Présentation au public lors de congrès ou événements,
- Diffusion sur le site web intitulé www.centre-expert.fr
- Ou sur tout autre support de communication Allyane

L'intéressé sera informé préalablement à la diffusion de tout support.

Fait à _____________, le ____ /____ /______ en deux exemplaires.

Signature

ANNEX XVI: Release general protocol of ALLYANE®

Déroulement :

- **Installer le patient sous l'Alphabox® en décubitus confortable et lui expliquer les deux types de sons : sons pulsés automatique et son associé.**
- **Lui faire choisir le son associé qui lui convient le mieux (5 choix)**
- **Lui expliquer et lui faire faire les trois respirations, avec répétitions :**
  - **1) Respiration haletante avec sollicitation rapide du diaphragme.**
  - **2) Respiration diaphragmatique**
  - **3) Respiration costale**
- **Exécuter ces trois respirations à la suite et à la fin de l'inspiration, faire une mise en apnée avec contraction maximale de tous les muscles du corps à l'exception de la tête.**
- **Lorsque le patient atteint sa limite de l'apnée, une expiration forcée est demandée avec prise de conscience de la sensation de relâchement en écoutant le son associé choisi.**
- **Trois répétitions sont effectuées en assisté avec le praticien.**