

A LINarm++

Affordable and Advanced LINear device for ARM rehabilitation

No	Participant organisation name	Short	Country	Type
1	Consiglio Nazionale delle Ricerche	CNR	Italy	RTD
2	Univerza v Ljubljani	UL	Slovenia	RTD
3	École polytechnique fédérale de Lausanne	EPFL	Switzerland	RTD
4	Idrogenet srl	IDRO	Italy	SME



Final Report

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Section 1: Executive summary

- *The goal of the project was to realize a technological solution enabling a multisensory, multimodal and patient-oriented neuromuscular rehabilitation of the upper limb.*
- *No off-the-shelf device featuring such functionalities is currently available.*
- *The proposed solution integrates a variable-stiffness end-effector rehabilitation device, a wearable neuromuscular electrical stimulation system, a virtual rehabilitation scenario, a low-cost unobtrusive sensory system and a patient model for adapting training task parameters according to the patient's performance and state.*
- *The developed prototype aimed to be a first complete modular platform enabling personalized hybrid robotic upper-limb rehabilitation interventions, featuring autonomy in adapting to the patient capabilities and performances, and targeting the market of affordable devices for low-resource settings. It was assessed through a set of usability tests performed by medical personnel, who judged the developed technology as promising to support neurorehabilitation.*
- *As foreseen within the project definition, LINarm++ addressed and led to advances in some important scientific and engineering topics as unobtrusive measurements of relevant physiological parameters, sensory fusion and interpretation of human related data, bio-mimetic and bio-feedback FES to assist patient during upper-limb rehabilitation, and design of variable stiffness actuators and related control techniques. In order to estimate possible socio-economic relapses, a business plan containing a market analysis and strategy has been produced. A tangible socio-economic impact on a large scale will require extensive clinical trials and a widespread commercialization, out of the scope of the current project.*



Figure 1 –LINarm++ mechatronic device interfaced to the virtual environment and with the user holding the cylindrical sensorized handle. In the right picture the rehabilitation task is supported by a wearable embedding a set of electrodes for functional electrical stimulation.

Section 1.1: Milestone overview

#	Description	status
M1	Requirements and specifications	Timely achieved
M2	Subsystems design	Timely achieved
M3	LINarm++ subsystems prototypes	Timely achieved
M4	LINarm++ demonstration at RIF	Timely achieved
M5	LINarm++ preliminary usability tests	Timely achieved

Section 1.2: Deliverable overview

#	Description	status
SB	Story Board	Timely submitted
MMR	Multi-Media Report	Submitted
RIF	Report on RIF visit outcome	Submitted
D1.1	Requirements and specifications	Timely submitted
D1.2	Exploitation plan	Timely submitted
D1.3	LINarm++ prototype	Submitted
D1.4	LINarm++ preliminary usability tests	Submitted (embedded in RIF)
D2.1	Control system architecture and components	Timely submitted
D2.2	Control system	Timely submitted
D3.1	Mechatronic device design	Timely submitted
D3.2	Mechatronic device	Timely submitted
D4.1	Proof-of-concept system for principles of user state assessment and design of sensory system	Timely submitted
D4.2	Final prototype of the sensory system and patient model and verification	Timely submitted
D5.1	NMES-based system design	Timely submitted
D5.2	NMES wearable systems for shoulder and elbow	Timely submitted
D5.3	Training scenarios and virtual environment	Timely submitted

Section 1.3: Technical KPIs

#	Description	status
1	Control A modular real-time multisensory and multimodal controller able to control all the functionalities of the platform has been realized.	Timely achieved
2	Mechanics A completely redesigned version of the mechatronic device, embedding a novel variable stiffness actuator, has been realized and is available.	Timely achieved
3	Sensors and patient model An unobtrusive low-cost sensor system has been designed, realized and embedded in the device handles.	Timely achieved
4	Feedbacks Different virtual environments, with both motor and cognitive challenges, have been developed and interfaced to the LINarm++ platform. A wearable NMES-based system has been developed and realized.	Timely achieved

Section 1.4: Impact KPIs

#	Description	status
1	System modularity and treatment personalization The whole system has been developed as a set of modules, managed by a patient-based control system.	Timely achieved
2	Cost-effectiveness The overall cost is below the maximum target cost €5000 foreseen in the DOW.	Timely achieved
3	Technologies exploitation Business plan delivered	Timely achieved
4	Technology Readiness Level TRL7 - system prototype demonstration in operational environment	Timely achieved
5	Clinical efficacy Usability tests	Timely achieved

Section 1.5: Dissemination KPIs

#	Description	status
1	Fair visit/ booth	Timely achieved
2	Journal publication	Timely achieved
3	Conference visits	Timely achieved
4	Coverage on local news	Not Achieved
5	Coverage in national news	Not Achieved
6	Coverage in special interest press	Timely achieved
7	Online coverage	Timely achieved
8	Experiment Flyer	Timely achieved
9	Experiment Website	Timely achieved
10	Demonstrator	Timely achieved

It is worth to note that it was not possible to cover local and national news because CNR press office preferred not to prepare press releases up to the availability of a complete clinical assessment.

Section 1.6: Additional (unplanned) achievements

At the definition of the project there were no certainties about the actual feasibility of performing relatively complex movements with strict linear movements as the ones performed with the LINarm. For this reason, no mention about specific movements was included in the Description of Work. Nevertheless, preliminary feasibility and usability tests of a complex movement (i.e. hand-to-mouth, ref. to D1.3) have been performed quite successfully during the period spent at the RIF. A properly connected cylindrical handle allowed the physiotherapists to emulate a hand-to-mouth movement, resembling the actual functional movement performed to bring an object to the mouth.

Section 2: Detailed description

Section 2.1: Scientific and technological progress

WP1 - Requirements, integration, assessment and exploitation

This workpackage dealt with the coordination of the whole experiment. It defined the guidelines of the project analyzing the state of the art of similar rehabilitation devices, reviewing off-the-shelf and pre-existent patents, and defining functional and technical specifications of the final prototype. In the last part of the project, it managed the overall realization of the demonstrator, integrating the modules developed in the other workpackages. Moreover, technical and usability assessments have been carried out within this WP. Finally, it paved the way for the final exploitation of the project preparing a business plan which includes a market analysis, a description of LINarm++, a possible strategy, and a marketing plan.

WP2 – Control

Applying the guidelines defined in the WP1, WP2 went into details and specified the architecture, the components, the connections and the communication protocols of the platform. Because of its modularity, reliability, and expandability, the ROS framework was chosen to realize the whole communication architecture. A set of classes and ROS nodes have been implemented to collect and dispatch available data, and to run real-time control algorithms. A demo mode has been included, in order to simulate the control of the platform without having the actual devices connected to the framework and test the functionalities even before the final completely integrated demonstrator. The complete control architecture has been finally tested in the last weeks of the project, when the final prototype was completely assembled.

WP3 – Mechanics

Starting from the previously existing prototype, namely LINarm, a completely new redesign of the mechatronic device has been developed, conceiving from scratch a novel variable stiffness architecture. This new architecture, based on spiral cams wrapped by wires, is more compact and easy to customize with respect to the one embedded in the previous version. A theoretical model of the system has been analytically formulated and embedded in automatic routines to analyze and synthesize a generic mechanism based on this new architecture. After having produced the detailed

mechanical design, the mechatronic device was manufactured, assembled and wired. Experimental tests have been performed to assess the correct functioning of the mechanism, controlling in real-time the position and the stiffness of the mechanism.

WP4 - Sensors and patient model

Physiological sensors were proven to be effective in implementing patient-specific training scenarios for motor rehabilitation as they provide additional insight into the patient's state, complementing the information about the motor capabilities. In order to satisfy unobtrusiveness and low cost criteria, which are needed in home rehabilitation, a novel sensory system was developed based on prior knowledge of high-end devices. The contact between the patient and sensors is achieved by grasping the robot handle, thus, no additional fixations are required, which makes the most important difference compared to other solutions. In order to adjust to different patients, the robot handle with embedded sensors was designed in two shapes – cylindrical and hemispherical.

The patient model was designed for automatic adaptation of training parameters to specific patient's needs. The model is designed in the form of a decision tree and combines clinical information, motor and task performance parameters as well as physiological measurements in the output that defines the behavior of the robot and the training task.

WP5 – Feedbacks - Training scenarios and virtual environment

Virtual training scenarios complement robot-based rehabilitation and enable adaptation of training parameters to specific patient's needs. In order to motivate patient for training, the designed scenarios combine motor and cognitive challenges (scenarios range from simple one degree-of-freedom movements to cognitively challenging Stroop test and car driving with parallel solving of cognitive tasks). Tasks were specifically designed for the LINarm++ system that is limited to one degree-of-freedom movement, whereas the movement direction can be adjusted passively. Therefore, also training scenarios allow task execution primarily in horizontal and vertical directions.

WP5 – Feedbacks - Wearable NMES-based system

Functional electrical stimulation has proven its efficacy in neurorehabilitation therapies, both used alone and coupled with a robotic device, but its use is still limited by the need for a complex procedure to optimize electrode placement and by the reduced selectivity of muscle recruitment. In order to facilitate its applicability and exploitation, an easy-to-wear system has been designed and developed. For simplicity of wearing and parsimony of the overall number of channels and electrodes, targeting the affordability LINarm++ requirement, groups of muscles and number of electrodes have been optimized and minimized for selected functional movements. Proper wearables and electrode matrixes have been designed and realized in order to facilitate the wearing of the NMES-based system. Finally, to further reduce the setup time and the competences required to caregivers, an automatic calibration procedure to identify the best electrodes and stimulation parameters has been conceived, implemented and integrated in the overall architecture.

Visit to the RIF

Representatives of the LINarm++ consortium joined in Volterra at the Bioengineering Lab at the Auxilium Vitae Hospital to finalize the integration of the device and to perform functionality and usability tests performed on a group of 12 physical therapists. The tests consisted of different trials during which subjects performed differently oriented movements using different control modalities. After tests, all subjects were requested to fill out the System Usability Scale (SUS), a ten-item scale giving a global view of subjective assessments of usability, and were also invited to report positive and negative matters along with some suggestions. SUS results were positive (score $(75 \pm 13)/100$), and most of the physical therapists would use the system once available.

Section 2.2: Scientific and technological achievements

Control

A fully-functional modular multimodal and real-time control architecture has been realized. The ROS-based framework allows to: control the LINarm2 mechatronic device; collect, manage and display all the system data; control the FES system supporting hybrid rehabilitation therapies; modify the control parameters according to the assistance level computed by the patient model. It embeds a set of force-based and assistive/resistive control modalities to fulfill the requirements of state-of-the-art robotic rehabilitation treatments. The developed framework is modular and components/devices can be enabled/disabled, allowing to optimize the system configuration, and therefore its overall costs, according to the actual requirements of a specific rehabilitation treatment.

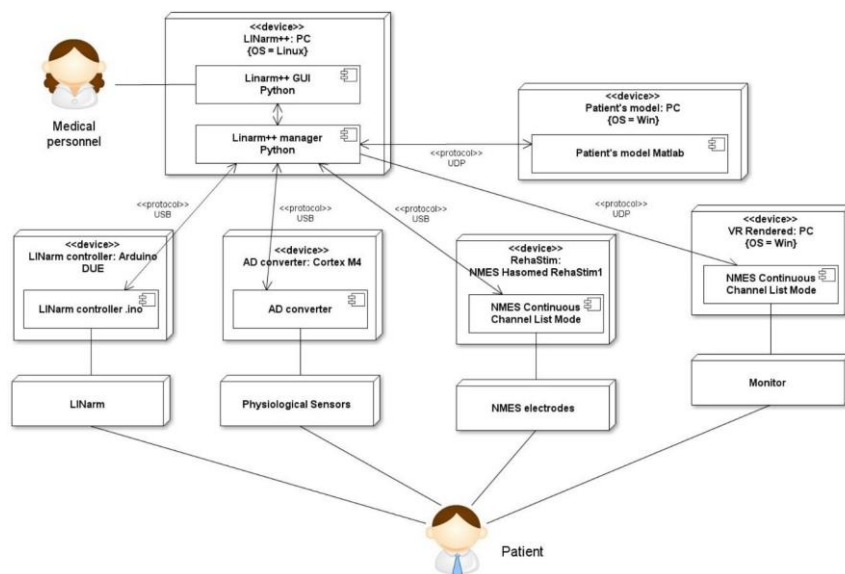


Figure 2 – UML representation of the LINarm++ architecture.

Mechanics

A novel variable-stiffness architecture has been conceived and embedded in the re-designed version of the mechatronic device. It allows a more compact solution and a customizable force-displacement

characteristic, thanks to its cam-based design. Its principle of operation can be easily embedded in other linear compliant actuators, also in different application fields. The design of the device took into account safety issues, ergonomic requirements and proper mechanical interfaces with other components of the system. Additionally, as better explained in the RIF deliverable, a new possible design approach to execute complex upper-limb movements (e.g. hand-to-mouth) has been investigated and preliminary assessed: it exploits a mere linear actuation direction coupled with a handle connected to the device through properly configured passive joints.

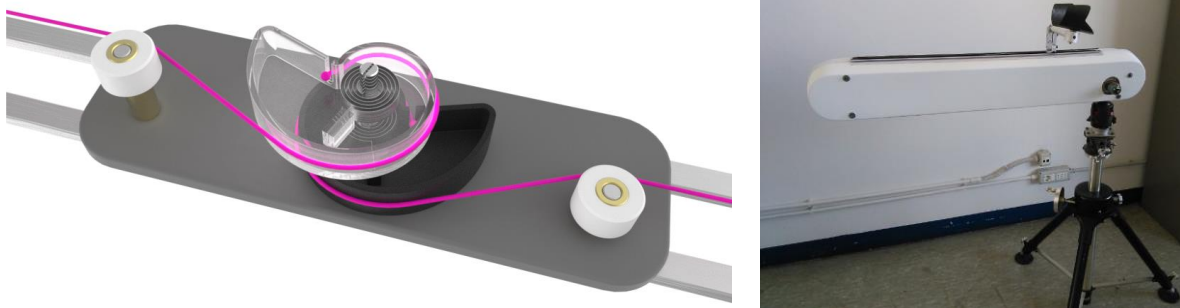


Figure 3 – Left: LinWWC-VSA, the variable stiffness actuator embedded within the LINarm++ mechatronic device. Right: LINarm++ mechatronic device with the covering.

Sensors and patient model

A fully functional and embedded sensory system for measuring physiological responses of a patient during the training with the robot has been developed, validated and tested in operational environment. The novel low-cost sensory system provides real-time information about patient's heart rate, skin conductance, skin temperature and force applied to the handle while being grasped. Electronics has been designed to comply with medical standards, thus making the use of the system safe in all circumstances. The system can be easily integrated with any robot-based or passive rehabilitation device, which makes it a general-purpose solution for rehabilitation.

Combined information from physiological sensors, the robot and the virtual training task is the input to the patient model that was initially specifically designed for the application. However, the decision tree form of the patient model makes it easy to read/understand and robust with parameters that can be adjusted to needs of different patient populations. Therefore, the model can be used with any rehabilitation system that is based on similar concept as LINarm++ (these are majorities of rehabilitation systems).

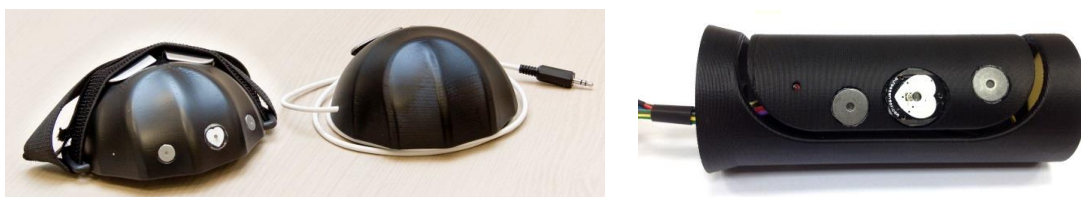


Figure 4 - Spherical and cylindrical handles with physiological sensors.

Training scenarios and virtual environment

Training scenarios and virtual environments were integrated within the LINarm++ system and validated in operational environment. The relatively simple mechanical architecture of the robotic device also limits the complexness of virtual environments, since only one degree-of-freedom can be actively manipulated in the environment. Nevertheless, the concept proposed for the design of training scenarios can be implemented also in other rehabilitation devices, as most often training of patients is limited to simple movements also with more complex devices. The tasks can, for example, be used for motor training of individual limb joints, where only one degree-of-freedom is actively moved at a time.



Figure 5 Catch-and-avoid game for two orientation of the robot: (left) horizontal and (right) vertical orientation.

Wearable NMES-based system

A 4-channel wearable NEMS system was developed and integrated within the LINarm++ architecture. The system consisted of a stimulator, The Rehasim One (Hasomed GmbH, Magdeburg, DE), a custom made SwitchBox, allowing easy change of the stimulation targeted muscles, and four wearable patches, each including 4 stimulation electrodes connected to a common ground electrode. A calibration procedure and software were developed allowing, for each muscle, an easy selection of the best electrode and the setup of the stimulation parameters. Software was developed to prepare a lookup table with the muscle stimulation profiles, which is saved in the LINarm++ controller for movement-synchronized stimulation (lookup tables are built based on the EMG activation pattern of healthy subjects performing the targeted movement). For functional testing, two lookup tables with the stimulation profiles of the deltoid anterior and triceps muscles and the biceps and brachioradialis muscles were prepared for the reaching and the hand-to-mouth movements, respectively.

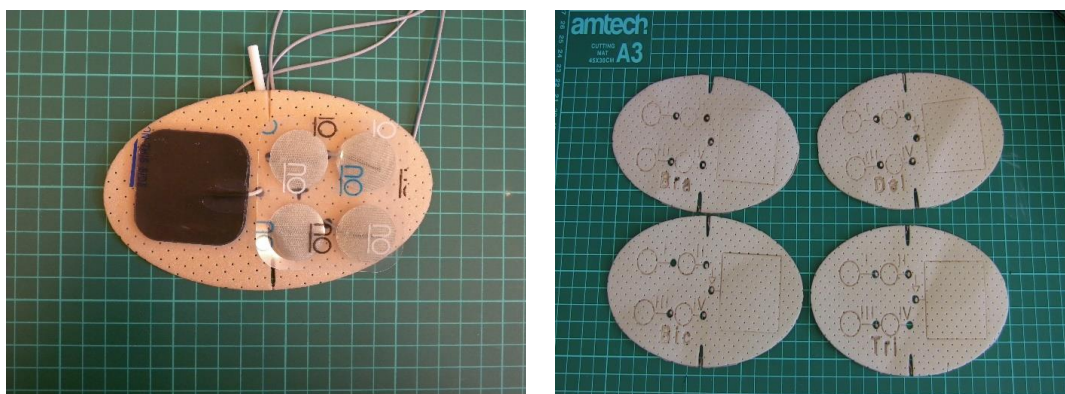


Figure 6 – Examples of custom pads for stimulation. Left: the skin side of the patch. Right: example of custom cut and engraving for labelling purposes.

Demonstrator

The whole demonstrator is a key technological achievement since no previously existing device for upper-limb rehabilitation embedded the whole set of functionalities of LINarm++. Its TRL increased from 2 - *Technology concept formulated* - at the beginning of the project, up to 7 - *System prototype demonstration in operational environment* - reached at the Bioengineering Lab of the Auxilium Vitae Hospital in Volterra. The visit to the RIF was useful to finalize the integration of the device, but especially to perform usability tests in collaboration with more than ten physiotherapists.

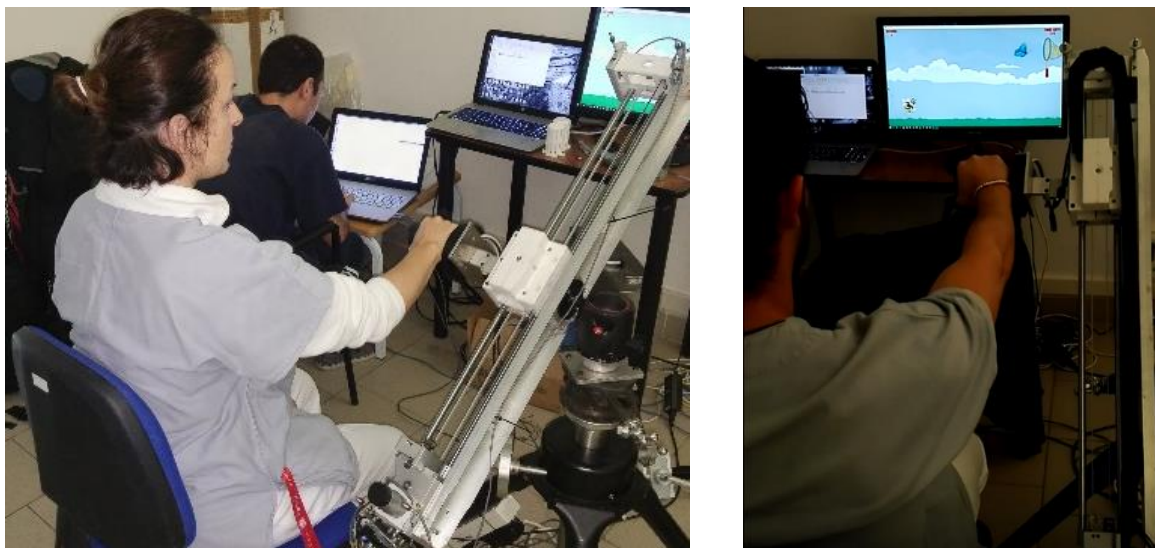


Figure 7 – Physiotherapists perform usability tests of the LINarm++ platform.

Section 2.3: Socio-economic achievements

The project had the ambition to develop a new cost-effective rehabilitation device for the medical rehabilitation market, leading to the execution of adaptable rehabilitation treatments in a partially autonomous way. This would facilitate the more and more pursued de-hospitalization process and would lead to more intense rehabilitation treatments in more comfortable environments. Nevertheless, no tangible socio-economic impact has been achieved so far. The development, assessment, certification and commercialization of a medical device is a long process, which requires subsequent steps and usually passes through the realization of more than one/two different prototypes. The commercialization phase is required to bring scientific results obtained in labs to a large scale and actually achieve a socio-economic impact. However, besides scientific results obtained during the project, interesting and promising feedbacks have been collected by medical personnel during demonstrations held in clinical centers, who confirmed the actual applicability of the platform and foresee real advantages in employing the platform in upper-limb rehabilitation treatments with respect to currently available off-the-shelf devices.

Section 2.4: Dissemination activities

Fair visit/ booth

The LINarm++ project has been presented at:

- Technology HUB (<http://www.technologyhub.it/>), edition 2016, within the CNR booth (Piazza Robotica Medica) and during a presentation dedicated to Rehabilitation Technologies.
- The Maker Faire Rome 2016 (<http://www.makerfairerome.eu/it/>), within the CNR booth (http://explore.makerfairerome.eu/poi/Exhibit_860).

Journal publications

Three papers have been prepared to promote the scientific achievements of the project:

- The paper *An affordable, adaptable and hybrid assistive device for upper-limb neurorehabilitation* submitted to the special issue *Affordable Rehabilitation and Assistive Robots and Technologies for Low Resource Settings in Developed and Developing Countries* of the *Journal of Rehabilitation and Assistive Technologies Engineering* was accepted ([link](#) to the proofread version).
- The paper *Analysis and synthesis of LinWWC-VSA, a variable stiffness actuator for linear motion*, submitted to the *Mechanism and Machine Theory* journal, was accepted ([link](#) to the accepted version).
- A major revision decision of the paper titled *An unobtrusive measurement method for assessing physiological response in physical human-robot interaction* sent to journal *IEEE Transactions on Human-Machine Systems* was received. The paper is again under review ([link](#) to the proofread version).

Conferences

The project has been presented at:

- XVII Congresso SIAMOC 2016 – A poster entitled “LINarm, un dispositivo end-effector lineare per riabilitazione post-stroke: test preliminari” - reporting experimental trials performed on the first version of the mechatronic device to better investigate the behavior of the mechatronic device applied to improve the second re-designed version.
- TeleMediCare 2016 workshop - Monitoring and Rehabilitation of elderly and disability people – October 3-4 – Desio, Italy. A presentation entitled “*An affordable, adaptable and multi-modal device for arm rehabilitation*” has been given.
- REHAB 2016 WORKSHOP – October 13-14, 2016 – Lisbon, Portugal. A work entitled *LINarm++: an affordable and advanced linear device for arm rehabilitation* has been accepted and presented.
- 2016 China (Beijing) International Technology Transfer Convention, November 15-17, 2016.

Coverage in special interest press

- The project has been mentioned in an article of the journal “Ortopedici e Sanitari” ([link](#), final section of the article entitled “Dispositivi per la neuro-riabilitazione”).
- An interview reporting the complete functionalities of the prototype has been recently given, and an article fully dedicated to the LINarm++ project will be published in few weeks in the same journal “Ortopedici e Sanitari”.

Online coverage

- Il Sole 24 ore ([link](#))
- CNR website ([link](#))
- An interview has been given to Finestra Aperta (<http://www.finestraperta.it/>) for an online article which will be published in the next weeks.

Experiment Flyer

- A flyer has been prepared and distributed in public events ([link](#)).

Experiment Website

- <https://sites.google.com/site/linarmplusplus/>

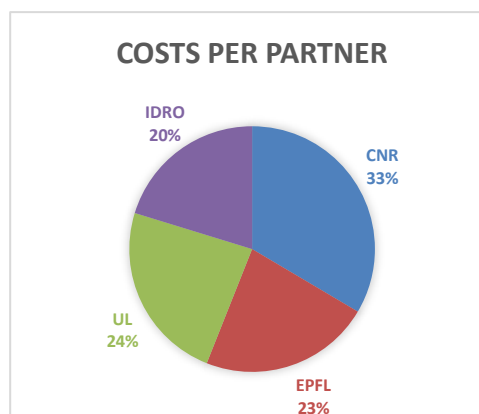
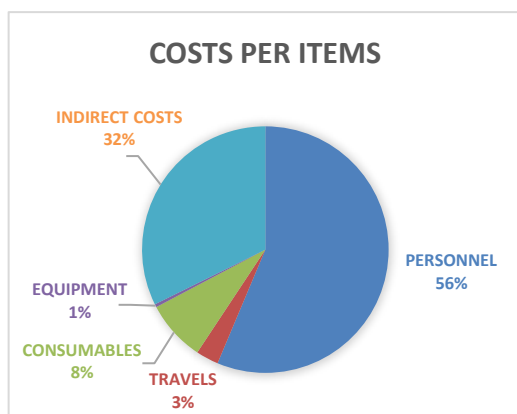
Demonstrator

Besides the dissemination means previously listed, the demonstrator has been presented to the medical personnel of three hospitals (Domus Salutis, Brescia, Italy; Fondazione Salvatore Maugeri, Lumezzane, BS, Italy; Habilita, Sarnico, BG, Italy). Moreover, it has been subject of a preliminary experimental assessment and dissemination activities at the the Pisa RIF, Volterra Auxilium Vitae Hospital. The visit to the Hospital was useful not only to have feedbacks from physiotherapists but even to disseminate in an operational environment the results of the project. A video which summarizes the highlights of the demonstrator is available [here](#).

Section 3: Resource usage summary

The resource usage is hereafter listed, split by items and partners. Since the cost reporting phase is still ongoing in partners' administration offices, final values can still be subjected to slight adjustments.

	CNR	EPFL	UL	IDRO	TOTAL
PERSONNEL	91,696.47 €	30,800.00 €	50,935.18 €	49,900.00 €	223,331.65 €
TRAVELS	6,110.66 €	5,000.00 €	372.61 €	300.00 €	11,783.27 €
CONSUMABLES	5,746.04 €	20,000.00 €	5,877.76 €	- €	31,623.80 €
EQUIPMENT	- €	- €	1,579.00 €	- €	1,579.00 €
TOTAL DC	103,553.17 €	55,800.00 €	58,764.55 €	50,200.00 €	268,317.72 €
INDIRECT COSTS	29,270.70 €	33,480.00 €	35,258.73 €	30,100.00 €	128,109.43 €
TOTAL	132,823.87 €	89,280.00 €	94,023.29 €	80,300.00 €	396,427.16 €
TOTAL (EU FUNDS)	99,617.91 €	66,960.00 €	70,517.47 €	60,225.00 €	297,320.38 €



Section 4: Deviations and mitigation

No relevant deviations from the Description of Work were required during the experiment duration. From a mechanical point of view, some criticism are still present in the wire-based mechanical transmission which does not guarantee a completely reliable solution, and had to be redesigned more than once during the project in order to reach an acceptable performance. From the assessment point of view, it was not possible to perform usability tests on patients due to insurance issues arose in the last weeks of the project.

Section 5: Future work

From the technical point of view it will be required to redesign the mechanical transmission of the mechatronic device in order to achieve the required reliability for an extensive use to perform clinical trials. Moreover, it will be required to improve the usability of the graphic user interface in order to allow the use of the device by medical personnel. From the experimental point of view, a complete clinical trial will be arranged in the next months. The actual market exploitation has not still completely defined, but the company in charge of industrializing and commercializing the system can take advantage of the business plan prepared within the project.

Section 6: Lessons learned

Some activities, as the development of the mechatronic device, required more efforts than the ones previously estimated, because of some reliability issues arose during the experimental trials. Moreover, the integration phase required particular attention and adjustments in the last phase of the project to allow different components, which were developed independently by some of the partners, to interface correctly among themselves. In conclusion, reliability and complexity are important aspects which must be, and will be in future projects, faced as soon as possible while developing a project, especially in human-robot application scenarios.