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Towards a multi-user experience approach to exploring key requirements to design smart habilitation devices for children with cerebral palsy

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Abstract

Introduction: This paper takes a multi-stakeholder approach to generate key requirements to design smart habilitation devices for children with Cerebral Palsy. Four groups of different relevant stakeholders of smart-habilitation devices were approached to participate in this study, including children with Cerebral Palsy, their parents, occupational therapists, as well as technical specialists.

Methods: Profiles of children with Cerebral Palsy were generated to have a concrete idea of their needs and desires. Meanwhile, for the three stakeholders, focus groups were used to gather their insights and requirements on a prospective smart habilitation device for children. Successively, a thematic analysis was conducted to analyse the qualitative data obtained during the focus groups.

Results: Eight design requirements were developed to generate designs which stimulate high quality user experiences in children and other users of smart habilitation devices. In addition, an initial framework of the process that design engineers would follow to design such devices for children was proposed.

Conclusion: Adopting this framework, and the respective requirements, will help design engineers to implement a multi-user approach and amend the design according to stakeholders' goals and desires. The resulted design should ensure a high quality user experience for both the active and potential passive users of smart habilitation devices.

Keywords
Design for Children, Habilitation Devices, Multi-Stakeholder Participatory Design, User Experience

Introduction

Nowadays, rehabilitation devices are being introduced to support end-users of different ages to achieve the functional skills required for daily living (Bitkina et al., 2020). In case of habilitation, therapy is targeted towards children's acquisition of functional abilities which they have not developed yet. Thus, the aim of habilitation devices is to help children with disabilities attain functions for daily living, during occupational as well as physical and speech therapy. This paper will denote habilitation devices for use by paediatric occupational therapists, with the aim of improving upper limb motor skills in children as a prerequisite for better participation in their daily life. Although habilitation devices may appear to provide an ideal way to support children in achieving their potential, studies have shown that such devices (and other similar

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artefacts) have a low acceptance rate (Biddiss and Chau, 2007; Sugawara, A. T., et al. 2018). The motivation behind this research is to proactively involve multiple users and other relevant stakeholders in the design process of habilitation devices which are ergonomic and provide a high-quality user experience (UX).

UX in habilitation devices goes beyond the functional and technical aspects by considering the aesthetic aspects, joy of use and the elimination of stigma which such devices might evoke. Bitkina et al. (2020) highlight the difference between usability and UX. Usability constitutes part of the user's experience and measures the extent to which an artefact can reach its functional goals. On the other hand, UX is defined as a holistic approach which considers the subjective responses and perceptions of individuals using the product, as defined in the International Organisation for Standardisation (ISO) (ISO 9241-210, 2019). Wilkinson (2016) studied the influence of participatory design in the development of assistive switch devices. This study resulted in robust evidence that the inclusion of the users' experiences contributes to the development of devices which are more likely to support the end-users' goals and their everyday living. Similarly, Giraldi (2020) stressed the importance of improving UX in healthcare devices for children and in paediatric hospitals, identifying different methods of research that can help improve their design. In this study, observations, workshops involving device use, as well as meetings with psychologists were conducted to understand better children's emotions and experiences when using medical devices.

As a research boundary of this study, children with cerebral palsy (CP) will be considered as the primary users of the smart habilitation devices. CP refers to a group of non-progressive motor disabilities which have an impact on the individual's ability to maintain posture and balance, as well as to move. CP is the most common disorder found in children, estimated to affect 3.2 per 1000 live births (McGuire et al., 2019). Children with CP attend occupational therapy sessions to develop skills they need to live a more independent life. Paediatric occupational therapy focuses on developing children's occupations, such as learning, playing and self-care, in order to enable them to participate better in daily life. There are different types of CP, but this study targeted those children with types that caused upper extremity dysfunction such as spastic quadriplegia and hemiplegia.

Another research boundary of this study is the context of children with CP with upper limb involvement in Malta which currently has a population of around 442, 000. The present birth rate for Malta is 9.730 births per 1000 people. In 2020, 3900 live births were registered in Malta. Hence in comparison to the international figures (McGuire et al., 2019) approximately eight to 12 children are expected to be born with CP each year, locally. Statistics obtained from the directorate of inclusive education in Malta support this hypothesis and show that the total number of children with physical disabilities attending state schools under the age of 12 years to date is 125 (Ghirxi, 2021, personal communication, 1 December, 2021). It must be said that this figure includes children with other physical disabilities besides CP and hence the reason for it being slightly higher.

To further support the incidence of CP locally one can also look at the data from active caseload of occupational therapists within the country's national occupational therapy service. By the end of 2021 this consisted of 94[1] children under the age of 12 with around 60 of these diagnosed primarily with types of CP[2] relevant for this study. Hence this data shows that for Malta the number of children with CP is small due to the size of the population and this means that the research participants for this study and the prospective research is somewhat restricted.

While substantial studies have been conducted to implement UX in medical devices design, a gap in literature was identified with regard to smart habilitation devices design. The main aim of this study is take a multi-user participatory based approach to recognize the requirements needed to design smart habilitation devices and ensure a positive interaction experience for its various stakeholders with the intention to help reduce the rejection rate that current devices have. In the context of this study, to help build a more holistic view than previous studies, the perspectives of the different user groups, including the children themselves, their parents and occupational therapists, will be considered to obtain their desires and needs to supplement a safer environment and a more effective habilitation experience to the child. Hence, this paper will address the research questions: "What are the key requirements to design a smart habilitation device for paediatric occupational therapy intervention, considering multi-UX aspects?" and "To what extent do the insights of the various stakeholders help to develop smart devices for paediatric habilitation?" Following the introduction in *Introduction* the rest of this paper is structured accordingly. *User Experience Design and User Classification in Paediatric Habilitation Devices* reviews related work on UX, medical devices, assistive products and (re)habilitation devices, formulating the respective research gap and boundaries. *Method* presents the methods used to investigate the above research questions. *Profiles Generated* presents four profiles which are referred to in this study. *Requirements Identified from the Thematic Analysis* discloses the requirements identified, which are then discussed in *Discussion, Future Work and Limitations*. Future research directions are also suggested. Finally, *Conclusion* draws key conclusions, highlighting the key contribution of this work.

User Experience Design and User Classification in Paediatric Habilitation Devices

Studies have shown that, due to user unfriendliness and stigma, body-worn devices and assistive technologies have a high rejection rate (50%–56%) by individuals with different needs, with around 15% of these artefacts never being used (Hocking, 1999; Ledger and McCaffrey, 2014). More recent studies are being conducted to determine what can be done to increase the acceptance of these devices. Papp (2020) highlighted the importance of considering UX aspects when designing such devices, in order to improve acceptance rates and encourage users to continue making use of the artefacts.

In this study, the artefacts considered are habilitation devices used as part of paediatric occupational therapy intervention for children with CP. Such technology is becoming more electronic based and, typically, body-worn, exoskeleton-like, with the inclusion of sensors and other embedded electronics for motion capturing purposes and biofeedback, depending on the goal of the artefact. An example of such technology is the Rapael Smart Kids, by the company Neofect, which is a wearable device for children to carry out motion-task training through game-like screen-based exercises (Neofect, 2019).

Law et al. (2009) established that UX scopes, not just the physical object (the product), but the service and system the user interacts with, too. In the case of habilitation, physical devices typically form part of a product-service-system, including software that transfers the data obtained from the motion-capture device into another respective device. Presently, 'serious games' (games designed to teach something, rather than for entertainment purposes) are becoming a common means to deliver therapy as part of the product-service-system of habilitation devices. For instance, AbleGames is an EU-funded project which provides a social-gaming platform service for children with CP, containing numerous games and tools for habilitation purposes (AbleGames, 2020). In addition, current serious games come with an extended reality (XR) environment, to further immerse the users during therapy. Further to the product-service-system provided with smart habilitation devices, input from occupational therapists conventionally consists of monitoring real-time data being captured and analysing it with previously recorded data to determine new goals for clients. In addition, occupational therapists must make sure that the devices fit their clients' needs and that they support them in reaching their potential.

On the European Union (EU) market, such smart habilitation devices fall under the classification Class IIa, according to the Medical Device Regulation (2017/745/EU). This classification refers to active devices or software with a low-to-medium risk to users, intended for monitoring or providing information for therapeutic purposes. A few therapeutic devices within this class include: Rapael Smart Kids (Neofect, 2019), Motus Hand Mentor (Motus Nova, 2019) and Pablo's upper extremity system (Tyromotion, 2018). Such medical devices should comply with usability and ergonomics designs, and other respective standards, to provide a safe environment to the users, in particular, to children.

Apart from the primary users, medical devices also have secondary and tertiary users. In the studies by Giraldi (2020) and Høiseth (2014), other users besides children were identified. These include parents, educators, paediatricians and caregivers, amongst other healthcare personnel. The same goes for habilitation devices for use in paediatric occupational therapy intervention. The primary users are the children who make active use of the products (Arriaga, 2020). On the other hand, the secondary and tertiary users are occupational therapists and the children's parents, respectively. These are classified as passive users. Occupational therapists do not make direct use of the products, but may use them indirectly to get some output or provide some input. Meanwhile, tertiary users, such as children's parents or teachers, may not use the product at all but are directly affected by the negative or positive consequences of the devices. A better visualisation of typical users and other stakeholders of paediatric habilitation devices is represented in Figure 1.

Method

This study forms part of an overall research project whose main research activities are illustrated in Figure 2. This paper focuses mainly on the study conducted with various stakeholders, including primary, secondary and tertiary users, as well as other relevant stakeholders. Further studies forming part of the overall research project will be conducted to support the preliminary findings of this study, as discussed further in Section 6.

Qualitative Data Collection

Introduction. In order to establish the UX of multiple users, both potential active and passive users of smart habilitation devices were approached to participate in this study. Prior to approaching the participants, due to the sensitivity of the data being collected and the vulnerability of some of these individuals, ethics approval had to be provided by the research ethics committee from the University of Malta. The ethics application of this study was reviewed by both the faculty and university research ethics committees, and was approved under the form reference number 15062020-6631. Once the application was approved and written, consents from participants were obtained, and the study could commence.

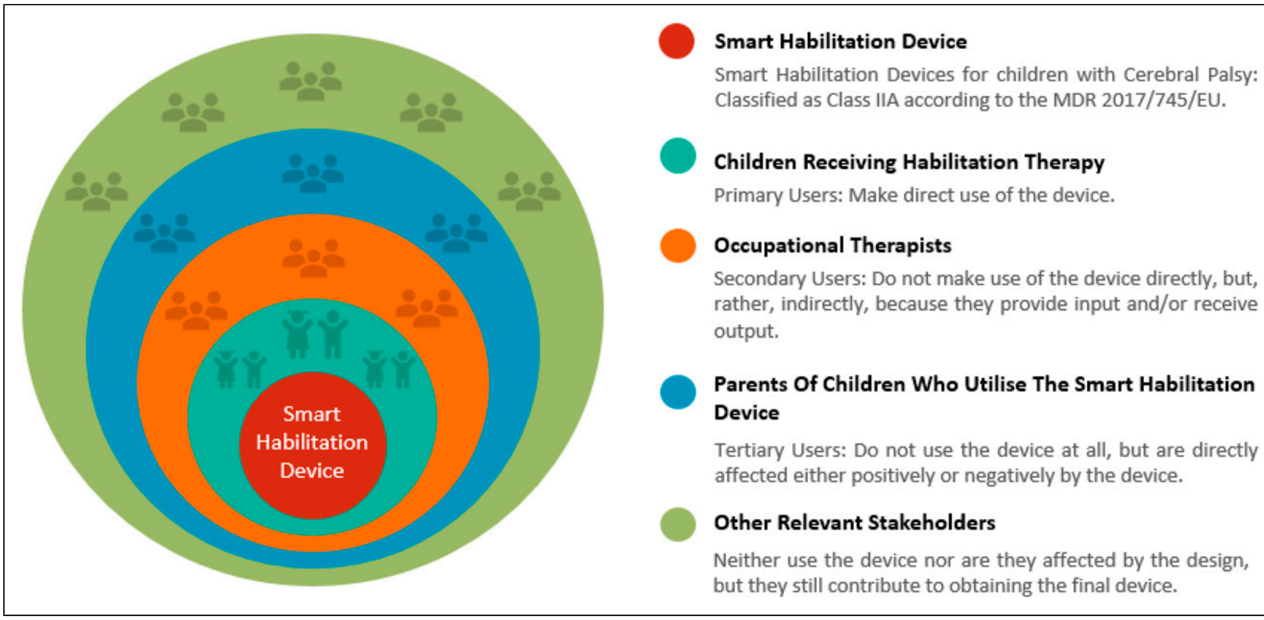

Figure 1. Categorising stakeholders of smart habilitation devices as users and other relevant stakeholders.

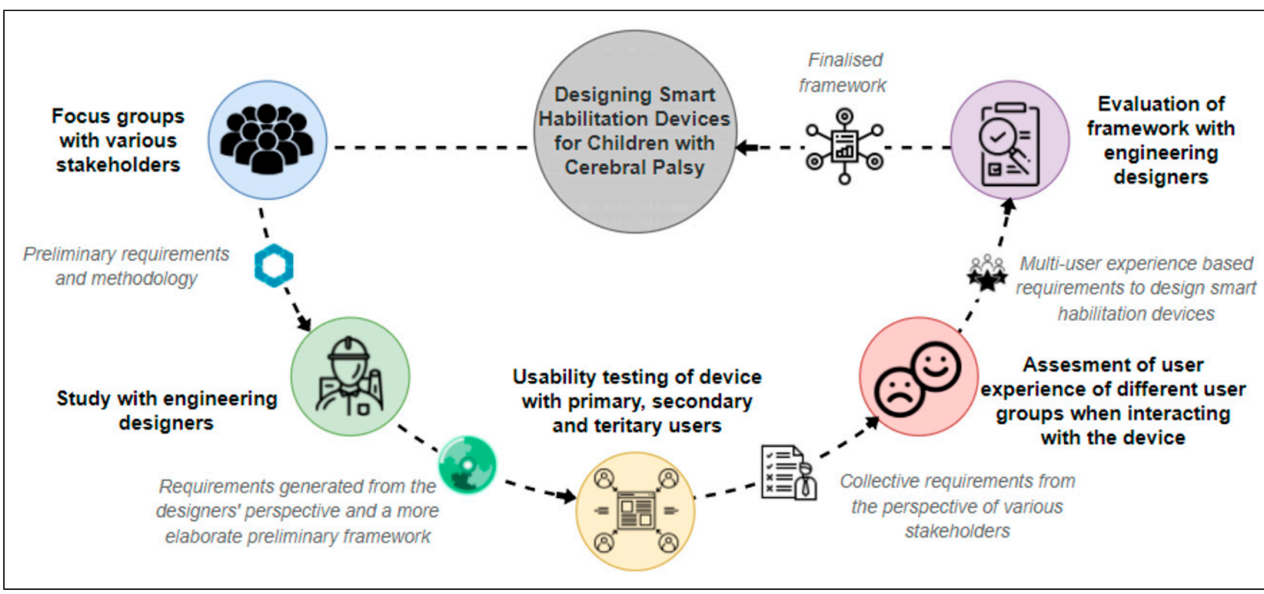

Figure 2. Overall methodology to design smart habilitation devices for children with CP.

Procedure. Starting off with the primary users, four parents of children with CP were approached through an occupational therapy clinical laboratory to allow their children to participate in this study. The children were involved in building their own profiles. This also served to break the communication barrier between the researcher and the primary users to help determine what the children wanted from such a device. In this case, the children were accompanied by their parents and occupational therapists, both of whom voiced their children's/clients' strengths and challenges. This was important because some of the children struggled to express their thoughts and needs into words, due to challenges in verbal communication. These profiles will be used as a means of identifying common and differing features of four children with CP, significant to their functional independence. Developing the primary users' profile will help design engineers implement a user-centred design approach to design for the individuals' needs.

Additionally, focus groups were conducted with other potential stakeholders of smart habilitation devices. Focus groups were used as they are a good UX analysis method, easy to conduct and able to generate a big enough sample size while gathering group data interaction (Schwerin et al., 2010; Houdt et al., 2014). In total, three focus groups were conducted; one with occupational therapists, one with parents of children with CP and another one with technical experts in related areas of smart device development. The latter stakeholders were taken into account for this study to help generate requirements which can provide realistic, yet optimal, smart devices which are obtainable with the current limitations in technology. Presently, pressure has increased to meet the requirements of different users of medical devices, hence, technical experts were engaged to help shape the usability and functionality aspects of prospective smart habilitation devices, because these factors are a solid foundation to design for UX (Bitkina et al. 2020). Two parents of children with CP participated in this focus group to help guide the discussion and keep in line with the goals of the parents and their children.

The focus group sessions consisted of various questions to help get insights about occupational therapists' and parents' experiences with children with a neuromotor disability such as CP. Some of the questions included; "*What are the strengths and challenges you encounter during a therapy session with a child with CP?"; "How can a smart habilitation device improve the UX of the child and an occupational therapist during a therapy session?"; "What is your experience as a parent raising a child with CP?"* On the other hand, the discussion of the latter focus group was on how and through what means one can generate a positive UX for these children through such a device. All focus group questions can be found in the supplementary material section.

The focus groups were held online due to COVID-19 restrictions and each session took around one and a half hours. To make sure that the online sessions were satisfactory, a pilot study was conducted prior to the first focus group, and the questions and respective layout were amended according to the feedback obtained throughout this trial. During the focus group sessions, the questions were presented to the participants through the "share screen" function, for them to reflect on the question for the duration of the discussion.

Data Analysis of Focus Group Sessions

Each focus group session was audio recorded with permission from the participants. Following each session, the discussion was translated from the participants' native language to English, and then transcribed for analysis purposes. The qualitative data obtained from these focus groups were analysed thematically (Braun and Clarke, 2006).

1. Once transcribed, the transcript was re-read for familiarisation with the material;
2. Initial codes were generated throughout the transcript;
3. Matching codes were collected to form potential themes;
4. The themes were reviewed, refined and checked with respect to the scope of the study.

This systematic method was followed for each focus group session conducted. Nvivo 12 software was used to code each transcript and group the codes into respective themes (QSR International Pty Ltd., 2020). To have homogenous and unbiased coding, three researchers conducted step two of the above mentioned method and an inter-rater reliability (IRR) factor was generated to confirm the consistency in between codes, prior to the generation of potential themes. The resulting IRR was 0.5 between the coding of the three researchers. Although this is considered quite a low value, one must take into account that the occupational therapists and parents have different perspectives and backgrounds, whilst factors such as their children's/clients' ages and abilities, linked to the type of CP they have, differed from one child to another. The low IRR, indicating sometimes considerable variation in how different raters interpreted the same situation, suggests that the results should be generalised with caution.

Participants

In total, 25 individuals participated in the previously mentioned qualitative studies. Details of the participants are provided in Table 1. Convenience sampling was used to select children with CP and their parents. These were approached through an occupational therapy clinical skills laboratory. For the occupational therapists' focus group, different service providers were approached to disseminate the invitation to their employees and identify whether they wished to partake in this study. Specialists in engineering and gaming were contacted through the University of Malta. The experience of the occupational therapists and specialists varied between five and 30 years, whilst the children of the parents who partook in the focus groups were between the ages of five and 14 (refer to Table 1). Overall, the number of recruited participants for the study was not as high as originally desired. This was partly because of the low absolute number of children with CP to choose from, and, consequently, the low absolute number of therapists (the incidence of CP with upper limb limitations was explained in the research boundaries section of this study), and partly because of COVID-19. The social restrictions imposed by the government to stop disease

Table 1. Participants who took part in the qualitative studies.

Study	Participants	Details	Designation	Background
Profile generation	Children with CP	3 Female, 1 Male; the children's condition varied from one child to another	C1	Spastic quadriplegia with spastic tone
			C2	Right side hemiplegia, with right arm/hand severely affected
			C3	Hemiplegia, with mild tone
			C4	Dystonia
Focus group	Occupational therapists	6 Female, 1 Male; approximately, an average of 18 years of experience in occupational therapy; institutions varied from; iLearn, Child Development Assessment Unit, Aġenzija *Sapport*, Augmentative and Alternative Communication Unit, Occupational Therapy Department at the Malta general hospital and UM[a]	O1	Orthotist/Prosthetist and OT with previous experience with children with CP
			O2	Senior OT
			O3	Over 20 years of experience as paediatric OT
			O4	Paediatric OT
			O5	OT with previous experience on assistive devices
			O6	Has previous experience as a paediatric OT
			O7	Over 20 years of experience as paediatric OT
	Parents of children with CP	6 Female, 2 Male; average age of children is 10.5 years (range 5–14 years); 3 of the children had siblings, whilst the other 5 did not	P1	Child has mild CP
			P2	Child has mild CP
			P3	Child has severe CP
			P4	Child has quadriplegic CP
			P5	Child has spastic diplegia CP
			P6	Child has hemiplegic CP
			P7	Child has hemiplegic CP
			P8	Child has quadriplegic CP
	Technical experts	2 Female, 4 Male	T1	Professor at the UM with background in electrical and control systems engineering, robotics and bioengineering
			T2	Associate professor at the UM with background in artificial intelligence, digital game development, web science and human computer interaction
			T3	Masters by research student in the area of systems and control engineering at the UM
		All the technical experts work at the UM	T4	Senior lecturer at the UM with background in electrical engineering, human machine interface and biomedical signal processing
		All participants have a good background in assistive or rehabilitation devices	T5	Senior lecturer at the UM with background in computer information systems, user-centred design and computer science
			T6	Lecturer at the UM with background in electrical engineering, image processing and assistive technology

OT: Occupational Therapist.
[a]UM: University of Malta.

transmission made meeting people for recruitment hard, particularly vulnerable individuals (children with CP fall under this category) who were extra cautious. However, despite the low numbers, all the services provided by the public sector in Malta (the private sector had to be excluded because of feasibility issues) were represented in the focus groups, and one hopes that, once the advantages of such devices become apparent and COVID-19 subsides, more participants for piloting them will come forward.

Profiles Generated

As briefed in the previous sub-sections, four children with CP were approached for this study to allow the researcher to get an idea of what the goals of these children with disability were and what they wish to achieve through a smart habilitation device. This consideration of their choices and likings would then be incorporated into prospective devices. Table 2 provides basic information collected during the profile-generation sessions. The parents and occupational therapists accompanied their children during these sessions. The adults' input was necessary to ensure that the children's views were transmitted accurately, due to their limitations in verbal communication. This was important for the generation of the profiles.

Additionally, to the information collected in Table 2, measures of the children's manual abilities were scaled according to ABILHAND-Kids by Arnould et al. (2004) and the International Classification of Functioning, Disability and Health Checklist (ICF-Checklist) by the World Health Organization (2003). These qualifiers were used to get a better understanding of the children's abilities, what activities they are capable of conducting and how well they can conduct them. The Manual Ability Classification System for Children with Cerebral Palsy (MACS) was also used to classify from a clinical aspect the children's performance when executing daily activities (Arner et al. 2002). This classification was based on the evaluations made by the occupational therapists and feedback from the children's parents.

Furthermore, anthropometric measurements of the impaired upper limb were noted, to get a basic idea of what size the device should be. Although the average sizing of children's upper limb can be averaged or approximated from anthropometric data found online of typically developing children, in case of habilitation devices, it is vital that the device provides the correct fit for the child to avoid causing any discomfort. This is especially important because size differs between one child and another. Factors that make a difference are age, growth rate, and the possible effects of CP.

Requirements Identified from the Thematic Analysis

From the thematic analysis conducted on the focus groups executed in Section 3, a collective set of requirements were extracted to help design smart upper limb habilitation devices for paediatric occupational therapy intervention.

Requirement 1: Paediatric habilitation devices should be co-designed alongside users and other key stakeholders

During the discussions of the focus groups, it was prioritised that stakeholders other than the primary users be included as part of the design process of a habilitation device for children, to build an optimal device. In the initial session, occupational therapists identified the importance of including crucial stakeholders such as parents as part of the assessment process, to make the device cater for their children's needs. Cooperation from the parents during the design process is of utmost importance for the product to work efficiently and effectively. Occupational therapists highlighted the importance of co-designing with parents, because parents are the primary caregivers who spend the most time with their children and so have a better view of their children's strengths and limitations.

Apart from parents of the children receiving therapy, other relevant stakeholders which one should involve are school teachers and learning support educators (LSEs). This outcome was highlighted especially in the case where children are too young to verbally share their insights, or in cases where their impairments restrict them from communicating their opinions clearly. Sims et al. (2017) implemented a multi-stakeholder participatory approach when designing paediatric upper limb prosthesis, similar to the research being discussed in this paper.

The stakeholders who took part in the focus group sessions highlighted the importance of including children during the design process, pointing out that the ideal situation would be to listen to the children's opinions and voices on what works best for them. The participation of children in the design process is not a new methodology, as previous studies by Rigby et al. (1996) and Light et al. (2007) considered child-oriented approaches to help design paediatric products. Current design approaches are increasingly taking into account child-product experiences and emotions. For instance, Giraldi et al. (2020) conducted observation sessions to acquire insights on children's emotions and experiences with medical devices. In this study, profiles were built at the initial stage of the design process to consider the children's likes and dislikes, to help determine the requirements and desires the children have with respect to habilitation devices, and, subsequently, to try and provide them with positive experiences.

Apart from co-designing the device with the relevant stakeholders to make it as effective as possible, relationship

Table 2. A representation of the information collected during the profile-generation sessions with children with CP.

	C1	C2	C3	C4
Gender	Female	Male	Female	Female
Age	10	5	3	12
Summary of condition	Spastic quadriplegia CP; variable tone, with upper left limb; predominantly more tone	Right side hemiplegia CP; right arm very affected	Hemiplegia CP; Mild tone; unrefined movements	Dystonia CP; restricted control
Motivation/ likes	Experimenting with make-up; cooking; writing; music	Playing with toys, especially cars; enjoys watching cartoons	Enjoys watching cartoons; likes animals; ballet; singing	Exploring new places; photography; swimming
Dislikes	/	Sensory overload – sensitive to excessive noise and rough material	/	/
Goals	Become more independent	Improve daily activities by using right hand	Refine movements and obtain strength in right hand	Use technology to become more independent
MACS[a]	Level 3: Handles objects with difficulty; needs help to prepare and/or modify activities	Level 3: Handles objects with difficulty; needs help to prepare and/or modify activities	Level 2: Handles most objects but with somewhat reduced quality and/or speed of achievement	Level 4: Handles a limited selection of easily-managed objects in adapted situations

[a]MACS: manual Ability Classification System for Children with Cerebral Palsy.

building and knowledge translation are needed so that children, parents and other users feel at ease and trust the outcome of the device (Missiuna et al., 2016). This was also remarked on by the occupational therapists during the focus groups.

Requirement 2: Careful consideration should be given to how users will be motivated to use smart devices for paediatric habilitation

Devices which motivate children to use them was a central theme identified from every focus group. Motivation was identified as a great source to maximise the capacity of children's ability. Without motivation, children will not be enthusiastic to make use of the device and carry out habilitation exercises repetitively. Parents of children with CP remarked that, if their children were given an artefact which they like or are motivated about, they would be more willing to participate in the activity, and hence overcome the restrictions caused by their physical limitations.

Maclean and Pound (2000) identified the psychological reasoning behind extrinsic motivation during rehabilitation, and how it impacts the level of engagement during therapy. Weightman et al. (2010) recognised motivation as a requirement when designing games for habilitation for children with CP, whilst Abela et al. (2021) highlighted this through a study with clinicians, as extrinsic motivation results in better engagement during therapy and thus achieves better outcomes. A similar study on assistive switches, by Wilkinson et al. (2016), also identified extrinsic motivation as an important element to encourage users to make use of the assistive device. Ziviani et al. (2012) point out that motivation is an important element to entice children to participate during therapy and thus have a successful therapy session.

Motivation is not generated by the device alone, though, so a product-service-system shall need to be provided along with the device, aimed to cater for the children's subjective functional goals, similar to the goals of a typical occupational therapy session. In this study, the profiles generated for each individual child helped to determine their subjective goals and likings, as one child's interests and goals are different from another's, and goals and interests can generate intrinsic motivation. By reaching their functional goals, children can become more independent, and, as parent *P3* stated: "Children's motivation is to do the tasks more independently," which is something they all strive for, as also concluded from the profile-generation sessions in Table 2. Wilkinson et al. (2016) remarked that becoming independent is also a great motivation for adults who interact with assistive switches. Apart from their individual likings and goals, children are motivated a lot by feedback. If positive activities are praised, the children will be motivated to do the activity again and again, and, through repetitions, be able to habilitate. From the focus group, it was determined that visual and auditory feedback should be provided on an external device to avoid taking the attention away from the exercise they are conducting.

Requirement 3: Apply a user-centred approach to design personalised and modular habilitation devices for children

Another central theme which was identified in all focus groups was the element of personalisation. Every child participant in this study possessed different strengths and limitations (see Section 4).

During the focus group sessions, stakeholders discussed the importance of empathising with every child and designing habilitation devices according to individual needs through a user-centred approach. This is especially important to enable end-users to reach their individual goals, as one device will not necessarily fit the needs of every other child. An element of modularity in the device is important, to cater for children's different goals and needs.

Feedback, as mentioned in Requirement 2, is a great source of motivation, but only if it is meaningful and suited to the specific child. Parent *P7,* of child *C2,* emphasised that her son has sensory overload due to his condition and, hence, tactile feedback from the device, such as vibration, would discourage him from using such a device for habilitation. Meanwhile, another parent, *P8*, said that his daughter, *C4*, was motivated more when her previous habilitation devices had vibration incorporated in them as a source of feedback. This further confirms that not every child is the same and customisability is an essential aspect to incorporate in habilitation devices. Giraldi et al. (2020) also emphasised the need to find specific solutions when designing healthcare devices for children, especially with respect to their age and cognitive abilities. Occupational therapists built on this and remarked that the device requires an element of versatility if it is to cater for different children, because children's anatomy varies according to their age and growth rate, among other things. Apart from the size of the hand, impairments could result in malformed hands, varying the arching of the palm, the length of the fingers and the overall size of the hand. Thus, based on a user-centred approach, a modular product architecture needs be obtained to cater for the primary user's individualistic differences and needs. Further information cannot be provided, to not divulge intellectual property.

Ultimately, this requirement proposes bespoke designs of habilitation devices, because universal off-the-shelf devices might restrict children from reaching their full potential. Excluding function, it was suggested that the aesthetics of the device also be personalised, because the attractiveness of the device is subjective to the individuals' likings. Thus, having the device personalised according to individual preferences will further entice children to utilise the device and participate during therapy.

Requirement 4: Key characteristics to consider when designing habilitation devices for children with Cerebral Palsy

A theme drawn from the parents' focus groups was related to the device's characteristics. Due to the fact that children with CP tend to be quite messy and clumsy, the parents noted that the device should be durable and waterproof. It also needs be wearable in a non-obtrusive manner to avoid interfering with the children's movements and current abilities, especially because children with CP, more often than not, are used to carrying out tasks in a unique manner, through their adaptability skills. With regard to ergonomics, all occupational therapists agreed that the device should be as lightweight as possible to avoid having resistance against movement. Furthermore, it was emphasised that the device needs to be securely fitted with the limb of the child to ensure accurate motion capture. As highlighted by clinicians in Abela et al. (2021), ergonomics are very important because, if a device is fitted well, it is not uncomfortable to the user. Anthropometric data of upper limb were collected during the user profile-generation sessions to get an idea of the size range a smart habilitation device should be designed for, ranging from three-year-olds up to twelve-year-olds. This is especially important to ensure that the device will fit individuals securely and not cause any discomfort. Additionally, it must be guaranteed that the motion-capture electronics are in their accurate position to capture the data correctly.

Furthermore, technical specialists emphasised that the device should not be complex to use and that, where possible, children should be able to use it independently. Although the majority of these children are able to adapt well to technologies such as laptops, mobile phones and tablets, it could be a burden for them to make use of a device which is too elaborate.

Ultimately, personal and environmental factors need to be taken into account when designing a device for habilitation. This includes aspects of the physical and social environment (Anaby et al., 2014). Typically, children with CP may be hesitant to comply during therapy sessions if they are in an environment that is not welcoming or if they experience pain and/or discomfort, amongst other factors. Hence, the design engineers need to observe children and record what makes them feel comfortable and what does not, to implement the correct characteristics in the device and help put children at ease when utilising the product. Henceforth, profiles are used to determine each child's desires and needs, and help design engineers focus on the user through a child-centred design approach.

Requirement 5: Key characteristics to consider when designing a serious game as part of a product-service-system for paediatric occupational therapy

Current smart devices for paediatric habilitation typically form part of a product-service-system which incorporates a type of software as indicated in the medical device classification referred to in Section 2. In relation to smart habilitation devices, serious games for paediatric habilitation purposes were discussed during the focus group session. From market research carried out on smart habilitation devices, it emerged that the use of serious games in an XR environment is becoming more common, and recent studies have been conducted to see the benefits of utilising such games to help deliver better therapy.

Technical specialists and parents of children with CP highlighted that serious games for therapy purposes need to be sufficiently motivational to encourage children to use the device and execute therapeutic movement, as briefed on the importance of motivation in *Requirement 2*. The more exciting the game, the more children will be motivated to use the device. Occupational therapists suggested making use of a token economy system and including several customisable elements so that each child can be catered for. Ideas include photos of children's relatives and songs they personally chose, among other things. These would further entice children to use the device and actively participate in their habilitation. The element of relatedness was outlined as well by parent *P7*, who acknowledged that her son is more engaged in an activity when he observes an avatar which resembles his appearance.

Madeira et al. (2017) designed a mobile serious game for therapeutic intervention to engage children during therapy, and this was evaluated on the UX generated. Meanwhile, Ni et al. (2014) conducted a similar study but considered virtual reality-based games and evaluated them specifically with children with CP. Both studies showed that the use of serious games engaged the children more during therapy sessions, generating a positive outcome.

Parents of children with impairments also proposed that the game include basic everyday functions, whilst add-on games should be incorporated to meet the unique goals of the individual in order to cater for the difference between one child and another. The latter would be based specifically on the profile built, as represented in Section 4. Customisable feedback from the serious game is also important. This should be based on the cognitive level of the child, and consider different means of feedback and stimulus. It was also recognised that feedback should be immediate, to provide immediate gratification for children in the task they have managed to accomplish. Meanwhile, occupational therapists noted that stimulus/feedback should not be applied too often as doing so might make it habitual and, ultimately, the child will end up ignoring it. This criterion applies to feedback coming directly from the physical habilitation device, such as vibration.

Furthermore, hand preparation should be included prior to commencing with the movement of the function, by incorporating warming-up exercises for every function, similar to a typical therapy session with an occupational therapist.

From the focus group with parents and technical specialists, it was determined that a narrative game with a backstory and a degree of randomness (for unpredictability) would be suitable. The level of randomness is important to keep the child's attention when playing, especially because the majority of young children have short attention spans. The game needs to include levels of difficulty that challenge children to do their best and encourage progress, as parent *P4* pointed out: "Once the challenge is surpassed, children are less motivated to continue." It was also highlighted that serious games for habilitation should include in-game assistance to avoid frustration if the user gets stuck in the middle of an exercise and cannot surpass it. Furthermore, from the profiles, it was identified that all four children enjoy exploring, thus, games that allow aspects of free-play would be ideal.

Another important element of the game is putting children at ease. This might be a subjective factor, according to how a specific child perceives the game and device, but, from a design engineer's perspective, it is important to consider the emotional response of these end-users. Technical specialist *T2* highlighted that, in cases where children feel uneasy during a typical therapy session, a balance needs to be reached between the game and the therapy by including exercises subtly, as a by-product of playing. *T2* continued that, if this balance topples, a child might be disheartened to interact with the device on a regular basis.

Parents noted that children with CP tend to get frustrated easily, especially when they try to obtain something that is restricted by their physical limitations. Hence, benchmarks need to be inputted in the game, including rest breaks from certain movements, especially motions which require a level of precision. These may be tiring for them and fatigue may lead to frustration.

Ultimately, the utmost important requirement for habilitation serious games to be successful is for them to be in-line with the functional goals of individual children, parents and occupational therapists. Hence, it is vital to design the product-service-system as a whole, to keep in-line with the initial goals identified during the user profile-generation sessions and according to the desires and wants of the parents and occupational therapists.

Requirement 6: Using habilitation devices at school and the respective social environmental aspects to take into account

Participants in all three focus group sessions raised the subject of using the device in school settings, in order to allow children to interact more during lessons by using it as a learning tool, as well as a means to play with their peers. In such cases, collaboration with the LSEs and/or teachers would be necessary to meet their demands and needs, and further promote the use of the device for short intervals during school activities.

It was noted that one must be careful to avoid designing the physical artefact as a stereotypical medical device, by making the device as attractive and mainstream as possible, so that children will choose to use it rather than perceive it is as a sort of burden. Hence, certain aesthetics considerations, and personalisation according to the likings of the child, as highlighted in *Requirement 3*. These would help children feel confident using the device in social environments with their peers. This was also identified by Weightman et al. (2010), under the requirement of social acceptability of the device by the users themselves, their peers, as well as the adult stakeholders.

In addition to what was highlighted in *Requirement 2*, all parents mentioned that their children are greatly motivated by their peers, especially when it comes to play; hence, social environmental factors should be included as part of the product-service-system, through multi-player games that allow children to play competitively or cooperatively with their peers at school, and maybe with their siblings too. In case of a competitive game, one must reach a compromise to avoid risks of frustration. A positive social environment is also necessary in games with virtual currencies and in-game purchasing. This is because an important element of purchasing something new is showcasing it (and the ability to obtain it) to one's peers. Technical expert *T2* explained that, if the game will only be played individually, showcasing won't be possible so in-game purchasing is devalued and will lead to less excitement. With respect to this criterion, the notion of in-game purchasing may require complex cognitive abilities that some children (especially the youngest ones) may find challenging, so it needs to be further studied before being implemented.

Requirement 7: Motion capture and real-time data processing specifications required to achieve a functional paediatric habilitation device

This requirement differs from the previous ones, as it is more based on the pragmatic qualities of the device to reach its functionality and usability aspects, rather than the hedonic qualities of UX.

Occupational therapists outline that, in the case of children with CP, the smart device should be able to detect very small degrees of movements, because children's movements and respective improvements may be very subtle and sensitive. Furthermore, it was highlighted that sensors need to overlook sudden dystonic movements, such as involuntary twisting or sudden movements, which may occur in children with CP. Hence, the building of the motion capture algorithm for real-time processing of a child's movements needs to take into consideration the tonal patterns and range of motion of the hand joints, in order to register any slight improvements in movement that may contribute to a child's functional skills. Although sensors are necessary to record fine movements, the number should not be so high as to add weight that would limit children from moving as they wish (as described in *Requirement 4*).

During the focus groups, the technical experts discussed the use of the different sensors in relation to the motion capture of the prospective habilitation device. It was highlighted that electromyography sensors will not be suitable to capture the motion of each and every phalange in the upper limb, whilst, when it comes to Inertial Measurement Unit (IMU), sensors are able to read smaller degrees of motion, easily obtaining higher sensitivity than the electromyography sensors. This is also important for reading motion precisely and portraying it correctly through a respective peripheral device, such as a tablet, because non-compliance with real-life hand motion might cause frustration in the child. This can also be the case if the delivery system of the motion being captured and what is being presented on the respective screen which displays the serious game are not in sync because of delays. Technical specialists said that such delays may cause children to become frustrated or annoyed, and hence less keen to interact again with the device.

Additionally, as part of the product-service-system of the habilitation device, occupational therapists should be able to refer to the movements being conducted by the child in both real-time and, subsequently, in the future. With access to this data, occupational therapists can analyse a child's movements and benchmarks reached to compare them with previously monitored data and determine whether a child managed to exhibit improvements, to be able to set future goals. The importance of this feature in habilitation devices was also identified by Abela et al. (2021), in which clinicians stated the importance of monitoring the biomechanics of the user.

Requirement 8: Environmental factors and set up aspects to acknowledge when designing paediatric habilitation devices

Consideration of the surrounding environment when designing smart habilitation devices was the final theme extrapolated from the focus group sessions with occupational therapists and technical experts. The design engineer must take into consideration where the device will be used, such as, at the home of the child, a clinic or at school, to design the device accordingly. Portability, weight, size and appearance, amongst other factors, will differ depending on the surrounding environment. Furthermore, setting up a stable environment for the child is important to output an objective measure, reducing variability and promising a more standardised assessment of the movement. Hence, consistency of a good posture and positioning of the child are critical and should be achieved by recording the seating and use of other peripheral devices, to stabilise and obtain a midline orientation. This applies especially if the product will be used in different environments. Although adaptive environments should be minimised, it is of paramount importance to keep consistency from one session to another and achieve reproducibility of the data being obtained.

Furthermore, the device should not be complex to set up, especially in the instance where the device will be used in busy environments such as schools. Keeping the set up simple will avoid discouraging parents, practitioners, LSEs and teachers from making use of the device. The technical knowhow necessary to use the device should be at a bare minimum to avoid discouraging its use, as noted by technical expert *T5*, "The more technology you have involved, the higher the hurdle would be to overcome." Ideally, a guided set up process is provided along the device to guide different individuals to set up the device. This is particularly critical for secondary or tertiary users who are not trained to set up such an artefact.

Discussion, Future Work and Limitations

This study addresses the research questions on how to design smart habilitation devices for children when considering a multi-UX approach, as well as illustrates the engagement of various stakeholders, tackling the research gap identified. As a result, eight requirements were identified, based on what should be taken into account when designing such devices for children. These requirements can serve as guidance for habilitation device design engineers, so that they can develop artefacts that potentially reduce children's rejection rates.

Primarily, this approach takes into account insights from different users of habilitation devices, including other relevant stakeholders, as stated in *Requirement 1*. When designing artefacts for paediatric habilitation, one must not overlook the children themselves, even though they might be too young or constrained due to their limitations. Their voice is crucial to help design the device, as identified in previous literature. Furthermore, the input of other users and relevant stakeholders to the design process is vital if a device is to cater for different users' needs and wants. *Requirements 2* and *3* emphasise the importance of creating a motivational device that provides personalised and empathic experiences according to children's likings and needs, especially when it comes to habilitation devices, as strengths and limitations vary from one child to another. The profiles presented in Table 2 were emphasised for the use of children with CP, as one child's limitations vary a lot when compared to another's, with a difficulty to generalise between different children. Thus, the profiles were used to consider a case-by-case study and portray better the primary users of the habilitation device and identify their goals and needs. Meanwhile, *Requirement 4* deliberates what characteristics a typical habilitation device should have to be suitable for children.

Requirement 5 takes into consideration the habilitation device as part of a holistic system, highlighting key aspects of how one can make serious games suitable for paediatric habilitation purposes and provide an enjoyable experience for children conducting therapy exercises. *Requirement 6* highlighted the prospect of utilising the device in a social environment such as a school and employing serious games on a social platform. If the habilitation device were to be used in such an environment, the design needs to have social inclusion in mind, so insights from other passive users, such as teachers and LSEs, need to be considered, as discussed in *Requirement 1*.

Meanwhile, *Requirement 7* identifies the functionality aspects of the habilitation devices used for occupational therapy intervention, in order to capture and convey the data to the therapist. *Requirement 7* and *8* relate to the usability aspects of the device from the perspective of occupational therapists and parents, as it is fundamental for their interaction and experience with the product. Bitkina et al. (2020) identified the importance of such product-human interaction aspects and their vital element of UX. Furthermore, *Requirement 8* identifies the importance of having an easy setup, especially in hectic environments, otherwise, parents, occupational therapists, teachers and LSEs could be discouraged from using the device and instead opt for other means of habilitation.

Apart from the requirements identified in the previous section, other discussions arose during the focus group sessions. The parents and occupational therapists gave their view on how the devices (and the respective serious game) can be disseminated. The passive users highlighted that it is important for them to get the opportunity to test the device prior to fully purchasing it, and, if necessary, pass through a number of iterations before obtaining the final desired product. This is attributed to the fact that there are a number of devices for habilitation available on the market but they do not necessarily cater for their children's/clients' subjective needs. This iterative approach can help design engineers make observational studies of the interactions between the users and the product, to identify what might be missing in this current design.

Figure 3 illustrates an initial framework of the design engineers would follow to design smart habilitation devices for children, taking into consideration multiple users and amending the design accordingly to meet the stakeholders' needs, desires and goals. Although it is typical for such devices to be iterated multiple times with clients, users and other stakeholders, considering their requirements at an early stage can help reduce the number of iterations and ultimately reach the end-user in a shorter period of time.

This study has a relatively small sample size of 25 people in total, and, for the users' profile, the sample size was of four due to the small number of individuals with CP in Malta (as highlighted in the research boundaries of this study), but because various stakeholders were considered, the sample sizes are considered adequate. The number is also not such an issue because each group session had between six to eight participants, a number established as ideal by Krueger and Casey (2009). Taylor and Francis (2002) even suggested four to six only, to allow for more in-depth views to be developed by individual participants. Furthermore, as illustrated in Figure 2 in Section 3, these preliminary findings will be evaluated and analysed further through future studies.

Future work of this study could involve the use and evaluation of the device with other childhood motor disabilities. These would help generate more general

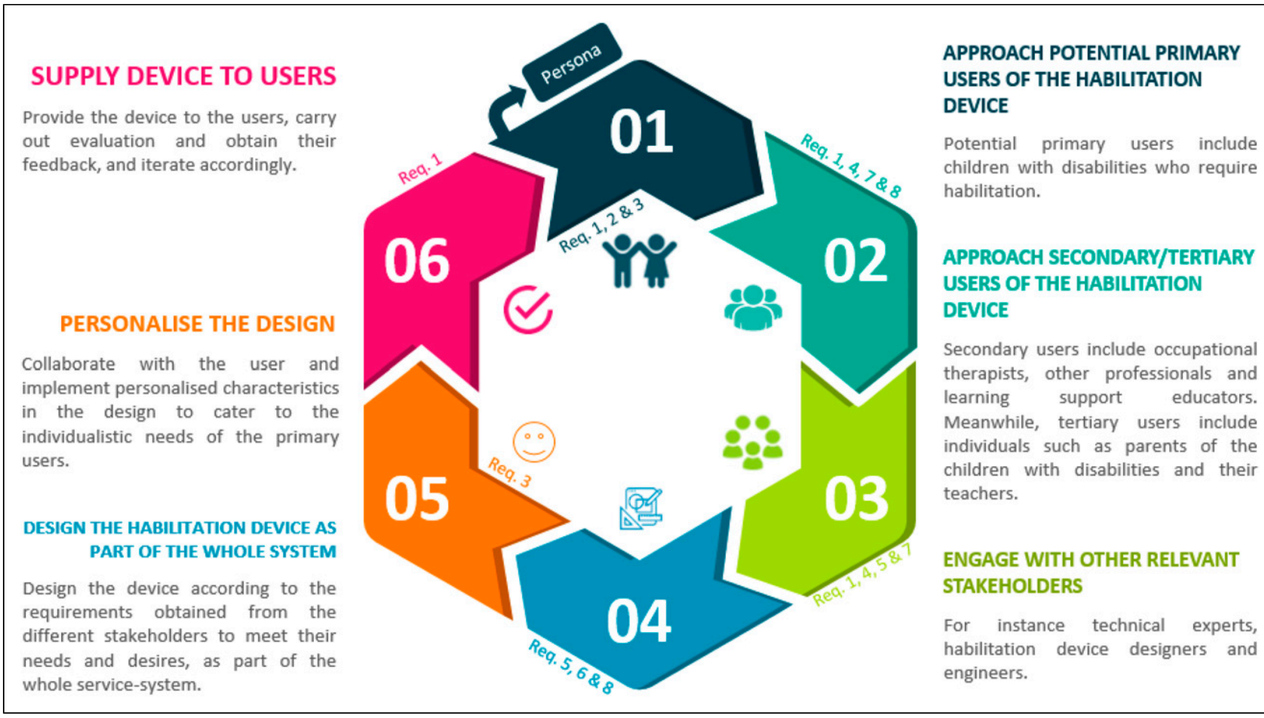

Figure 3. A preliminary multi-UX design approach framework for developing smart paediatric habilitation devices.

requirements for the design of client-centred smart habilitation devices that cater for a wider range of children.

Further work on *Requirement 6* should be conducted by approaching other relevant stakeholders, in case the device is used in different environments other than at home or at a clinic. In case of schools, stakeholders such as teachers and LSEs would be ideal for inclusion as part of the design process, to acquire their insights and experiences, and, hence, amend the design of the device to their needs and desires.

Given that the outcomes of this study are still in their preliminary stages, future work will be conducted to refine the requirements and respective methodology obtained, involving more subjects to generate a more robust framework. Envisioned are focus groups which will be conducted to validate the requirements generated and contribute towards improving the characteristics of the device. Future work will also encompass the requirements in an actual habilitation device for children, as, currently, these are only theory based. As part of future studies, the requirements resulting from this study should be implemented as part of a new design approach to develop smart habilitation devices to enhance paediatric occupational therapy intervention. Based on such a study, the design engineers can determine the applicability of the requirements and the respective effect of considering multiple users' experiences and insights of other relevant stakeholders. Ultimately, the end device and respective service-system can be evaluated by the respective stakeholders, including children and their families, as well as occupational therapists, to determine if their desires and needs have been satisfied, and, if not, consequently determine what might be done to improve the design. A comparative study can also be conducted to define the impact factor of the generated requirements/approach, as compared to previous methods to design smart habilitation devices for children, and determine whether the general acceptance rate is affected.

Moreover, the dynamics of UX are being considered more in studies on design for UX. Hassenzahl and Tractinsky (2006), and Ortíz Nicolás and Aurisicchio (2011) emphasised the importance of taking into account the evolution of emotions and how they differ between experience, experiencing and an experience. This could be another interesting aspect to study, based on the dynamics of the multiple users and their experience with paediatric smart habilitation devices.

Studies with design engineers of habilitation devices will be conducted to get their insights on paediatric habilitation devices development, and determine how these requirements can be portrayed better to guide them during their design process. Meanwhile, they can help identify what might be missing from current habilitation devices for paediatric occupational therapy intervention. Furthermore, another research direction would entail the evaluation of the design engineers on the proposed framework in Figure 3.

Conclusion

The contribution of this study lies in adopting a novel multi-user approach to determine the key requirements to design client-centred smart habilitation devices for children with CP. Taking this approach, different insights and perspectives were discussed, and through a thematic analysis of the information collected, the wants and desires of these relevant stakeholders were explored. In this study, four relevant stakeholders, including the primary end-user, were considered to help generate the requirements of such smart devices for use in paediatric occupational therapy intervention. Successively, these requirements were incorporated in a preliminary multi-UX framework approach aimed at guiding design engineers in designing habilitation devices for children. Ultimately, this framework and the respective requirements results will be evaluated through future studies with more subjects, to determine the extent of impact to help develop devices which are more efficient, user-friendly, safe, acceptable and in-line with the desires of the potential users.

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Author's Contribution

MB researched the literature, and with the assistance of PF and NB, conducted the study. NB was involved in recruitment of the participants. The first draft of the manuscript was written by MB. PF and NB reviewed the manuscript, provided their feedback and approved the final version of the manuscript.

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Supplemental material

Supplemental material for this article is available online.

Notes

1. This figure includes children with spastic quadriplegia (35), dystonia (6), hemiplegia (13), hypertonia (15), hypotonia (5), Erb's Palsy (1), Ataxia (1), Diplegia (2), agenesis of corpus callosum (1) and others with an emerging picture of CP (15).
2. Data obtained through personal communication with an occupational therapist focal person in pediatrics (Bondin, personal communication, 2 December, 2021), 60 children were identified as having primarily either spastic quadriplegia and hemiplegia, the types of CP most relevant to this study.

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