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Ablefit: Development of an Advanced System for Rehabilitation

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Abstract: Bedridden patients risk presenting several problems caused by prolonged immobility, leading to a long recovery process. There is thus a need to develop solutions that ensure the implementation of physical rehabilitation programs in a controlled and interactive way. In this context, the ABLEFIT project aims to develop a medical device to physically rehabilitate bedridden patients with prolonged immobility. A partnership was established between the school of nursing, business enterprises and an engineering institute to develop a prototype. After creating the prototype, a pre-clinical experimental usability study was created using the user-centred multi-method approach (User and Human-Centered Design) to assess the device's functionality, ergonomics and safety. The pre-clinical stage was initiated with a sample of 12 health professionals (that manipulated the device's functionalities) and 10 end-users (who used the device). During the pre-clinical stage, the need to incorporate in the final version joint stabilizers was observed. Another important finding was the importance of the continuous monitorization of vital signs on Ablefit, namely, heart rate and SPO_2. Therefore, the development of the Ablefit system allows the monitoring of a set of variables and conditions inherent to immobility. At the same time, this device will be a dynamic solution (using gamification and simulation technologies) by generating personalized rehabilitation plans.

Keywords: rehabilitation; rehabilitation exercise; programs; bedridden persons

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1. Introduction

Immobility is a major public health concern, commonly triggering complications, such as pneumonia, pressure ulcers and deep vein thrombosis [1]. These complications are strongly related to hospital mortality rates or even post-discharge [2,3]. Additionally, hospitals can spend up to 25% of their internal resources just to manage bedridden patients [4].

The previously mentioned scenario, which is of great concern for patients and families and a potent disruptor of health services' economic balance, can be mitigated through an adequate and efficient physical rehabilitation approach. In fact, recent studies have highlighted that early mobilization and rehabilitation techniques, particularly respiratory exercises, are effective in improving physical function at discharge [5–7]. To date, technology has been a favourite ally to healthcare services [8], namely, rehabilitation technology, which aims to help people with physical disabilities increase their independence [9].

Among these, new devices have been produced to help bedridden patients maintain or increase their muscle tone, flexibility, range of motion and general function. A recent patent review [10] evidenced that devices have solely focused on lower limbs or both upper and lower limbs. It also highlighted that important features that were taken into consideration were modularity, flexibility and automation.

Several mechanical and electronic devices can aid in physically rehabilitating individuals with diseases or injuries. Some examples include exoskeletons and external mechanical devices that help strengthen and support body movements [11,12]. Another example is electrical stimulation therapy, which involves devices stimulating inactive muscles through controlled electrical impulses [13,14]. Virtual reality therapy is also available, using virtual reality to aid physical rehabilitation through interactive exercises [15–17]. Rehabilitation robots are computer-controlled mechanical devices that assist in physical rehabilitation through precise and repetitive movements [18,19]. Muscle strengthening devices, such as weights, resistance bands and exercise equipment, also play a role in rehabilitation by helping to strengthen specific muscles [20,21]. These are just a few examples, but many other devices can be used to aid in physical rehabilitation, depending on each patient's specific needs.

In light of the devices mentioned earlier, which only offer partial solutions, we aim to create an innovative device that is more multifaceted and allows for a more comprehensive approach to physical rehabilitation. Exoskeletons are mostly used for lower limb support, virtual reality helps with interactive exercises but is most suited for mobile individuals, electrical stimulation helps stimulate inactive muscles but does not offer much in terms of overall functionality, and muscle strengthening devices require the use of weights and resistance but is only suited for individuals who can perform movements. Most products in the rehabilitation robotics market can only complete part of the rehabilitation process, either serving only upper or lower limbs or only allowing rotational or linear movements, not both. They may use weights or resistance but leave out individuals who cannot perform movements and need passive mobilization, and most do not incorporate gamification to promote motivation [11–21].

Thereby, the Ablefit device aims to address these gaps with a modular structure that allows linear and rotational movements, as passive, active and resisted movements. Additionally, Ablefit comprises a gamification module, which includes real-time biofeedback during exercise and the ability to monitor vital signs and alert users when safety parameters are exceeded.

The development of new devices implies contrasting their features with experts' theoretical and practical knowledge [22]. The development process of the Ablefit prototype involved the participation of various experts, including rehabilitation nurses from the consortium, and consultation with external experts such as physiatrists, physical therapists and multiple rehabilitation nurses. The development of the device was also based on a previous study that mapped existing rehabilitation programs for this population through a scoping review, contributing to the development of a more sustainable prototype [23].

In this sense, this study aims to assess the usability of the developed prototype, particularly regarding its functionality, ergonomics and safety.

2. Materials and Methods

A pre-clinical usability study with an experimental user-centred design [24,25] and a multi-method approach was conducted. The data were analyzed using a mixed methodology: quantitative analysis of the empirical instruments (such as surveys) and qualitative analysis of the testimonies from the interviews.

2.1. Participants

Participants were recruited using the non-probabilistic purposive sampling technique. Study participants were divided into two distinct groups:

Group 1—professional users (manipulated and evaluated the device's functionalities): 12 health professionals. Considering that this sample requires people handling the machine from the care provider's perspective, health professionals with experience caring for bedridden people or/and senior adults were selected.

In this pre-clinical phase, the experts' professional users were considered healthcare professionals with experience caring for this population. A minimum experience of two years was considered to ensure the clinical experience to provide rich information. This criterion allowed us to have a diverse range of healthcare professionals, some with more clinical experience and others with less. There are professionals with a degree, some having a master's degree and also a PhD, providing a diverse range of professionals with varying levels of experience and education. Nonetheless, diversity also provides for a range of professionals, even based on their ages, who are more or less familiar with the technologies (an important component in this study).

Health professionals were shown the device's functionalities and how it could be manipulated to perform the planned exercises/movements; this included the mechanical learning of the device and introduction of end-users' data into the platform to program Ablefit. This process was accompanied by members of the research team (rehabilitation nurses) to clarify doubts and obtain feedback on the handling of the device.

Group 2—end-users (to whom the device was applied): 10 senior adults aged 65 years or over and in a healthy physical condition.

Participants were recruited using the following inclusion criteria:

- Health professionals—minimum academic qualifications of a degree and clinical experience in a hospital setting of 2 or more years.
- Senior adults—aged 65 years or over with a healthy physical condition.

It is relevant to reinforce the need to have two samples with different characteristics, as their use for the Abefit device is distinct—the person providing care (professional users) vs. the person receiving care (end-users/senior adults).

Health professionals or senior adults would be excluded from the study if they had had any previous contact with the Ablefit device and in the case of senior adults having any impeding physical condition.

Participants' records were kept confidential and anonymized following the general regulation on data protection (RGPD). The personal data of the participants were used exclusively for scientific research.

All participants signed the informed consent, free and clarified, being the present study authorized by the Ethics Committee of UICISA:E (P879_05_2022). Participants in this study were informed about the purpose of the study, procedures and possible benefits and risks. They were also informed that their participation was voluntary, with no penalty for non-participation.

The study occurred at ESEnfC (Laboratories) facilities in Coimbra, Portugal.

2.2. Medical Device (Ablefit)

Ablefit is a mechanical device composed of several models that can be removed or attached according to the convenience of the healthcare professional and rehabilitation goals. It is meant to be attached to the bed, allowing upper and lower limb mobilization with the supervision of a healthcare professional.

As distinctive and innovative features, it includes a touchscreen tablet embedded in the structure, which allows patient data input and the real-time visualization of biofeedback signals, such as heart rate (HR) and forces exerted. The main structure includes a metallic arm that the patient can use to perform exercises with different difficulties (active and active resistive movements). The device also includes a passive mode for the patient, where Ablefit performs the desired movement for the patient with the instructions provided by the healthcare professional. For the lower limbs, the device can attach an ergometer with the same options previously described (active or passive movements).

In terms of instructions for use, it is recommended that Class IIa Mds and CIass I can be used safely in the absence of instructions for use [26]. However, our device was accompanied by an instruction leaflet to help reduce the associated risks with its improper use (Figure 1).

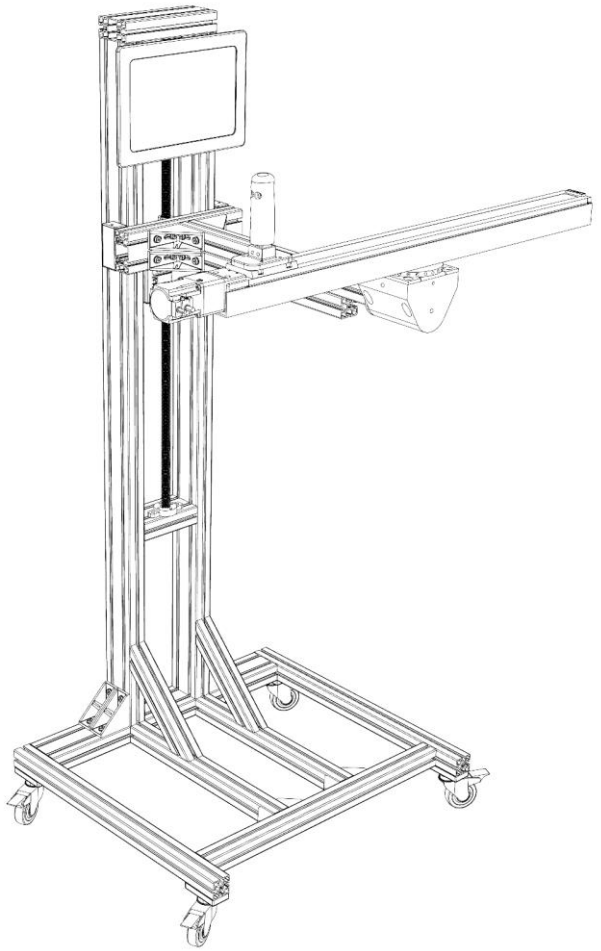

Figure 1. Schematic representation of Ablefit.

2.3. Pre-Clinical Usability Study

2.3.1. Professionals

We considered "Professionals" as the individuals that manipulated and evaluated the device's functionalities. All observations performed by these professionals were registered by the investigation team for further analysis. At the end of the evaluation sessions, the professionals were asked to fill out a usability questionnaire measuring 4 dimensions: usefulness; ease of use; ease of learning and satisfaction/intention of use). The Usability Questionnaire consisted of 42 items. It used a 7-point Likert response scale, where 1 point corresponds to "strongly disagree", and 7 points correspond to "strongly agree", with a maximum possible score of 294 points.

The usability questionnaire was developed in this context, considering several evaluation instruments, such as the Quebec User Evaluation of Satisfaction with Assistive Technology, System Usability Scale, After Scenario Questionnaire, USE Questionnaire, Post Study System Usability Questionnaire and Rating Scale Mental Effort [27–32]. These are all instruments for evaluating the usability of assistive technologies, providing a way to measure user satisfaction with a given product or system.

2.3.2. End-Users

We considered "End-users" as the individuals asked to perform the activities the screen/professional indicated.

The activity (rehabilitation plan) involved performing 2 series of 8 repetitions, with the flexion/extension of the elbow and shoulder being performed on the upper limb. On the lower limb, hip and knee flexion and extension were performed. The device allows passive (the device performs the movement for the person) and active mobilizations (the person conducts the move). In the implemented program, end-users tried out the two modes of use. The testing program had three components: (1) warm-up, (2) implementation of the defined plan and (3) relaxation. Vital signs, such as blood pressure (BP), heart rate and oxygen saturation (SPO2), were registered for each participant before and after using Ablefit. Height and weight were also registered for each participant (before using the Ablefit device), and both end-users and professionals filled out a sociodemographic questionnaire. The end-users conducted a semi-structured interview at the end of Ablefit utilization.

2.4. Data Analysis

An element of the investigation team transcribed the end-users semi-structured interview. Content analysis was performed according to Bardin's inductive approach [33,34]. Means (Ms), standard deviations (SDs) and frequencies were calculated for the quantitative data. The results of the usability questionnaire were charted.

3. Results

3.1. End-Users/Senior Adult

The end-users group consisted of 10 senior adults residing in Coimbra, aged between 69 and 89 years (M = 78.60; SD = 6.98), seven (70.0%) of whom were female. Regarding education, most participants completed the 4th grade, one the 9th grade and one had a bachelor's degree.

Of the 10 participants, only one had a significant experience of immobility in bed (between 1 and 2 months) after performing a total hip replacement on the right. Four of the participants (40%) participated in rehabilitation programs using devices, such as treadmills (exercise for lower limbs) or pulleys (exercise for upper limbs). In general, the participants reported improvement after this participation, namely, relief of knee pain or greater comfort and resistance when remaining in an orthostatic position.

A biometric assessment of each participant was performed, with weight ranging between 64.5 and 74.4 kg (M = 69.82 kg; SD = 4.39).

A biometric analysis was also performed before and after using Ablefit, according to the established protocol. Differences were not significant, highlighting only a slight average decrease of 4 bpm in HR after use. Referring to the mean values, the BP was 131.1/75.8 mmHg before using the device and 132.28/78 mmHg after. Concerning HR, it ranged from 68.5 bpm before and 64.5 after. Saturation was 95.9% before and 96.1% later.

Regarding the qualitative analysis performed on the end-users/senior adult interviews, after the data saturation that occurred with 8 participants, 5 categories were identified.

3.1.1. Device Security

The first category concerns device security, with end-users considering the device secure: "(. . .) for me it even had security (. . .). This is an important element." (IA53). "I think it's great; I don't see anything negative (. . .) I didn't identify anything that would put me in danger." (IP40). Another participant mentioned that "sometimes in the movement, I would start a few things, but the force was absolutely within my possibilities; it was not exaggerated" (JS36).

3.1.2. Ease of Use/Learning

Concerning the second category identified, participants referred to some difficulties associated with the device's ease of use. One participant mentioned: "sometimes I was not able to use this device." (IA53) or "It is better to have a professional in charge, helping" (JS36). They also mentioned that it is essential to have a prior explanation to know how to use the device—"At home, it has to be a person with information, correct... you have to know the material you are going to use" (JF50). The idea was reinforced by another participant when mentioning: "(. . .) No, no, I didn't find it complicated, and it's nothing scary (. . .) maybe there should be an explanation" (RN32). Thus, the importance of having a health professional present early when using the device and explaining how to use it was reinforced multiple times for excellent safety. The device's size turns out to be challenging to use "(. . .) if it were smaller" (MB44). They also suggested changes to the device in terms of simplicity were made—"maybe smaller and without wires, so the size and that iron (. . .)" (MP51).

3.1.3. Comfort

Most participants reported that they felt comfortable using the device: "For me, it was very good; it was easy" (CA39). Other elements reinforced this idea—"I had the essential comfort" (MB44) and "For me, it was even comfortable (...)" (IA53). However, they also revealed some concerns: "(. . .) with holding the handle they need more support (Figure 2)" (CA39). One participant could not use the handle due to arthrosis—"The arthrosis in my hands hurts a lot, I can't" (MP51).

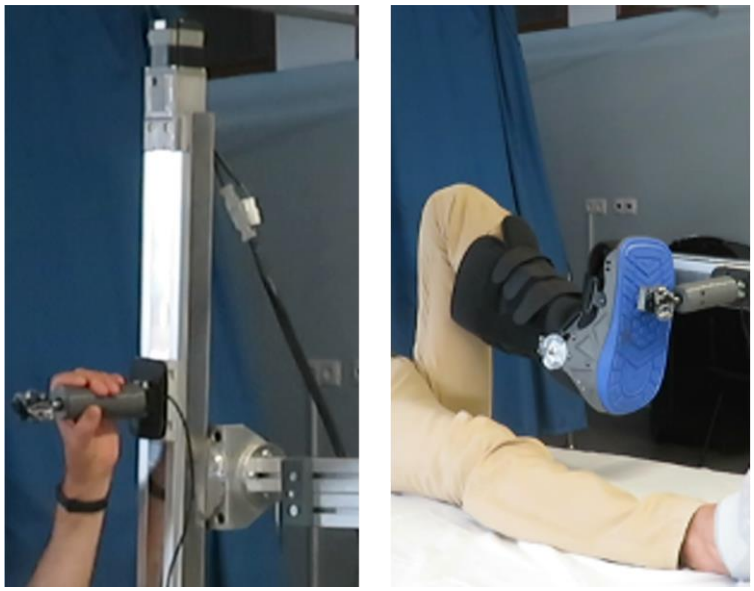

Figure 2. Ablefit handle for upper limbs (**left**) and Ablefit boot for lower limbs (**right**).

3.1.4. Movements

Concerning the allowed movements by the device (upper and lower limbs), the participants stated that it was essential for the device to have this versatility in use, which would allow it to be specific to the needs of each one—"At this moment, as I have in the leg, I think it was great. But that will depend on each one" (IP40). Other participants reinforced the importance of its multivalence—"(. . .) the leg is always very necessary for people, isn't it? To move, and the arm too, both things are very necessary" (CA39) and "I think it is useful in both" (JS36).

3.1.5. Benefits

Regarding this category, the participants considered the device helpful and an added value in the care provided to people. They mentioned that "(. . .) I think this will be very useful in the future" (CA39). An idea reinforced by the information that the device "(. . .) is great, I think it's good, and for those who really have difficulties (. . .) it helps her, it helps her, so in that regard, I think it will be great" (IP40), "The device is pleasant, it is modern and should be used a lot in the elderly with mobility difficulties. It is one of the fundamental things they could acquire" (MI41).

3.2. Professional User

Concerning the professional user, note that 12 health professionals aged between 23 and 59 years (M = 37.5; SD = 9.01) participated in this study, of which 11 were nurses and 1 a physiotherapist. The sample mainly consisted of female elements (58%), and professional experience had a minimum of 2 pre-established years and a maximum of 20 years. Regarding education, 6 (50%) completed a degree, 4 (33%) had a Master's degree and 2 (17%) had a PhD.

Regarding the usability questionnaire completed by professional users, it can be observed that the dimensions of the device (average score of 2.45 out of 6) and flexibility of use (3.67) were the ones that presented lower scores (Figure 3).

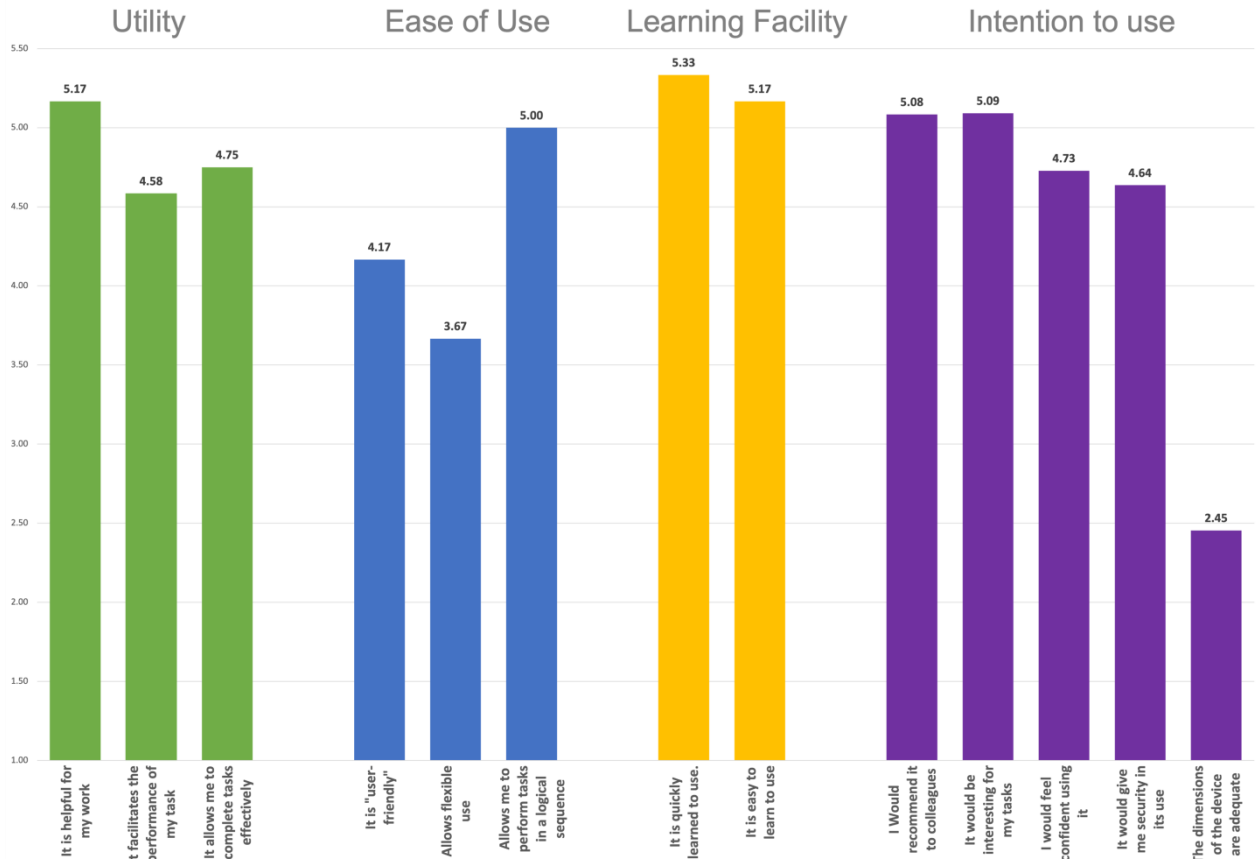

Figure 3. Professional usability questionaire.

Regarding the safety of using the device, the professionals mentioned that the strong point, considering the end-users of the device, was the possibility of defining the security force and monitoring the biometric data (image) ("Oxygen saturation is a parameter that should be bear in mind" (NC79)).

Considering professionals who will use it, the risk of professional falls (due to existing wires in the current prototype) must be considered. They also stated that the device must be stable and safe, requiring prior training from the professional.

About functionality (transport, storage, handling), 50.0% of professionals said that the equipment at present is too large (for handling and storage)—"I don't think it is functional in terms of size because we don't have space in the wards" (JB90). They reinforced the concern with the hygiene of the components ("To clean the services is not adequate" (FP82)) and with the positioning of the equipment with the bed.

Concerning the positioning of the upper limbs, 75.0% of the professionals were concerned about the lack of fasteners for hand and wrist positioning (Figure 2)—"Fixation with a glove with a velcro system, the glove that is being fastened, eventually cover the wrist to stabilize when you are doing the flexion movement" (NC79). For the lower limbs, 33.0% thought the boot did not guarantee the necessary stability to the hip, foot and knee (Figure 2)—"The idea is that the foot is not well supported" (ES90).

Concerning the allowed movements, 42.0% of the professionals mentioned limitations in the amplitudes of upper limb exercises. However, they also reinforced that "Although the amplitudes are not complete, any amplitude is better than none" (NC79).

A total of 58.0% of the professionals referred to the potential risk (joint and muscle) that the device presented some joint instability and needed joint support. As a result, there is a risk of the internal/external rotation of the thigh—"The joints are not protected, and this could lead to injury" (JB90).

Regarding the main limitations, the professionals stated that, for the patient, physical and cognitive conditions could limit the use of the device. For professional use, the noise of the equipment was one of the aspects highlighted. They stated that an attempt should be made to obtain a final prototype that is simpler and easier to use. They also recommended the proximity of the software control from the device. Additionally, the bar used to perform the exercise had a dimension that made access difficult for the patient outside a hospital setting—"It would have to be much more user-friendly; I see this more for a hospital than for a home (. . .)" (NC79).

Concerning the benefits of using Ablefit, 33.0% considered it a good assistant to a professional. In the future, the device could help compensate for the lack of professionals. Furthermore, they mention that it is one of the few devices that allow the upper limbs to be exercised—"You can have a person working assisted by the device and the professional assisting another" (NC79).

During the pre-clinical experimental study, the research team observed some restraints regarding the software and hardware. The practical problems and proposed solutions are described in Table 1.

Table 1. Research team observations.

OBSERVED PROBLEM	SOLUTION PROPOSAL
Software	**Software**
1. In the person's active mode, the definitions of maximum and minimum do not limit the range of movements;	1. Limit the maximum and minimum amplitudes, similar to the passive mode;
2. When there is excessive force, the program suspends, and it is not possible to resume;	2. Possibility of resuming exercise in case of suspension due to too much force;
3. When the program is cancelled in the software, the equipment's response is slow;	3. Cancellation must have an immediate effect on the machine for security reasons;
4. When defining the number of repetitions and the time the machine has to enter the speed.	4. The software should automatically determine the speed.

Table 1. *Cont.*

OBSERVED PROBLEM	SOLUTION PROPOSAL
Hardware	**Hardware**
1. The handle does not allow rotation during movement, which poses a risk of injury to the wrist;	1. The handle must be rotatable to follow the movement of the wrist;
2. There are no fasteners for the hand, which causes wrist instability;	2. Develop a hand gripper that stabilizes the wrist;
3. Thigh and knee instability.	3. Develop equipment for thigh and knee stabilization.

4. Discussion

This study addressed different dimensions of our advanced system for rehabilitation using Ablefit, such as safety, functionality and ergonomics, from the perspective of both end-user and professionals.

4.1. Safety

Safety evaluation is mandatory for any new medical device [35]. This aspect is relevant to Ablefit since it targets a frail population: bedridden persons that are mostly older and have comorbidities [2]. In this study, end-users felt secure with Ablefit, and no adverse effect was observed. Health professionals stressed the importance of vital signs' monitorization incorporated on Ablefit, namely, HR and SPO2. In a scoping review mapping the existing physical rehabilitation programs for bedridden patients with prolonged immobility, Cardoso et al. [23] concluded that the most common parameters accessed in these programs were vital signs, namely, heart and respiratory rates, and that their use was essential for monitoring the safety of studies focusing on interventions for bedridden patients. Together, these data reinforce the importance of continuously monitoring HR and SPO_2 when using Ablefit (biofeedback). Moreover, the Ablefit platform allows the professional to define maximums and minimums for HR and sound an alarm whenever these values are exceeded. Health professionals were also concerned about joint stability and the positioning of the limbs when using Ablefit. This scoping review also noticed the absence of specific information regarding muscular and osteoarticular risks, specifically in controlling joint stability on the robotic devices mapped. Therefore, we proposed the use/development of equipment to stabilize joints and limbs when using our device.

Regarding the professionals' safety, the main risk identified was the risk of falls due to existing wires and the stability of the device [22,36]. Taking this into account, the most recent prototype hides the cables and is more stable, which increases the safety of Ablefit for professionals manipulating the device and anyone around it. Another concern of the professionals and end-users was the need for training to use Ablefit. Instructions will accompany the final version of this device, and training will be provided to address this concern. Nevertheless, the questions addressing the learning facility in the usability questionnaire had high scores (higher than 5 in a maximum of 7 points possible).

4.2. Functionality and Ergonomy

Regarding the functionality of Ablefit, one of the most negative points stated by both end-users and professionals was the device's size and flexibility, which could make the transport, storage and handling of the device difficult in hospital wards, namely, the positioning of the equipment with the bed. As Zamzam et al. [37] mentioned, the utilization level can be affected by the location of the equipment and the situation in which the equipment is used. The device needs to have a user-friendly design [35]. Professionals were also concerned with the cleaning and noise of the device. Therefore, the update of Ablefit should be easier to manipulate in a more silent area and constructed with accessible cleaning materials. Regarding its functionality in mobilizing end-user limbs, almost half of the professionals were concerned with the limitations in the amplitudes of the upper

limb exercises; however, as stated by one of the professionals, any amplitude is better than none. As mentioned by Winnard et al. [38], movements at all amplitudes is beneficial, even if they are inferior at lower amplitudes.

Regarding the ergonomy and comfort of Ablefit, most participants reported that they felt comfortable using the device. However, the end-users, professionals and the research team pointed out the need for better fixation and positioning of the hand, wrist and foot. Thus, it is necessary to develop equipment to stabilize these parts for a safer, more comfortable and more effective use of Ablefit. As Bitkina et al. [35] mentioned, adherence to usability and ergonomic design principles is one aspect of the effective development of medical equipment.

4.3. Benefits of Ablefit

Both end-users and professionals considered Ablefit helpful and an added value in the care provided to people. Namely, some professionals stated that Ablefit could help compensate for the lack of professionals. Furthermore, they mentioned that it was one of the few devices that allowed the upper limbs to be exercised. Our scoping review showed that most of the programs were directed to the lower limbs [23], evidencing a lack of a more global approach. Ablefit allows the mobilization of both upper and lower limbs, actively and passively, and training both the musculoskeletal and cardiovascular domains. In addition, Ablefit will have a gamification component to motivate the user and a biofeedback system that will allow the health professional to follow the evolution of the user over time, namely, in terms of vital signs and force.

The gamification feature incorporated in Ablefit has two main functions: real-time feedback and motivation. As for the first one, during any active or passive movement, the patient is able to observe how fast and strong the movement being performed is. This is possible through a vehicle that moves throughout the movement cycle. Regarding the latter, and according to the goals negotiated between the professional, caregiver and patient, the movement should be necessary to follow a second vehicle, which represents the functional goal.

Another benefit of the Ablefit system is the generation of personalized rehabilitation plans.

4.4. Limitations

Some limitations may be associated with the fact that the pre-clinical experimental study was not developed in a hospital setting, but in a controlled environment, which may have resulted in the absence of some important variables when using Ablefit. Additionally, the type of participants, specifically the end-users, may not be fully representative of the majority of the population of senior adults due to the moderate to high level of literacy observed. Additionally, this is a pre-clinical study; therefore, it was condcuted with a small sample size, which was a limitation. However, the aim was to test the device's functionality, ergonomics and safety and not to generalize the results.

This was not a study aimed at evaluating the effect of the device used on the senior population, but rather to assess the device's functionality, ergonomics and safety. For this reason, no statistical analysis compared means before and after the intervention. The goal was to use the information from the pre-clinical study to make adjustments to the existing prototype and then conduct clinical research to effectively evaluate the intervention's effect.

5. Conclusions

The ABLEFIT project is a novel solution to address the challenge of physical rehabilitation for bedridden patients with prolonged immobility. Through the collaboration of nursing, business and engineering fields, a prototype was developed that monitors the key variables and conditions related to immobility and provides personalized rehabilitation plans through gamification and simulation technologies. The pre-clinical study using the user-centred multi-method approach demonstrates the device's functionality, ergonomics

and safety. It highlights the importance of incorporating joint stabilizers and promoting the motivation and awareness of the recovery process.

Participants considered the device secure, but found it challenging to use and preferred to have a professional present to explain how to use it. They felt comfortable using the device but had concerns with holding the handle. Participants found the device versatile and helpful in their care. Professional users also considered the device to help improve mobility and found it easy to use and adjust.

The ABLEFIT device has the potential to revolutionize physical rehabilitation for bedridden patients, providing a controlled and interactive solution to improve the recovery process and outcomes.

Future Directions

This study helped the consortium develop a new optimized prototype capable of addressing many of the issues observed during this pre-clinical experimental study. A new pre-clinical study will be developed to understand the impact of the changes made in the same and new participants.

Added value was found in gamification and the motivation generated by a feedback system to the end-user, demonstrating the need to develop person-centred solutions.

Additional future directions include developing effective methods to evaluate and measure robotic rehabilitation outcomes and conducting case studies to assess the device's efficacy for different types of injuries or medical conditions. Another future goal is to integrate additional technologies, such as artificial intelligence, to personalize therapy further. These incorporations could expand the application to other types of treatment beyond physical rehabilitation, such as cognitive rehabilitation. One of the steps is partnering with healthcare institutions and professionals to implement and integrate the device into rehabilitation programs.

Thus, Ablefit has the potential to become a state-of-the-art device that will be the gold standard for robotic assistive rehabilitation.

6. Patents

118367 SISTEMA MODULAR DE REABILITAÇÃO FÍSICA, SEUS MÉTODOS E USOS (MODULAR PHYSICAL REHABILITATION SYSTEM, ITS METHODS AND USES).

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References

1. Wu, X.; Li, Z.; Cao, J.; Jiao, J.; Wang, Y.; Liu, G.; Liu, Y.; Li, F.; Song, B.; Jin, J.; et al. The Association between Major Complications of Immobility during Hospitalization and Quality of Life among Bedridden Patients: A 3 Month Prospective Multi-Center Study. *PLoS ONE* **2018**, *13*, e0205729. [CrossRef] [PubMed]
2. Cao, J.; Wang, T.; Li, Z.; Liu, G.; Liu, Y.; Zhu, C.; Jiao, J.; Li, J.; Li, F.; Liu, H.; et al. Factors Associated with Death in Bedridden Patients in China: A Longitudinal Study. *PLoS ONE* **2020**, *15*, e0228423. [CrossRef] [PubMed]
3. Jiao, J.; Li, Z.; Wu, X.; Cao, J.; Liu, G.; Liu, Y.; Li, F.; Zhu, C.; Song, B.; Jin, J.; et al. Risk Factors for 3-Month Mortality in Bedridden Patients with Hospital-Acquired Pneumonia: A Multicentre Prospective Study. *PLoS ONE* **2021**, *16*, e0249198. [CrossRef]
4. Salz, I.W.; Carmeli, Y.; Levin, A.; Fallach, N.; Braun, T.; Amit, S. Elderly Bedridden Patients with Dementia Use over One Quarter of Resources in Internal Medicine Wards in an Israeli Hospital. *Isr. J. Health Policy Res.* **2020**, *9*, 21. [CrossRef]
5. Kanejima, Y.; Shimogai, T.; Kitamura, M.; Ishihara, K.; Izawa, K.P. Effect of Early Mobilization on Physical Function in Patients after Cardiac Surgery: A Systematic Review and Meta-Analysis. *Int. J. Environ. Res. Public Health* **2020**, *17*, 7091. [CrossRef]
6. Zhang, L.; Hu, W.; Cai, Z.; Liu, J.; Wu, J.; Deng, Y.; Yu, K.; Chen, X.; Zhu, L.; Ma, J.; et al. Early Mobilization of Critically Ill Patients in the Intensive Care Unit: A Systematic Review and Meta-Analysis. *PLoS ONE* **2019**, *14*, e0223185. [CrossRef] [PubMed]
7. Coles, S.J.; Erdogan, M.; Higgins, S.D.; Green, R.S. Impact of an Early Mobilization Protocol on Outcomes in Trauma Patients Admitted to the Intensive Care Unit: A Retrospective Pre-Post Study. *J. Trauma Acute Care Surg.* **2020**, *88*, 515–521. [CrossRef]
8. Alaparthi, G.K.; Gatty, A.; Samuel, S.R.; Amaravadi, S.K. Effectiveness, Safety, and Barriers to Early Mobilization in the Intensive Care Unit. *Crit. Care Res. Pract.* **2020**, *2020*, 7840743. [CrossRef]
9. Aqel, M.O.A.; Brabazon, D.; Issa, A.; Elsharif, A.A.; Ghaben, S.; Alajerami, Y.S.M.; Khalaf, H.; Alrayyes, T.; Bratanov, D.; Debeljak, M. Review of Recent Research Trends in Assistive Technologies for Rehabilitation. In Proceedings of the 2019 International Conference on Promising Electronic Technologies (ICPET), Gaza, Palestine, 23–24 October 2019; pp. 16–21. [CrossRef]
10. Bernardes, R.A.; Santos-Costa, P.; Sousa, L.B.; Graveto, J.; Salgueiro-Oliveira, A.; Serambeque, B.; Marques, I.; Cruz, A.; Parreira, P. *Innovative Devices for Bedridden Older Adults Upper and Lower Limb Rehabilitation: Key Characteristics and Features*; Springer: Cham, Switzerland, 2020; Volume 1185, ISBN 9783030414931.
11. Masengo, G.; Zhang, X.; Dong, R.; Alhassan, A.B.; Hamza, K.; Mudaheranwa, E. Lower Limb Exoskeleton Robot and Its Cooperative Control: A Review, Trends, and Challenges for Future Research. *Front. Neurorobot.* **2023**, *16*, 913748. [CrossRef]
12. Zhou, J.; Yang, S.; Xue, Q. Lower Limb Rehabilitation Exoskeleton Robot: A Review. *Adv. Mech. Eng.* **2021**, *13*, 168781402110118. [CrossRef]
13. Sharififar, S.; Shuster, J.J.; Bishop, M.D. Adding Electrical Stimulation during Standard Rehabilitation after Stroke to Improve Motor Function. A Systematic Review and Meta-Analysis. *Ann. Phys. Rehabil. Med.* **2018**, *61*, 339–344. [CrossRef]
14. Toh, S.F.M.; Chia, P.F.; Fong, K.N.K. Effectiveness of Home-Based Upper Limb Rehabilitation in Stroke Survivors: A Systematic Review and Meta-Analysis. *Front. Neurol.* **2022**, *13*, 964196. [CrossRef]
15. Gumaa, M.; Rehan Youssef, A. Is Virtual Reality Effective in Orthopedic Rehabilitation? A Systematic Review and Meta-Analysis. *Phys. Ther.* **2019**, *99*, 1304–1325. [CrossRef]
16. Patsaki, I.; Dimitriadi, N.; Despoti, A.; Tzoumi, D.; Leventakis, N.; Roussou, G.; Papathanasiou, A.; Nanas, S.; Karatzanos, E. The Effectiveness of Immersive Virtual Reality in Physical Recovery of Stroke Patients: A Systematic Review. *Front. Syst. Neurosci.* **2022**, *16*, 880447. [CrossRef] [PubMed]
17. de Rooij, I.J.M.; van de Port, I.G.L.; Meijer, J.-W.G. Effect of Virtual Reality Training on Balance and Gait Ability in Patients With Stroke: Systematic Review and Meta-Analysis. *Phys. Ther.* **2016**, *96*, 1905–1918. [CrossRef] [PubMed]
18. Li, L.; Tyson, S.; Weightman, A. Professionals' Views and Experiences of Using Rehabilitation Robotics With Stroke Survivors: A Mixed Methods Survey. *Front. Med. Technol.* **2021**, *3*, 780090. [CrossRef] [PubMed]
19. Qassim, H.M.; Wan Hasan, W.Z. A Review on Upper Limb Rehabilitation Robots. *Appl. Sci.* **2020**, *10*, 6976. [CrossRef]
20. Hurst, C.; Sayer, A.A. Improving Muscle Strength and Physical Function in Older People Living with Sarcopenia and Physical Frailty: Not All Exercise Is Created Equal. *J. R. Coll. Physicians Edinb.* **2022**, *52*, 166–171. [CrossRef]
21. Bårdstu, H.B.; Andersen, V.; Fimland, M.S.; Aasdahl, L.; Raastad, T.; Cumming, K.T.; Sæterbakken, A.H. Effectiveness of a Resistance Training Program on Physical Function, Muscle Strength, and Body Composition in Community-Dwelling Older Adults Receiving Home Care: A Cluster-Randomized Controlled Trial. *Eur. Rev. Aging Phys. Act.* **2020**, *17*, 11. [CrossRef]
22. Dumas, J.S.; Fox, J.E. Usability Testing. In *Human Computer Interaction Handbook. Fundamentals, Evolving. Technologies, and Emerging Applications*, 3rd ed.; CRC Press: Boca Raton, FL, USA, 2012; pp. 1221–1241. [CrossRef]
23. Cardoso, R.; Parola, V.; Neves, H.; Bernardes, R.A.; Duque, F.M.; Mendes, C.A.; Pimentel, M.; Caetano, P.; Petronilho, F.; Albuquerque, C.; et al. Physical Rehabilitation Programs for Bedridden Patients with Prolonged Immobility: A Scoping Review. *Int. J. Environ. Res. Public Health* **2022**, *19*, 6420. [CrossRef]
24. Johnson, S.G.; Potrebny, T.; Larun, L.; Ciliska, D.; Olsen, N.R. Usability Methods and Attributes Reported in Usability Studies of Mobile Apps for Health Care Education: Scoping Review. *JMIR Med. Educ.* **2022**, *8*, e38259. [CrossRef] [PubMed]
25. Sylvain, F.; Chaniaud, N. Multi-User Centered Design: Acceptance, User Experience, User Research and User Testing. *Theor. Issues Ergon. Sci.* **2023**, 1–16. [CrossRef]
26. European Parliament. Council of the European Union Regulation (Eu) 2017/745 of the European Parliament and of the Council on Medical Device Regulation—Annex I, Section 23.1(D). *Off. J. Eur. Union* **2017**, *60*, 1–175.

27. de Carvalho, K.E.C.; Gois Júnior, M.B.; Sá, K.N. Tradução e Validação Do Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0) Para o Idioma Português Do Brasil. *Rev. Bras. Reumatol.* **2014**, *54*, 260–267. [CrossRef]
28. Kortum, P.T.; Bangor, A. Usability Ratings for Everyday Products Measured With the System Usability Scale. *Int. J. Hum. Comput. Interact.* **2013**, *29*, 67–76. [CrossRef]
29. Lewis, J.R. Psychometric Evaluation of an After-Scenario Questionnaire for Computer Usability Studies. *ACM SIGCHI Bull.* **1991**, *23*, 78–81. [CrossRef]
30. Lewis, J.R. Psychometric Evaluation of the PSSUQ Using Data from Five Years of Usability Studies. *Int. J. Hum. Comput. Interact.* **2002**, *14*, 463–488. [CrossRef]
31. Rosa, A.F.; Martins, A.I.; Costa, V.; Queiros, A.; Silva, A.; Rocha, N.P. European Portuguese Validation of the Post-Study System Usability Questionnaire (PSSUQ). In Proceedings of the 2015 10th Iberian Conference on Information Systems and Technologies (CISTI), Aveiro, Portugal, 17–20 June 2015; pp. 1–5.
32. Ghanbary Sartang, A.; Ashnagar, M.; Habibi, E.; Sadeghi, S. Evaluation of Rating Scale Mental Effort (RSME) Effectiveness for Mental Workload Assessment in Nurses. *J. Occup. Health Epidemiol.* **2016**, *5*, 211–217. [CrossRef]
33. Mendes, R.M.; Miskulin, R.G.S. Content Analysis as a Methodology. *Cad. Pesqui.* **2017**, *47*, 1044–1066. [CrossRef]
34. Vears, D.F.; Gillam, L. Inductive Content Analysis: A Guide for Beginning Qualitative Researchers. *Focus Health Prof. Educ. A Multi-Prof. J.* **2022**, *23*, 111–127. [CrossRef]
35. Bitkina, O.V.; Kim, H.K.; Park, J. Usability and User Experience of Medical Devices: An Overview of the Current State, Analysis Methodologies, and Future Challenges. *Int. J. Ind. Ergon.* **2020**, *76*, 102932. [CrossRef]
36. Koppelaar, E. *Use and Effect of Ergonomic Devices in Healthcare*; Erasmus University Rotterdam: Rotterdam, The Netherlands, 2017; Volume 60, ISBN 9789461693518.
37. Zamzam, A.H.; Abdul Wahab, A.K.; Azizan, M.M.; Satapathy, S.C.; Lai, K.W.; Hasikin, K. A Systematic Review of Medical Equipment Reliability Assessment in Improving the Quality of Healthcare Services. *Front. Public Health* **2021**, *9*, 753951. [CrossRef] [PubMed]
38. Winnard, A.; Debuse, D.; Wilkinson, M.; Samson, L.; Weber, T.; Caplan, N. Movement Amplitude on the Functional Re-Adaptive Exercise Device: Deep Spinal Muscle Activity and Movement Control. *Eur. J. Appl. Physiol.* **2017**, *117*, 1597–1606. [CrossRef] [PubMed]

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