

Universidad deValladolid



UNIVERSIDAD DE VALLADOLID

ESCUELA DE INGENIERIAS INDUSTRIALES

Grado en Ingeniería de Organización Industrial

ANÁLISIS DE COSTES Y EFECTIVIDAD DE LA REHABILITACIÓN MODERNA EN IRCCS BONINO-PULEJO.

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Valladolid, Marzo 2019.

TFG REALIZADO EN PROGRAMA DE INTERCAMBIO

- TÍTULO: "Cost-effectiveness analysis of modern rehabilitation in IRCCS Bonino-Pulejo"
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- FECHA: 12 de Marzo de 2019
- CENTRO: DICEAM Universitá degli studi Mediterranea di Reggio Calabria
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Resumen

La rehabilitación robótica trata de aplicar los conocimientos propios de la ingeniería para complementar y mejorar la medicina tradicional. En este trabajo se estudia el potencial impacto de la implementación de los métodos de rehabilitación moderna, tanto sobre la viabilidad económica como sobre la efectividad de los resultados obtenidos con los pacientes.

Con este propósito, se han analizado los servicios de rehabilitación moderna que ofrece el hospital I.R.C.C.S Neurolese Bonino-Pulejo situado en la ciudad de Messina (Sicilia, Italia) detallando las características de los distintos dispositivos utilizados en dicha rehabilitación y todos los costes que conllevan.

No obstante, la efectividad de estos recursos no ha sido ampliamente demostrada debido a su escaso tiempo de aplicación aunque si se pueden apreciar ciertas ventajas frente a la rehabilitación tradicional (reproducibilidad, resultados facilmente medibles, etc). En este trabajo se estudia dicha efectividad mediante el análisis de las últimas investigaciones en este campo de conocimiento.

Palabras clave

Ingeniería en la sanidad, análisis de costes, análisis de effectividad, rehabilitación robotica, rehabilitación tradicional.

Abstract

Robotic rehabilitation seeks to apply the field of engineering to complement and to improve conventional rehabilitation. In this bachelor thesis, feasibility is studied both in economic terms and in the effectiveness of the new methods of modern rehabilitation.

For this purpose, we have analyzed the modern rehabilitation services offered by the I.R.C.C.S Neurolese Bonino-Pulejo hospital located in the city of Messina (Sicily, Italy), breaking down the devices used in rehabilitation and all the costs involved.

However, the effectiveness of these resources has not been widely demonstrated due to its limited application time, although certain advantages can be appreciated compared to traditional rehabilitation (reproducibility, easily measurable outcomes, etc.). In this work, this effectiveness is studied through the analysis of the latest research in this field of knowledge.

Keywords

Health engineering, cost analysis, effectiveness analysis, robotic rehabilitation, traditional rehabilitation.







BACHELOR THESIS

COST-EFFECTIVENESS ANALYSIS OF MODERN REHABILITATION IN I.R.C.C.S BONINO PULEJO

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Greetings:

I would like to thank Angel Gento as well as Carlo Francesco Morabito for allowing me to do this Erasmus exchange.

A Maria Da Cola, for being my contact at the hospital and for helping me with the information and corrections.

And, finally, I would like to thank Jesús Álvarez-Campana Rueda, Irene Rodríguez Rojo and Álvaro Álvarez-Campana Rodríguez for supporting me every day and being my fundamental pillar. Because of them, I am who I am today.



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Università Mediterranea di Reggio Calabria





1. Introduction

This final thesis has been developed through an Erasmus exchange program in Università degli Studi Mediterranea di Reggio di Calabria. It was carried out at IRCCS Neurolese Bonino-Pulejo in Messina after suggestion of Professor Morabito, whose advice appointed doctor Bramanti as the co-tutor at the hospital.

In the robotic rehabilitation, the human-machine interaction reaches its greatest exponent. Rehabilitation tasks usually focus on repetitive movements performed with the help of the physiotherapist. However, with modern rehabilitation, the robot will allow the patient to execute those movements, being the initial setting of the robotic device program and its surveillance the only tasks due to the physiotherapist.

Trusting a robot for health-related issues is common in several medical techniques where its effectiveness has been completely proven. Neverthless, and due to the lack of experience and results on robot action in rehabilitation treatments, risking the investment cost of acquiring the devices may not seem a very appealing option at first glance. Therefore, this thesis will analyse both the cost and the effectiveness of modern rehabilitation method with robotic interaction.

1.1. Health service in Italy

In Italy the health-care system provides universal coverage free of charge at the point of delivery¹. National health service is regionally

¹Italian health-care system principles are based on three pillars: universality of assistance, equality of access and solidarity



organized being the region responsible of delivering and organizing health care. At a national level the Ministry of Health set the fundamental goals of the health system and allocates national fund to the regions. At local level ASLs (Aziende Sanitary Localy)² deliver public health, community health services and primary care through public hospitals or accredited private providers.

Each region performs several legislative activities which include, among others, the followings:

- General principles and general rules regional authorities should carry out.
- Criteria for financing public and private providers.
- Guidelines for service provision and planning.

ASL are named differently depending on the region, and they are provided with a high level of autonomy to take decisions. ASLs throughout the country are:

- Alto Adige: Azienda Sanitaria dell'Alto Adige (ASDAA)
- Basilicata: Azienda Sanitaria locale di Potenza (ASP) e Azienda Sanitaria locale di Matera (ASM)
- Calabria e Sicilia: Azienda Sanitaria Provinciale (ASP)
- Emilia-Romagna, Toscana e Umbria: Azienda Unità Sanitaria Locale (AUSL)
- Friuli-Venezia Giulia: Azienda per l'assistenza sanitaria (AAS) e
 Azienda sanitaria universitaria integrata (ASUI)
- Lombardia: Agenzia di Tutela della Salute (ATS)
- Marche: Azienda Sanitaria Unica Regionale (ASUR)
- Molise: Azienda Sanitaria Regionale del Molise (ASREM)
- Sardegna: Azienda per la Tutela della Salute (ATS)

² ASLs are geographically based local health authorities



- Trentino: Azienda Provinciale per i Servizi Sanitari (APSS)
- Valle d'Aosta: Azienda Unità Sanitaria Locale della Valle d'Aosta (AUSL VDA)
- Veneto: Azienda Unità Locale Socio Sanitaria (Azienda ULSS)

Patient's rights are not determined by a single law but by several parts of Italian legislation, such as Italian Constitution and the funding law of health system. Despite these laws, the service varies across the country as it does the satisfaction of the citizens with health care³.

The Ministry of Health is also supported by several permanent government agencies:

- ISS (The National Institute of Health) carries out scientific research and diffusion of knowledge. They counsel the Ministry of Health.
- II. AGENAS (National Agency for Regional Health Services) ensure organizational quality, efficiency and efficacy in the delivery of care. Moreover, they are the link between the Ministry of Health and the regional authorities.
- III. CCM (National Centre for Disease Prevention and Control) design national strategies for disease prevention, health promotion and equality in access to care.
- IV. AIFA, the national authority for pharmaceutical regulation.

Representatives of these entities (scientists, physicians and other recognized experts) take part in the National Health Council (CSS), being the most consulted entity.

³ Legal actions have been taken because of these differences.



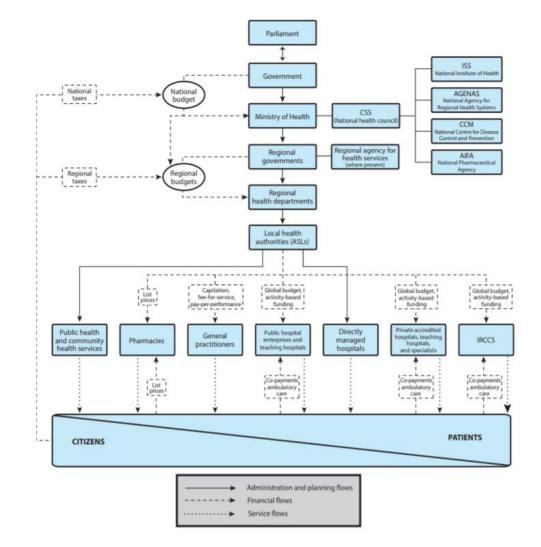


Figure 1: Italian health-care organizational overview.



1.2. Healthcare financing in Italy

The national health service is funded through national and regional taxes. In addition, these funds are supplemented by co-payment for pharmaceuticals and out of patient care.

The healthcare financing in Italy in 2017 was 74.03% state-funded, whereas the other 25.97% was privately financed.

Italian public health care system is financed through:

- A corporate tax (Imposta regionale sulle attività produttive (IRAP)). The 30% of Italian health care expenditure is financed by IRAP revenue and the tax rate is set at 3.9% of value-added produced by a company. In addition, regions have the flexibility to raise the level.
- "Imposta sul reddito delle persone fisiche" (IRPEF). The tax rate in Sicily is set at 1.5%.
- A proportion of national value-added tax (VAT) revenue collected by the central government. It is used to provide resources to regions unable to raise sufficient resources to provide the principles. It is worth mentioning that about 38% of the fund collected with VAT is for health budget.

In Italy there are substantial differences in funding among regions mainly due to significant regional variation in tax rates. It means that poorer regions would need to increase their regional tax what could be translated into businesses' profits impact and social consequences derived from the fiscal pressure.



In 2017 total health-care expenditure accounted for 8,9% of the GDP in Italy. In the figure 2 it is showed the evolution of the health-care GDP percentage from 2000 to 2017⁴:

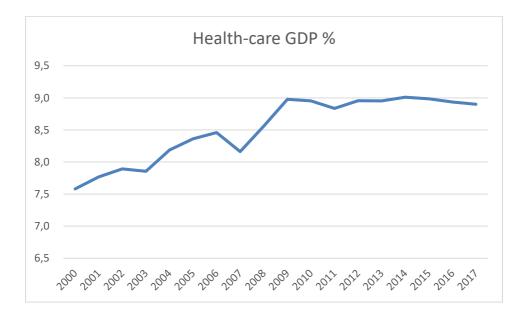


Figure 2: Health-care GDP percentage

1.3. IRCSS

1.3.1. What is I.R.C.C.S

I.R.C.C.S is the abbreviation for "Instituto di Recovero e Cura a Carattere Scientifico" (Institute of hospitalization and care of a scientific nature) which denominate a group of hospitals where clinical research and hospitalization services are provided. Their objective could be diverse depending on the field of specialisation.

⁴ Source: OECD statistic database



The IRCCS are hospitals of excellence that perform high-quality hospitalization and care service. These institutions receive national and regional funding. The number of IRCCS hospitals recognized by the Ministry of Health are 49; 21 of them are public, whereas the other 28 are private and carry out research that must necessarily find an outlet in therapeutic applications in hospitals.

The Ministry of Health, in order to verify the impact on the care of the patient, supervises the IRCCS. Moreover, a special procedure has to be completed in order to be included in IRCCS list.

On the other hand, the private IRCCS have more freedom of action and the control over them is focused only on the value of their scientific researches.

Institutes of hospitalization and scientific care can receive such recognition for a single subject or for multiple areas. The areas where IRCCS conduct their research are:

- Dermatology
- Diagnostic Images
- Pharmacology
- Gastroenterology
- Genetics
- Geriatric
- Infectious diseases
- Medicine of complexity
- Neurology
- Neurorehabilitation
- Ophthalmology
- Oncology
- Orthopaedics



- Paediatrics
- Psychiatry

1.3.2. I.R.C.C.S Bonino-Pulejo

The activity of the IRCCS Neurolesi Center "Bonino-Pulejo" has as its main objective to guarantee the appropriate services for the protection, care and recovery of health, ensuring the three fundamental principles of the National Health Service in Italy: universalism of assistance, equality of access, solidarity⁵.

Although the structure can take care of patients who suffer from any type of neurological disability, the users that came to the hospital are the ones who have serious outcomes of head injury, cerebrovascular accident and vegetative state. In particular, patients admitted to the IRCCS Bonino-Pulejo are generally classified into different categories:

- Sub-intensive patients who come from hospitals, departments or intensive care units, with the presence of a brain lesion such as motor deficit. However, they are clinically stable with normal breathing.
- Patients in which the presence of a lesion of the nervous system that require intervention is determined. The patient's internal, metabolic and general clinical conditions must allow the implementation of a therapeutic program that guarantees an adequate recovery on the functional level and reintegration.
- Patients with minimal consciousness. Their primary objective is to combine the recovery of consciousness and motor deficit with a treatment aimed at reducing the deficits linked to the state of chronicity.

⁵ See Antonio Freire's final thesis for the history of I.R.C.C.S Bonino-Pulejo.



- Sub-acute, patients from hospitals, or departments of neurology or neurosurgery who have had a recent nervous system injury (less than 6 months). In these subjects the treatment is aimed at the highest motor recovery of the injured party.
- Patients with spinal cord injury due to spinal traumas involving changes in motion and sensitivity. The rehabilitation activity is aimed at recovering the maximum autonomy and independence of the patient. Its general condition is consciousness compatible with the realization of a participatory rehabilitation project.
- Post-intensive, patients requiring extensive rehabilitation in hospitalization in order to recover disability during the stabilization phase.

The care activity is oriented both to the management of high complexity pathologies through the use of a multidisciplinary approach and the involvement of all the operators, as well as to the definition and application of models and appropriate procedures aimed at improving the diagnostic, integrating all activities with research carried out within the IRCCS.

The rehabilitation activities carried out by specialized employees in the fields of neuromotor rehabilitation, speech therapy, cognitive, respiratory and cardiological, includes all the traditional pathologies of the nervous system and is conducted as a normal hospitalization and as an outpatient rehabilitation day hospital.



2. Purposes of the thesis

This final thesis has three main purposes.

The first purpose is to make a cost analysis of the modern rehabilitation methods offered by I.R.C.C.S Bonino-Pulejo ⁶. It is needed to perform a cost study taking into account direct cost (such as machine, personal and amortization costs) and also indirect cost (those that are not related directly with the patient).

IRCCS Bonino-Pulejo has a capacity problem, given that their theoretical number of sessions is really far from the real one. This issue defines the second purpose of the thesis, which is indeed to explain why this happens and to propose solutions.

The third purpose is to assess modern rehabilitation effectiveness. IRCCS Bonino-Pulejo needs to prove that their rehabilitation therapies are better than the traditional ones. This implies a difficult task because of the outcomes lack for modern rehabilitation⁷. In this thesis, I will use the "state of the art" to study the effectiveness of modern rehabilitation.

To achieve all purposes, I will classify all the costs that the hospital has related to rehabilitation, taking into account that the main difference talking about cost are the modern therapy devices, whose functioning will also be described in detail.

⁶ The amount is not entirely asked for the patient but a part.

⁷ It takes time to quantify a valid outcome and most of the studies are new.



3. Methods of rehabilitation.

In IRCCS Bonino-Pulejo two methods of rehabilitation are carried out: traditional/conventional and modern rehabilitation. On one hand, conventional methods are, at first sight, cheaper than new techniques of rehabilitation with robotic and electronic devices. On the other hand, new methods are far more efficient. The solution given to most of the patients is a combination of traditional and modern methods, being the best way for them to recover their mobility.

3.1. Traditional method.

Traditional method entails doing some physical task under supervision as well as taking physiotherapy sessions. They are known to be more effort demanding than the robotic treatment but they are also necessary for the complete recovery of the patient.⁸

3.2. Modern method.

This method implies the use of some modern devices that help the patient in the rehabilitation process. Being the result of years of investigation and development. Some devices are used to assist patients for walking, improving the mobility of limbs or doing telematic rehabilitation. The range of possibilities is considerable.

⁸ For further information, see the work of Antonio Freire: "STRATEGIC ANALYSIS OF I.R.C.C.S. MESSINA & COST THEORY APPLICATION" pages 60-82.



3.2.1. Armeo

These devices are developed by HOCOMA, the world's first company in creating robots that embrace the whole upper extremity rehabilitation. Each device is developed for a specific stage of rehabilitation.

 Armeo®Power is a robotic arm exoskeleton for arm and hand rehabilitation that implements assistive force in order to reach the goals. It detects through sensors when the patient cannot finish a movement helping to guide the arm in order to complete the physical exercise proposed. It is used in an early stage of rehabilitation.

The device adapts its arm movement guidance to patients changing abilities. This implies that the device is useful during a large part of the rehabilitation. This assist-as-needed device also encourages patients to participate actively in their training.

 Armeo®Spring is an exoskeleton with five degrees of freedom that uses springs (rather than robotic actuators) to guarantee passive arm weight support and guidance. It is used in cases when the patient can move the hand and the arm.

The Armeo exoskeleton permit users to achieve a large range of motion in a 3D workspace. In each session, subjects use a system software to simulate intense and meaningful tasks in order to reach their goals. Therapists check the session, adjusting the exercises, weight and workspace according to each patient's evolution. As patients improve, therapists would increase the number of repetitions as well as introduce more difficult tasks in the training system.



In the traditional rehabilitation exist some limitations that are covered with Armeo:

- The traditional therapy is highly limited by the availability of therapist. With Armeo you need less people in charge of the patients.
- The patient's feedback of the rehabilitation is unclear. Armeo monitories all the improvements instantaneously.
- Traditional rehabilitation is limited because of the changing needs of patients.
- Keeping patients motivated is more difficult in traditional therapy compared to Armeo usage.

Therapy efficiency is improved with the use of Armeo given that it reduces the need for continuous supervision of the therapist⁹.



Figure 3: ArmeoSpring Robot

⁹ For understanding his efficiency see the work. "Efficacy of Armeo®Spring during the chronic phase of stroke. Study in mild to moderate cases of hemiparesis"



3.2.2. ErigoPro

Erigo is a robotic device that is thought for highly disabled people who can hardly move. It was designed for empowering patients from the very beginning. This rehabilitation robotic device consists of a verticalization table and an integrated leg movement mechanism. By moving the patient's legs, cyclic leg loading is applied to the lower limbs of the patient during early verticalization. The Erigo is controlled via PC.

The ErigoBasic offers all basic functionalities to perform early and safe patient mobilization. With the ErigoPro, patient stimulation is additionally enhanced by the synchronized FES¹⁰. The FES - generates impulses, to activate paralyzed muscles via surface electrodes.

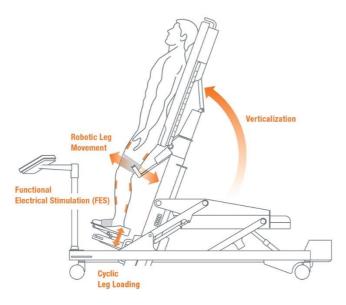


Figure 4: Erigo Pro

The limitations of traditional rehabilitation are:

¹⁰ FES: Functional Electrical Stimulation



- Limited training duration because of the patient's cardiovascular stability.
- Limited training duration due to the lack of resources.
- Difficulties of putting the patient upright.
- Physiotherapists are highly exposed to the strain.

The ErigoPro device is intended for general rehabilitation for:

- Relaxation of muscle spasms.
- Prevention or retardation of disuse atrophy.
- Increasing local blood circulation.
- Maintaining or increasing range of motion.

ErigoPro help with the cardiovascular stabilization thanks to the muscle activation of the legs stimulating the central nervous system. Therefore, ErigoPro patients have fewer possibilities of suffering a drop in blood pressure. Moreover, Erigo has a positive effect in patient's body awareness and consciousness.

Moreover, it also reduces the time spent in accurate care because of the early mobilization improving cost-efficiency related with time¹¹.

3.2.3. Lokomat

The Lokomat® is a gait orthosis that is used with body-weight support. It is a device aimed at recovering the ability to walk for patients who have no mobility or some difficulties with the gait.

LokomatPro is composed by:

¹¹ For effectiveness, see the work "Early Poststroke Rehabilitation Using a Robotic Tilt-Table Stepper and Functional Electrical Stimulation"



- An adjustable robotic gait orthosis which helps the patient moving his legs in the most natural way a robot can achieve. The orthosis is fixed to the frame of the body-weight support system.
- A treadmill in order to walk statically.
- A bodyweight support system consists of straps which are attached to thighs and to the waist. Its purpose is to bear the weight so the patient can walk with less weight
- User interface. The therapist can set the optimal options for each patient easily in this intuitive device
- Augmented performance feedback. The patient's evolution and activity are shown on the screen. There are also some rehabilitations tasks that are shown in order to encourage the patient achieving his goals.

There are another two Lokomat devices; Lokomat Nanos that differs from Lokomat Pro in the lack of virtual reality; and Lokomat V6, which includes a FreeD device that makes the orthosis move more naturally.

Like the other devices, it is far more useful than traditional rehabilitation, being the following the main reasons:

- In traditional rehabilitation, it is needed two or more people for each patient whereas with this device only one person is required during the activity.
- Limited training duration and intensity
- Limited feedback
- Therapist are exposed to physical strain

Lokomat permits the therapist to focus on the patient and the most appropriate therapy enhancing staff efficiency and safety which leads to superior patient care.



In Lokomat Pro and Lokomat V6, the patients are challenged to improve their personal capabilities through a specific task so they are motivated to reach their objectives. Studies have shown that the use of augmented performance feedback can increase muscle activation.

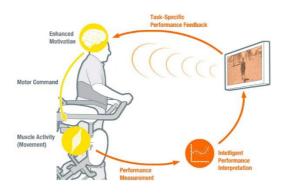


Figure 5: LOKOMAT device

All patients look forward to receive the most effective training and Lokomat ensures high-quality rehabilitation, a reason why patients decide to come to IRCCS Bonino-Pulejo.



Figure 6: LOKOMAT robot.



3.2.4. Nirvana

Nirvana is a device that uses virtual reality methods for rehabilitation of neuromotor disordered patients. NIRVANA accelerates the rehabilitation process, supporting the therapist to perform the exercises dedicated to the recovery of the committed functions.

It is a totally non-invasive system that works in a realistic environment. It uses sensorineural stimulation in real time.

Projecting scenarios, it creates an environment on the wall or on the floor; the patient interacts with the stimuli offered by the scenario; A motion analysis system detects the behaviour of the patient and modifies the scenes providing an audio-visual response.

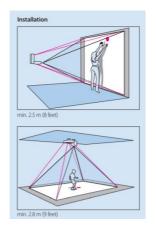


Figure 7: Nirvana device

It has also adaptable exercises for levels of difficulty, speed of exercise, sensitive area (range of motion) according to the different types of patients.

The strengths of this device are:



- Freedom of movement. The patient is free to move naturally without any impediment.
- It is the only system in which the patient interacts directly with the virtual environment.
- It is the only system that allows the rehabilitation of the body as well as cognitive rehabilitation, in a single product.

Because of the modern nature of this device is impossible to compare this modern rehabilitation with the traditional one.

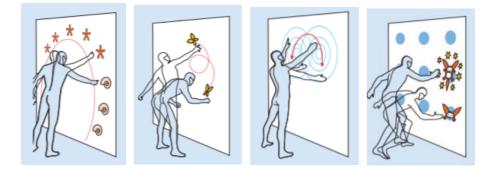


Figure 8: Nirvana activities

3.2.5. Amadeo

The Amadeo system is as an external manipulator with end-effector workspace appropriated for covering the human hand fingers workspace. The robot performs an intensive training combined with visual feedback.

The exercises should be accompanied by rehabilitation games with a specific goal whose difficulty varies upon the patient's progress



It is also used in assistive and interactive therapies for individual fingers and thumbs movements¹².



Figure 9: Amadeo

This device can be set-up in few seconds so it is easy and quick to use. The therapist has just to put the device in an appropriate height and secure the wrist and the forearm. Then it is necessary to activate the appropriate rehabilitation program depending on the necessities of the patient:

- Continuous passive motion therapy
- Assistive therapy
- Interactive therapy

3.2.6. System VRRS

VRRS is a virtual reality system for rehabilitation and telerehabilitation. It is composed by sensors that you may adjust to the patients before each exercise and a screen where the methods movements and the right execution of the exercise are shown.

VRRS is remarkably easy to use, the simple interface allows the therapist getting real feedback. Indeed, it has a large number of possibilities

¹² See "Hand Robotics Rehabilitation: Feasibility and Preliminary Results of a Robotic Treatment in Patients with Hemiparesis"



because of its versatility. It is conceived as a central hub where you can connect different devices for different patients request.

It is used as a clinical routine for the rehabilitation. With the wide spectrum of modules, you can treat numerous neurological and orthopaedic diseases

This device implies far more benefits than traditional rehabilitation:

- <u>Clinical benefits</u>: many international scientific journals have certified its effectiveness. Moreover, its gaming activities are a motivational mechanism for the achievement of goals.
- <u>Social benefits</u>: it covers the increasing rehabilitation demand with a mechanism where a therapist is not always needed.
- <u>Organizational benefits</u>: It allows to have medical records and patient's evolution monitoring their activities.
- <u>Scientific benefits</u>: it is also played as a tool for scientific research.





Figure 10: System VRRS





Figure 11: Patient using VRRS

3.2.7. Erica-Power AFA

Erica and Power AFA are software that can be used in a computer and they are aimed at a different type of rehabilitation. On one hand, Erica helps the patient with the rehabilitation at a cognitive level. On the other hand, Power AFA is used for speaking recovery.

3.2.8. Ekso

Ekso is a robotic wearable exoskeleton which helps the patient with the gait training. This exoskeleton helps with any extent of lower extremity weakness or paralysis. It has an adjustable, battery-powered motor that facilitate neuromuscular walking function. In addition, it helps the therapist allowing more freedom to concentrate on patient's recovery.

The traditional method to get the same recovery is known to be more difficult not only for patients but for the therapist who has to help the patients training lower limbs mobility from an early stage. In the middle stage, when the patients are able to stand up but not to walk, therapists are exposed to high a strain carrying patients weight. What is more, at



this stage two therapists are needed. With EKSO, however, requires less staff.



Figure 12: EKSO

Ekso consists of three parts:

- Exoskeleton: It helps with early mobility and the correction of the posture, which means a more effectively and quickly way to obtain the rehabilitation results.
- Controller: It allows to adjust the exoskeleton during the rehabilitation. That is an effective way of reaching the changing goals
- Software: enables personalization and customization during rehabilitation sessions.



3.2.9. Pegaso Ciclo – System RT200

Pegaso Ciclo is a motorized cycle which includes functional electrical stimulation (FES) that allows to carry out the physical recovery of lower and upper limbs.

It adapts to the needs of the patients as it provides both active and passive training. This device also has an electronic control system able to recognize the level of muscular effort of the patient providing the most appropriate level of exercise.

Pegaso Ciclo is aimed at all subjects with motor deficits, whether permanent or temporary. It is useful for both upper and lower limbs rehabilitation.

A correct rehabilitation therapy makes possible to recover from critical aspects related to difficulties of movement, and lack of muscular tone.

Therefore, Pegaso Ciclo is aimed at subjects suffering from the following pathologies:

- Paraplegia and quadriplegia from spinal cord lesions
- Multiple sclerosis
- Muscular deficits

as well as to all those in need of post-operative neuromotor therapy or geriatric rehabilitation.

Additionally, System RT 200 has the same goal as Pegaso Ciclo but combining both upper and lower limbs rehabilitation at the same time.





Figure 13: Ciclo FES lower limbs



Figure 14: System RT 200

3.2.10.Vibra

Vibra is a machine designed for the rehabilitation of different pathologies, which produces sound mechanical waves by air compression and expansion. Through a powerful internal compressor governed by a CPU with touch display, it is possible to control the frequency and amplitude of application. For application on the patient at the muscular level, applicators of different sizes are used depending on the muscular area to be treated.

Vibra has different applications depending on the frequency and amplitude of use, improving the rehabilitation of the patient in the face of neurological or traumatic damage.



Figure 15: VIBRA device



4. Costs overview

In this section, I will classify the most relevant costs related to the rehabilitation process.

Some cost not only affects one method but both of them. For example, machine cost just affects robotic rehabilitation, whereas employees and support service affects both methods. Although the robotic method is more expensive than the traditional one, without any kind of doubt it is more effective.

4.1. Main costs

4.1.1. Employees cost

There are a lot of people working around rehabilitation; physiotherapist, speech therapist, laboratory technician, radiology technician among others. In order to specify the resources I will focus on those employees that are directly related with the rehabilitation process¹³.

Employees of the I.R.C.C.S Bonino-Pulejo taking part in the rehabilitation process are:

 Physiotherapist: In traditional rehabilitation, physiotherapists create sets of repetitions of movements intended to relieve pain or restriction of mobility caused by illness or injury. In robotic rehabilitation, they are also in charge of supervising patients who are using the machines adjusting the machine for each patient.

¹³ The reason why I have excluded other employees is because they are not relevant in the comparison between rehabilitation methods.



- Speech therapist: their task is to help patients doing active and passive exercises to improve mobility, tone, power and muscle strength of the affected organs (lips, tongue, ...).
- Occupational therapist: they are not responsible for treating a person's injury, but rather helping him to daily cope with his condition, to transform his environment with its new capabilities.
- Nurse: in robotic rehabilitation, they have the same task as the physiotherapist. Indeed, most robotic machines are used by both of them.

In the next employees' table salaries, hourly cost, unitary cost, and total cost of each kind of employee are shown. The unitary cost is calculated taking into account how many times the machine could be used, further explanation about this issue will be provided in detail hereunder.



RUOLO	Profilo Prof.le	Costo Totale Annuale con ratei XIIIª	COSTO ORARIO	COSTO ORARIO X PRESTAZIONE ROBOTICA	N° Personale	COSTO COMPLESSIVO
	Collab.re Prof.le SanFisioterapista - Cat. D	€ 38.987,12	€ 20,83	€ 24,07	3	€116.961,36
SANITARIO	Collab.re Prof.le SanLogopedista - Cat. D	€ 38.987,12	€ 20,83	€ 24,07	1	€ 38.987,12
SANI	Collab.re Prof.le SanTerapista Occupazionale - Cat. D	€ 38.987,12	€ 20,83	€ 24,07	2	€ 77.974,24
	Collab.re Prof.le SanInfermiere - Cat. D	€ 39.580,52	€ 21,14	€ 24,43	7	€277.063,64

Figure 16: Employee salaries



4.1.2. Machine cost

The way IRCCS Bonino-Pulejo makes the difference is through its modern rehabilitation therapy, which is unique in Sicily among those provided by any public institute. Those machines imply a high cost because of the purchase price, amortisation and maintenance.

This topic is the main reason why we are comparing modern and traditional rehabilitation. Machine's cost is so expensive because of his complexity. These costs are the reason why the hospital wonders if they are so much better than traditional therapy, which is less expensive. I will carry out the effectiveness study later.

The point is that in the short-term you have to make a huge investment¹⁴ in order to offer a complete modern rehabilitation therapy. In addition, and aiming to support this investment rationale, they should be more effective than the traditional methods, making a call-effect for people coming to Bonino-Pulejo hospital.

The device's cost is disaggregated in the next table (figure 17):

¹⁴ They pay for the machines through public funding.



DEVICE	PURCHASE COST	AMORTISATION COST	MAINTENANCE COST
SYSTEM VRRS	27.450€	5.490€	1.500,00€
NIRVANA	44.042€	8.808€	1.500,00€
COGNITIVO COMPUTERIZZATO (ERICA- POWER AFA)	2.178€	436€	
LOKOMAT (MEDIA DEI TRE)	332.300€	66.460€	14.000,00€
LOKOMAT V6	423.500€	84.700€	14.000,00€
LOKOMAT NANOS	250.100€	50.020€	14.000,00€
LOKOMAT PRO	323.300€	64.660€	14.000,00€
ERIGO PRO	76.860€	15.372€	7.000,00€
ARMEO (POWER)	190.320€	38.064€	7.000,00€
ARMEO (SPRING)	62.220€	12.444€	7.000,00€
AMADEO	122.000€	24.400€	7.000,00€
EKSO	208.000€	41.600€	14.000,00€
PEGASO CICLO FES A.I.	19.520€	3.904€	3.000,00€
PEGASO CICLO FES A.I.	19.520€	3.904€	3.000,00 €
PEGASO CICLO FES A.S.	19.520€	3.904€	3.000,00 €
SYSTEM RT 200	61.000€	12.200€	3.000,00 €
Vibra	35.380€	7.076€	1.500,00 €

	Figure	17:	Robot	costs
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4.1.3. Support service costs

Indirect costs are all the costs that cannot be directly allocated to patients treatment. Indeed, they are calculated for the whole hospital and then a percentage is estimated to be assigned to the gym where the rehabilitation takes place.

This is the way we have to distribute all these costs that are significant and necessary but they do not affect only the rehabilitation task.

According to their nature, the costs are subdivided as follows:



BA1570	B.2.B.1) Servizi non sanitari	2273	DATA	SPESA	Palestra
BA1580	B.2.B.1.1) Lavanderia	2274	31/12/2017	144.407	99
BA1590	B.2.B.1.2) Pulizia	2275	31/12/2017	747.077	511
BA1600	B.2.B.1.3) Mensa	2276	31/12/2017	-	-
BA1610	B.2.B.1.4) Riscaldamento	2277	31/12/2017	-	-
BA1620	B.2.B.1.5) Servizi di assistenza informatica	2278	31/12/2017	-	-
BA1630	B.2.B.1.6) Servizi trasporti (non sanitari)	2279	31/12/2017	-	-
BA1640	B.2.B.1.7) Smaltimento rifiuti	2280	31/12/2017	65.691	45
BA1650	B.2.B.1.8) Utenze telefoniche	2281	31/12/2017	28.990	20
BA1660	B.2.B.1.9) Utenze elettricità	2282	31/12/2017	364.361	249
BA1670	B.2.B.1.10) Altre utenze	2283	31/12/2017	106.839	73
BA1680	B.2.B.1.11) Premi di assicurazione	2284	31/12/2017	22.570	15
BA1690	B.2.B.1.11.A) Premi di assicurazione - R.C. Professionale	2285	31/12/2017	-	
BA1700	B.2.B.1.11.B) Premi di assicurazione - Altri premi assicurativi	2286	31/12/2017	-	
BA1710	B.2.B.1.12) Altri servizi non sanitari	2287	31/12/2017	926.504	633
BA1720	B.2.B.1.12.A) Altri servizi non sanitari da pubblico (Aziende sanitarie pubbliche della Regione)	2288	31/12/2017	36.860	
BA1730	B.2.B.1.12.B) Altri servizi non sanitari da altri soggetti pubblici	2289	31/12/2017	81.109	
BA1740	B.2.B.1.12.C) Altri servizi non sanitari da privato	2290	31/12/2017	808.536	

• Not sanitary service:

Figure 18: Non-sanitary service costs

• Counselling, partnership and other no sanitary service¹⁵:

BA1750	B.2.B.2) Consulenze, Collaborazioni, Interinale e altre prestazioni di lavoro non sanitarie	2291	DATA	Spesa	Palestra
BA1760	B.2.B.2.1) Consulenze non sanitarie da Aziende sanitarie pubbliche della Regione	2292	31/12/2017	4.963	-
BA1770	B.2.B.2.2) Consulenze non sanitarie da Terzi - Altri soggetti pubblici	2293	31/12/2017	-	-
BA1780	B.2.B.2.3) Consulenze, Collaborazioni, Interinale e altre prestazioni di lavoro non sanitarie da privato	2294	31/12/2017	131.108	-
BA1790	B.2.B.2.3.A) Consulenze non sanitarie da privato	2295	31/12/2017	31.484	
BA1800	B.2.B.2.3.B) Collaborazioni coordinate e continuative non sanitarie da privato	2296	31/12/2017	-	
BA1810	B.2.B.2.3.C) Indennità a personale universitario - area non sanitaria	2297	31/12/2017	-	
BA1820	B.2.B.2.3.D) Lavoro interinale - area non sanitaria	2298	31/12/2017	-	
BA1830	B.2.B.2.3.E) Altre collaborazioni e prestazioni di lavoro - area non sanitaria	2299	31/12/2017	99.624	
BA1840	B.2.B.2.4) Rimborso oneri stipendiali del personale non sanitario in comando	2300	31/12/2017	-	-
BA1850	B.2.B.2.4.A) Rimborso oneri stipendiali personale non sanitario in comando da Aziende sanitarie pubbliche della Regione	2301	31/12/2017	-	
BA1860	B.2.B.2.4.B) Rimborso oneri stipendiali personale non sanitario in comando da Regione, soggetti pubblici e da Università	2302	31/12/2017	-	
BA1870	B.2.B.2.4.C) Rimborso oneri stipendiali personale non sanitario in comando da aziende di altre Regioni (Extraregione)	2303	31/12/2017	-	

Figure 19: Other non-sanitary service costs

¹⁵ This type of support service does not apply to the gym.

• Formation:

BA1880	B.2.B.3) Formazione (esternalizzata e non)	2304	31/12/2017	89.384	61
BA1890	B.2.B.3.1) Formazione (esternalizzata e non) da pubblico	2305	31/12/2017	8.081	
BA1900	B.2.B.3.2) Formazione (esternalizzata e non) da privato	2306	31/12/2017	81.303	

Figure 20: Formation costs

• Maintenance and reparation

BA1910	B.3) Manutenzione e riparazione (ordinaria esternalizzata)	2307	31/12/2017	93.892	64
BA1920	B.3.A) Manutenzione e riparazione ai fabbricati e loro pertinenze	2308	31/12/2017	43.308	
BA1930	B.3.B) Manutenzione e riparazione agli impianti e macchinari	2309	31/12/2017	26.805	
BA1940	B.3.C) Manutenzione e riparazione alle attrezzature sanitarie e scientifiche	2310	31/12/2017	-	-
BA1950	B.3.D) Manutenzione e riparazione ai mobili e arredi	2311	31/12/2017	-	-
BA1960	B.3.E) Manutenzione e riparazione agli automezzi	2312	31/12/2017	-	-
BA1970	B.3.F) Altre manutenzioni e riparazioni	2313	31/12/2017	23.779	

Figure 21: Maintenance and reparation costs

Indirect costs are distributed according to the number of square meters that the gym takes up of the total space. Since the rehabilitation gym takes up 250 square meters on the total area of the hospital (365.761 square meters) the percentage attributable to the rehabilitation therapy is 0,684%.

The last column shows the attributable cost to the rehabilitation activity. All these costs add up to $1.770 \in$.



5. First purpose

"The first purpose is to make a cost analysis of the modern rehabilitation methods offered by I.R.C.C.S Bonino-Pulejo. A cost study taking into account both direct cost (such as machine, personal and amortization costs) and also indirect cost (those that are not related directly with the patient) is needed"

In the previous chapters all the relevant cost necessaries to perform our cost analysis have been described. It is need noteworthy that the economic study carried out in this part of the thesis is aimed at a non-benefit structure, as IRCCS Bonino-Pulejo is. But in all institutions there are costs that might be paid.

The regional authority is in charge of paying a high percentage of these costs. In order to report these cost to the regional authority, we have to estimate how much the hospital will pay for a patient. It is a difficult task because of different patient needs, thus, I will use a parameter that in the Italian language is called "prestazione". It concerns to one hour of treatment.

However, it is not a complete hour of treatment because there are some tasks that should be performed before the rehabilitation process, for example, therapists have to secure the patients to the machines. This process implies about 15 minutes and this time is considered as a part of the rehabilitative session. Moreover, some machines require two therapists during a short period of time.

The hospital has set a standard number of sessions taking into account the hours that the rehabilitation gym is opened in a normal year. It



resulted in: eight hours per day, five days per week and fifty weeks per year. Saturdays the rehabilitation gym is only opened in the morning so we have to add those hours. Summing up, the estimation is 2200 sessions per year and per machine. This is an estimated number because we can have some problems of different nature that imply some variations.

We are going to distribute all costs with the theoretical number of sessions rather than the real ones, since not all the theoretical sessions are performed in one year, thus, this discrepancy should not be considered. Less used machines would be more expensive. The objective of the IRCCS should be to improve the real number of sessions (purpose 2, capacity problem).

We will consider one unitary cost per each machine (cost per session) and we will work with it. In this manner we will find the right cost for each session.

The total cost of a session is calculated like:

$$Total \ cost = \ Employees \ cost + \frac{Amortization \ cost}{Number \ of \ sessions} + \frac{Maintenance \ cost}{Number \ of \ sessions} + \frac{Support \ service \ cost}{Number \ of \ sessions}$$

5.1. Employees cost

As it has been shown above, there are different employees who are in charge of rehabilitation as well as different salaries among them. Now I am going to figure out how much cost one session in terms of the employee cost.



For that purpose, we will use the employee hourly cost and the time he/she is working on the machine per session. So the calculus is made as follows:

 $\sum \frac{x}{4} \times n^{2}$ employees needed \times employees salary

Where the x is the number of quarters of hour needed.

MACCHINARIO	QUALIFICA PROFESSIONISTA IMPIEGATO NELLA PRESTAZIONE	TEMPO IN MINUTI PER PROFESSIONISTA (MINUTI)		COSTO ORARIO PER PRESTAZIONE ROBOTICA	COSTO ORARIO PROFESIONISTA
SYSTEM VRRS	FISIOTERAPISTA O LOGOPEDISTA	60		24,07€	24,07 €
NIRVANA	PSICOLOGO	60		24,07€	43,07 €
COGNITIVO COMPUTERIZZATO (ERICA-POWER AFA)	PSICOLOGO O TERAPISTA OCCUPAZIONALE	60		24,07€	33,57€
LOKOMAT (MEDIA DEI TRE)	FISIOTERAPISTA/INFERMIERE	15 PER 2 OPERATORI	45 PER 0,5 OPERATORE	24,07€	30,54 €
LOKOMAT V6	FISIOTERAPISTA/INFERMIERE	15 PER 2 OPERATORI	45 PER 0,5 OPERATORE	24,07€	30,54 €
LOKOMAT NANOS	FISIOTERAPISTA/INFERMIERE	15 PER 2 OPERATORI	45 PER 0,5 OPERATORE	24,07€	30,54 €
LOKOMAT PRO	FISIOTERAPISTA/INFERMIERE	15 PER 2 OPERATORI	45 PER 0,5 OPERATORE	24,07€	30,54 €
ERIGO PRO	FISIOTERAPISTA/INFERMIERE		45 PER 0,5 OPERATORE	24,07€	30,54 €
ARMEO (POWER)	FISIOTERAPISTA	15 PER 1 OPERATORE	45 PER 0,5 OPERATORE	24,07€	15,00€
ARMEO (SPRING)	FISIOTERAPISTA/INFERMIERE	15 PER 1 OPERATORE	45 PER 0,5 OPERATORE	24,07€	15,00€
AMADEO	FISIOTERAPISTA	15 PER 1 OPERATORE	45 PER 0,5 OPERATORE	24,07€	15,00€
EKSO	FISIOTERAPISTA	15 PER 1,5 OPERATORE	45 PER 1,5 OPERATORE	24,07€	36,00€
PEGASO CICLO FES A.I.	FISIOTERAPISTA/INFERMIERE	15 PER 1 OPERATORE	45 PER 0,5 OPERATORE	24,07€	15,00€
PEGASO CICLO FES A.I.	FISIOTERAPISTA/INFERMIERE	15 PER 1 OPERATORE	45 PER 0,5 OPERATORE	24,07€	15,00€
PEGASO CICLO FES A.S.	FISIOTERAPISTA/INFERMIERE	15 PER 1 OPERATORE	45 PER 0,5 OPERATORE	24,07€	15,00€
SYSTEM RT 200	FISIOTERAPISTA/INFERMIERE	15 PER 1 OPERATORE	45 PER 0,5 OPERATORE	24,07€	15,00€
Vibra	FISIOTERAPISTA/INFERMIERE	15 PER 1 OPERATORE	45 PER 0,5 OPERATORE	24,07€	15,00€

Figure 22: Employees costs per session



5.2. Amortization cost

At national level, the period of amortization of electro-medical machines is set at 5 years, therefore the percentage of amortization is 20% for these machines.

Hence, in order to obtain the total cost of one year, I have applied this percentage to the machine's purchase cost. Moreover, I have divided by the theoretical number of sessions obtaining the unitary cost. The results obtained is in figure 23:

DEVICES	THEORETICAL SESSIONS	PURCHASE COST	AMORTISATION COST	AMORTISATION COST PER SESSION
SYSTEM VRRS	2200	27.450,00€	5.490,00€	2,50€
NIRVANA	2200	44.042,00€	8.808,40€	4,00€
COGNITIVO COMPUTERIZZATO (ERICA-POWER AFA)	2200	2.178,00€	435,60€	0,20€
LOKOMAT (MEDIA DEI TRE)	2200	332.300,00€	66.460,00€	30,21€
LOKOMAT V6	2200	423.500,00€	84.700,00€	38,50€
LOKOMAT NANOS	2200	250.100,00€	50.020,00€	22,74€
LOKOMAT PRO	2200	323.300,00€	64.660,00€	29,39€
ERIGO PRO	2200	76.860,00€	15.372,00€	6,99€
ARMEO (POWER)	2200	190.320,00€	38.064,00€	17,30€
ARMEO (SPRING)	2200	62.220,00€	12.444,00€	5,66€
AMADEO	2200	122.000,00€	24.400,00€	11,09€
EKSO	2200	208.000,00€	41.600,00€	18,91€
PEGASO CICLO FES A.I.	2200	19.520,00€	3.904,00€	1,77€
PEGASO CICLO FES A.I.	2200	19.520,00€	3.904,00€	1,77€
PEGASO CICLO FES A.S.	2200	19.520,00€	3.904,00€	1,77€
SYSTEM RT 200	2200	61.000,00€	12.200,00€	5,55€
Vibra	2200	35.380,00€	7.076,00€	3,22€

Figure 23: Amortization cost table



5.3. Maintenance cost

The maintenance cost is obtained in the same way as the amortization cost, considering the theoretical number of sessions:

DEVICES	THEORETICAL SESSIONS	ANUAL MANTENANCE COST	MANTENANCE COST PER SESSION
SYSTEM VRRS	2200	1.500,00€	0,68€
NIRVANA	2200	1.500,00€	0,68€
COGNITIVO COMPUTERIZZATO (ERICA-POWER AFA)	2200		0,00€
LOKOMAT (MEDIA DEI TRE)	2200	14.000,00€	6,36€
LOKOMAT V6	2200	14.000,00€	6,36€
LOKOMAT NANOS	2200	14.000,00€	6,36€
LOKOMAT PRO	2200	14.000,00€	6,36€
ERIGO PRO	2200	7.000,00€	3,18€
ARMEO (POWER)	2200	7.000,00€	3,18€
ARMEO (SPRING)	2200	7.000,00€	3,18€
AMADEO	2200	7.000,00€	3,18€
EKSO	2200	14.000,00€	6,36€
PEGASO CICLO FES A.I.	2200	3.000,00€	1,36€
PEGASO CICLO FES A.I.	2200	3.000,00€	1,36€
PEGASO CICLO FES A.S.	2200	3.000,00€	1,36€
SYSTEM RT 200	2200	3.000,00 €	1,36€
Vibra	2200	1.500,00€	0,68 €

5.4. Support service cost

Unlike the above information, this cost has an equitable distribution for all the machines. The amount of indirect cost $(1.770 \in)$ is divided by the number of theoretical sessions. This means that the unitary cost of the support service is:

$$\frac{1.770 \notin}{37.400 \text{ sessions}} = 0.05 \notin$$



5.5. Total cost per session

Summing up all the information presented above I have expressed the total amount. I have also considered the management cost that implies the 10% of this amount.

In the next figure we can see all the unitary cost per session and machine:

MACCHINARIO	N. PRESTA ZIONI POTENZ IALI ANNUA LI	COSTO AMMORTAMEN TO N. PRESTAZIONI POTENZIALI	COSTO ORARIO professionis ta	COSTO MANUTENZ IONE PER PRESTAZIO NE POTENZIAL E	COSTO SERVIZI PER PRESTAZIO NE POTENZIAL E	TOTAL	COSTO GESTIONE (10%)	COSTO STANDARD UNITARIO
SYSTEM VRRS	2200	2,50€	24,07€	0,68€	0,05€	27,29€	2,73€	30,02€
NIRVANA	2200	4,00€	43,07€	0,68€	0,05€	47,81€	4,78€	52,59€
COGNITIVO COMPUTERIZZATO (ERICA- POWER AFA)	2200	0,20€	33,57€	-€	0,05€	33,81€	3,38€	37,20€
LOKOMAT (MEDIA DEI TRE)	2200	30,21€	30,54€	6,36€	0,05€	67,16€	6,72€	73,88€
LOKOMAT V6	2200	38,50€	30,54€	6,36€	0,05€	75,45€	7,55€	83,00€
LOKOMAT NANOS	2200	22,74€	30,54€	6,36€	0,05€	59,69€	5,97€	65,66€
LOKOMAT PRO	2200	29,39€	30,54€	6,36€	0,05€	66,34€	6,63€	72,98€
ERIGO PRO	2200	6,99€	30,54€	3,18€	0,05€	40,76€	4,08€	44,83€
ARMEO (POWER)	2200	17,30€	15,00€	3,18€	0,05€	35,53€	3,55€	39,08€
ARMEO (SPRING)	2200	5,66€	15,00€	3,18€	0,05€	23,89€	2,39€	26,27€
AMADEO	2200	11,09€	15,00€	3,18€	0,05€	29,32€	2,93€	32,25€
EKSO	2200	18,91€	36,00€	6,36€	0,05€	61,32€	6,13€	67,45€
PEGASO CICLO FES A.I.	2200	1,77€	15,00€	1,36€	0,05€	18,19€	1,82€	20,00€
PEGASO CICLO FES A.S.	2200	1,77€	15,00€	1,36€	0,05€	18,19€	1,82€	20,00€
SYSTEM RT 200	2200	5,55€	15,00€	1,36€	0,05€	21,96€	2,20€	24,15€
Vibra	2200	3,22€	15,00€	0,68€	0,05€	18,95€	1,89€	20,84€

Figure 24: Unitary cost table



6. Second purpose

"IRCCS Bonino-Pulejo have a capacity problem. They are working at maximum level and they are not achieving their theoretical capacity. This topic will be the second purpose of the thesis, to explain why this happens"

IRCCS Bonino-Pulejo is one of the best hospital in south Italy. It is proved by their modern methods of rehabilitation and the amount of scientific publications. They are at the vanguard of rehabilitation and this makes a call-effect for all the people in the south of Italy. Indeed, it is the best prepared public hospital for this purpose in Sicily so people who have not enough money to pay for a rehabilitation therapy have the possibility to do it in a highly prepared hospital.

However, they are not achieving their theoretical capacity. In this section, I will try to investigate on the reason why this happens.

In figure 25 we can see how those resources are underused.



MACCHINARIO	N. PRESTAZIO NI POTENZIALI ANNUALI	E NEL 2017	PORCENTAJE DE UTILIZACION DE LA MAQUINA (2017)
SYSTEM VRRS	2200	775	35,23%
NIRVANA	2200	1615	73,41%
COGNITIVO COMPUTERIZZATO (ERICA-POWER AFA)	2200	1267	57,59%
LOKOMAT (MEDIA DEI TRE)	2200	1478	67,18%
LOKOMAT V6	2200	1323	60,14%
LOKOMAT NANOS	2200	800	36,36%
LOKOMAT PRO	2200	2311	105,05%
ERIGO PRO	2200	1528	69,45%
ARMEO (POWER)	2200	562	25,55%
ARMEO (SPRING)	2200	578	26,27%
AMADEO	2200	931	42,32%
EKSO	2200	378	17,18%
PEGASO CICLO FES A.I.	2200	1799	81,77%
PEGASO CICLO FES A.S.	2200	985	44,77%
SYSTEM RT 200	2200	544	24,73%
Vibra	2200	1332	60,55%

Figure 25: Summary of the rehabilitation sessions

Three are the potential reasons that could cause the underlying problem:



I. There is not enough personal to meet the demand

In order to get the solution to the problem, I did a study of how many employees were strictly necessary. For this purpose, I made the next table (figure 26):

- A. In the first column figures the name of each machine used in the hospital.
- B. Second and third columns are used to put the number of potential sessions and the number of sessions effectuated respectively.
- C. In the fourth one appear the qualification needed for each machine.
- D. The fifth column shows the number of employees needed and how much time they are needed.

With this information, I have tried to figure out the number of employees needed for one session of each machine (sixth column). To estimate the number, I have divided the session in 4 quarters, fifteen minutes each. Moreover, if 0.5 employees are needed it implies that one employee can be in charge of two machines at the same time.

$$\sum \frac{x}{4} \times n^{2}$$
 employees needed

Where the x is the number of quarters needed. To explain it better I will present an example with Lokomat machine:

$$\frac{1}{4} \times 2 \text{ employees} + \frac{3}{4} \times 0,5 \text{ employees} = 0,875 \text{ employees}$$

As it is obvious, having 0,875 employees is impossible, so that I have rounded the number at the end.

MACCHINARIO	N. PRESTAZIO NI POTENZIALI ANNUALI	N. PRESTAZIO NI EFFETTUAT E NEL 2017	QUALIFICA PROFESSIONISTA IMPIEGATO NELLA PRESTAZIONE	TEMPO IN N PROFESS		PROFESIONISTA NECESSARI PER PRESTAZIONI	ORE PER GIORNO	GIORNI LABORATIVI	PROFESIONISTA NECESSARI PER ANNO	NUMERO DI PROFESSIONIST A CHE SAREBBE STATO NECESSARIO L'ANNO SCORSO
SYSTEM VRRS	2200	775	FISIOTERAPISTA O LOGOPEDISTA	60		1	8	253	1,086956522	0,382905138
NIRVANA	2200	1615	PSICOLOGO	60		1	8	253	1,086956522	0,797924901
COGNITIVO COMPUTERIZZATO (ERICA-POWER AFA)	2200	1267	PSICOLOGO O TERAPISTA OCCUPAZIONALE	60		1	8	253	1,086956522	0,625988142
LOKOMAT (MEDIA DEI TRE)	2200	1478	FISIOTERAPISTA/INFERMIERE		45 PER 0,5 OPERATORE					
LOKOMAT V6	2200	1323	FISIOTERAPISTA/INFERMIERE		45 PER 0,5 OPERATORE	0,875	8	253	0,951086957	0,571949111
LOKOMAT NANOS	2200	800	FISIOTERAPISTA/INFERMIERE		45 PER 0,5 OPERATORE	0,875	8	253	0,951086957	0,345849802
LOKOMAT PRO	2200	2311	FISIOTERAPISTA/INFERMIERE	-	45 PER 0,5 OPERATORE	0,875	8	253	0,951086957	0,999073617
ERIGO PRO	2200	1528	FISIOTERAPISTA/INFERMIERE		45 PER 0,5 OPERATORE	0,875	8	253	0,951086957	0,660573123
ARMEO (POWER)	2200	562	FISIOTERAPISTA		45 PER 0,5 OPERATORE	0,625	8	253	0,679347826	0,17354249
ARMEO (SPRING)	2200	578	FISIOTERAPISTA/INFERMIERE		45 PER 0,5 OPERATORE	0,625	8	253	0,679347826	0,178483202
AMADEO	2200	931	FISIOTERAPISTA		45 PER 0,5 OPERATORE	0,625	8	253	0,679347826	0,287487648
EKSO	2200	378	FISIOTERAPISTA		45 PER 1,5 OPERATORE	1,5	8	253	1,630434783	0,28013834
PEGASO CICLO FES A.I.	2200	1799	FISIOTERAPISTA/INFERMIERE		45 PER 0,5 OPERATORE	0,625	8	253	0,679347826	0,555521245
PEGASO CICLO FES A.S.	2200	985	FISIOTERAPISTA/INFERMIERE		45 PER 0,5 OPERATORE	0,625	8	253	0,679347826	0,304162549
SYSTEM RT 200	2200	544	FISIOTERAPISTA/INFERMIERE		45 PER 0,5 OPERATORE	0,625	8	253	0,679347826	0,16798419
Vibra	2200	1332	FISIOTERAPISTA/INFERMIERE		45 PER 0,5 OPERATORE	0,625	8	253	0,679347826	0,411314229

Figure 26: Employees and robots summary



I have also calculated how many employees are needed in one year.

Taking in count that the hospital has estimated 2200 sessions per year and considering that employees work 8 hours per day, 253 days per year (in average) the number of employees is calculated as follows:

 $\frac{\frac{2200\ sessions}{year} \times n^{\underline{o}} \frac{employees}{1\ session}}{8\ hours \times 253\ days}$

With this calculus we obtain the number of employees needed in one year per machine. In an informative way, I have put in the last column the number of employees that the hospital would have needed in 2017 using the real number of sessions effectuated.

I will resume the results in the next table:

	Estimation of th	ne maximun employees needed (A)	Real numbe	r of employees needed (B)	Employees in 2017 (C)	
FISIOTERAPISTA	2,989130435	3	0,741168	1	3	
FISIOTERAPISTA/INFERMIERE	7,201086957	8	4,194911	5	7	
PSICOLOGO O TERAPISTA OCCUPAZIONALE	1,086956522	2	0,625988	1	2	
PSICOLOGO	1,086956522	2	0,797925	1		
FISIOTERAPISTA O LOGOPEDISTA	1,086956522	2	0,382905	1	1	

Figure 27: Employees needs

The number of employees needed is calculated for both the estimated (A) and the real number of sessions (B).

As we can see the capacity problem of the hospital is not a matter of employees. Indeed, the hospital has more employees than it needs (C). Even if the estimation of maximum employees needed is in some cases higher than the number of employees, we have to consider that most machines can be used by various kinds of employees (for example, physiotherapist and nurse).



The conclusion is that their problem is not explained because of the lack of employees.

II. There is low demand for certain devices.

At this point I am going to study the robot therapy demand. There could be months when a lot of patients have to use one specific machine and other months that the same machine is underused.

The instrument that I am going to use is the SPC (Statistical Process Control) applied to health-care demand. SPC is used for monitoring the evolution of the demand. It also shows when the problem has happened allowing the user to make specific changes in their process.

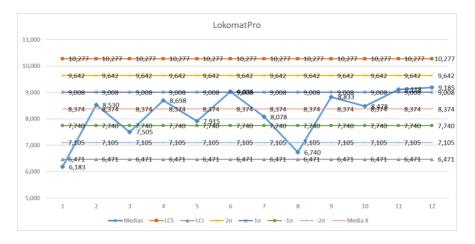
Applying this fact to the rehabilitation demand we can see in which months the demand has increased/decreased and take actions.

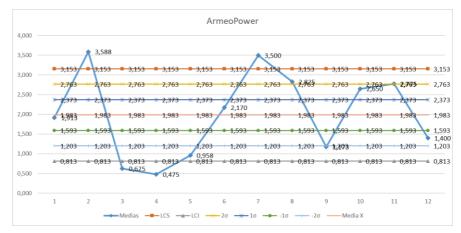
The hospital has given me detailed information of the robotic rehabilitation therapy day by day during the year 2017 and I have grouped in periods of 7-8 days having 4 samples per month.

With this SPC we can determinate if there is a month when the total demand is far above the mean or if it is far below the mean causing dead times and, thus, underused devices.

Now I will show the average sessions per week and per month of LokomatPro (105,05%) and ArmeoPower (25,55%):







As we can see, the fact that the hospital is not achieving their theoretical capacity could be explained by a lack of demand in certain months.

- On one hand, we can see in the LokomatPro device that the daily average number of sessions is stable, without straying too far from the general daily mean (8,37 sessions per day). This fact means that the demand for this device is stable. It has to be noted that if demand increase during a long period of time the hospital can take actions to boost their sessions.
- On the other hand, regarding ArmeoPower, the daily demand by month is not stable. There are months when the demand is far



from the mean (1,98 sessions per day). The chart shows a high daily demand variation between months.

Taking into account that the theoretical capacity is supposed to be 8 sessions in a day for all the devices we can see the difference between the average demand of Lokomat and ArmeoPower

This tool could be used in the future in order to monitor all the demand device by device¹⁶. However, it is important to say that with SPC we are not going to solve the capacity problem but explain it and know when it happens. Actions should be taken in order to fix it.

Nonetheless, we have to take into account also the fact that the device use is linked with the kind of pathology. Therefore, most common pathologies will request the same machine. This could be the reason why some machines are underused. Consequently, we will disaggregate the session information by machine and by the kind of patient, considering that there are inpatients and outpatients (day patients and occasional patients).

¹⁶ See Annex 1 for the other's device demand evolution



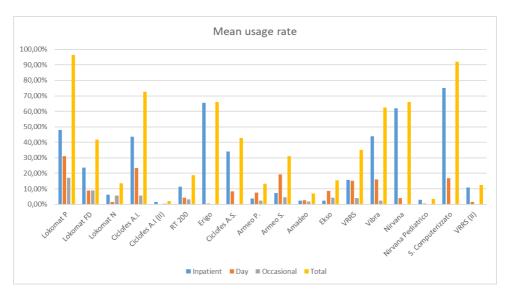


Figure 28: Monthly mean usage rate

As we can see in the chart (figure 28) there are differences between which kind of patient use each machine. We can't act on the resident patient's number of sessions because the hospital has a certain capacity whereas we can act on the number of external patients.

For this goal we can consider the possibility of increasing publicity at a regional level and therefore boosting the number of sessions effectuated.

III. Their estimation of sessions is wrong

The theoretical number of 2200 session is calculated (as we have seen previously) with the number of hours, days and weeks that the employees work.

At the moment of truth, there are a lot of death times that makes these 2200 sessions actually decrease (employees delay, difficulties setting the devices, difficulties carrying patients, etc). The patient has one hour of rehabilitation, if there is any delay, the total number of sessions in a year



would be less than 2.200 sessions. Indeed, this number of sessions implies that all the machines are working uninterruptedly. But, as we have seen above, this is not real because there are machines which treat less common pathologies so they have less demand. Moreover, bad management of the number of patients and absence of patients can also explain a part of the difference.

So we can conclude that the estimation of 2200 sessions per machine is appropriate for devices that treat most common pathologies but not for the others.

It would be useful to adapt the session estimation of each machine to their real demand.

All in all, we have seen that the difference between the theoretical number of sessions and the real number could be explained by a bad estimation at the time of setting the maximum sessions.

Even though, this fact does not explain all the difference. There is another important reason: there are underused devices due to the lack of demand.

Moreover, we cannot assess the human mistake collecting data or the reasons for absence of patients, which means that further studies are needed.



7. Third purpose

"The third purpose is to compare traditional rehabilitation with modern rehabilitation in terms of cost and effectiveness. IRCCS Bonino-Pulejo needs to prove that their methods of rehabilitation (modern rehabilitation) are better than the traditional ones. This implies a difficult task due to the lack of outcomes for modern rehabilitation. In this thesis I will use the "state of the art" to study the effectiveness of modern rehabilitation."

First of all, it should be highlighted that the rehabilitation robots are more expensive than the traditional tools to carry out the rehabilitation. It is useless to do a comparison. It is all a matter of finding out if the initial outlay worth it. For that objective, an effectiveness study should be made.

Modern rehabilitation methods have only been implemented recently implying that there is not enough information to assert categorically that the modern rehabilitation is far better than the traditional one. The results depend on the kind of injuries that the patient has.

Therefore, I have done a research about "the state of art" of the robotic machines in rehabilitation and the effectiveness of these machines. I will mention and discuss different essays about this topic.



Robotic rehabilitation for cerebral vascular disease

Doctor Pavel Loeza (National medical centre "20 de Noviembre" ISSSTE) has carried out an investigation into the current state and effectiveness of robotic rehabilitation. He has relied on information and articles contained in PubMed, ScienceDirect, Mediagraphic and GoogleScholar database.

In this article, apart from studying the effectiveness of robotic rehabilitation, he has taken into account the fact that the patient's acceptance is also important in robot-mediated rehabilitation. He points out that to increase this acceptance, patients should be well informed about the procedure and benefits of this kind of rehabilitation.

Regarding the effectiveness, he mentions that despite not being proved that the robotic rehabilitation is better than conventional one, it reduces the human effort as well as the human resources needed. Indeed, these methods can optimize the time and offer other advantages as:

- Reproducibility
- Specific task programmes
- Quantified progression
- Recreational activities

While there are some remarkable advantages, there are no clear results of being better than conventional therapy. However, numerous investigations carried out assess and prove that combined therapies have shown positive results.

He concludes with the idea that although robotic rehabilitation cannot substitute conventional therapy, with a combination of both, patients will take profit of the advantages of each therapy.



Combining Upper Limb Robotic Rehabilitation with Other Therapeutic Approaches after Stroke

This review article has been carried out by Stefano Mazzoleni, Christophe Duret, Anne Gaëlle Grosmaire, and Elena Battini, medical researchers from different institutions of Italy and France.

They have made a review collecting different studies on the effectiveness of robotic rehabilitation in order to analyse the results obtained. The aim of their article is to review studies of combined treatments based on robotic rehabilitation.

Firstly, they introduce robotic devices as advanced-robotic systems which can offer highly repetitive, reproducible, interactive forms of training with quantifiable outcomes. These devices also provide useful feedback to patients, which can positively influence them.

Secondly, they remark that this kind of rehabilitation, despite the quality of evidence is low to very low, is known to be safe and useful reducing motor impairments of the limbs. They also point out the fact some studies suggest which is that the combination of robotic and conventional rehabilitation is particularly effective. It also depends on the patients' disease, being more effective in chronic stroke patients than in acute stroke patients.

Thirdly, they treat the robotic rehabilitation combined with new rehabilitation techniques such as FES and virtual reality (VR). In this paper, FES is described as a therapeutic innovation which can stimulate up to three specific muscle groups facilitating the recovery of functional movements. However, there are also some limitations depending on the severity of the impairment. Studies have shown that FES improve motor function in patients with moderate paresis but not in severe impairment



patients. But combining FES with other robotic therapies patients can reach important improvements; this is explained by the fact that robotic devices are usually directed to joint's recovery while FES stimulate the muscles, providing a complete limb recovery.

On the other side, virtual reality can be used to provide sensorimotor training in complex environments that could be possible to design in real life. What is more, patients with stroke use similar strategies in virtual environment as in the real world. VR can also be used as a research tool to investigate how the patient reacts to different environments. Furthermore, the results of different studies suggest that the use of VR can lead to improvements in motor function and in daily living.

Finally, authors conclude that robotic systems should be considered as vehicles that enable evidence-based, impaired-oriented treatment providing intensive, interactive and highly repetitive experience. There are also some evidences that suggest that the combination of therapies is more effective than individual therapy methods. Unfortunately, studies have many limitations as small sample size, heterogeneity of technological device, etc. It is required more complete studies to assess categorically this information.



Robotic Technologies and Rehabilitation: New Tools for Stroke Patients' Therapy

Researchers from the University of Padua, Italy, has done a study about the topic. In their study they have work with the information in the PubMed, Cochrane, and PeDRO databases.

In this text the authors mention the importance and the usefulness of robot in the post-stroke therapy. They remark the advantages of robotic rehabilitation (like all the studies overviewed in this thesis) and they also consider robotic rehabilitation as a helping therapy for the conventional one, allowing a remarkable effort and time-saving.

In addition, robotic systems may be used not only to do repetitive movements but also to generate a more complex, controlled multisensory stimulation of the patient. This is really useful for controlling the improvement of the patient in order to modify the treatment.

A higher level of stimulation can be produced. The feedback can be also offered to the patient, providing knowledge of results and/or of performance during robotic training. This can promote the enrolment of the patient in the rehabilitation exercise encouraging them to take an active role at the therapy, which is not able to do in conventional therapy.

To conclude authors remark that robotic technology, differently from other physiotherapy options, allows quantifying objectively the amount and quality of multisensory stimulations and measure patient outputs and outcomes.

They assess that robotic rehabilitation can be used in acute, subacute and chronic phases, despite the fact that in most of the studies it has been used in patients in a chronic phase.



Assessing Effectiveness and Costs in Robot-Mediated Lower Limbs Rehabilitation: A Meta-Analysis and State of the Art

The relation between cost and effectiveness has been studied also in this meta-analysis.

Authors use Cochrane database and recent studies to determinate the efficacy of both methods. In those studies, patients have the same characteristics in order to do a useful study. Using all these data, they have divided the patients into two groups:

- Group A: patients who have done a robot-mediated rehabilitation and some additional conventional session
- Group B: patients who have done only conventional rehabilitation

They have also considered two outcomes instead of one. The first one is the ability of the patients to recover walking independence. For this purpose, the way to consider the effectiveness in each article used for the study is to calculate the odds ratio:

$$\frac{a_i \times d_i}{b_i \times c_i}$$

Where:

- *a_i* is the number of patients in group A who recover the independence of walk.
- *b_i* is the number of patients in group A who did not recover independence.
- *c_i* is the number of patients in group B who recover the independence of walk.
- *d_i* is the number of patients in group B who did not recover independence.



This index measures the number of patients who recover walking independence at the end of robotic rehabilitation compared to the traditional one.

If this index is over 1 it means that robotic rehabilitation is more effective than conventional one whereas if it is below 1 is just the opposite.

In order to clarify which kind of robot machine is more effective the authors have divided the data into two main groups:

- Operational machines
- Wearable machines

The results obtained are the following:

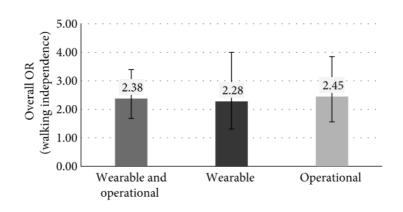


Figure 29: Overall OR

The results show that in the three cases robotic rehabilitation is more effective than the conventional one (overall OR>1) in order to recover the walking independence. What is more, operational machines have better results than wearable robots. This difference is explained because robot



joint links usually are not perfectly aligned with human joints and undesired forces are produced.

The second studied outcome is the average walking speed. It is calculated with the mean difference between the average speed that patient reach after robotic rehabilitation and the average speed patients reach after conventional rehabilitation.

The results suggest that operational machines are better than wearable robots and better than conventional therapy. However, the results for wearable machines are not statistically significant so, in terms of walking speed, we can say that conventional therapy and wearable robot therapy have the same effects.

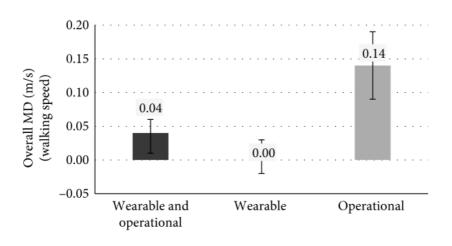


Figure 30: Overall MD

For cost analysis, authors have considered that in the studies they have investigated there are some costs that are the same for robotic rehabilitation and for conventional rehabilitation.



- Medications, meals and electricity for hospitalized patients.
- Hourly cost of a single therapist.
- Average session duration.
- The number of sessions for the entire rehabilitation process.

In their study, two therapists working shifts have taken into account¹⁷ to get an idea of how many hours per day the robot can be used for rehabilitation sessions:

- 1st case: robot used 7.12 hours per day, 5 days a week (weekly working hours for a single therapist).
- 2nd case: robot used 12 hours per day, 6 days a week (weekly working hours for two therapists, one working in the morning and the other in the afternoon).

Specific and total costs are shown in the next table, where a comparison between both cases and conventional therapy has been made in order to compare the final costs of both methods.

As it could be imagined, robotic therapy is far more expensive than the conventional one because of the robot purchase cost, the robot amortisation cost and the robot maintenance cost.

¹⁷ Collaboration with the Polyclinic General Direction of Campus Bio-medico (Rome, Italy)



	Rob	C (;	
	1st case	2nd case	Conventiona
Parameters			
$C_{\mathrm{h}}^{\mathrm{therapist}}\left({\mathrm{\epsilon/h}} ight)$	20.00	20.00	20.00
$n^{\mathrm{therapists}}$	1	1	1.19
t ^{session} (min)	52.72	52.72	52.72
n ^{sessions}	17.91	17.91	17.91
$C_{\text{Robot purchase}} (\epsilon)$	225,000.00	225,000.00	_
y ^{amortization} (years)	5	5	_
$C_{y}^{\text{maintenance}}$ (€/year)	22,500.00	22,500.00	_
Daily robot use (hours per day)	7.12	12	_
Weekly robot use (days per week)	5	6	_
Results			
C ^{therapy} (€/h)	56.46	38.03	23.80
C ^{therapy} (€/session)	52.44	35.32	22.10
$C_{ ext{total}}^{ ext{patient}}\left(\epsilon ight)$	1,023.36	716.76	480.10

Figure 31: Total costs of the therapy

Finally, in order to compare cost and effectiveness they use an incremental cost-effectiveness ratio (ICER). It is calculated as:

$$ICER = \frac{C_A - C_B}{E_A - E_B}$$

Where:

C_A is the cost of the entire rehabilitation process for robotmediated therapy.



- *C_B* is the cost of the entire rehabilitation process for conventional therapy.
- E_A is the effectiveness of robotic therapy (1st or 2nd outcome).
- E_B is the effectiveness of conventional therapy (1st or 2nd outcome).

The ICER ratio is the difference of costs weighted by the difference of effectiveness. A low value in the numerator indicates a small difference between cost whereas a high value in the denominator means that robotic rehabilitation is more effective.

The results are shown in the following tables:

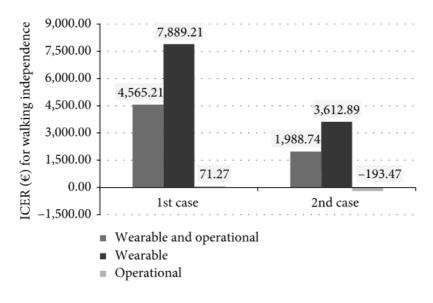


Figure 32: ICER for walking independence



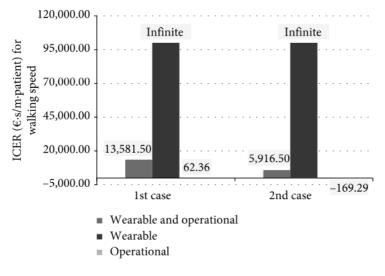


Figure 33: ICER for walking speed

Figure 31 shows ICER values for walking independence recovery. In first case, ICER for wearable and operational robots is $4565,21 \in$ whereas if we divide them into two groups depending on the kind of machine we can see that wearable robots are far more expensive than operational robots (7889,21 \in - 71,27 \in).

If we increase the number of hours of possible use (second case) we see a negative ICER value for operational machines. This means that the operational machine therapy not only is more effective than the conventional one but also cheaper.

On the other hand, figure 32 shows ICER ratio for the second outcome. In the first case we can appreciate that wearable machines are not appropriate for increasing walking speed because the ICER ratio is really high¹⁸. This means that wearable robot therapy is far more expensive

¹⁸ Infinite implies that the cost is really high, far from the axis limit.



and useless than conventional therapy in terms of the second outcome. For operational machines is different. In the first case they are more expensive ($62,36 \in$ more expensive) but, if we boost the number of hours we can see that it is not only cheaper but also more effective.

The conclusions of the authors are:

- Robotic rehabilitation has proven to be more effective than conventional therapy for walking independence.
- Therapy based on operational machines is the most effective (due to limitations of wearable robots)
- Robotic rehabilitation is the best one for patients who cannot walk independently. For patients who can walk there is not proven evidences for assessing that it is better than the conventional one. Further studies are needed.
- In an economic point of view, the robotic rehabilitation is far more expensive than the conventional one but operational machines therapy is economically more sustainable.



8. Final conclusion

As above mentioned, robotic rehabilitation is expensive not only due to the machines' prices but also to the maintenance they entail. Carrying out this study of costs in the IRCCS Bonino-Pulejo, it has been found out a proxy of the cost incurred in the treatment of each patient although there is high variability depending on the number of sessions and the type of machines that should be used. This analysis will help the pertinent public institution to allocate funds appropriately to the hospital.

The current use of these machines is not optimal. A lack of demand causes these machines to be underused, which could be partially solved with an increase in the hospital advertising for pulling demand. It will be possible to monitor this change in demand through the facilitated statistical process control (SPC). It would also be appropriated to adapt the estimate of maximum sessions for each machine as they treat different diseases, and some of them can be less common.

Although robot rehabilitation is costly, various surveys agree on the fact that, combined with conventional rehabilitation, provides better results than separately. Nevertheless, there are some controversies about the efficacy of some machines for treating certain diseases. To obtain better results regarding efficiency we must study each patient's case in detail providing combined rehabilitation therapy according to patients' requirements.



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Nirvana



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https://www.btsbioengineering.com/es/products/nirvana/

VRRS

http://khymeia.com/en/products/vrrs/

Erigo

https://www.accessdata.fda.gov/cdrh_docs/pdf13/K132416.pdf

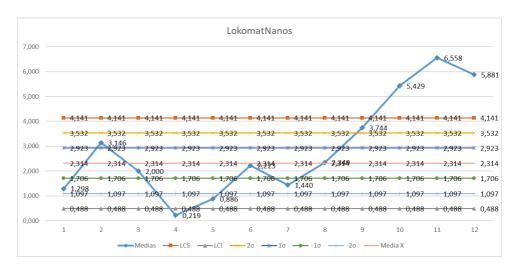
Amadeo

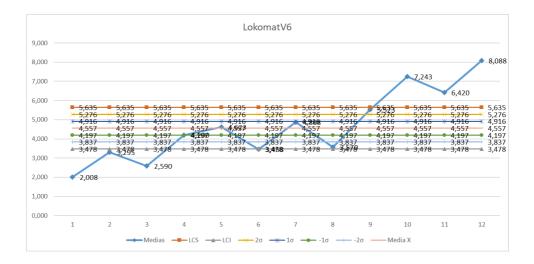
https://tyromotion.com/en/produkte/amadeo/



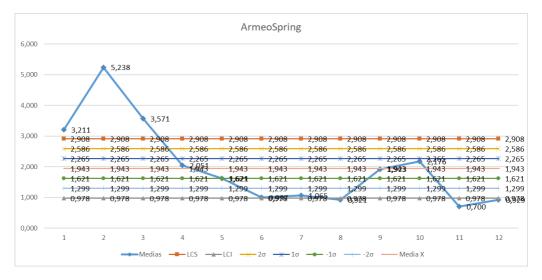
I. Annex I

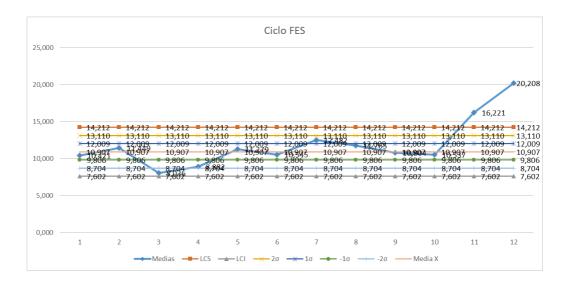
The annex I is dedicated to the SPC charts of each machine. Those charts show the average daily demand month by month.



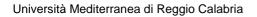




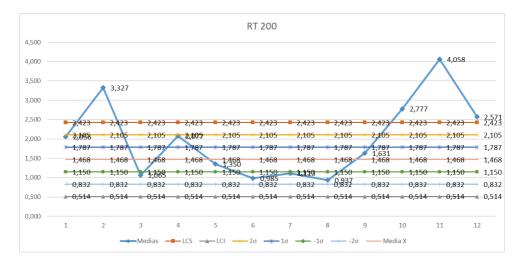




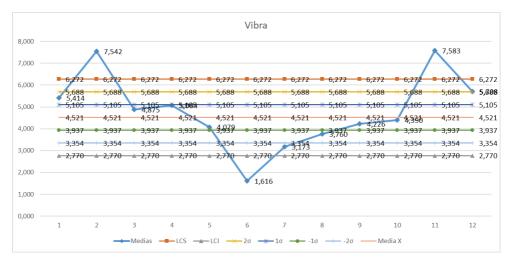
*There are three Ciclo FES devices: two for upper limbs and one for lower limbs. Maximum sessions per day \rightarrow 24 sessions.



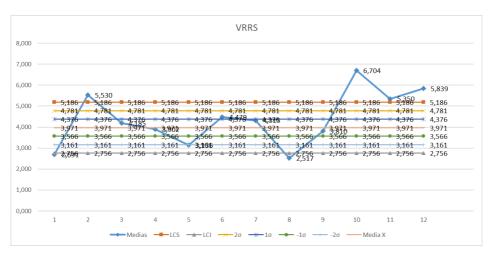


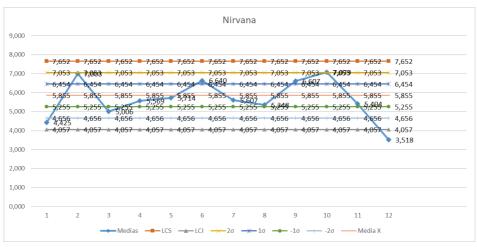




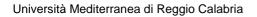








There are two VRRS devices and two Nirvana devices. Maximum sessions \rightarrow 16 each.



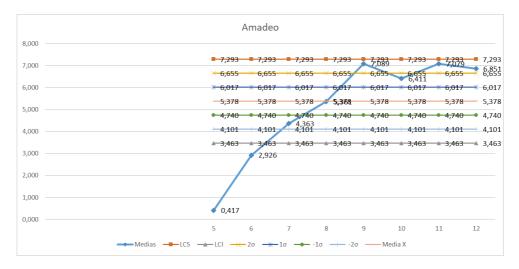












*Amadeo device was bought in March 2017