FEATHERS, A Bimanual Upper Limb Rehabilitation Platform: A Case Study of User-centred Approach in Rehabilitation Device Design.

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Abstract: The healthcare sector is increasingly becoming dependent on medical devices and technologies. This is facilitated, in part, by the emphasis that is being put on the robustness of the design of medical and rehabilitation devices. The robustness of the design, and thus the adoption of a new medical device, relies heavily on its ability to fit into the multifaceted medical environment and satisfy a wide range of user needs. In order to achieve this, users and stakeholders must be involved early and frequently in the design process. In this paper, we outline a user-centred approach to design of physical therapy devices using a case study on developing an upper-body motor rehabilitation platform.

1 INTRODUCTION

Stroke is the most common source of long-term disability among adults in North America and one of the leading causes of disability in children diagnosed with cerebral palsy. Hemiparesis, especially weakness and loss of control of the upper and lower limb on one side of the body, is the main impairment after stroke (Van Peppen et al., 2004). In children with cerebral palsy (CP), hemiparesis and impaired function of the upper extremity has a prevalence of one in three cases (Gordon et al., 2006). Hemiparesis can lead to non-use of the affected side of the body and a near-exclusive reliance on the unaffected upper extremity, which in turn leads to loss of independence in activities of daily living.

Individuals post-stroke need to complete a rehabilitation therapy program in order to recover from the hemiparesis caused by stroke and to regain their motor function and psycho-social health. The main clinical goal of such rehabilitation programs is to speed up the recovery process as much as possible. To guide this process, physical and occupational therapists work alongside each other to deliver a rehabilitation program that is tailored to the needs and conditions of each individual. However, this important goal of individualization is usually overlooked when biomedical engineers embark on designing new therapy tools. The end goal of “speed up the recovery process for the therapy clients as individuals” is often assumed to be “use technology to speed up the process of motor function recovery”. Without involving the users and stakeholders in the design process, such false assumptions become accepted and unquestioned which leads to development of devices that will not be accepted by the users.

1.1 Background and Prior Art

Traditionally, development of physical therapy devices has been based on motor learning principles and relies on the strengthening effect of physical exercise (Lohse et al., 2014a). Motor learning principles are largely driven by the findings of Neuroscience: in order to acquire new motor skills or to recover lost motor function, intensive, high-dose, repetitive physical exercises are required to induce brain plasticity and initiate long-term changes in the structure of the brain (Schaechter, 2004). A large variety of motor rehabilitation programs have emerged in the past two decades by applying these motor learning principles (Langhome et al., 2009), such as: constraint induced movement therapy, splinting, repetitive physical fitness training, and functional electrical stimulation. The same principles have been used in developing therapy tools that incorporate physiological biofeedback (Novak et al., 2011; Guerrero et al., 2013; Shirzad and Van der Loos, 2013 and 2014a), robotics (Patton et al., 2004; Brewer et al., 2007; Shirzad and Van der Loos, 2012), and virtual reality (Lohse et al., 2014b; Saposnik and Levin, 2011).

Physical therapy needs to be repetitive and task oriented (Sucar et al., 2014). However, the motivation of the therapy clients during exercise regimens also plays an important role in the success of the therapy they receive. Motivation to continue therapy exercises is key to therapy compliance and reduces the chance of early abandonment of therapy (Colombo et al., 2007; Harris and Reid, 2005). Using virtual reality (Saposnik and Levin, 2011), game design principles (Lohse et al., 2013), variations in task challenge (Shirzad and Van der Loos, 2015), and adding social connectedness through social medias (Alankus et al., 2010) are suggested to address this issue.

Despite the clinical research results that have shown the robustness of new rehabilitation tools developed in the recent years, most of these new technologies are not adopted by its users long-term. This is due to the fact that development of physical therapy devices is mainly driven by what “can” be achieved by technology and not by what “needs” to be achieved by technology (i.e., technology driven and not user-driven). The clinical environment of physical therapy is a multifaceted setting that delivers a program based on the needs of the therapy clients. In conventional therapy, the client is always involved in forming the therapy regimen. In order to bridge the gap between what users need and what biomedical engineers can produce, the design philosophy has to shift from traditional goal-oriented view of the past couple of decades to a user-centred approach.

1.2 Paper's Approach and Structure

The user-in-the-loop approach in design of medical technologies has gained momentum in the past decade to study, and ultimately to fix, the link between device design, human error, ergonomics, bad usability and patient safety. The traditional design strategies usually exclude the user from the development process and only involve them at the end of the design process to evaluate efficiency of the device in achieving the functional goals. This indicates that acceptance by the users and device adoption is "assumed" to be only a matter of the functional effectiveness of the device. Unfortunately, ample evidence exists to show that the adoption of medical devices actually depends heavily on their ability to fit into their complex medical setting and satisfy the users' needs (Zenios et al., 2009; Martin et al., 2012; Shirzad et al., 2014b). The user-centred design (UCD) approach that will be demonstrated in this paper shows the critical role of users in the iterative process of design as early as possible and as often as possible. Following the UCD process has the potential to improve the overall quality of the final product by subjecting the early prototypes to rigorous usability and user testing. Resolving possible usability issues makes the final product more likely to be adopted by users. However, the UCD process increases the time and cost of the design process, mainly due to the involvement of users in the process of creating several iterations of prototypes.
In the following sections, we first introduce the three steps of the UCD process. This is followed by a detailed discussion of each of these steps in separate sections. A case study on utilizing the user-centred approach to design a bimanual upper-body rehabilitation system is presented to highlight the details of implementing the UCD steps.

2 USER-CENTRED APPROACH IN DESIGN OF REHABILITATION TOOLS

The outcomes of the research in the field of Ergonomics have led to industry regulations that make the user-centred design approach a necessity in design of medical devices (FDA, 2000). However, the increase in industry regulatory requirements and awareness about efficacy and benefits of user-centred design has not led to an increase in publication of practical guidelines on implementation of this design approach. In this paper, we aim to address this issue by presenting a case study on implementation of the user-centred approach to design a bimanual upper-body rehabilitation system called "FEATHERS" (Functional Engagement in Assisted Therapy through Exercise Robotics).
The user-centred design (UCD) process involves three core steps: assessment of user and functional needs, development of prototypes with users in the loop to ensure the user needs are met, assessment of the solutions that are derived from the prototypes to ensure the functional needs are met (Figure 1). UCD is a top-heavy and iterative process. The main emphasis is on: 1) understanding the contextual needs (i.e., the first step) making UCD a top-heavy process, and 2) meeting the contextual needs (i.e., the second step) by iterating different prototypes through user testing and user feedback. In the following sections we provide more specifics on each of the three above-mentioned steps.

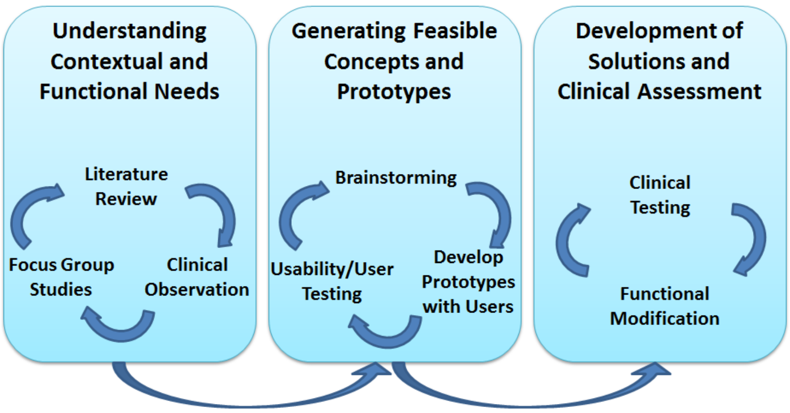

Figure 1. User-centred design approach

3 STEP 1: ASSESSMENT OF CONTEXTUAL AND FUNCTIONAL NEEDS

As the UCD process starts with needs finding, the main focus of the first step is on identifying a technology gap. This, from an industry or research perspective, is usually done by a thorough literature review in the field of interest. As applied now to the medical sector, consultation with medical professionals, clinical research, and clinical immersion must be considered. Oftentimes innovators become experts in a particular medical or clinical domain as they spend their time designing and developing new concepts and tools in that field. These innovators, who have now become experts in a particular field, can easily spot technology gaps and initiate the design process to address such gaps. This was the case for the FEATHERS project. By experience, we knew that even though most of the developed devices for upper-body therapy are functionally efficient, the therapy clients and therapists do not use them in therapy regimens.

Once a technology gap is discovered, the design team needs to gain an unbiased understanding of the functional needs in the context of the relevant medical setting. As illustrated in Figure 1, this involves reviewing the literature to understand the functional needs, observing the clinical culture of utilizing the traditional solutions, and developing an in-depth understanding of the user needs through mechanisms such as focus group studies.

The stroke therapy literature shows high-dose therapeutic regimens result in substantial improvements in function. A high-dose regimen involves tens of thousands of repetitions; however, currently in a regular clinical setting only up to 30 repetitions is practiced per therapy session (Lang et al., 2009). Through our FEATHERS clinical observations, we have learned that the limited practice opportunity and the necessary repetitive nature of current therapy compromise the motivation of individuals with hemiplegia to persist. Patients frequently report that traditional rehabilitation exercises are uninteresting, making it difficult to maintain motivation for sustained treatment. Our understanding of the problem up to this point was that a new physical therapy tool or regimen needs to be repetitive in order to be clinically effective, but at the same time the repetition of the exercises needs to be engaging.

In order to get a deeper understanding of the issue and to find out what type of solutions might be appealing to the users (therapy clients and therapists), we conducted four focus group studies, two with physical therapists, and two with therapy clients and their families or caregivers (Tatla et al., 2015; Lam et al., 2015). Despite reporting several challenges in integrating gaming and social media technology in therapy, therapists identified opportunities in this integration and showed interest in partaking the development of an upper-body training system that could make therapy more “fun” for therapy clients with hemiplegia. Both user groups agreed that by considering the needs of therapists and clients, the developed technologies will have a higher chance of being used routinely. From the focus group studies, we learned that an exercise system that utilizes upper-arm movement to play games and connects users via social media platforms has the potential to address both functional and contextual needs. Specifically, the user would play their favourite video games on a social media platform (i.e., Facebook©) and would receive positive social and therapeutic feedback from his/her social network. The games are controlled through a modified commercial motion capture system that maps the user’s arm motions to computer cursor motion.

4 STEP 2: DEVELOPMENT OF SOLUTIONS WITH THE USER IN THE LOOP

Based on what we learned in the need-finding step, we started developing different concepts and prototypes to address different aspects of the identified needs. The key point in this second step is to involve the users in the ideation-evaluation iterations to produce concepts around the contextual needs. This ensures that the design is driven by the context and what the technology needs to do rather than a technology-driven design that might not be able to address user needs. The concepts are then further developed to verify they are capable of producing the desired therapeutic effects (i.e., functional needs). Based on this the second design step, development of solutions with the user in the loop, is divided into two sub-steps: 1) interaction engineering to meet the contextual user needs and 2) rehabilitation engineering to meet the functional needs.

4.1 Interaction Engineering to Meet User Needs

In this section, we describe the design process of the FEATHERS System based on the identified user needs in the first step. A motion tracking application, adapted controllers, and a social media interface were developed and tested. Specifically, the motion tracking application allows the users to control computer cursor using bimanual upper-arm motions while holding the adapted controllers.

4.1.1 FEATHERS Motion Controllers

The controller design involved transforming the original PlayStation® Move hardware (Figure 2, left) into a device more suitable for the targeted population (*FEATHERS Controllers*). The design process began with research in the form of verbal interviews with physiotherapists, user observations, empathy studies, gesture explorations, and a literature review on the emotional and therapeutic needs of potential users. The analysis of the aforementioned data indicated that ease of use and ergonomics were some of the most important factors contributing to the users' sense of control when interacting with a computer, which in turn would enable them to improve performance and have fun playing games.

Based on these criteria, a number of prototypes were developed and tested with users, and the design was refined based on the received feedback. The body of the final prototype consists of two parts: an ABS plastic upper body and a bottom wooden tip (Figure 2, right). The smooth wooden pointed tip aids in the insertion of the controller into the grasp of a hand with high muscle tone, which is the case for a large proportion of the target population. The wooden parts also mirror each other in the left and right controllers, thus enabling the user to identify which controller goes into which hand prior to starting the game.

The control buttons are programmable, allowing the therapists to prescribe fine motor exercises of the affected hand as the user progresses, preventing the unaffected hand from doing all the work. An adjustable strap is also designed to allow the user to easily fasten the controller to a flaccid hand, which is the case for users who have impaired grasp ability (Figure 3). The new position of the tracker was strategically placed in the front of the controller, to enable the therapist to prescribe a wide range of hand movements while the user maintains a sense of control over the cursor on the screen, as the users feel that they are pointing towards the screen, rather than having the tracker on the top as in the original PlayStation controller (Figure 4).

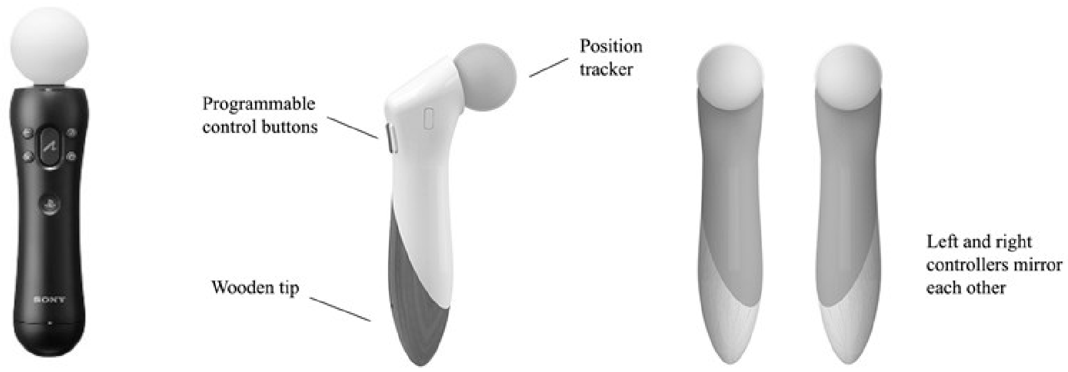

Figure 2. Original PlayStation® Move controller (left) and FEATHERS controllers (right)

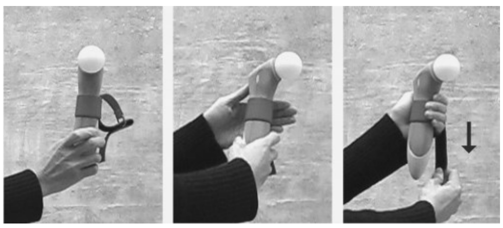

Figure 3. Adjustable strap for the affected hand

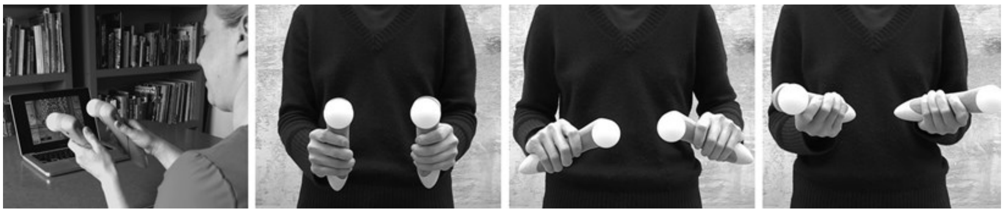

Figure 4. New tracker position allows for a more natural user interaction

4.1.2 Social Media Application: FEATHERS Play

In order to increase user engagement in rehabilitation, we developed a social media application (*FEATHERS Play*) on Facebook for the two different user groups (therapy clients and therapists) based on the outcomes of the focus group studies. Two similar interfaces were designed for each user group with slightly different functionality. For therapy clients, this application serves as an online community that promotes interactions between them and their therapists, or other clients, as well as a platform to access a large variety of games and the client's game scores. For therapists, in addition to communicating with their patients, they can monitor their patients' progress and recommend specific games depending on their clients' rehabilitation goals. The initial design of the application interface (Figure 5, left) was tested in a usability study with rehabilitation professionals (N=11, Jacob Nielsen's Discount Usability suggested N>5). Four Likert-type questions regarding the application's interface and function were administered in a "cognitive walkthrough" setting:

Q1. It was simple to review my game scores using the Facebook patient/therapist application.

Q2. There was enough information provided in the Facebook patient/therapist application to help me complete all the required tasks.

Q3. The steps for starting and registering in the Facebook patient/therapist application were easy to follow.

Q4. It was simple to link to a therapist using the Facebook patient/therapist application.

The initial design of the interface received 73% or more positive responses from rehabilitation professionals (Figure 6, left) on each of the questions. Qualitative comments were also recorded throughout the test session for specific design improvements (Valdés et al., 2014). Based on this feedback, the second iteration of the application was developed (Figure 5, right) and tested with 5 teenagers with CP and 5 stroke participants. Only Q1 and Q2 were administered due to the design changes. The modified interface design did not receive any strong negative feedback from teenagers with CP and stroke participants (Figure 6, right).

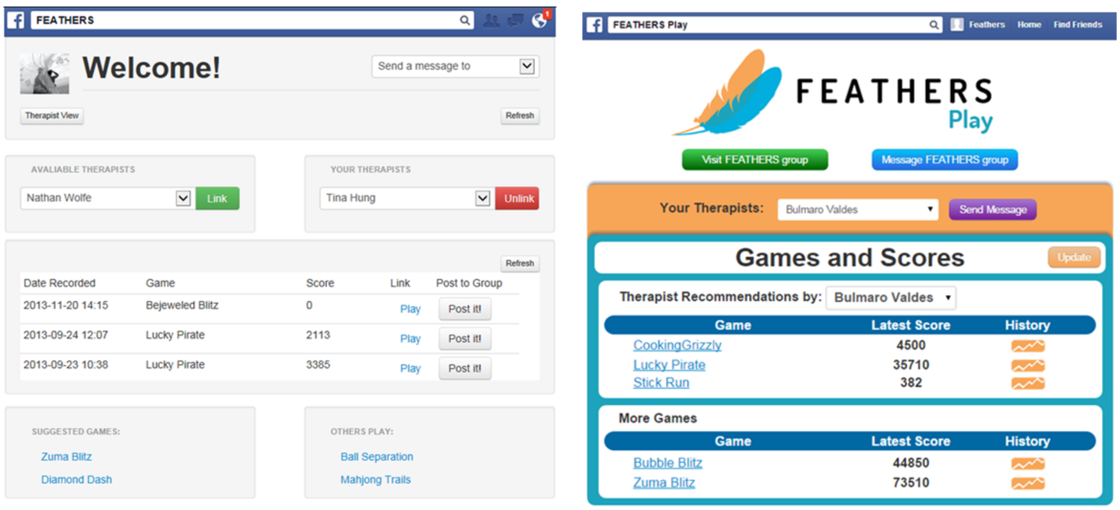

Figure 5. Initial FEATHERS Play interface (left), finalized FEATHERS Play interface (right)

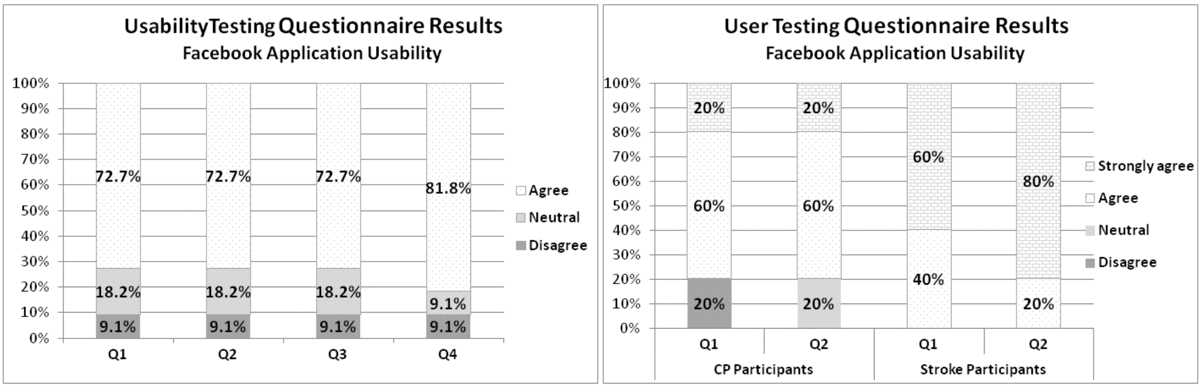

Figure 6. Results of usability testing with therapists (left), user testing results (right)

4.1.3 Design of Feedback to Keep Therapy Clients Engaged

From the focus group study with therapists, one of the key features needed in a virtual rehabilitation system was identified as the ability to provide adequate feedback to the users when their gaming session is over. By doing so, users are able to track their progress and get information about their functional ability and level of achievement (Glegg et al., 2014, Valdés et al., 2015). This feedback takes the form of three key measurements: *time played*, *distance travelled* by the user's hands and *game scores*. The metric *Time played* indicates how much time the user has spent using the rehabilitation system, and it can be observed in different time frames, e.g., days, weeks, or months. *Distance travelled* by the user's hands measures the total three dimensional movement during a single gaming session, and the information is given for both the paretic and non-paretic hands of the users, encouraging the user to move more symmetrically. Finally, the *game scores* are taken directly from the Facebook games and are charted to allow users to see if they are getting higher scores over time. This is a popular method in the game industry to increase the replay value of games, which in our case will lead to an increase in the replay value of the FEATHERS system and thus an increase in dose of therapy.

4.2 Rehabilitation Engineering to Meet Functional Needs

A bimanual therapy computer application (*FEATHERS Motion*) was built around the interfaces described in the previous section. The goal of this application is to provide a means of interacting with a personal computer by controlling the computer cursor using bimanual hand movements. The technologies that were selected as input interfaces were the *FEATHERS Controllers* and the Microsoft Kinect™. These technologies provide sufficient motion capture accuracy, have a low cost and are commercially available, all of which make them a suitable match to our design specifications.

The initial applications were stand-alone programs that worked independently for each of the systems. After the completion of the usability testing with the rehabilitation professionals, it was decided that combining the two applications into one would improve their ease of use and reduce the cognitive load on users and therapists. This led to the second iteration of *FEATHERS Motion* (Figure 7).

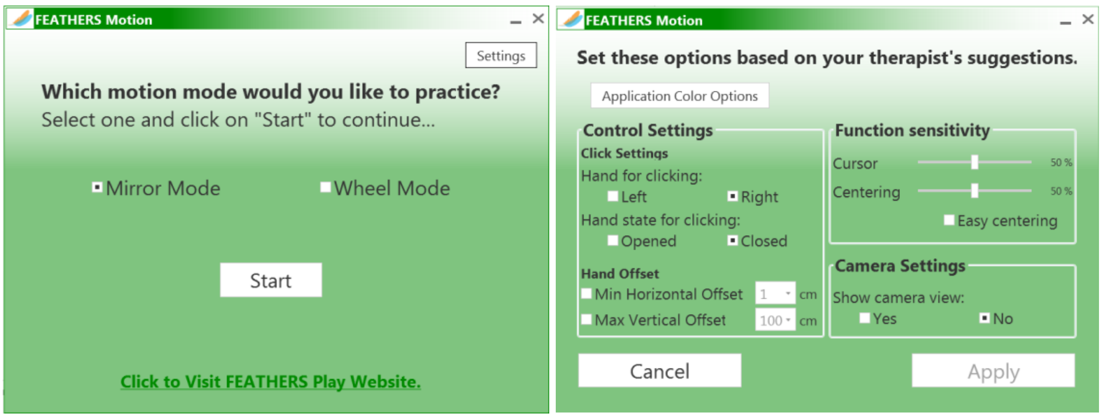

Figure 7. Finalized FEATHERS Motion application

Based on the therapists' comments from the focus group studies, two motion modes were implemented. These were the Mirror Mode (Visual Symmetry) and the Wheel Mode (Point Mirror Symmetry), both are shown in Figure 8. The Mirror Mode requires participants to move both hands independently in a symmetrical manner (both at the same time, and in the same direction) in the frontal plane: both vertical and horizontal movements are mapped into the cursor's motions. This condition was implemented to promote the use of the affected side and to prevent users from compensating with their unaffected arm. For the Wheel Mode, users are required to move their hands around an imaginary circle, and turn them in opposite directions to turn left and right, similar to when turning a steering wheel of a vehicle. In addition, the vertical motion remains the same as in the Mirror Mode: moving both hands up and down. Both modes were selected because therapists wanted their clients to practice symmetrical tasks using both hands, similar to activities that users would encounter in everyday activities, e.g., lifting objects, pushing carts or doors, and reaching for objects in front of them, among others. At the same time, therapists wanted users to cross their bodies' midline with the Wheel Mode as a means of practicing reaching across their body, and lifting their hands against gravity.
Apart from the two available motion modes, the applications can be adapted depending on the users' motor abilities. Using a "Settings" menu (Figure 7, right), therapists are capable of adjusting the cursor sensitivity, which allows them to adjust the FEATHERS system to the therapy client's range of motion. Also, therapists can choose which hand the users will be using for clicking, depending on whether the user is capable of grasping with the weak hand.

Figure 8. Bimanual motion modes

5 STEP 3: ASSESSMENT OF THE SOLUTION IN THE CLINICAL SETTING

While the second step in the UCD process ensures the developed concepts and solutions meet the contextual needs of the new medical device, the third step is necessary to ensure the functional efficiency of the design. This step is similar to the evaluation step of the traditional design method and involves clinical testing of the device. Usability testing and user testing that are carried out in the second step of UCD are mainly done in the controlled environment of design studios and usually do not expose the prototypes to real-world conditions. However, the goal of clinical testing in the third step is to study the functional robustness of the design under real working conditions and in clinical settings.
The literature on the design of clinical studies is very rich and the methods of experimental design are well established. In general, such studies involve stress testing of the device to show that the device embodies the minimum required specifications. Moreover, in the field of physical therapy, it is required to show that the device is capable to initiate and sustain therapeutic effects in the user. This involves long-term comparative studies in which a group of control participants receive a conventional, best-practices method of therapy and a second group of participants (the experimental group) receives therapy exercises that utilize the new intervention, in our case a new device. The effectiveness of the new device and its therapeutic effects as well as its effects on the clients' psychosocial health is then compared with the baseline effects that are expected from conventional methods of therapy. We are in the process of conducting a Phase-1six-month study and will publish the results in future publications.

6 CONCLUSION

This paper has outlined the user-centred design process as adapted to the biodesign sector, and specifically applied to the design of rehabilitation devices. The FEATHERS project as a case in point has maintained a central tenet grounded in the theory that neural plasticity will lead to functional upper-limb improvements through highly repetitive movements, and that bimanual exercising has the potential to speed recovery of function when used in conjunction with unimanual exercise (Lum et al., 2006).

However, the design process does not end at Step 3. First, the goal of this research and development is to create demonstrably effective therapies and devices that improve healthcare delivery. Follow-on multi-site trials, and trials with a more varied clinical population than initially targeted, are essential to establish the safety and usefulness of the system. Second, devices can only be made available to clients if successfully converted to products, so the business case must be developed in parallel with the clinical case. [For FEATHERS, commercialization efforts are being pursued.] Third, usability is only one component of user acceptance and interest in the devices as a consumer. With the increasing empowerment of the consumer in health care decision-making, and the increase in available income among older persons (i.e., those most at risk for stroke), choice of products, such as the WiiFit™ and other health-focused client-bought technologies, is obviously driven by product attractiveness and effectiveness.

FEATHERS has a long road of R&D and commercialization ahead. The adoption of the design process described above from the beginning has provided the team with substantial user-centred grounding to instil the confidence to proceed to future implementation and deployment steps.

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