MEDICAL DEVICE FOR REHABILITATION AFTER PROXIMAL FEMUR FRACTURE: USABILITY STUDY

Dispositivo médico para reabilitação pós fratura do femur proximal: estudo de usabilidade

Dispositivo médico para rehabilitación tras fractura de fémur proximal: estudio de usabilidad

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ABSTRACT

Background: the Proximal Femur Fracture (PFF) is a serious public health concern, and the ABLEFIT Medical Device (MD) may be an added asset in the patient's process of rehabilitation after PFF. **Objectives:** to assess usability and ergonomics of the ABLEFIT for patient rehabilitation after PFF. **Methodology:** a descriptive observational study, using a mixed methodology, with data sourcing through two focus groups and usability questionnaire. Focus groups made up of eight participants each, one group with end users and one with Nurses Specialized in Rehabilitation Nursing (NSRN). All ethical principals were met. The quantitative data were analyzed using the Statistical Package for the Social Sciences (SPSS) v25 software, in addition to content analysis technique for focus groups. **Results:** the descriptive analysis of the quantitative data shows a positive appreciation, with higher scores in group A. Overall, participants considered the device to be useful for patient rehabilitation after PFF. Some group B participants perceived the learning process and usability of the medical device as complex. **Conclusion:** this study allowed to assess usability and improvement of the ABLEFIT for patient rehabilitation after PFF, and to contribute to better quality in Rehabilitation Nursing care services.

Keywords: medical device; exercise therapy; proximal femur fractures; usability

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Como referenciar:
Domingues, F.L., (2023). Dispositivo médico para reabilitação pós fratura do fémur proximal: estudo de usabilidade. *Revista de Investigação & Inovação em Saúde*, 6(2), 63-77. https://doi:10.37914/riis.v6i2.380

Recebido para publicação: 10/03/2023
Aceite para publicação: 10/09/2023

RESUMO

Enquadramento: a Fratura do Fémur Proximal (FFP) é um grave problema de saúde pública, o Dispositivo Médico (DM), ABLEFIT, poderá trazer mais-valias no processo de reabilitação da pessoa pós FFP. **Objetivos:** avaliar a usabilidade e ergonomia do ABLEFIT para a reabilitação da pessoa pós FFP. **Metodologia:** estudo observacional descritivo, metodologia mista. Recolha de informação através de dois grupos focais e questionário de usabilidade. Grupos focais de oito participantes, um de utilizadores finais, e outro de Enfermeiro Especialista de Enfermagem de Reabilitação (EEER). Foram cumpridos todos os princípios éticos. Para análise dos dados quantitativos foi utilizado o programa informático Statistical Package for the Social Sciences (SPSS) v25, e a técnica de análise de conteúdo para os grupos focais. **Resultados:** da análise descritiva dos resultados quantitativos, evidencia-se uma apreciação positiva, pontuações mais elevadas no grupo A. Globalmente, consideram o dispositivo útil na reabilitação da pessoa pós FFP. Alguns dos participantes do grupo B, tem perceção de que a aprendizagem e utilização do DM é complexa. **Conclusão:** este estudo permitiu aferir a usabilidade e aperfeiçoamento do ABLEFIT na reabilitação da pessoa pós FFP, e contribuir para a prestação de cuidados de Enfermagem de Reabilitação de maior qualidade.

Palavras chave: dispositivo médico; terapia por exercício; fraturas proximais do fémur; usabilidade

RESUMEN

Marco contextual: la Fractura de Fémur Proximal (FFP) es un grave problema de salud pública, el Dispositivo Médico, *ABLEFIT*, puede aportar un valor agregado en el proceso de rehabilitación de la persona después de la FFP. **Objetivo:** evaluar la usabilidad y la ergonomía de ABLEFIT para la rehabilitación post-FFP. **Metodología:** Estudio observacional de carácter descriptivo, con recurso a metodología mixta. La información fue recogida por medio de dos grupos focales y un cuestionario de usabilidad. Los grupos focales formados por ocho participantes, uno de usuarios finales y otro de Enfermera Especialista en Enfermería de Rehabilitación (EEER). Se respetaron todos los principios éticos. Para el análisis de los datos cuantitativos se utilizó el programa informático Statistical Package for the Social Sciences (SPSS) v25, y la técnica de análisis de contenido específica en el caso de grupos focales. **Resultados:** del análisis descriptivo realizado a los resultados cuantitativos fue posible observar a existencia de una apreciación positiva, con puntuaciones más altas en el grupo A. En general, consideran útil el dispositivo en la rehabilitación de la persona después de la PFC. Algunos de los participantes del grupo B perciben que el aprendizaje y uso del DM es complejo. **Conclusiún:** este estudio permitió evaluar, por un lado, la usabilidad y la mejoría de *ABLEFIT* en la rehabilitación de personas después de un PFC y por otro, contribuye para la prestación de cuidados de Enfermería de Rehabilitación de mayor calidad.

Palabras claves: dispositivo médico; terapia de ejercicio; fracturas de fémur proximal; usabilida

INTRODUCTION

The Proximal Femur Fracture (PFF) is one the major and most serious concerns associated with aging and public health, with high mortality, morbidity and functional disability rates, having a negative impact on the quality of life of the elderly (Felicissimo & Branco, 2017; Santos, 2010; Silva et. al., 2018). In this context, Nurses Specialized in Rehabilitation Nursing (NSRN) have the technical skills and knowledge in patient rehabilitation to play a key role, as their early, focused intervention, through the implementation of a rehabilitation program, allows to reverse complications (Regulamento nº 392/2019 da Ordem dos Enfermeiros, 2019).

On the other hand, implementing an adequate rehabilitation plan with the use of the innovative ABLEFIT device, developed for health purposes in the field of rehabilitation and designed to carry out physical exercise in bed, may be an added asset in Motor Functional Rehabilitation, while also contributing to reduce hospitalization times, hospital costs and to improve health. Research and innovation are increasingly valued in today's health sector, allowing to develop highly innovative diagnostic products and treatments for countless diseases (Agência para o Investimento e Comércio Externo de Portugal [AICEP], 2016a). Investment in research and innovation in the field of rehabilitation allows for accurate knowledge of phenomena due to the rigor in methods and techniques, adding great contribution to this professional activity, as well as recognition and validation of the health profession. Overall, this usability study follows the Human-Centre Design model in which the product's development process is entirely focused on end users, together with the Technology Acceptance Model (TAM), centered on factors influencing people's behavior regarding the acceptance of a new technology. The study's main goal is to assess the usability and ergonomics of the ABLEFIT medical device prototype for patient rehabilitation after PFF.

Data on the Portuguese reality, alongside the scarce existence of published studies on this topic, reflect the utmost need for research development in this field. Moreover, Rehabilitation Nursing entails a greater involvement and participation of NSRN in research projects, as well as the need to incorporate new findings in this clinical practice (Regulamento nº392/2019 da Ordem dos Enfermeiros, 2019).

BACKGROUND/THEORETICAL FRAMEWORK

PFFs are associated with high morbidity and mortality rates, considered an orthopedic "epidemic" and a serious public health concern, with a negative impact on people's quality of life due to the inherent functional disability, as only 50% of elderly resume pre-fracture Daily Life Activities (DLA) (Laires et al., 2015). According to estimates by the Portuguese Directorate-General for Health (DGS – *Direção-Geral da Saúde*), in 2006, there were 9532 femoral neck fractures in Portugal, which consumed circa 52 million euros, in differentiated health care alone. Thus, PFFs represent a dependence-triggering event in selfcare, with major repercussions in the quality of life of the elderly and family members who care for them, as well as an economic challenge due to the high related costs (Felicissimo & Branco, 2017; Santos, 2010). The Self-Care Deficit Nursing Theory by Dorothea Orem determines when nursing care is necessary or not, whether there is a need to assist others in the provision

of self-care, that is, if there is a need for nursing care (Soares, 2019). According to this theory, the basic limitations resulting from PFF are health deviation self-care requisites, with a need for therapeutic self-care (Orem, 2001, p. 223). In turn, NSRN have the technical skills and knowledge in patient rehabilitation to play a key role, and the sooner NSRN can intervene through a rehabilitation program, the higher the chances to reverse complications after PFF. NSRN play a crucial role in the rehabilitation process throughout the several stages of the surgical process (Soares, 2019). The technical skills and knowledge of NSRN allow them to determine motor function, changes in functionality, establish diagnosis, design and implement training plans for motor performance, maximizing the patient's potential for recovery and promoting independence in DLA (Regulamento nº392/2019 da Ordem dos Enfermeiros, 2019).

Infarmed (2016), the Portuguese National Authority of Medicines and Health Products, defines Medical Device as any instrument, device, equipment, software, material or article used alone or in combination with diagnostic or therapeutic purposes for human use. Among others, these enable the prevention, control and treatment of illness, as well as alleviation or compensation for injury or disability.

Taking into consideration the Regulation of Quality Standards in Specialized Care in Rehabilitation Nursing, a structured rehabilitation program upon survey of patients' needs after FPP, combined with innovative Medical Devices that enable the performance of physical exercise sessions, can be advantageous to optimize the rehabilitating process, with benefits for injured patients, and for NSRN as instruments to facilitate rehabilitation care (Regulamento n.º 350/2015 da Ordem dos Enfermeiros, 2015).

The health sector in Portugal is placing more and more value on research and innovation, claiming its international recognition. Investment in technology in this sector in Portugal allows to enhance its notoriety. Technology has proven to be a strong ally, enabling the highly innovative development of diagnostic products and illness treatment (AICEP, 2016a). In an increasingly technological world, the health sector in Portugal is achieving a remarkable growth, both national and internationally (AICEP, 2016b).

The interest in reaching better care at low costs makes way for the creation of equipment developed within academic projects, which may suppress this need in the current market (Costa et al., 2018). According to the literature, the most approached Medical Device in rehabilitation programs is the ergometer, with variations for the upper and lower limbs (Torres et al., 2016; Trevisan et al., 2015). However, the existing devices available in the market are bulky and of hospital use (Dedov & Dedova, 2013).

The development of an MD follows the norms set by the European Parliament and other internationally standards, which regulate medical devices with reference to functional performance, safety parameters and the products' technical qualities (International Organization for Standardization [ISO], 2018, 2019a, 2019b; Regulamento 2017/745 da União Europeia, 2017).

When conceptualizing and developing a technology, the identification and comprehension of user opinion regarding its acceptance and use allows to not only reduce possible user-resistance, but also increase its effective use (Parreira et al., 2018). As of now, the most

quoted approached to assess usability is one centered on the user, the Human-Centered Design (HCD) put forward by Harte (2017). This designation, on account of being centered on the people for whom the solutions are created, sets specific procedures to be implemented in this initial stage of the device development, addressing their needs and abilities, product safety and its experience. The HCD allows for a methodological exploration, resorting to new and emerging procedural models, factoring in the relevance of user functional knowledge.

Throughout the process of creating solutions, the researcher changes a from concrete to abstract thought pattern, identifying topics and opportunities, later returning to a concrete pattern with solutions and prototypes, which paves way for innovative ideas to arise and meet users' needs, while also considering financial sustainability. According to Harada et. al. (2016), recent studies regarding design development show there is a heightened attention to human aspects, as this approach is increasingly more current. This approach is supported by Roma (2016), for whom a successful Medical Device must be efficient, safe, effective, reliable and meet the following requirements: to be Useful, Efficient, Effective, Satisfactory, Easy to Learn, and Accessible.

On the other hand, the Technology Acceptance Model (TAM), a theory put forward by Davis in 1979, enables a deeper analysis of factors influencing people's behavior, perceived usefulness and perceived ease of use, in regards to the acceptance of a new technology (Aguiar, 2016).

People's perceived usefulness regarding the use of a new technology, whether it will be useful to them or not, may lead to a greater intention in use. In turn, ease of use in any technology is a determining factor so that using said technology is not too complicated. The correlation between these two factors allows for a greater intention to accept the technology and later attitude towards use (Aguiar, 2016). Therefore, users first take into consideration the new technology functionality and only then analyze how easy or difficult it is to use. Albeit being different constructs, they are interrelated, as perceived ease of use conditions perceived usefulness of the new technology (Parreira et al., 2018).

The ABLEFIT (Escola Superior de Enfermagem de Coimbra [ESEnfC], 2016), is an innovative Medical Device prototype, developed for health purposes in the field of rehabilitation and designed to carry out physical exercise in bed, may be an asset in patient motor functional rehabilitation after PFF. This prototype is being developed at the Health Sciences Research Unit: Nursing (UICISA: E), a monodisciplinary unit under Nursing School of Coimbra (ESEnfC – *Escola Superior de Enfermagem de Coimbra*) in partnership with the Mechanical Engineering Department of the Institute of Engineering of Coimbra, submitted as patent application no. PT108083A to the Portuguese Institute of Industrial Property. The ABLEFIT consists of a group of devices with attachable, versatile and customizable components, which allow to carry out several different exercises in an adapted manner. The ABLEFIT allows to perform active and active assisted exercises of the upper and lower limbs, contributing to fight immobility through functional rehabilitation. The characteristics of this Medical enable its wide suitability to users' different capabilities, for its components can be combined or used independently. ABLEFIT features a set of pulleys coupled to a shock

absorber, with handles and cables of single resistance and size, which can be secured onto the bedframe or headboard, in order to perform active or active assisted exercises of the upper limbs. The structure is foldable, compact, light, easy to carry (small wheels on the base), store and clean. In addition, it also includes an ergometer to mobilize lower limbs, which can be assembled. This is a prototype that is still in need of improvement and development.

Hence, the purpose is to thus obtain data pertaining to its usability, as well as inputs towards the development of the MD prototype for patient rehabilitation after PFF.

METHODOLOGY

This is a descriptive, observational study, with a mixed method (MM) design comprising two stages, a first one consisting of the completion of a questionnaire, and a second stage consisting of a focus group A and focus group B. This is considered a pre-clinical usability study, determining in order to ascertain safety of the device (ISO, 2019b), as well as effectiveness and efficiency parameters (ISO, 2018). The goal of usability tests is to contribute to increase safety in the use of devices (Martins, 2013). In general, this study followed the Human-Centered Design (HCD) model put forward by Harte (2017), and the Technology Acceptance Model (TAM) put forward by Davis in 1979. Accordingly, the study aims to assess usability and ergonomics of the ABLEFIT for patient rehabilitation after PFF, as well as to identify the dimensions valued by the NSRN and users regarding the characteristics of the ABLEFIT medical device prototype for patient rehabilitation after PFF. Data were collected using the focus group technique and completion of a usability questionnaire. Both focus groups included eight participants, with one group of end users – patients after PFF – and one with NSRN. This is a non-probability convenience sampling method, with two independent groups of participants recruited in accordance with the inclusion criteria determined for each group.

The version of the usability questionnaire used in this study is an adaptation from the usability questionnaire used by the SERINGA DUO (Project POCI-01-0247-FEDER-01604) project, having been applied under guidance of the authors (Parreira et al., 2020). It is made up of 42 questions, and the degree of satisfaction regarding the functional prototype of the device is determined by 7-point Likert response scales, measuring four dimensions: “Usefulness”, “Ease of Use”, “Ease of Learning” and “Satisfaction/Intention to Use”. This is a valid scale, already used in device usability studies among the Portuguese population, easy to fill in, with the possibility of being used in small samples and producing reliable results. On the other hand, the focus group technique allows for a faster and more realistic data collection, with a closer analysis of the practical reality, as in the case of Nursing science (Bernardes, 2021; Lima, 2015). The sessions followed a Script, and upon presentation of the points in the agenda, the concept of the prototype was put forward using a video demonstrating the main possible exercises and participants were asked to fill in the Socio-demographic Characterization Questionnaire, along with the Usability Questionnaire. Upon confirming all questionnaires were filled in, there was a group discussion, lasting approximately one hour. The session was recorded in audio format and fully transcribed by two auditors, as participants and data anonymity and confidentiality were safeguarded

throughout the entire process. The Group A session took place in the meeting room of a hospital service, while participants in group B were patients in a private Rehabilitation Unit. This research project was granted the favorable opinion (no. 699/07-2020 of 14/10/2020) of the Ethics Committee on Research Studies, Ethics Committee of the Health Sciences Research Unit: Nursing, of the Nursing School of Coimbra. The Informed Consent, free and clear, is in compliance with the stipulations of the Portuguese applicable legislation, namely the General Data Protection Regulation and the DGS norm (DGS, 2015; Regulamento n.º 58/2019 da Assembleia da Républica, 2019).

Quantitative data analysis relied on the SPSS v25 software, while the focus groups were analyzed using the content analysis technique (Bardin, 2016).

RESULTS

Group A is made up of 8 specialist nurses in rehabilitation nursing, all female. Participants' ages vary between 32 and 52 years, with an average age of 39. As regards to academic qualifications, 75% (6) of participants hold a Post-Graduate/Specialization Degree in Rehabilitation Nursing, whereas 25% (2) hold the Master's Degree in Rehabilitation Nursing. Participants' professional practice time vary between 10 and 31 years of service, while service years as Specialist Nurse vary between 4 and 14 years. Among the 8 participants in group B, 37.5% (3) are male and 62.5% (5) are female. Participants' ages vary between 66 and 87 years, with an average age of 74.9. As regards to academic qualifications, most participants completed the 1st Cycle of Basic Education, corresponding to 87.5% (7), while only 12.5% (1) completed Higher Education. All participants are retired and living in own homes, 25% (2) of participants rely on help from a significant person or family member for DLA, presenting a low degree of dependence, while the remaining 75% (6) have no help. All of the inquired mentioned associated pathologies, as well as having undergone some type of functional rehabilitation process without resorting to any Medical Device. In terms of auxiliary devices for walking, one of the participants uses crutches while the other uses a frame, totaling 25% (2), while the remaining 75% (6) do not use any walking aids.

Looking at the quantitative results, in group A, regarding Usefulness of the ABLEFIT as a Medical Device for mobility in bed, score on the 12 items ranged from 53 to 67 points, with a 60-point average. Regarding Ease of Use of the ABLEFIT, the score on the 10 constituting items ranged from 44 to 57 points, with a 52.5-point average. Regarding Ease of Learning of the ABLEFIT, the score on the 6 items ranged from 27 to 40 points, with an average of 33.13 points. In turn, Satisfaction/Intention to Use, considering the possibility of future use of the ABLEFIT, made up of 14 items, ranged from 64 to 78 points, with a 71-point average. Lastly, total score of the Usability Questionnaire ranged from 197 to 231 points, representing an average of 216.63 points. In group B, regarding Usefulness of the ABLEFIT as a Medical Device for mobility in bed, the score refers to 12 items (1 one of the items was not evaluated due to inapplicability to this group of participants, as this usability questionnaire was adapted from that of another Medical Device, as per mentioned above), ranging from 38 to 51 points, with an average of 44.88 points. Regarding Ease of Use of the ABLEFIT, the score

on the 10 constituting items ranged from 32 to 52 points, with an average of 42.38 points. Regarding Ease of Learning of the ABLEFIT, the score on the 6 items ranged from 20 to 35 points, with an average of 25.63 points. In turn, Satisfaction/Intention to Use, considering the possibility of future use of the ABLEFIT, made up of 14 items (2 items were not evaluated by the participants, per abovementioned reasons), the score ranged from 53 to 70 points, with an average of 60.5 points. Lastly, total score of the Usability Questionnaire ranged from 146 to 208 points, representing an average of 173.38 points.

Following the content analysis of the Focus Groups, these were the emerging Categories: "Functionality"; "User Involvement"; "Characteristics"; "Dimensions/Design"; "Safety"; "Comfort"; "Hygiene/Maintenance", which integrate the topic of "Medical Device Usability". Participants are represented by the letter "E" – "E.A." represents the participant from focus group A, while "E.B." represents the participant from focus group B. In turn, "E.A.1" represents the participant 1 from focus group A.

During the discussion, participants from both groups highlighted the functionality of the Medical Device for functional rehabilitation integrated in a rehabilitation program after PFF. "*Appears to allow to perform exercises that are well tolerated by the patient, both exercises for the upper limbs and with the pedal… its integration seems beneficial to the rehabilitation process, namely for muscle strengthening (…) within a program of home rehabilitation"* (E.A.1); "*Exercises for the arms are very important in order to use crutches"* (E.B.2). However, participants noted some shortcomings and limitations regarding the functionality of the device, such as the reduced variety of exercises, particularly for the lower limbs, and the fact that the pedal is suitable fit for post-surgical in certain PFF interventions. In addition to not allowing to adjust the level of difficulty and intensity of exercises, as the device has no system for progressive load or resistance, allowing only for an ongoing movement: *"Lacks greater variety of exercises for the lower limbs"* (E.A.3); "*The device allows to perform constant exercises (…) but without (…) changing the level of difficulty"* (E.A.3); "*Exercises with the pedal (…) ergometer are not at all suitable for certain surgical interventions after PFF (...) there should be an alternative device (…) endurance exercises (…) such as bands or barbells"* (E.A.7); "*For legs, it only offers the pedals (…) or even the ergometer for the arms"* (E.B.7); "*It has pedals (…) at the Hospital I was told I couldn't use them"* (E.B.2).

Participants' opinion about the potential of the Medical Device in terms of enabling user involvement is positive. It is seen as a strong ally to NSRN in health education, stimulating both for professionals and for patients in a rehabilitation process, promoting their autonomy, quality of life and wellbeing. Nevertheless, a few drawbacks were also noted, such as user difficulty in handling the device, which may lead to their discouragement. In addition to the fact that these difficulties could be perfectly overcome with the presence of a healthcare professional until the patient is fully independent in its use, other strategies were further suggested to bypass possible difficulties. In particular, it was highlighted that this entire process would involve everyone in the patient's rehabilitation, making this device an added asset: *"I believe the healthcare professional and patient are involved in its use… it may be challenging for both (…) to use*

something different (…) that is new (…) it stimulating" (E.A.4); "*I would say it is intuitive to use and may even be stimulating (…) leaving more time to carry out other tasks…, for an elder patient (…) handling and using may be complex and become discouraging (…) it's important to accompany the process until the patient feels safe and able to do the exercises alone (…) the device would undoubtedly allow to involve everyone in the rehabilitation process and in the promotion of health education"* (E.A.8*); "A guide or a video might help"* (E.A.3); "U*sing the device would be nice (…) I would feel more motivated to do exercises"* (E.B.3); "*It looks difficult to use"* (E.B.2); *"It could have an instruction manual, I might forget how to do the exercises"* (E.B.7); "*Or even a video might help!"* (E.B.4); "*I believe using this device would involve me in my rehabilitation process, granting me even further responsibility and autonomy (…) so the healthcare professional (…) can have more time for other tasks"* (E.B.5).

In the course of the analysis, positive characteristics were highlighted, such as the fact that integrating an innovation into a rehabilitation program is stimulating for both professionals and users. Likewise, there is room for improvement in certain aspects, such as allowing for a greater variety of exercises with adjustment of resistance or loads, and the sense that, from an evolutionary perspective of the patient's rehabilitation process, the device can be used other than in bed, allowing for a seated position: "*This is an innovative device (…) most certainly appealing for healthcare professionals and users (…) allows to perform mobility exercises of the upper and lower limbs (…) but it could be more versatile (…) should feature other components that would enable greater variety of exercises for the lower limbs, in addition to the pedal, it could have… endurance exercises (…) or even the pedal itself could also be used for the upper limbs (…) it is even good and stimulating for the patient to use it in a seated position"* (E.A.3); "*The pedals cannot be used on patients with total hip prosthesis, there should a way to adapt a similar device to the one used for upper limbs (…) that could allow to adjust intensity of the exercises"* (E.A.7); "*Arm exercises may help gain strength to walk with crutches (…) but I can't perform the leg exercises (…) I can't use those pedals because of the surgery I underwent (…) there could be other things so that I could exercise my legs… maybe even similar to those for arm exercises (…) and when I felt stronger, I could use it while not in bed (…) but sitting"* (E.B.4); "*There should be more exercises for the legs (…) or for the arms (…) if I could perform them sitting down, it would also be nice" (*E.B.5). For future improvement of the device, participants from both groups strongly suggested the use of biofeedback and coupling the monitorization of safety parameters through telemetry, with real-time access by the patient and the healthcare professional, like vital signs, exertion levels and dyspnea (signs of possible effort intolerance), "*Incorporating real-time monitoring (…) telemedicine (…) would be an asset for all (…) healthcare professional, patient (…) of vital signs like heart rate, blood pressure and oxygen saturation"* (E.A.6); "*It's important to determine safety levels"* (E.A.7); "*feedback on their performance"* (E.A.6); "*I remember being measured regarding my blood pressure (…) my heart before and after the exercises (…) it would be important to see if everything is alright"* (E.B.2).

Both groups reported concerns regarding adaptability to household furniture and transportation due to its dimensions, also mentioning some suggestions

regarding the design: "*I doubt it can be adapted to home furniture"* (E.A.4); *"the design could be customizable (…) having only the required devices for the exercises needed"* (E.A.1); "*It could look more appealing, with smaller dimensions, in a resistant but light material, easy to carry"* (E.A.2); "*I don't know if I can attach it to my bed (…) the device seems large and heavy… I don't know if I can carry it"* (E.B.4); *"It could be customizable (…) to choose the color"* (E.B.6).

In the course of the analysis, participants from group A expressed concerns regarding the fragile look of the device, and that it should respect the healthcare professional's adoption of correct ergonomics: "*It looks fragile and not very safe, the structure wobbles throughout (...) in a home context, it's important to not compromise the nurse's ergonomics"* (E.A.3). In turn, opinions in group B were contrasting, mentioning, "*It looks safe"* (E.B.8); "*It seems resistant and durable"* (E.B.1). Regardless, these participants did mention the concern for having a periodical checkup of the device functionality, as well as some customer support system in case of any malfunction, "*It would be convenient for a professional to periodically check it is working correctly"* (E.B.5).

Comfort in using the device was widely reported and opinions were generally positive, although participants from group A provided some suggestions for improvement, "*Handling it seems comfortable (…) the handles seem a bit stiff (…) they could have more padding (…) pedals could have some fastening system"* (E.A.6); "*It looks comfortable to me"* (E.B.3); *"It looks comfortable to use"* (E.B.1).

The category of hygiene/maintenance was a constant concern throughout the discussion, not so much in terms of cleaning the device, as opinions in both groups were unanimous in that it seems easy to clean, but rather in terms of maintenance and related costs, "*It looks easy to clean (…) there should be periodic maintenance checkups by experts (…) if it had some monitoring attached (…) with an alarm (…) to alert in case of safety concerns (…), it would be safer for users"* (E.A.6); "*The best would be for the device and its use to be economically accessible"* (E.A.8); "*'It looks easy to clean (…) if it breaks down (…) will someone come over to fix it? (...) I am afraid of how much it might cost, I have a low pension"* (E.B.7); "*It would be convenient for a professional to periodically check it is working correctly (…) and what would be the costs involved"* (E.B.5).

DISCUSSION

Upon analyzing the Dimensions in the Usability Questionnaire, it could be said there is great consensus among participants from both groups in every dimension, as it was interesting to discover the same response variability, although it can be argued that scores were higher in group A across all dimensions. As regards to Usability of the MD, they were very positive in group A (M=216.63), while half of group B (M=172.38) presented positive scores and the other did not. Both groups were unanimous in considering the MD useful for rehabilitation and in their intention to use it. In group A, dimensions of Ease of Use (M=52.5) and Ease of Learning (M=33.13) received a positive assessment. On the other hand, in group B, there were divergent opinions regarding the medical device's Ease of Use (M=42.38) and Ease of Learning (M=25.63). For half of the participants in group B, learning and using the Device is complex. Therefore, it could be said that, for participants, the device is useful

and there is intention to use it as a complement in a rehabilitation program for patients after PFF, as most participants considered the device easy and simple to learn and use. In contrast, half of the participants in group B, end users and patients after PFF, did not share this opinion. It is important for users to perceive the MC as useful and easy to use, so that there is a feeling of usefulness regarding the MD (Parreira et al., 2018; Roma, 2016).

In terms of the categories which emerged from content analysis, one of the valued aspects was Functionality and Characteristics of the Medical Device. There was a positive perspective on its functionality, namely its use for functional rehabilitation within a rehabilitation program after PFF, the possibility to perform well tolerated exercises, and that it can be used while continuing a rehabilitation program at home. There are several studies showing that the use of medical devices associated with conventional rehabilitation, as a complement to the healthcare professional's practice, is imperative for an ongoing improvement of quality of care provided by NSRN to patients after PFF (Burtin et al., 2009; Dedov & Dedova 2013; Harne et al., 2018; Needham et al., 2009; Santos, 2015). However, some limitations were mentioned, such as reduced variety of exercises for lower limbs; ergometer that is contraindicated for certain interventions after PFF; inability to adjust the level of difficulty and intensity of exercises; non incorporation of biofeedback; non implementation of a more tailored and adapted rehabilitation plan after PFF; non association of telemetry with monitorization of safety parameters. According to Pino (2019) and Soares (2019), movements performed with the ergometer are potentially luxating, also defending the rehabilitation program should have an increasing difficulty level.

The biofeedback technique allows to inform patients on internal physiological events, normal and abnormal, enabling beneficial therapeutical effects, as the incorporation of safety parameters through telemetry is key for patients' safety during physical exercise (American College of Sports Medicine, 2022; Lopes et al., 2014). This group of functionalities widely suggested from participants in the focus groups enables the implementation of a customizable rehabilitation plan after PFF, allowing patients to be aware of their limitations, goals to be achieved according to their abilities, and to do it in a safe and controlled manner.

One other valued aspect was the Medical Device/Users Duality, as all participants agreed that, overall, the MD involves every intervenient – users, caregivers and healthcare professionals – in the rehabilitation process, with the potential to be a strong ally to NSRN in health education, promoting the patients' autonomy, quality of life and wellbeing. Nonetheless, there was emphasis on having the assistance of a healthcare professional until patients can use the device independently, adding that if patients perceive using the MD as favorable, both personally and professionally, there will be an added intention to use the MD, as well as higher intention to accept the technology and attitude to use (Aguiar, 2016).

Dedov and Dedova (2013) refer that existing devices in the market are bulky and only used in a hospital setting. In terms of Dimensions/Design and Comfort, participants reported doubts about adaptability of the MD to household furniture and its transportation. They have a positive opinion on comfort and design, albeit

having suggested for the handles and pedal to be improved. Pedals should feature some fastening for greater stability, and the design could be customizable, both for functionality and general appearance.

Lastly, the development of any MD must follow the ISSO (2019b) and those stipulated in the European Medical Devices Regulation, which are determinant in order to ascertain the device's safety (Regulamento 2017/745 da União Europeia, 2017). Hence, Hygiene/Maintenance and Safety was another valued aspect. Participants in group A considered the device to look fragile and questioned whether the healthcare professional's correct ergonomics would be compromised, while participants in group B shared the opinion that the device looks safe and durable. Participants in both groups agreed that there should be periodic checkups/maintenance on MD's functionality, but there is concern for related costs, and the suggestion that there should be a customer support service in case of any malfunction or doubts in use. Everyone shared the opinion the MD is easy to clean. Notwithstanding, there was still mention to the contraindication of the ergometer in arthroplasties which compromises patient safety, per mentioned in the "Functionality and Characteristics of MD" category. Thus, in order for the new prototype to have greater user acceptance and effective use in patients' motor functional rehabilitation after PFF, it should take into consideration the following usability, safety and ergonomics prerequisites: simple structure and components that are easy to learn and use, user friendly; elastic bands with different resistance levels and barbells of different weight, to be used both with the upper and lower limbs; removable ergometer, that can be used both with the upper and lower limbs; incorporate progressive difficulty levels overall, with safety parameters through telemetry; biofeedback monitors for the patient, with possibility of real-time interaction, accessible to the healthcare professional through telemetry; device customization per the client's preference; customer support and periodic maintenance.

This study had the following limitations: the fact that it is a convenience sample, with a reduced sample size, not allowing for population representativity and thus limiting the results; inability for users to handle and use the device may have led to construed perceptions of advantages or limitations, biasing results; the applied questionnaire was an adapted questionnaire with omitted responses to some items by participants in group B.

CONCLUSION

PFFs are one of the major and most serious health concerns for the elderly, representing a selfcare dependence-triggering event, in which a rehabilitation process in combination with an MD, the ABLEFIT, may be a facilitator in the recovery process and lead to health gains. This study allowed to assess the ABLEFIT's functionality and safety, as well as to identify limitations and improvement inputs. It is integrated in the NSRN skill set, as Rehabilitation Nursing entails the participation in preclinical research projects with user involvement, as well as the incorporation of new findings in clinical practice.

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