# Optimization Process of an Innovative Rehabilitation Device based on Pre-Clinical Results

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*Abstract:* Commercially available technical solutions used in physical rehabilitation processes have not responded effectively to the crucial needs of customized rehabilitation programs. As such, a partnership between a nursing school, technological enterprises – ORTHOS XXI and WISEWARE - and engineering institutes was established to implement a project entitled ABLEFIT to overcome the identified lack of technical solutions in the market. ABLEFIT has the main purpose of making available a rehabilitation device in the market that ensures the implementation of physical rehabilitation programs in a controlled and interactive way so that patients can regain their physical, psychological, and social functions as soon as possible. The loss of these capabilities is closely related to Prolonged Immobility Syndrome (PIS), being the morbidity and mortality associated with the complications resulting from prolonged inactivity or even a sedentary lifestyle seen both in the elderly population and in adults and young people with some type of restriction of mobility or disability. This paper describes the optimization process of the ABLEFIT device based on the pre-clinical trials performed. The optimization process starts with the design of an initial prototype, followed by the construction of a second prototype, and finally the planning of an additional iteration, which will involve the construction of a third prototype that will look identical to the version that will be available in the market. The two iterations of the ABLEFIT prototype device developed up to now provide undeniably an advanced solution to support physical rehabilitation, since they combine a biomechanical system to aid physical exercise, in passive and active modes, in bed and a wheelchair, with a control system for monitoring and storing biofeedback variables and motivational stimulus through interaction with gamification. The ABLEFIT device significantly contributes to the reduction of morbidity and mortality associated with complications resulting from prolonged inactivity.

*Key-Words:* - Immobility Syndrome, Rehabilitation Devices, Rehabilitation Customized Plan, Active/Passive Customized Training Plans, IoT, Gamification, Pre-Clinical Trials

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# 1 Introduction

Regardless of the cause that gave rise to it, e.g. pathology, trauma, aging, injury, etc., Prolonged Immobility Syndrome (PIS) has serious consequences on the functioning of the human body, whether due to loss of muscle mass or increased stiffness of the joints, [1], [2], [3], [4], [5]. The negative impact of this phenomenon assumes several dimensions, both in terms of the individual's health and the inherent social and economic effects, [6], [7], [8], [9], [10]. As such, it is urgent to develop and implement strategies and technical solutions that minimize the consequences of PIS, thus helping patients to regain their physical, psychological, and social functions as soon as possible.

Nevertheless, the solutions available in the market are very limited and limiting, [7], [8], [9], [10], [11], [12], [13], [14], [15], [16]. An integrated solution that ensures: i) the application of rehabilitation programs adapted to each user profile, ii) the application to beds and wheelchairs, iii) the execution of exercises in both active and passive modes, iv) the execution of exercises of both the upper and lower limbs, v) the execution of linear and curved trajectories and rotational movements, vi) the monitoring of patient's vital signs over time, and vii) data recording and storage, is not available in the market. Additionally, devices available in the market have no IoT communication system or other types of human-machine interface, which is essential not only for controlling, recording, and storing the parameters defined in the rehabilitation plan but also for playing a key role in motivating the user to complete the entire prescribed rehabilitation plan, [9], [10], [11], [12], [13], [14].

Identified the development opportunities, a consortium composed of academic and I&D research groups and technology-based companies was established to develop and provide the market with an advanced solution to support physical rehabilitation – the ABLEFIT device. This device combines a physical system to aid physical exercise, in passive and active modes, in bed and a wheelchair, and a control system for monitoring and storing biofeedback variables and motivational stimulus through interaction with gamification.

The following sections describe the evolution process of the ABLEFIT device, from the design and build of the prototype, going through the design and construction of a second prototype based on the results of the first pre-clinical tests, until the second round of pre-clinical trials results that will give rise to the commercial prototype that will be submitted to clinical tests before being placed on the market. Nevertheless, the two versions of the system built and tested allow us to conclude that, not only the limitations found in different technical solutions available on the market have been overcome, but also that the advantages gathered in a single solution lead to full compliance with the individually prescribed rehabilitation plan.

# 2 First Prototype of ABLEFIT

Fig. 1 shows the 3D CAD model of the prototype of the ABLEFIT device. To ensure the different types of movement to be performed in the exercises, two modules (to be alternatively coupled to the device's main structure) were developed as illustrated in Fig. 1: i) the linear module (Fig.1a)) that ensures the performance of linear (e.g. flexion, extension) and amplitude (linear movements with curvilinear paths, such as adduction and abduction), or ii) the rotary module (Fig. 1 b)), which ensures the performance of rotational movements (e.g. internal and external rotation).

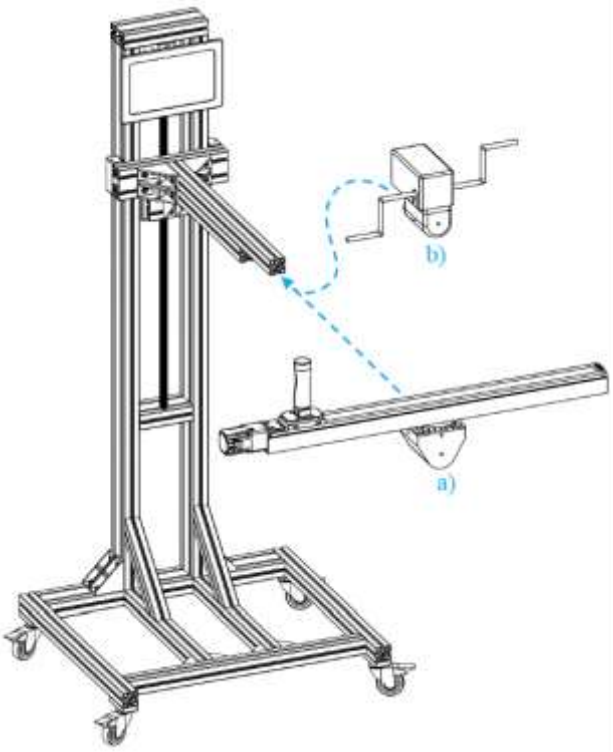


Fig. 1: 3D CAD model of the first ABLEFIT Prototype.

An easy-fit mechanism has been specially designed for easy switching between the two modules, [17]. Any of these modules is activated by an actuator that allows exercises in active mode (i.e., the machine moves the user) or passive mode (the patient makes the machine move). Actuator control

ensures the incremental application of different values of load, speed, and amplitude, to the movements to be performed. Additionally, a mechanical system was adapted to each of these modules, allowing not only the use of the module either by the feet or by the hands, i.e., any of the modules can be used for rehabilitation plans applied to the upper limbs or the lower limbs, but also the possibility of using immobilization aids and fixing parts of the limbs, as shown in Fig. 2 for the lower limbs.

The suitability of the ABLEFIT device for different types of beds and wheelchairs is ensured by the vertical movement of the horizontal bar that integrates the device structure. This movement is controlled by an actuator that moves a threaded rod attached to the horizontal bar. It ensures its up-and-down movement (or stop) to adapt the device's height to the type of exercise intended, regardless of whether it is performed on a bed or in a wheelchair.

The Human-Device interface developed and integrated into the ABLEFIT device ensures, in real-time, the visualization, registration, storage, and communication with other operating systems of all biofeedback and training parameters of the patient, e.g. peripheral blood oxygen saturation, heart rate, blood pressure, force, velocity, time, etc. This allows the continuous assessment of the evolution and recovery progress of the patient. The communication between the patient or caregiver and the clinical team, if the patient does not have the capacity and autonomy to do so or if the patient is in a home environment, is also guaranteed by this interface. In addition, the interface encourages patients to practice certain exercises of the rehabilitation plan through interactive games – gamification – increasing the efficiency and effectiveness of rehabilitation plans, since there is a progressive increase in the motivation and emotional involvement of the patients, [18].

The preliminary usability study presented in the next section was performed to evaluate the behaviour of the prototype built, namely regarding its functionality, ergonomics, and safety, both from the end users and the health professionals' perspectives. The results and solutions presented in sections 2.1 and 2.2 gave rise to the second prototype of ABLEFIT (section 3). A human-centered design was used, through a mixed-method study, [19].

The pre-clinical research to explore usability issues of devices under development is a mandatory and important component of this type of research, namely to assess safety (ISO/IEC Guide 63:2019) and efficiency and efficacy parameters (ISO 16142-1:2016).

In this sense, the pre-clinical phases focused on human factors related to ergonomy and usability, in compliance with the ISO 9241-210: 2010 and ISO 9241-11: 2018 regulations.

## 2.1 Pre-clinical Trials Results

Fig. 2 and Fig. 3 show the usability tests performed respectively for the lower and upper limbs using the linear module of the ABLEFIT device. Fig 2. illustrates the knee extension/flexion movement and Fig 3. illustrates the same kind of movement but for the shoulder and elbow. Fig. 4 demonstrates the rotational movement of the upper limbs.

Fig. 2: Usability tests using the linear module of ABLEFIT for lower limbs.

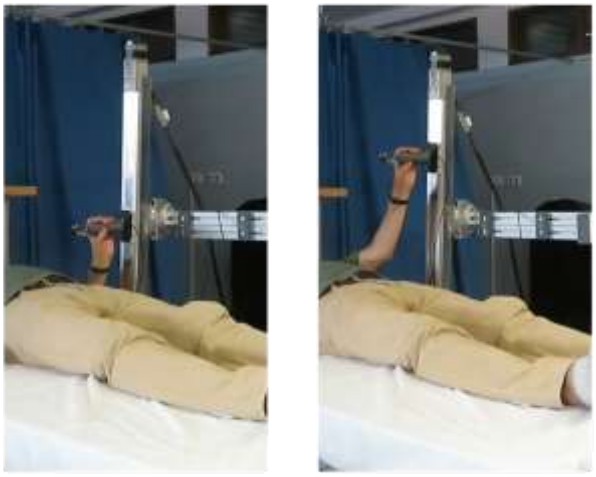

Fig. 3: Usability tests using the linear module of ABLEFIT for upper limbs.

Fig. 4: - Usability tests using the rotary module of ABLEFIT for upper limbs.

#### 2.1.1 End-Users

A total sample of 10 older adults was recruited for the study, with a mean age of 78.6 years. Criteria for their selection were presenting a healthy physical condition, with no mobility restrictions. Preferably they could have past experiences as bedridden patients. A pre-study questionnaire was performed to prevent unavoided physical problems, like the presence of ankle or knee prostheses. The same rehabilitation program was executed for each individual, after which he was asked a few questions in a semi-structured interview to assess the perceptions regarding the device's usability.

#### 2.1.2 Profissional-Users

A total of 12 healthcare professionals, with a mean age of 37.5 years, were recruited to manipulate, handle and assess the device's functionalities. In the end, the participants were asked to answer a usability questionnaire, which provided a quantitative score of the device's usefulness. The criteria applied for this group was having at least a minimum of two years of clinical experience in the hospital setting.

### 2.2 Identification of Drawbacks vs. Proposed Solutions

For the first prototype, Table 1 and Table 2 summarize respectively the shortcomings identified from pre-clinical trials and possible ways to solve these limitations.

Table 1. Identified Limitations

| **OBSERVED PROBLEMS** |
|---|
| **Software** |
| The definition of maximum and minimum positions for active movements has no practical consequences on the device's behaviour. |
| When the program is interrupted for any reason, it is not possible to resume it. |
| **Hardware** |
| Lack of structural stability. |
| Lack of structure resistance. |
| The hardship of linear and rotational module assembly/disassembly. |
| The handle does not allow rotation during movement, which poses a risk of injury to the wrist. |
| There is no support for the hand, which causes movement instability. |
| Thigh and knee instability. |

Table 2.Proposed Solutions

| **SOLUTIONS PROPOSAL** |
|---|
| **Software** |
| Provide a limitation to the range of motion. |
| Include an option to resume the program, if needed, at any time. |
| Cancellation must have an immediate effect on the machine for security reasons. |
| **Hardware** |
| Redesign the structure to make it more resistant and stable. |
| Develop a system to stabilize the hand throughout the range of motion. |
| Develop modules for thigh and knee stabilization. |

## 3 Second Prototype of ABLEFIT

Based on the observed problems and the solutions proposed from pre-clinical trials, the second prototype of ABLEFIT was designed and built as shown in Fig. 5.

Fig. 5: Second prototype of ABLEFIT device

It should be reported that this second prototype guarantees the specifications already ensured by the first prototype, i.e.: i) realization of customized rehabilitation plans, ii) different types of movements of the upper and lower limbs, iii) in active or passive modes, iv) parameterization, telemonitoring, visualization, recording, and individual storage, in real-time, of the parameters prescribed in the rehabilitation plan and biofeedback parameters, and v) use of gamification methodologies to motivate and encourage the user to comply with the rehabilitation plan.

Regarding the shortcomings of the software interface reported in Table 1, Fig. 6 illustrates how they were overcome.

Fig. 6: Demonstration of the software overcoming limitations identified in Table 1.

Concerning the identified hardware shortcomings, the structure of the device was redesigned to overcome the lack of stability and resistance reported in the pre-clinical study by means of a device frame (chassis) in a double T shape that ensures robust structural support. The front wheels are smaller in size to allow adjustment of the equipment chassis under the hospital bed chassis. The larger wheels integrate a central mechanical braking system, which ensures the device's immobilization during its use. In the future, this mechanical system will be replaced by an electromagnetic system.

The chassis was also designed to support two flat sheets to which all the control and power components of the device are connected, including the Human-Machine interface. The fit device positioning relative to the patient's positioning to perform exercises is guaranteed by the two lifting columns that can set the angle and height of the linear or rotary modules. Additionally, the arm where the linear module or the rotary module are alternatively coupled has an electric linear actuator to adjust the length of the arm according to the patient's needs, that is, whether the exercises are being performed by the upper limbs or by the lower limbs.

Concerning the reported software limitations, they have been overcome through i) the implementation of upper limits for the range of movements, ii) the possibility to resume, at any time, the rehabilitation program following any type of involuntary or forced interruption, and iii) possibility to ensure the immediate stop of the device for security reasons.

### 3.1 Pre-clinical Trials Results

The second prototype was developed using the feedback received from end-users, thus contributing to person-centered care and medical device development. The premises were the same used in the pre-clinical trials for the first prototype.

#### 3.1.1 Professional End-Users

Due to project time constraints and safety issues regarding the newly developed prototype, only healthcare professionals were invited to test the new features. The same criteria as for the first pre-clinical trials were applied.

### 3.2 Identification of Drawbacks vs. Proposed Solutions

Table 3 and Table 4 summarize, respectively, the shortcomings identified in the second prototype from pre-clinical trials and the possible ways to solve these limitations.

The software limitations identified will be easily overtaken, given that they are confined to programming adjustments and do not require new developments. Concerning hardware enhancements, such as easy and fast interchangeability between rotary and linear modules or an improvement in the device´s compactness and portability –so that it can be easily placed in any hospital, clinic, or home environment–, they represent challenges that still require further development, optimization, and implementation work. Furthermore, the development of auxiliary systems to the ABLEFIT device is imperative to ensure the necessary support and stability for both the lower and upper limbs during the execution of movements in order to avoid unwanted injuries. In addition, the device placed on the market cannot include loose cables or sharp edges. As such, several improvements are still required to the architecture of the device as well as the development of flexible components to increase usability, safety, and easy cleaning. Finally, issues like energy efficiency, noise reduction, and the use of recycling materials will be accounted for to provide a low-cost rehabilitation device.

Table 3. Identified Limitations

| **OBSERVED PROBLEMS** |
|---|
| **Software** |
| Regular screen blackouts/instability. |
| Touchscreen requires external devices to work. |
| Unable to save previously inserted data regarding patient and program development. |
| **Hardware** |
| Easy and fast interchangeability between rotary and linear modules. |
| User-friendly operability. |
| Compactness. |
| Ease of cleaning. |
| Portability. |
| Low cost. |
| Use of recycling materials. |
| Autonomy. |
| Energy efficiency. |
| Cable fixing. |
| Noise. |

Table 4. Proposed Solutions

| **SOLUTIONS PROPOSAL** |
|---|
| **Software** |
| Provide more details in the graphical display. |
| Offer a more user-friendly touchscreen (e.g., adequate size of options and fonts). |
| **Hardware** |
| Reduce the device's size so it can be easily placed in any room. |
| Develop flexible components to increase usability and safety. |
| Develop an extra component to accommodate the patient's upper limb or lower limb, while moving it or in a resting position. |
| Hide the cables inside an architecture, and avoid sharp edges. |

## 4 Conclusion

To minimize the negative impacts of the PIS phenomenon on individual health and the social component and economic impact, a group of academic and business entities comes together to jointly develop a technical solution that responds to identified market failures with that respect.

This technical solution – the ABLEFIT device – provides customized physical exercises, in active and passive modes, for patients permanently or

temporarily bedridden or in a wheelchair. The device incorporates an intelligent platform for control, evaluation, and record of the patient's performance during the rehabilitation process, making possible the permanent assessment of the patient's status and thus contributing to an integrated knowledge of their condition by health professionals. Furthermore, it is also possible to generate simulation environments and create interactive models to stimulate and motivate the user.

A feasible contribution is thus expected to counteract the immobility syndrome and the morbidity and mortality associated with the complications resulting from prolonged inactivity or even a sedentary lifestyle that can be seen both in the elderly population and in adults and young people with some type of restriction of mobility or disability. Nevertheless, a third iteration is still required to overcome the limitations reported in the results of the second pre-clinical test. As such, a third prototype will be built, which will undergo rigorous clinical tests before being placed on the market. These results will briefly present.

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**Contribution of Individual Authors to the Creation of a Scientific Article (Ghostwriting Policy)**

-Rafael Bernardes, Vítor Parola, Remy Cardoso, Hugo Neves, and Arménio Cruz were responsible for the execution of pre-clinical tests and for paper writing.

-William Xavier was responsible for the execution of human-machine interfaces of both the first and second prototypes.

-Rúben Durães was responsible for the execution of the second prototype.

-Cândida Malça was responsible for the execution of the first prototype and for paper writing.

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**Ethics**

The study was approved by the Ethical Committee of the Health Sciences Research Unit: Nursing (UICISA:E), from the Nursing School of Coimbra (ESEnfC), reference nº P879_05_2022.

**Conflict of Interest**

The authors have no conflict of interest to declare.