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A HUMAN-CENTRIC DESIGN FOR HOME USE VESTIBULATOR: A LOW COST PORTABLE THERAPEUTIC DEVICE FOR SENSORY INTEGRATION OF CHILDREN WITH AUTISM SPECTRUM DISORDERS

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ABSTRACT

Background: An emerging development in the healthcare industry is the tremendous rise in the number of medical devices individuals use at home. Although home healthcare is a rapidly growing industry and home use medical devices are an evolving market, the current COVID-19 pandemic situation parted ways of families of autistic children with their therapists as social distancing became an important method for managing the spread of Coronavirus. This development formed great implications for the scope and design of home-use medical devices for sensory integration through the Vestibulator. The Vestibulator is an innovative therapeutic device for human vestibular stimulation to answer the global problem of developmental disabilities such as cerebral palsy, autism spectrum disorders (ASD), attention deficit hyperactivity disorder (ADHD), and learning disabilities (LD). **Purpose:** This paper aimed to review the design process of Home use Vestibulator and presented a methodology that allowed the designer to identify potential sensory integration therapy that may be applied to children with ASD when lay users operate portable Vestibulator at home. **Methodology:** Through a structured methodology based on the human-centered design theory, a conceptual design in which sensory integration therapy with the use of low-cost portable Vestibulator in a home environment by a group of lay users was developed. To evaluate the design of home use Vestibulator, qualitative and questionnaire-based opinion was sought from the expert and ASD children's parents and caregivers. **Findings:** The new conceptual model showed evidence for efficacy, patient comfort, and ease of use of home use Vestibulator for children with ASD. The evaluation of expert and lay users found that the resulting design is appealing and perceived as useful for sensory integration therapy through Vestibulator at home. The study confirmed the feasibility of home use Vestibulator and informed continued product development and clinical trials afterward. **Unique contribution theory, practice and policy:** The paper provides knowledge about the implementation of human-centered design theory in the design of home medical device – Vestibulator. The new model proposed Home use Vestibulator clearly illustrated how system manufacturers must take into account several human factors during the design process in order to have commercial success with the home use Vestibulator.

KEYWORDS: Vestibulator; Sensory Integration; Human centered design; Autism Spectrum Disorders; COVID-19.

INTRODUCTION

Autism spectrum disorder (ASD) is a multifaceted neurodevelopmental condition characterized by disrupted social experiences and elevated repetitive behaviors in which specific conduits are compromised in the sensory, prefrontal, hippocampal, cerebellar, striatal and other midbrain regions.[1] The children with ASD display unusual reactions to sensory experiences as opposed to the response provided by developing children of the same age.[2] Children with ASD also exhibit inappropriate behaviors such as stereotypic motor movements, aimless jumping, aggression, and self-injurious behaviors.[3] A recent report estimated the prevalence of ASDs at about 1 in 54 children.[4] Occupational therapists are experts in delivering rehabilitation exercises that have proven essential for successful care of children with ASD.[5] One approach widely mentioned by occupational therapists for people for ASD is sensory integration.[6] Treatment based on sensory integration theory is designed to offer controlled sensory experiences to produce an adaptive motor response, enhance behavioral sensory control, and increase social interaction abilities.[7] Vestibular stimulation through a novel therapeutic device Vestibulator[8] is found to improve sensory integration and balance in children with ASD.[9]

The Vestibulator is an innovative healthcare device with a digital healthcare solution that provides stimulation for vestibular, neurodevelopmental, and sensory integration to children with ASD. The operator of the Vestibulator is usually a professional in a healthcare facility that provides interventions for several hours a week. COVID-19 has become a pandemic and several government decrees have imposed stringent measures to prevent it from spreading further.[10] Social distancing[11] strategies found to effectively mitigate the local progression of pandemic diseases. However, due to social distancing, families and ASD children are unable to attend outside interventions by their therapists. The treatment of children with ASD may be difficult for families and therapists in this situation. Given limitations in therapies, while staying at home, an unmet medical device need remains for new, low cost, portable and home use model of the Vestibulator. Also, E-health and telemedicine development have enabled the transfer of healthcare services from the healthcare facility to homecare settings.[12] A home-use medical device is a medical device designed for home use without the need for experts to operate it and committed to improving the quality of life of the patient.[13] As the medical device is built based on low-cost materials and a simple manufacturing process, the development of home-use portable Vestibulator can be viewed as a cost-effective device.

The home-use medical devices are usually operated by a trained non-professional who vary in terms of their knowledge and skills.[14] Such individuals are also called as "lay users" defined as individuals without formal training in a relevant medical field of discipline.[15] If the home-use medical devices meet lay user's needs and expectations, then home healthcare will provide substantial benefits for patients, both in terms of quality of life and treatment costs.[16] During the conceptual stages of the design process, product designers need information and data about the product's target users to accurately determine its usability in the home environment. In order to achieve a high level of user acceptance, it is critical not just the technological and engineering elements, but also the human aspects of these technologies and how they meet the needs and expectations of users about usability, comfort and their expectations for useful perceived home-use medical devices.[17] Therefore, an important consideration in the design of home use low-cost portable Vestibulator is the usability and human factors characteristics of the device and, thus, the user experience they offer for the children with ASD and their caregivers at home.

This paper explores the unique design of a medical device for home healthcare from a human-centric design perspective to illustrate the user's different needs and problems. The study focuses on the usability and human factors characteristics of medical devices designed for a clinical setting at home. The purpose of this work is, in particular, to design a low-cost portable Vestibulator in a home care environment for lay users through a structured methodology based on the human-centered design theory. The paper is organized as follows: First, the effects of sensory integration in ASD children using the Vestibulator in a clinical setting are introduced. Second, research methodology based on human-centered design theory and the application of the methodology to design low-cost portable Vestibulator for home use is described. This section of the paper also reports the interviews conducted with the experts and lay users to assess the usability and human factors of low-cost portable Vestibulator. Third, the findings of the interview study and the future of this work are discussed. Finally, implications and limitations of the research are discussed before the conclusion to continue product development followed by clinical trials is drawn.

1. Effects of sensory integration in ASD children through the Vestibulator

Children suffering from Autism have a defective network in certain areas of the nervous system. The defective network in the area of trunk representation at the cerebellar level, vermis of the cerebellum, results in impairment in the understanding of the total body in space. They seek extra vestibular input by fast rotations of the body in space or run around aimlessly without eye contact to understand the inhibited environment. They move around fearlessly and many a times hurts themselves. Their auditory network gets with an overactive vestibular network which affects processing the language.

Children and adults with autism, as well as those with other developmental disabilities, may have a dysfunctional sensory system – referred to as sensory integration disorders. The idea of sensory integrative dysfunction was first proposed by A. Jean Ayres, an occupational therapist and educational psychologist, in the 1950s and 1960s. Ayres developed sensory integration therapy in the late 1970s as a treatment for children with difficulties processing sensory information.[18] Sensory integration focuses primarily on three basic senses–tactile, vestibular, and proprioceptive. Their interconnections start forming before birth and continue to develop as the person matures and interacts with his/her environment. The three senses are not only interconnected but are also connected with other systems in the brain. Sensory integration is the ability to receive, process, and make sense of multiple sensory inputs at the same time.

Vestibular system dysfunction is a characteristic of autism.[19] Autistic children frequently engage in self-stimulatory behavior such as rooking, whirling, head banging, and spinning of objects, all of which stimulate the vestibular system either through direct input, optokinetic effects, or both.[20] This behavior represents an excessive need for vestibular stimulation as well as a means of facilitating sensory integration.[21] Many case studies have shown that improving the integration of the

vestibular system using swings resulted in the improvement of the subject's postural control, movement, exploration, and emotional well-being.[22,23]

1.1 Application of sensory integration therapy to ASD children

Anatomical structures related to postural control show three main tracts which originate from vestibular nuclei; lateral vestibulospinal, medial vestibulospinal and reticulospinal tracts. Medial vestibulospinal tracts originate from the vestibular nuclei and most of its fibers terminate at the cervical spinal tract. Therefore, it is reasonable to assume that stimulating the vestibular system would influence cervical postural control. The most important impact is related to the lateral vestibulospinal tracts because it passes through all parts of the spinal cord. Results obtained from experimental trials have shown the facilitator efficacy of lateral vestibular nuclei, on the activity of spinal mechanisms controlling muscle tone.[24] These neural pathways have an important role in balance. Both stability and movements[25]; thus, vestibular stimulation has a strong effect on postural control and balance in children with cerebral palsy, especially through the medial and lateral vestibulospinal tracts. The vestibular labyrinth has a critical role to play in the balance system. The balance system is not limited to just the vestibular system.

A more accurate picture of the balance system consists of various sensory inputs (visual, proprioceptive, and vestibular) integrated by automatic and coordinated postural control of muscles. Visual and proprioceptive information is changing all the time but the vestibular reference (that is gravitation) remains the same. Vestibular stimulation is necessary for the development of the ability to exclude excess information about posture, movement, and equilibrium from consciousness so that learning may occur.[26] Language development progresses as the child gains the ability to close out much of the sensory input which is received. Based on the above discussion it can be very well concluded that vestibular stimulations are an integral part of the comprehensive treatment module for Autism Spectrum Disorders (ASD). Vestibular Stimulation is achieved using various equipment like tilt boards, stability trainers and swings. All these equipment are manually handled have limitations as these cannot be quantified or graded.

1.2 Offering sensory integration therapy through Vestibulator

The Vestibulator is a therapeutic device to provide sensory integration designed and patented by Transpact Enterprises Limited[27] in collaboration with IRCC, IIT Bombay. It is a dynamic device used by physiotherapists and occupational therapists for the rehabilitation of children having development disorders including ASD, It is an automated programmable device capable of providing multiple matrices of body postures and motions, there are added variants of speed and duration. It has more than 1 million therapeutic modules for vestibular stimulation, which can be used for the treatment of multiple sensory integration dysfunction based disorders. The machine is designed to activate controlled Vestibular inputs for sensory integration therapy depending upon the need of the child. It is programmed to give specific motions, at a specific posture at a specific speed for a specific duration to the specific child.

Figure 1: Vestibulator – A sensory integration therapy device.

The machine activates the vestibular network by offering anteroposterior tilts, lateral and angular tilts, horizontal acceleration, and vertical acceleration over and above rotation from 0 to 360 degrees as illustrated in Figure 1. The speed, velocity, duration, and angle of motion is controlled and it may be increased or decreased by therapist depending upon the need of a particular patient. Vestibulator is ergonomically designed to optimize human well-being and overall system performance. Safety, accuracy, and efficiency are tested at various

level. The integrated software in the machine is designed for keeping a detailed record of the patient's medical history, treatment, and progress report. The cloud-based data storage of personalized records aims at easy access and monitoring of treatment. It is easier to achieve the desired qualitative results with combined treatment. The faster results with combined treatment lessen the financial burden of the family and save the time and energy of the therapist which helps her to have the time to handle more patients.

Therapists are using various equipment since last many years to use vestibular stimulation as sensory integration as in many previous studies it was found that Vestibular Stimulation is key therapy for sensory Integration.[28] Vestibulator enables the therapist to store personalized treatment combinations of the patients for monitoring and comparing. The Vestibulator has proven clinical effectiveness in the treatment of ASD children with CP, ADHD, learning disability, autism, etc. during the clinical study. The subjects have demonstrated very good improvements. ASD Children became less fearful on the moveable surfaces also their number of falls had reduced. There was a noticeable improvement in academics in some children- even handwriting.

1.3 COVID-19 and Need of compact low-cost portable Vestibulator in home environment

According to UN Enable, around 10% of the world's population, 650 million people, live with disabilities. In India, 1.67% of the 0-19 population has a disability. 35.29% of all people living with disabilities are children. Other estimates say that India has 12 million children living with disabilities. Only 1% of children with disabilities have access to school and one-third of most disabilities are preventable. Developmental disabilities are a group of conditions due to an impairment in physical, learning, language, or behaviour areas. These conditions begin during the developmental period, may impact day-to-day functioning, and usually last throughout a person's lifetime. Most developmental disabilities begin before a baby is born, but some can happen after birth because of injury, infection, or other factors.

People with disabilities generally have more health-care needs than others both standard needs and needs linked to impairments and are therefore more vulnerable to the impact of low quality or inaccessible health-care services than others. All these kids needed regular therapy for their better survival, communication and skills development. Autism Spectrum Disorder is a prominent development disorder and presently contributes about 1 percent of the world population.[29]

Autistic kids need Sensory stimulation along with other therapies regularly but during COVID-19 it is not possible due to restriction on public meetings and mandatory social distancing. COVID-19 which has been described as "the war of our generation", children with ASD are suffering lack of school playgrounds and rehabilitation centres for these kids are closed down, people are asked to be at home many countries imposed lockdown including India. The pandemic situation questions young children's routine with ASD and they are called to respect rules and habits which are not always understandable to them.[30] They have been missing their special education, behavioural therapy, occupational therapy, speech services, and other regular therapies along with social stimulation. Aggressive and self-injurious behaviours may also increase during this time of fear and uncertainty. Discontinuation in therapy may lead to delay in the rehabilitation program of these kids as well as may cause some deformities in their bodies.

Children with ASD needing sensory integration therapy have been unable to see their therapists in person for several weeks because of the continuing Covid-19 crisis. Due to social distancing measures amid the Covid-19 pandemic, the regulators have issued new recommendations on medical devices and tools for the treatment of psychiatric conditions, waiving some regulatory criteria. There is no question that technology has been instrumental in developing the health system. Discussion with therapists and caregivers of ASD children related to therapeutic problems faced during the lockdown, it has become a need to design a compact, low cost, and portable Vestibualor to provide sensory integration therapy in the home.

A low-cost portable and compact Vestibulator for sensory integration at home can be a great asset for the children with ASD. Through Tele-therapy and telemedicine technology, all types of sensory integration therapy can be provided to these kids by Vestibulator not only on these days of pandemic but also for the rest of the time. The home-use version of the Vestibulator shall be capable of performing most of the vestibular stimulations and provide the sensory integration therapy, which can be operated by a layman under the therapist's instruction. It fulfills the requirement of the sensory integration therapy for the children with ASD.

2. Using Human-Centered methodology to design Home-Use portable Vestibulator

Hospitals, therapy centers, and healthcare facilities are usually structured, well regulated, and operated under close medical supervision and firm regulations. Environmental parameters such as sterilization, electromagnetic disturbances, and visitor congestions are controlled to ensure a suitable and secure atmosphere for the performance of the equipment. In contrast, home settings are unpredictable and unregulated environments. The home of every patient is distinct, and the location of medical devices at home is also not known. The typical problems in the home environments are electrical contacts with home utensils, a non-sterile environment, cables, and line clutter, background noise, dust, disturbances, and crowding. These can limit and interrupt

the operation and use of safe and functional medical devices.[31] While designing home-use devices, consideration should be given to where and how the equipment will be installed and used, stored, cleaned, repaired, and disposed of, not just at home, but also at works, schools, shopping spots, and in vehicles when commuting. Besides, home-use equipment must avoid the appearance of disease or disability.[32]

The key functions of home-use equipment and devices include diagnosis, prevention, treatment, recording, disease alleviation, and rehabilitation. Diagnostic devices such as thermometers are available in almost every home. Monitoring and diagnostic capabilities have also expanded thanks to innovative e-health and telemedicine technologies with integrated systems and wireless sensors that enable continuous information transmission to specialized healthcare facilities.[33] Researchers have posed concerns about the user-friendly nature of healthcare devices as significant criteria for effective home telemonitoring.[34] Disease treatment medical devices broaden the responsibility for prevention, further degradation, and treatment from hospitals and clinics to the home and offer care where appropriate. The home rehabilitation equipment enables patients to receive routine treatments at a convenient time using procedures adapted to their unique needs. Integrated digital solutions with rehabilitation devices can improve and upgrade physical activity and enhance patient satisfaction, motivation, and compliance. Home rehabilitation and therapy are in line with the wellness paradigm and part of the contemporary gym and fitness equipment phenomenon that has also shifted to the home environment.

In their Medical Device Home Use Initiative, the Food and Drug Administration (FDA)[35] identified three specific challenges for the production of home-use medical devices. First, Medical devices can be too complicated for lay users to operate safely and effectively without training.[36] Second, the Home environment can involve threats that can impact the user experience or product performance.[37] Third, the usability of home-use medical devices and active involvement of human factors.[38] The International Organization for Standardization (ISO) defines *usability* as "the degree to which a user can use a product to achieve specific objectives with performance, effectiveness, and satisfaction in a given context".[39] The American National Standards Institute and the Association for the Advancement of Medical Instrumentation define the term *human factors* as "the application of knowledge about human capacities (physical, tactile, emotional, and intellectual) and limitations to the design and creation of resources, equipment, structures, environments, and organizations".[40] During the design process, the FDA called for usability and human factors evaluation of medical devices which require evidence of end-user involvement.[41]

2.1 Introduction of Human-Centered Design

Human-centered design (HCD) is a philosophy of design that aims at placing the end-user at the core of the design process.[42] The ISO 9241-210 standard describes the human-centered design as "an approach to system design and development that seeks to make interactive systems more accessible by focusing on system efficiency and applying knowledge and techniques of human factors/ergonomics and usability".[43] The standard explains the potential advantage of adopting a design strategy that enhances usability and human factors including improved efficiency, increased accessibility, prevention of stress, and reduced harm risk. The key objective of HCD is to improve the medical device's usability to generate maximum patient satisfaction and improve the device's safety output.

Several approaches to usability design have been considered for medical design production. Quality Function Deployment (QFD) is a human-centered design methodology that relates user specifications to observable design metrics.[44] Although research work has indicated that designers typically have a strong understanding of metrics that suit ergonomic outcomes such as ease and usability, the methodology lacks both formalism and adequate stakeholder access.[45] Another approach suggested a "design by intent" method in which designers seek to avoid undesirable user behaviors by integrating design attributes that lead users to behaviors that designers find desirable.[46] However, the approach is largely limited to early design and may not be well suited to all user populations, thereby reducing its usefulness in the design of medical devices. Other HCD methodologies have also been considered in the literature. Moelenbrook et al. developed an anthropometric database and imagining method focused on measurements of the longitudinal population.[47] While the data visualization is comprehensive and well structured, their generalizability is ultimately limited and human data remains a distant step from the process.

In recent works, a three-phase methodology derived from the process as outlined in ISO 9241-210 that followed the principles of human-centered design has been considered.[48] The approach suggested a three-phase human-centered design methodology to improve the usability, accessibility, and functionality of healthcare devices. The first phase of the methodology involves the creation of a user document framework for documenting use case scenarios, mock-ups, and user feedback. The second phase suggests expert inspections and usability walkthroughs, and the third phase emphasizes usability testing to develop the final prototype. In the end, the approach reported successful implementation of a three-phase methodology for the design and development of a home-use therapeutic device.

2.2 Application of Human-Centered methodology for design of home use healthcare device

The three-phase human-centered methodology is applied to design the usability, human factors, and user experience of Vestibulator, a therapeutic device to provide sensory integration to ASD children in a home environment. The three-phase human-centered design methodology is in line with ISO 9241-210 and is designed for use with healthcare devices by streamlining the various steps in the HCD process. In addition, the proposed methodology addresses a need not only for devices that achieve acceptable levels of usability but also for devices that may be correlated with rapid development cycles. More recently, guidance on how to execute the design and development process for home-use healthcare devices in terms of usability has been established.[49] Adequate documentation of the design process is crucial in the production of medical devices, especially if the device is to comply with a requirement such as that of the International Electrotechnical Commission (IEC), IEC 62366-1. When evaluating industry pre-submissions, the FDA needs proof of end-user participation during the design process.[50] The three-phase methodology adheres to the need for planning and documentation as outlined in IEC 62366-1.

The three-phase HCD methodology was applied to the design of the low-cost portable Vestibulator with the aim to provide sensory integration to ASD children at home. Therapists perform sensory integration techniques with ASD children using Vestibulator and recommend similar routine practice at home. However, as with the complex medical device, Vestibulator is only available through a therapist in rehabilitation centers, who then offer sensory integration therapy for ASD children under their supervision. A home-use portable Vestibulator could provide the necessary sensory integration to ASD children on a daily basis while at home. Also, sensory stimulation can provide intrinsic motivation to regularly perform essential therapy at home.[51]

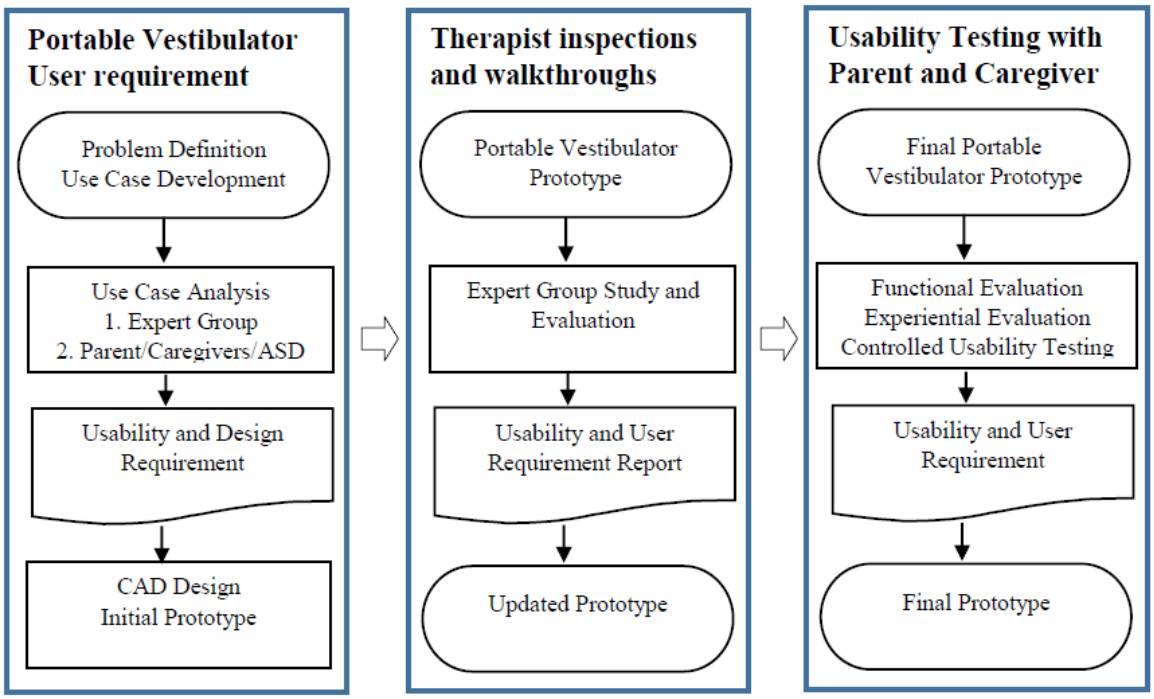

Figure 2: Three-phase Human-Centered Design Methodology

To deepen the understanding of how a portable Vestibulator can provide effective sensory integration therapy, the suggested methodology focused primarily on integrating usability and human factors into the design process. It illustrated how the design process resulted in conceptual design of a home-use portable Vestibulator. Finally, experiential prototypes of the conceptual design were developed and used with medical experts and end-users for a first formative evaluation. For the design process, three-phase HCD methodology was described that fulfilled the objectives in three phases: (1) Establishing the context of portable Vestibulator use and user requirements; (2) Therapist inspections and walkthroughs of the rehabilitation device in the home environment; (3) Usability testing with parent and caregiver in the home environment. Figure 2 presents a three-phase HCD methodology illustrating the design process and its constituent phases.

2.2.1. Phase 1: Establishing context of portable Vestibulator use and user requirements

This phase focused on understanding the functional and experiential requirements and designing the technology that underpinned the portable Vestibulator. The use case document was created with contributions from all project stakeholders, who were able to express their thoughts on how the Vestibulator should function in home settings and how it would be used for. The document outlined

scenarios that defined the tasks that the user would perform with the device, the order in which the tasks were performed, and the context in which the tasks were performed. This also included possible risks that the user could experience through their interaction with the portable Vestibulator. A number of stakeholders discussed the use cases, which included target end-users – ASD children, parents, caregivers, designers, and health professionals and people with specific knowledge who may not actually be end-users but have experience developing similar devices. The designer examined each user scenario.

The portable Vestibulator device users include not only the ASD children who use the device for therapeutic purposes but also their parents and caregivers who play an important role in promoting the use of the device by the ASD children. The design of portable Vestibulator devices is dictated by functional and experiential requirements. The functional requirements are derived from the regulatory elements and child-centered psychological influences. The experiential requirements of therapy, sensory stimulation, and user experience directly influence the design decisions. In designing the home-based rehabilitation device, the following five design requirements, functional as well as experiential requirements, were deemed essential.

1. *Sensory Integration Therapy:* The type of stimulation the therapy program would facilitate and how these corresponded to the appropriate movements that a physiotherapist should encourage a child to perform.
2. *Vestibulator functionality:* The performance of the portable Vestibulator including control level of assistance, functional workspace, smooth movement and robustness.
3. *Safety in the home environment:* Strong emphasis was placed on the portable Vestibulator's safety, both as regards mechanical, and electrical functionality.
4. *Usability:* How users, parent, and caregivers experienced the use of the device was taken into consideration.
5. *Human factors and experience:* This included any element of the device deemed to encourage the ASD children to use the product.

The first three requirements are functional, and the last two requirements are experiential. All the requirements are combined that used to inform medical device design. This list of requirements can be dealt with immediately, as most of them would be visual and apparent, while more difficult requirements can be addressed in functional prototypes, such as those related to concepts and flow. Prototypes are models used to demonstrate the shape and feel of a product.[52] A prototype can be a custom-made assembly to imitate the final design closely, whereas a common household object used to represent something else in a discussion could also be considered a prototype. Prototypes are useful throughout the conceptual design process. ASD children, their parent, and caregivers were utilized to iterate the initial designs of prototypes satisfying all the above requirements. This involved increasingly developing and refining computer-aided design (CAD) and semi-functioning prototypes with input from the appropriate stakeholders.

2.2.2. Phase 2: Therapist inspections and walkthroughs of the Vestibulator in the home setting

Having developed a semi-functional prototype of the portable Vestibulator able to provide the sensory integration therapy, the next step was to evaluate its usability and ergonomics with experts for design inspection and walkthrough. Although Phase 1 used a small group of experts to identify and review any apparent issues, the goal at this phase was to obtain a more representative response from a wider community of experts. The initial Phase 1 experts performed a double-part usability inspection. Firstly, the experts reviewed the solutions to the problems they found in Phase 1 using the new version of the use case. Secondly, they inspected the CAD design and semi-functioning prototype.

The second phase of the design process also involved developing the initial prototype of the home-use Vestibulator and validating the efficacy of the prototype for evaluation in the home setting. This phase involved several meetings to discuss preliminary design criteria involving design engineers, medical doctors, pediatric physiotherapists, mechanical engineers, and computer scientists. The experts were asked to use the initial prototype. The research team also observed this and analyzed the prototypes with respect to the design requirement. The expert feedback led to working prototypes until they were considered effective enough to be included in the usability evaluation. In this phase, data on the five requirements outlined in Phase 1 were collected through informal conversations and feedback with the experts, with the goal of recognizing and resolving obvious problems prior to next phase testing, rather than receiving illustrative feedback.

A prototype was developed that provided the highest level of assisted movement, specifically both position and movement, required for the sensory integration therapy, named the home-use portable Vestibulator. The device had a standard chair footprint that would be suited to a confined home environment. This design supported the arm of the child in all the plane and had a fully adjustable working area. All moving parts are shielded from the child while a protective handgrip is used and assisted by adjustable frames that allowed the child to position themselves in a required position. The aluminum tubing system and fiber were used for weight reduction and improved dynamic response. The principal materials used to develop this prototype are low cost, off-the-shelf components, and available globally. Although the home-use portable Vestibulator does not provide the same quality and level of assistance as of

conventional Vestibulator because it does not support the complete six positions and six motions of the Vestibulator, it still has the potential to provide sensory integration therapy in 4 positions and six motions (Figure 3). The assistive component of the rehabilitation device provides support for the therapeutic activity when applying the control that assesses the amount of assistance provided to complement the child's voluntary effort. The feedback received during this phase of the expert inspection was used to inform device development that was running in parallel with the expert walkthrough.

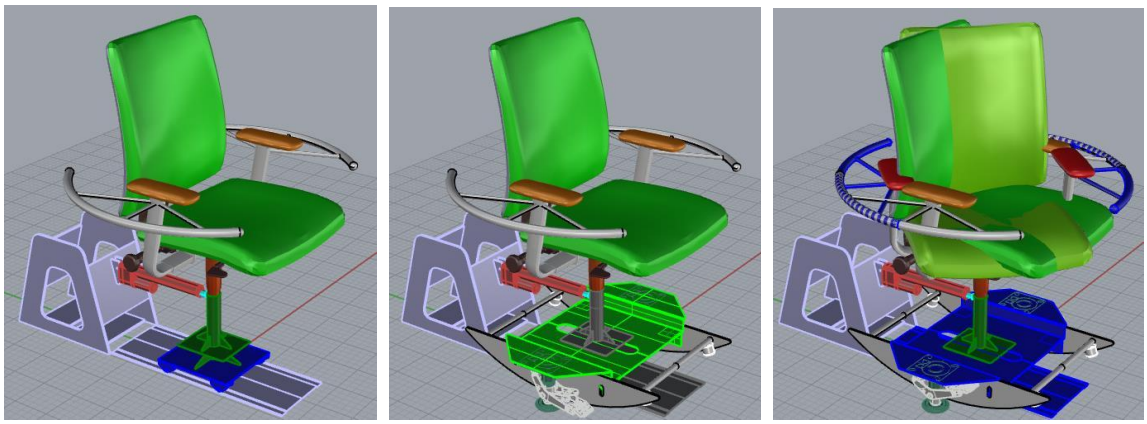

Figure 3: The Home-Use Portable Vestibulator prototype

The prototype of the home-use portable Vestibulator's conceptual design has been evaluated from the physiotherapy clinic POSAT Foundation in Mumbai with an expert child physiotherapist. To allow the expert to thoroughly evaluate the home-use Vestibulator and to transition from a semi-functional paper prototype to a working practical prototype, the device was introduced to the expert using a cognitive walkthrough methodology.[53] The cognitive walkthrough approach is used to define usability problems in interactive device, with a primary emphasis on assessing how easily and reliably new users can access and operate a device. All observed issues were reported and summarized in a study on usability and human factors.

2.2.3. Phase 3: Usability testing with parent and caregiver in the home environment

While Phase 2 focused on immediate reviews and feedback to the device, this phase focused on understanding how ASD children used and reacted in the intended home environment over some time. In this phase, an advanced working prototype with user manuals was introduced to end users in managed collective user testing where possible. Any major device problems found in the expert inspection should have been resolved by this time, particularly any issues which could adversely affect the end user's safety. The prototypes of the final design were distributed for use in the ASD children's homes for 2 weeks during which informal verbal input and questionnaires were used to capture the effects of sensory integration therapy through home-use portable Vestibulator and user interaction process.

The testing was carried out in the home of the ASD children and aimed the lay user's evaluation at acceptability and usability of the home-use Vestibulator. The assessment was set up in such a way that received valuable input from different stakeholders on the implementation of the design. Therefore, formative evaluation methodology was applied from the field of human-computer interaction, since this is more suitable for this conceptual design of the home healthcare device.[54] Besides, the medical ethical committee's ethical approval was not necessary for this formative evaluation. Parents and caregivers of the participants were informed and asked to sign a consent form before the study date. The parents and caregivers were asked to operate the home-use Vestibulator and perform the tasks defined in use case. Before the testing began, the researchers directed the lay user through the process using the user manuals. A user group meeting was held at the end of the trial period to obtain input from parents and caregivers on home use and to determine the views of users on their design process experiences.

A focused group meeting was organized with parents, caregivers, physiotherapists and design engineers. The group used both informal interviews and questionnaires to provide information. A project overview was provided with an opportunity to seek direct input from those interested in the design project, and notes were made of the resulting conversations. The five user requirements in Phase 1 gave rise to five questions to be answered by the user throughout the testing process.

1. Were the lay users able to operate the home-use Vestibulator for themselves at home?
2. Did the ASD children find the device comfortable to use at home?
3. Did the lay users use incentives to help motivate ASD children to use home-use Vestibulator?
4. Did the end users find the appearance of the device attractive?
5. What improvements, if any, would lay users like to see in product?

These were the key questions to be addressed with users when testing prototypes. Additional questions were used to better understand why children feel the way they were doing and how the prototype could be enhanced. In general, the home-use Vestibulator was found useful and received positively. One parent explicitly mentioned that she liked the appearance of the device. The ASD children liked the device at home as an electronic game and supporting tool. Nevertheless, for all the parent and caregivers, the potential benefits of the home-use Vestibulator was evident, and they were optimistic and awe-inspiring.

DISCUSSION

Product design requires an engineering and designer team to handle a complex and possibly complicated design, maintain design consistency, and eventually align stakeholder's expectations and requirements with those of the designing organization. In the case of medical device design, the involvement of a large number of stakeholders, and especially complex use environments, makes this task more difficult. In this paper, we have presented in detail the HCD methodology that integrates and translates current theories into a design implementation. The methodology has proven useful for informing our design process of creating a home-use therapeutic device in two main ways. Firstly, it offered structured process as a basis for product design, secondly, it offered a solid foundation for development of therapeutic device that can facilitate home-based sensory integration therapy to ASD children. The design process emphasized the participation of users, and used a variety of approaches to accomplish this.

The adapted three-phase HCD methodology is differentiated from other design approaches found in literature in two significant ways. First, this design approach takes into account a clear involvement of users, experts and other stakeholders alongside details about both the design itself and the process that contributed to the design being developed. This approach has many advantages. Firstly, it promotes beneficial design activities, such as ensuring specifications traceability, preserving and contextualizing experience, encouraging the reuse of design skills, and eventually utilizing a human-focused approach to the design of medical devices. Secondly, if combined with rational abilities, the method enables direct assessment of the effect of a design option on the results of specific users without substantial expansion of the designer's effort, potentially allowing for quicker and better informed ergonomic decision-making. This is an especially demanding problem in medical device settings where access to stakeholders is limited and skills of stakeholders can differ greatly. The second area where the proposed methodology differentiates from other design approaches is that it incorporates a clear perspective across the design and user viewpoints. This methodology is beneficial because it allows a large number of concepts to closely related, requiring a large number of iterations which pose a problem with usability.

The resulting home-use portable Vestibulator used the three-phase HCD methodology that followed the ISO 9241-210 standards. Concerning the cost factor, the benefits of the proposed device are associated with quick prototyping, increased versatility, and flexibility to incorporate a variety of low-cost components minimizing the cost of the portable Vestibulator. In this project, designs focused solely on specific stakeholders were followed by specifications and requirement documents. However, what is more relevant is the consequences of how similar user scenarios might be used. This is noteworthy because it means that pure affiliation with some group of stakeholders can be used to identify criteria for design in part. The methodology also promotes traceability of user requirements by connecting each phase back to specific activities with particular stakeholders. The approach used a simple rule to investigate the usability based on the lay user's performance. The approach also demonstrated how more comprehensive testing can be used to reduce the designer's need for direct input while still allowing for evaluations. The approach started with a process that aimed to gain a clear understanding of end users, therapy tasks and environments and attempted to resolve the entire user experience by creating a use case. This use case scenarios allowed end-users and therapy experts to participate and evaluate the system design, prototype and user therapy steps. We successfully incorporated various perspectives into our home-use Vestibulator design, using experts from diverse backgrounds such as product design, physiotherapy, mechanical engineering, and ergonomics.

The formative evaluation with parent, caregivers and ASD children was used to create a first impression of how the target audience experiences the concept, to determine whether they would initially be inspired to use the low-cost portable Vestibulator for home therapy and to gather input for further development of the design. The evaluation suggested that the target stakeholders liked the home-use therapeutic device built and could use it in home environment. Nearly all of the users including parent and caregivers suggested that they would possibly use the home-use portable Vestibulator. However, we need to adjust the style of the device and add accessories to make it more appealing to the target segment of ASD children. Expert therapists found that the new program will be highly useful to ASD children to practice sensory integration therapy with this home-use Vestibulator to treat vestibular dysfunction. The therapist has also confirmed that the home-use Vestibulator is an automated device that functions as a therapist at home. It was further noted that the low-cost portable Vestibulator device may also have a means of analyzing the severity of the vestibular symptoms in home environment with the close interaction of parent operating the device.

Limitations

Though promising, there are some limitations to the research discussed in this paper. As with any system designed to make intervention based on data, the outcome proposed in this paper ultimately relies on the quantity and quality of the stakeholder's input data and documents. In particular, in the field of medical device human performance, going beyond simple inputs of stakeholders might prove labor intensive and involve a broader and much more complex set of process, documentation, rule set, and regulations. Similarly, the usefulness of the design approach only occurs when adequate amount of data have been correctly collected into the design, since the process of data collection is relatively labor intensive. It probably doesn't make sense for a designer to collect information specifically for one design of the product, since the process would require the collection and parsing of all the data needed to simply manually evaluate the design. While we have argued that such detailed stakeholder's feedback may well pay substantial benefits across prototype development, this is a significant impediment for further product development.

We have also found other potential limitations that need to be addressed in our adapted three-phase HCD methodology. The prototype was only tested with experts from various disciplines in the Phase 2 of the design approach. The recruitment of experts can be expensive. Despite these limitations, there are many benefits to the design approach taken in this paper.

CONCLUSIONS

Designing medical device for home use is a challenging process. Although, these devices are medical devices, it is used by lay users who do not have the medical expertise to properly operate the device. Therefore, usability and safety of these devices is important, particularly because lay users are dependent on these devices. This emphasizes the usability, human factors and user experience of these devices to avoid mistakes in their use. Because of these challenges, the design approach for home use medical devices is different from the processes for medical devices and general healthcare products. These factors pose additional challenges to designers during the design process, and therefore designers need an extensive information collection process when designing home use medical devices.

This paper presented a design process model called three-phase HCD methodology for home use medical devices. The model is proposed to provide a methodological blueprint for prospective designers to follow an HCD process which adheres to a standardized structure but also allows for rapid development cycles. The proposed three-phase methodology is found comprehensive and highly descriptive, able to contain details as diverse as the composition of different usability elements for prototype, use case scenarios, regulatory documentation and human performance data. Overall, the work presented in this paper can be seen as an example of how available theory on three-phase HCD methodology can be used in the design of innovative low cost medical devices for home environment. This kind of research is important in order to build a knowledge base about how to develop low-cost portable medical device in the home context with portable rehabilitation devices and other interactive tools for sensory integration therapy to ASD children, especially during the time of social distancing in pandemic situation.

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