Computer Assisted Robotic Therapy for Incomplete Spinal Cord Injury: Can it work in the acute setting?

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Abstract

Problem: Computer assistive robotic therapy is an innovative treatment offering an interactive experience that may benefit individuals with spinal cord injury, however it is not known if such a treatment is feasible in the acute setting. **Aims:** To assess the experience of individuals and practitioners during the process of implementing computer assisted robotic therapy and to determine the feasibility of using such a therapy during acute rehabilitation. **Methods:** To accomplish the aims of this study a qualitative feasibility study was carried out, consisting of semi-structured interviews (N=4) with a participant, their partner and the administering practitioners at a public hospital in a metropolitan area of Australia. These interviews were conducted using a guide created to ensure comprehensive and rich responses. These responses were then transcribed verbatim and thematic analysis was completed using NVIVO 11. Established feasibility constructs were then related to the exposed themes. **Results:** This study provided qualitative findings on the implementation of computer assisted robotic therapy with a patient with cervical spinal cord injury and interrelated these findings with theoretical constructs relating to feasibility. **Conclusion:** High demand for computer assisted robotic therapy both from patients and practitioners was reported along with many potential benefits especially regarding participant immersion, motivation and engagement. However, the practicality of such a treatment is complicated by prohibitive costs, time constraints and the vulnerable state of patients. Consequently, when considering current protocol, computer assisted robotic therapy may not be feasible in acute spinal cord rehabilitation. More rigorous research is suggested to support this therapy given the context.

Keywords: *Robotic Therapy, Tyromotion, Diego, Spinal Cord Injury, Qualitative, Feasibility*

Table of Contents

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Literature Review

Introduction

In the year 2014, 264 traumatic spinal cord injuries (SCIs) occurred within Australia (AIHW, 2018). Demographically these injuries primarily effect men, making up 80% of the population, the predominate age range of these individuals is 15-24 (AIHW, 2018). These injuries are often traffic accidents (42%) or falls, typically from sports/leisure activities (40%) (AIHW, 2018). Any SCI is traumatic, however, injury to the cervical spine is especially catastrophic leaving individuals with limited use of their upper extremities (Bashar & Hughes, 2017). These individuals spend a significant amount of time in the inpatient rehabilitation setting, approximately 219 days or close to seven months (AIHW, 2018). However, very little discussion appears within the literature regarding the experience of these individuals during this phase of their treatment. To address this gap in the literature, this study sought first to describe the experience of an individual in this setting.

Computer assisted robotic therapy is an innovative treatment yet to be tested with cervical spinal cord injuries. Similar treatments, such as Activity Based Therapies (ABTs) have shown promise in helping individuals with SCI recover (Behrman, Ardolino, & Harkema, 2017). Additionally, research has shown general robotic therapy to be a viable option in the treatment of cervical spinal cord injuries (Frullo et al., 2017; Hornby, Zemon, & Campbell, 2005; Siedziewski, Schaaf, & Mount, 2012; Singh et al., 2018; Zariffa et al., 2012). It is thought that robotic therapy may be a valuable tool in facilitating the recovery of individuals with incomplete spinal cord injury by allowing participants to engage in therapy for longer periods of time with

less assistance from therapists (Frullo et al., 2017; Zariffa et al., 2012). However, the accounts of these individuals are limited in the acute setting and it is unknown if such a therapy could work within such a context. The primary aim of this study is to assess the feasibility of such a treatment in the acute setting.

To assess the experience of individuals during this period of their recovery and the viability of implementing such a treatment, a qualitative feasibility study was conducted. This was accomplished by directing a series of semi-structured interviews with the initial patient, their partner and the administrating practitioners who organized and carried out the trial and treatment. Utilizing inductive reasoning through qualitative analysis, a gap in knowledge was filled guiding further research on computer assisted robotic therapy. Prior to this, it was necessary to investigate the literature. This was done by utilizing various medical data bases including MEDLINE, SCOPUS and CINHAL. First assessing the available qualitative information on individuals with spinal cord injury, then addressing possible points of interest for the study. Various texts were consulted through the University of Sydney to inform the structure of the study. The following information was gathered, informing the direction of the study and enabling its formation.

Clinical Utility and Feasibility

Clinical utility refers to how useful (utility) an intervention, assessment or any other variable is in patient care. The usefulness of an intervention can be demonstrated from a variety of perspectives including: clinical, humanistic and/or economic (Lesko, Zineh, & Huang, 2010). Before initiating more rigorous investigation it is increasingly important to deduce an interventions practicality. Doing so avoids the unwarranted use of time and resources by

researchers, practitioners and patients. Due to the growing number of innovative treatment modalities clinical utility examination have become more common in recent years (Smart, 2006).

In line with clinical utility, feasibility studies allow researchers to determine whether further investigation of an intervention is reasonable (Bowen et al., 2009). At early stages of assessing an intervention, feasibility studies can help determine the acceptability, demand, implementation and practicality of a study (Bowen et al., 2009). Acceptability refers to how well suited a therapy is for a setting or appropriate it is judged to be by the practitioners and participants (Bowen et al., 2009). The demand for an intervention can refer to an intervention's fit: how it is used or the perceived interest in the intervention from the public and from medical practitioners (Bowen et al., 2009). Implementation refers to the degree to which the intervention was successfully or unsuccessfully put into use and what resources were required to do so (Bowen et al., 2009). When judging an intervention's practicality, one must determine if the time and cost of using an intervention is suitable to the environment and the pragmatics of using an intervention in a given setting, or with a selected client group (Bowen et al., 2009).

Implementing qualitative methodology can help answer these questions through the interpretation of patients and practitioners (O'Cathain et al., 2015). Conducting a qualitative study helped determine: how practical using computer assisted robotic therapy was; what the barriers were to implementing such a therapy; and what the benefits may be in the acute setting. By interviewing a participant, their partner and the facilitating practitioners, multiple vantage points were mined for information. The patient and his partner were able to communicate what benefit they felt came from the experience and the practitioners were able to provide information, not only about the clinical benefits, but also how reasonable it was to use such an intervention in the acute setting. The practitioners were also able to make direct

recommendations about what might be useful for future researchers and how the process of implementing such a therapy might be made easier in the future.

Technology

The rapid pace of technology has changed all of our lives, and it has also had a significant impact on those with SCI. Assistive technology has enabled individuals to learn more about their personal care (Kaltoft, Nielsen, Salkeld, & Dowie, 2015), participate more in the community (Kim et al., 2014) and adds to individuals overall wellbeing (Mattar, Hitzig, & McGillivray, 2015). For example, Environmental Control Systems (ECSs) have enabled individuals to control their immediate physical environment with voice controls or other devices that require subtle movements (Myburg, Allan, Nalder, Schuurs, & Amsters, 2017). Enabling this ability decreases the individual's dependence on carers. Additionally, ECSs improve comfort, add safety / security and provide individuals with a sense of psychological control (Myburg et al., 2017). Individuals expressed that ECSs were best implemented when they felt ready and suggested that ECSs be prescribed on a case by case bases (Myburg et al., 2017). Conducting this study broadened the knowledge base on implementing technology. It further informed the literature and helped guide future research on how best to administer a specific technology.

Robotic Therapy

Although in its infancy, robotic therapy has shown great promise as an intervention for a variety of conditions. The device being investigated in this trial is the Diego, a computer assisted robotic therapy device created by Tyromotion, a robotic therapy manufacturer based in Graz, Austria. Robotic assisted therapy refers to an intervention that utilize robots to assist in patient movements during a variety of physical interventions (Kwakkel, Kollen, & Krebs, 2008). Computer assisted robotic therapy adds a computer user interface to this therapy, the

participant's movements are tracked by series of sensors attached to a computer, which in-turn enables the user to participate in a variety of different games and activities on a computer. The therapeutic value of these machines is enhanced by therapists who plan activities on the machine, targeting the participants needs. This is a new treatment that has not been extensively investigated, however, the Diego itself has shown promise and possible effectiveness in the treatment patients post stroke (Weber & Stein, 2018).

There is a paucity of research with regard to SCI and robotic therapy and the most commonly researched area is not focused on the upper limb, rather lower limb gait training completed at later stages of therapy (Holanda et al., 2017; Hornby et al., 2005; Mehrholz, Harvey, Thomas, & Elsner, 2017). This is not surprising due to the great emphasis placed on mobility within our society. Whether it be an athlete returning from injury or a teenager recovering from a car accident, a person's first steps post injury are something well documented in popular culture. With regard to upper limb rehabilitation, early findings have indicated that robotic therapy may have a positive effect on recovery from incomplete injuries, however more detailed investigation is required (Frullo et al., 2017). A similar device to the Diego, the Armeo Spring has shown promise as an effective treatment for patients with SCI, especially those with some perceived hand function following treatment (Zariffa et al., 2012). Another device, the REO GO, has been demonstrated as having some benefits with similar clientele (Siedziewski et al., 2012).

In summary, the literature indicates that robotic therapy is a capable new therapy for patients with SCI especially those with incomplete injuries (Frullo et al., 2017). However with each new device, evidence is needed to justify its use. Protocols are required to ensure a devices proper implementation and practitioner must be advised on how to properly implement such an

intervention. The first step in accomplishing this is testing the accessibility of such a treatment. By conducting this study, the experience of individuals using the Tyromotion Diego was assessed. The initial participant with a spinal cord injury to use the Diego was able to provide information on what he felt were the benefits of such a treatment and how he thought it might be improved. The practitioners were able to voice what went well and what didn't, and whether such a treatment was worth the costs. Ultimately a determination was made on how appropriate such a treatment was for patients with SCI in the acute rehabilitation phase of treatment.

Subjective Wellbeing

The physical implications of SCI are obvious, even the untrained eye can notice drastic changes in sensory, muscle, neuromusculoskeletal and movement function (Bashar & Hughes, 2017). However, the psychosocial impact resulting from such an injury cannot be overlooked. The subjective wellbeing (SWB) of individuals following SCI is decreased significantly, often resulting decreased mood and at time clinical depression (Papathomas, Williams, & Smith, 2015). This translates to individuals having lower levels of life satisfaction and higher levels of stress following injury, especially in the acute setting (Post & van Leeuwen, 2012). This is not surprising, as one can only imagine how difficult it would be to cope if one were able to complete basic selfcare activities and mobility tasks one day, only to be reliant on others to complete these tasks the next. The literature indicates that social supports and skills are vitally important in improving an individual's SWB (Müller, Peter, Cieza, & Geyh, 2012). The wellbeing of these individuals is adversely impacted by social isolation, many individuals report having a rush of support following injuries but as time goes on this support dwindles and they are left stuck in a society ill-suited to accommodate them (Smith & Caddick, 2015). However, participating in meaningful activities can lead to a perceived increase in SWB (DeRoon-Cassini,

de St Aubin, Valvano, Hastings, & Brasel, 2013). Psychosocial intervention strategies have yet to be comprehensively investigated and the impact of various therapies on this area is not well documented (Post & van Leeuwen, 2012).

Although this study did not specifically look at psychosocial intervention strategies or measure directly measure the SWB of patients, such issues could not be overlooked. The mental wellbeing of participants was monitored throughout the interview process and possible changes in a patient's attitudes were noted. If a patient felt that computer assisted robotic therapy was a positive, they were able to communicate this via interview. By conducting a qualitive study, the patient was empowered, being able to inform the research on why or why not computer assisted robotic therapy might help or hinder SWB. Practitioners were also able to report what they felt were the benefits of such a treatment and if they felt any change in the participants overall attitude. Furthermore, conducting this analysis will enable future researchers to decide what areas of SWB warrant further investigation or what steps might need to be taken to ensure the SWB of patients during their investigations.

Resilience

Perhaps the most discussed characteristic of individuals with an ability to recover from SCI is resilience. Resilience is defined as an individual's ability to overcome adversity during their recovery and adapt to a new life following a traumatic event (Kornhaber, McLean, Betihavas, & Cleary, 2018). It is an attribute determined by an interaction between a person, their experience and the environment they are in and is a key to break down avoidance - characterised by a person no longer having the emotional capacity to continue recovery (Kornhaber et al., 2018). Social support and psychological stamina are key if a person is to develop resilience (Monden et al., 2014). Resilience leads to psychological strength, adaptive coping perspectives,

spirituality and an ability to serve as a role model (Chuang, Yang, & Kuo, 2015; Machida, Irwin, & Feltz, 2013; Monden et al., 2014). Being such a key factor, it was important for this study to gauge what role utilizing computer assisted robotic therapy might play in developing resilience.

By conducting a series of interviews, this study was able to assess what role the Diego might play in the development of resilience of individuals with SCIs. The participant was able to express whether he felt participating in such an activity lessoned the burden of therapeutic activity. The patient's partner was also able to voice whether she felt the Diego helped the patient in wanting to move forward or if she felt the participant would have been just as resilient without the therapy. Practitioners were also able to voice their opinion on the Diego, describing the patient's ability to overcome low points in therapy. Positive findings might add to the feasibility of acquiring the device by further justifying its use.

Empowerment

A sudden dependence on others to complete the most basic tasks can lead to feelings of powerlessness or feeling that one has no control of one's life during the rehabilitation process (Prey et al., 2014). Learning new roles and participating in the community are key in empowering individuals post SCI (Rohatinsky, Goodridge, Rogers, Nickel, & Linassi, 2017). Furthermore, the ability to participate in high intensity exercise has led to feeling of empowerment amongst individuals with spinal cord injury (Luchauer & Shurtleff, 2015). Considering this, computer assisted robotic therapy might play a crucial role in empowering individuals during their acute rehabilitation. By enabling participants to engage independently with minimal assistance from a therapist, the Diego may lead to feelings of control and ultimately hope that they might be able to do other activities with limited assistance. Or individuals might not be able to participate in said therapy and feel less empowered.

By asking a participant about their experience in acute rehabilitation and their experience using the Diego, this study assessed the degree to which the patient felt empowered by the Diego. Using qualitative analysis and inductive reasoning, this study was able to interpret whether computer assisted robotic therapy led to feelings of empowerment within individuals or if such a therapy was just adjunct to traditional therapy. The participant and their partner were able to communicate whether they felt the therapy contributed to the participant's independence. And the practitioners were able to compare the Diego to more traditional therapies and gauge how it compared. This provided a comprehensive look at how the Diego might help or hinder a participants feeling of independence and empowerment.

Agency

A person's willpower, motivation and determination to overcome obstacles and recover from a traumatic event are crucial, the sum of these attributes can be defined as agency (Parashar, 2015). During a person's recovery from SCI they will experience highs and lows and it is critical for therapists to find ways to motivate individuals to remain engaged in therapy (Joseph, Wahman, Phillips, & Nilsson Wikmar, 2016). The literature clearly states that peer support and access to meaningful programs can give patients hope and increase their willpower in the rehabilitation stage of therapy (Beauchamp et al., 2016; Parashar, 2015; Wilbanks & Ivankova, 2015). However, little is known about what might facilitate greater engagement in the acute setting. Programmes for improving agency have not been assessed and interventions that motivate individuals are not well documented.

While in the acute setting, patients are at a critical stage in their recovery, conducting a semi structured interview with a patient and his practitioners allowed the expression of what possible implication computer assisted robotic therapy might have on the agency of similar

patients. After analysing these interviews, themes emerged regarding what aspects of such a therapy might contribute to a client's motivation and if this therapy might facilitate increased engagement by participants. The participant and their partner were able to assess whether they felt the Diego impacted the participants willpower. The practitioners were able to communicate how the participant's agency compared to other patients and if they felt the Diego helped the participant's will to get better or if they felt the participant was a naturally motivated person. These findings may assist further research into how computer assisted robotic therapy motivates individuals with a larger qualitative study involving more advances psychometric properties.

Athletic Identity

A common characteristic of people who make a successful recovery form SCI is athletic identity (Hawkins, Coffee, & Soundy, 2014; Rauch, Fekete, Cieza, Geyh, & Meyer, 2013; Ruoranen, Post, Juvalta, & Reinhardt, 2015). Athletic identity refers to the attributes a person associates with themselves around sports they play and activities they compete in (Hawkins et al., 2014). The diminished ability to participate in competitive activities can lead to a perceived loss in athletic activity, however, adding activities that preserve a person's competitiveness can aid in a person's recovery (Machida et al., 2013). Many of these studies focus on engagement in sports following discharge from hospital, such as wheelchair basketball, rugby and other community activities. Whether participating in a game-like activity in the acute setting will help these individuals is not known and the range of such activities is low due to the limited functionality of patients early on in their recovery. Since computer assisted robotic therapy has a video game like component involving some sporting activities, it may take advantage of a person's competitiveness and therefore their athletic identity.

Conducting a qualitative study with an individual with a SCI allowed them to express whether they felt computer assistive robotic therapy took advantage of their athletic identity. The participant was able to voice whether they felt the games were competitive enough or if they would like more initiatives in game play. Practitioners were also able to voice how well this therapy took advantage of this component. They were able to communicate on how the device enabled competition and in what ways it may be able to improve in this area. This was especially inciteful due to the dearth of information on individuals engaging in such activities in the acute setting. In the future this might enable researchers to assess athletic identity and computer assisted robotic therapy further and the results may inform creators on how to improve their products and add features corresponding with the findings. Furthermore, these findings may contribute to the feasibility of using such a treatment.

Flow

Flow has long been a been concept differentiating Occupational Therapy from other healthcare professions (Reid, 2011). Flow is a state of mind which emerges when an individual is completely immersed in a task or activity (Jacobs, 1994). When a participant enjoys a task that they are doing or are captivated by it in some way, they might lose track of time and space. For example, an individual playing soccer might run the same amount as an individual running for fitness without realizing how far they ran or how long it took them to run. By having individuals participate in meaningful occupations, therapists can take advantage of this state of mind, allowing participants to engage in therapy without realising it and participate for longer at increased repetitions (Feighan & Roberts, 2017). Recently the advent of interactive video games has reinvigorating this topic, individuals may gain the benefit of therapy in a more immersive

way, allowing them to perform at higher levels than they previously thought possible (Maloney et al., 2015).

Computer assisted robotic therapy may be able to take advantage of such a concept. By programming a machine to be receptive to specific body movements and having different games and activities respond to these movement this therapy is very similar to an interactive video game. However, quantitative analysis alone would not enable researchers to determine if patients entered a state of flow during their treatment. By interviewing a patient and conducting qualitative analysis, this study was able to gauge whether this specific treatment allowed patients to enter a state of flow. The participant was able to express their thoughts during treatment and whether they lost track of time or forgot that they were engaging in treatment. This information will help inform the literature on computer assisted robotic therapies possible ability to help participants achieve a state of flow. This may facilitate the further investigation of this concept and its ability to maximise therapeutic engagement.

Fit with Occupational Therapy

Due to computer assisted robotic therapy's ability to facilitate greater participant involvement in therapy without the direct physical assistants of therapist, it may be a promising therapy for individuals with incomplete cervical spinal cord injury. In the future, as these robotic therapies continue to evolve they may offer participants even greater benefits. Computer assisted robotic therapy adds dimensions to therapy that will be useful to occupational therapists. Occupational theory and its emphasis on therapy through the participation in occupation fits well with computer assisted robotic therapy. Its ability to immerse patients in therapy may help them enter a state of flow and be able to perform at a higher level than they perceived possible (Maloney et al., 2015). Furthermore, this intervention may fit well into the models of

occupational therapy. By taking advantage of a patient's volition, the internal driving force of a person, therapist may be able to help patients recover from intervention. A concept well supported by the Model of Human Occupation (Kielhofner & Duncan, 2009).

One might also argue that to gain the maximal utility of such a device an Occupational Therapist might be necessary. Patients may not gain the full benefits of such a machine without proper grading and it may not be safe to use such a machine without thorough understanding of the participants neurological anatomy. Expertise in neurology may be necessary to avert further injury of the patient, especially in the acute phase of their recovery when participants are in a fragile state of recovery. If patients are pushed too hard early on they may suffer further injury, but if they are not pushed hard enough they may not gain the full benefit of therapy. A knowledgeable therapist is also necessary to programme the specific movements into the machine prior to use. Without knowing the necessary range of movements or physical function, the intervention may not be successful. Furthermore, Occupational Therapy's unique ability to translate ability into function is needed in this area. Robotic therapy alone will not directly translate into selfcare tasks or activities of daily living. A therapist is needed to plan out a progression of movements that will enable participants to gain functional abilities later in recovery.

Conclusion

In conducting this study, the experience of individuals in acute rehabilitation was assessed then the feasibility of using computer assisted robotic therapy with individuals following incomplete cervical spinal cord injuries was determined. Previous research has indicated that upper limb robotic therapy maybe a credible use of therapy in subacute spinal cord rehabilitation with incomplete spinal cord injuries in which patients have some use of their hands

(Zariffa et al., 2012). However, it has been indicated that further investigation into this area is warranted specifically with devices targeting the upper extremities (Frullo et al., 2017). However, before moving on to more rigorous investigation we must first ask the question, “Can computer assisted robotic therapy work in acute spinal cord rehabilitation?” To do this we conducted a qualitative feasibility study to determine the acceptability, demand, implementation and practicality of the Diego, a computer assisted upper limb robotic intervention.

In determining the acceptability of the Diego: the satisfaction of the participant in using the device and practitioner in administering the therapy was assessed; the intent of the therapist to continue use was analysed; and appropriateness of the device was investigated. This was accomplished by asking the participant about his experience using the device and what he felt the positives and negatives were. The practitioners were then asked their vantage point, how they felt about administering the treatment, did they think it was appropriate to their setting, would they like to continue using this therapy, have they used similar therapies in the past and would they use similar therapies in the future. Analysing these factors helped determine whether the Diego was acceptable to patients and practitioners.

A vital aspect of determining the feasibility of the Diego was assessing what the demand was like from therapists and patients for such a device. If patients and practitioners were not interested in it there would be no reason to suggest a hospital or clinic in investing a considerable sum of time and money. To assess its demand, the patient was asked how interested he was in the device. The practitioners were then asked what they felt the demand was from patients for such therapies and to provide examples. They were also given the opportunity to voice what the demand was like from the therapeutic community and within their immediate environment.

Gathering this information allowed a comprehensive look at the demand for computer assisted robotic therapy.

To conduct further studies into the Diego it was necessary to assess whether it was implementable. To do this it was necessary to assess: how much time and resources were necessary to put the device into use; what knowledge and skills were necessary to use the device on the part of the practitioner; what level of ability was necessary on the part of the patient; and how successful executing the therapy was. This study enabled practitioners to directly inform the literature on what barriers there were to implement the Diego in the acute setting. They were able to communicate what time constraints there were in their setting, and what physical and psychosocial issues may exist among patients, preventing them from participating. Furthermore, they were able to inform future practitioners on the process of obtaining and implementing a computer assisted robotic device.

Ultimately this study assesses the practicality of using the Diego with cervical spinal cord injured patients during the acute phase of their rehabilitation. The patient was able to voice the positives and negatives they associated with the therapy, and these attributes were then analysed and compared to the literature to assess correspondence. The patient was able to communicate whether the Diego motivated them, whether they looked forward to it, the level of which the therapy immersed them and if their attitude changed based on the therapy. Finally, therapists were given the opportunity to express how practical they felt the Diego was. How they felt it compared to traditional therapy, how long it took to facilitate an intervention, how much training time was required, how long did the set up take, was there enough time in the acute setting for such a treatment, did they feel the machine was worth the cost and did the positives outweight

the negatives. Following this a judgement was made on whether the Diego warranted further investigation and in what way such an investigation would best be conducted.

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Implication for Rehabilitation

- Cervical spinal cord injury is a devastating injury resulting in the loss of sensory, motor and muscular function of the upper and lower limbs.
- Computer assisted robotic therapy may be an ideal treatment for individuals post injury in the acute setting.
- This study takes a qualitative approach and assesses the potential benefits of the treatment and determines how feasible it is in the acute setting.
- Computer assisted robotic therapy presents many potential benefits, however it is very resource intensive.

Computer Assisted Robotic Therapy for Incomplete Cervical Spinal Cord Injury: Is it Feasible in the Acute Setting?

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Computer Assisted Robotic Therapy for Incomplete Cervical Spinal Cord Injury: Can it work in the Acute Setting?

Purpose: To assess the experience of individuals and practitioners during the process of implementing computer assisted robotic therapy and to determine the feasibility of using such a therapy during acute spinal cord rehabilitation.

Materials and Methods: A qualitative feasibility study was conducted, consisting of semi-structured interviews (N=4) with a participant, their partner and the administering practitioners at a public hospital in a metropolitan area of Australia. These interviews were facilitated using a guide created to ensure comprehensive and rich responses. The responses were then transcribed verbatim and thematic analysis was completed using NVIVO 11 software. Established feasibility constructs were then related to the exposed themes.

Results and Conclusion: This study provided qualitative findings on the implementation of computer assisted robotic therapy with a patient with cervical spinal cord injury and interrelated these findings with theoretical constructs relating to feasibility. High demand for computer assisted robotic therapy both from patients and practitioners was reported along potential benefits including participant immersion, motivation and engagement. However, the practicality of such a treatment is complicated by prohibitive costs, time constraints and the vulnerable state of patients. More rigorous research is suggested to support this therapy's use given its demand on resources.

Keywords: Robotic Therapy, Tyromotion, Diego, Spinal Cord Injury, Qualitative, Feasibility

Background

Spinal cord injury (SCI) is a catastrophic injury impacting approximately 250 Australians per year [1]. The severity of this injury is well documented, often resulting in the loss of upper and lower limb function [2]. However, less is known about the inpatient rehabilitation experience of these individuals, a stage of therapy lasting up to 7 months [3]. What has been

documented indicates the need for treatment modalities that are engaging and allow participation in therapy at an early stage in recovery [4]. Adding computer assisted robotic therapy (CART) as a treatment modality for these individuals may be a suitable solution to address this problem, however the feasibility using such a treatment in the acute setting has yet to be determined.

What is Computer Assisted Robotic Therapy?

CART is treatment modality that provides participants with physical assistance with the movement of their limbs via robotics, and simultaneously these devices track the patient's movements allowing participants to interact with a user interface. This allows them to participate in a various games and activities without any direct physical contact from therapists. Early indicators support robotic therapy's use with patients with spinal cord injury [4, 5, 6, 7, 8], and early findings suggest robotic therapy may be an effective treatment for patients with incomplete cervical spinal cord injuries in the subacute setting [9].

Recovering from Spinal Cord Injury (SCI)

SCI is a devastating injury that has a traumatic impact on the lives of the impacted individuals. Following injury, individuals often have trouble accepting the consequences of the injury, this can lead to depression and an overall decrease of an individual's subjective wellbeing [10, 11]. To make a successful recovery individuals must be resilient in the face of adversity [12], and find ways to motivate themselves, taking advantage of their willpower [13]. Empowerment is also crucial; individuals must feel as though they can control their lives and have hope of independence[14]. By providing individuals the opportunity to participate in a fun and engaging treatment independently, CART may take advantage of these themes of recovery and prove a valuable tool for therapists in spinal cord units.

Why a Feasibility Study?

To justify treatments in modern medicine, practitioners must prove that such interventions are evidence-based. However, conducting more rigorous studies such as randomised control trials requires a significant amount of time and resources. Conducting a feasibility study allows researchers to determine if a treatment is possible in a given context before moving on. By assessing the acceptability, demand, implementation and practicality of an intervention researchers answer the question “Can it work?”[15]. Qualitative methodologies can help researchers answer these questions[16].

Methods

Device Specifics

The Diego by Tyromotion is a CART device developed in Graz, Austria. It is an upper limb therapy device with four straps attaching to the forearms just below the elbow and just above the wrist (see figure 1). These straps are connected to cords which are controlled by a computer giving participants varying amounts of support based on settings set by a facilitating therapist. After setup, the participant can play a variety of games and therapeutic exercises on a computer screen by moving their arms in a variety of different motions determined by the therapists. The therapists can also set up the device to support the participants arms during functional activities facing away from the computer screen.

Philosophy and Rationale

This study was created using a social constructivist worldview. Meaning it was shaped assuming that individuals seek to make meaning out of the places in which they exist [17]. By asking a patient, their partner and practitioners open ended questions related to their experience of implementing and using the Diego, an organic picture formed of how well suited the intervention was within their contextual framework. The small sample size of this

study was rationalized by its revelatory nature as a unique case. Revelatory cases study phenomenon yet to be investigated by researchers[18]. CART is in its infancy and has yet to be studied with patients with SCI. This study enabled the exploration of CART in a new area, with a new client group.

Study Design

Prior to the study ethical approval was gained from the National Health and Medical Research Council (NHMRC), the North Sydney Local Health District HREC and the NSW Ministry of Health. During the creation of the study, the CARE guidelines for case reports were followed and were correlated with the COREQ criteria to ensure proper protocols were adhered to[19, 20].

To assess the utility of the Tyromotion Diego in the acute rehabilitation setting a qualitative feasibility study was completed. Such studies are critical to assess acceptability, demand, implementation, practicality, adaptation and integration of an intervention[15]. It is important to determine how well an intervention will work in a given circumstance and how realistic it is for practitioners to implement such a therapy before entering into more resource intensive studies. Furthermore, these studies are important in providing guidance for future, more thorough investigations[21].

Being such an innovative treatment modality, the Diego has not been subject to any investigation with patients with SCI. Prior to moving on to more thorough investigations, it was determined that an analysis of the initial user's experience would help guide further investigations. By conducting a qualitative inquiry into this individual's experience, the facilitators and barriers were assessed regarding the Diego's implementation, as well as what the positives and negatives were from the perspective of the interviewees.

Data Collection and Analysis

Semi-structured interviews were the primary source of information for this study. To ensure validity in qualitative research information gathering must be consistent [22]. To accomplish this guides were created based on established models to elicit rich responses from participants [23]. Interviews were conducted with the first user of the device, their partner and the two Occupational Therapists responsible for procuring and implementing the Diego. All interviews were conducted post-implementation, the participant and practitioners were interviewed in hospital, and the partipant's partner was interviewed via cell-phone. These interviews were transcribed verbatim then read and reread. These interviews were then inputted into NVIVO 11 software and coded to determine themes within the interviews. These themes were then confirmed by an experienced researcher whom conducted independent thematic analysis. This process is well established as a method of thematic analysis[17].

Personal Characteristics and Relationships

The interviewer was male, a characteristic thought to be advantages as the participant in the study was also male. The participant may have been more comfortable and open with an interviewer with similar life experiences. Prior to interviewing the participant, the interviewer researched and created interview guides and conducted a practice interview with an individual with SCI to gauge the appropriateness of the questions and hone his own skills. Prior to the interview the patient and his partner had no relationship with the interviewer. The interviewer did not have a relationship with the practitioners, however, the interviewer had developed a working relationship with the practitioners prior to the stage of study involving their cooperation. All participants knew why the research was being conducted, the practitioners had initiated the study and the participant was informed prior to commencing

therapy and gaining consent. The interviewer's primary interest in the topic sprouted from the possibility for its utility in occupational therapy provision. Although this interest may have resulted in a positive bias, this was avoided by creating guides that asked balanced questions.

Results

Demographic Information

The interviewees of this consisted of three parties: the participant (the person participating in the therapy), the partner and the two facilitating practitioners. The participant and his partner were both in their early to mid-50s and lived an active suburban lifestyle with three children, all above the age of 10. The participant's injury was the result of a sporting accident and occurred approximately four weeks prior to the interview. Considering the severity of the injury, the participant had a very positive attitude as reported by his wife and therapists. Prior to the injury the participant was self-employed and earned a good living. The therapy and interview occurred at a public hospital in a spinal cord acute rehabilitation unit within a major metropolitan area of Australia.

The practitioners were both Australian-trained occupational therapists with varying degrees of experience with SCI, however both had more than 3 years of experience in spinal cord injury at the hospital of implementation. Both therapists had experience with robotic therapy in Australia and one therapist had additional experience in the UK. However, they had no experience using the Diego in practice. To appropriately use the device, each therapist had to partake in approximately 4 hours of training with a certified representative from Tyromotion. Once trained, they were able to train others on how to use the device. However, they did report that an extensive knowledge of neurology and experience in occupational therapy were required to get the most out of using such a device in spinal cord rehabilitation.

Is it suitable?

When considering acceptability, it is important determine if practitioners and participants intend to use the Diego and if they perceive it to be appropriate. The participant of this study clearly stated that he enjoyed the experience both in the interview and to the practitioners. And the practitioners clearly stated that they intended to use the device and have continued to seek new eligible patients. Furthermore, they stated that the Diego specifically was well suited for their setting, stating, "…in the acute phase I think there is a place for it. The shoulder and the elbow are what we work on first."

Is it wanted?

Considering the demand for an intervention is important, if participants and practitioners are not interested in therapy there is little point in acquiring it. Throughout the interview process the participant and the practitioners showed great interest in using the Diego. The participant expressed that he would like to continue using the machine and the practitioners continually expressed their interest expressing it not only interview but also by their action in persistently attempting to acquire said device. More globally, the practitioners expressed interest in such devices, stating that patients often seek out clinics that have similar devices. Furthermore, they reported interest from colleagues within their setting.

Is it usable?

Putting the Diego into use was not an arduous process, however clearing the barriers to use in a public hospital was reported as being "painful… …very painful." The facilitating therapists had been in contact with a Tyromotion representative for some time and had expressed interest in the machine however due to the cost of the machine (approximately $130,000) the therapist had not been able to convince their administration to make such a purchase without evidence. However, an opportunity presented itself and the therapist were given the

opportunity to use the device given that they conduct research in spinal cord rehabilitation, an area previously uninvestigated. Upon receiving the device, the practitioners needed to obtain ethical approval. Given the vulnerable medical state of the patient population and the interactive nature of the treatment, this proved to be a time consuming and challenging task lasting over 7 months (see figure 2).

Once cleared for use, initiating the trial with a patient was not difficult. Setting up the device was straight forward, and the therapy fit well into the participants therapy as an adjunct. The practitioners wanted to stress this stating:

"… that is what I want to emphasize because that is what I have been [told] on units where no one is using [similar devices] because they are fearful of the set-up time. But too many therapists just look at it and go, "too hard, it will take too long.""

Overall, once the initial barriers were overcome and a participant was selected, facilitating the participation in the use of the Diego was a very simple process and the therapy was executed without any difficulty. The practitioners reported that "the actually device itself, there [are] no barriers to using it in this environment."

Does it fit?

Time Consumption

From a practicality stand point, the biggest barrier to using the Diego was finding the time to do so. The acute setting is busy, not only for therapist but also for the patient. This was summed up well by the practitioner:

"… We are busy, but the patient is also busy. We are in the acute phase of treatment, so the patients go off, if they are unwell… …for scans, they're going off for tests… …there are still a lot of doctors' appointments happening…. …. So, for us to be able to fit them into the number of sessions that we need can be challenging at times."

Not only is finding the time for treatment difficult, but the patients often do not stay long enough in the acute setting to enable the full participation in a course of treatment as desired by the practitioners. Initially, the desire was for participants to have six weeks of treatment however this has not been feasible. Patients have been discharged to another rehab facility sooner than anticipated:

"We had heaps of time back then, so we thought this six-week program would work very easily, but it's proving to be hard now because the length of stay is four weeks for new injuries."

These time constraints have been further exacerbated by the time it takes patients recover to the point where they are eligible to use the machine:

"… it takes a couple of week to stabilize [the participants] and allow them to actually stay up in their wheelchair for long enough to actually participate in the study and for them to feel well enough to participate."

Sense of Competition

Do to the interactive video game experience provided by the Diego, it did well to take advantage of the participants competitive nature. The participant reported that the Diego has "challenges in it, in that it is a competition and I like a bit of competition." When asked if the therapy would be even better with other participants using it at the same time to compare his scores to the participant responded "[expletive] yeah, if they could get four stars I would be very upset (laughter), Yeah that would be [good]." Supporting this statement, the practitioner voiced that "… he was very competitive as well, so he wanted to achieve the three-star top ranking and he wasn't achieving three stars he wanted to go back and play again, so he could achieve three stars."

Feelings of Progress

A theme common among the interviews was the sense that the participant had made progress both biomechanically and functionally. It was made clear by the participant and the practitioners that this progress could be due to several factors, including the participant's simultaneous participation in a physio therapy trial in the unit. Nevertheless, the patient was impressed by the gains he had made especially at a functional level, when asked about his progress the patient communicated:

"I think that if we actually tried those activities at the start before you put on the Tyromotion, I probably wouldn't have been able to do them. But that would certainly show the improvement being made… …for sure I wouldn't have been able to do it three weeks ago before I started using the Tyromotion… …the activities I can understand doing what I do how it has helped doing those lifestyle activities."

Making progress is important when recovering from any injury, and the participant communicated that progress he made was especially important to him. His partner voiced that:

"I think the improvement. The measurements they took at the beginning of the trial and when they took them before he had to go to rehab, there was a significant improvement… …. Whether or not that would have happened through physio alone, I don't know… … [but it was] awesome to have those results, they're right in front you and you can see it. It's great if you can get any, any small improvement it's a good improvement but [the participant's] were quite significant so he was quite raptured with that."

Furthering this sense of improvement was a realization on the part of the participant that they may have more function than they previously anticipated. The practitioners communicated that "they feel like their limbs are moving more than normal" that the participant "felt like [he] was being pushed more, he was working more at the end of his

range [of motion].” Furthering this point, the practitioners also stated that this was an attribute that the Diego shared with other assistive robotic devices stating:

“That’s a common feedback, with both the Armeo Spring and this, that they didn’t feel they had this much movement but they… …don’t focus on their impairment they focus on what they can do.”

Increased Engagement

Along with feelings of improvement, the practitioners also communicated a sense that patients engage at a higher level in robotic therapy than they do in traditional therapy. When describing the participant’s engagement with the Diego the practitioners stated that:

“… to have someone engage in upper limb therapy for that long and push themselves that hard and long, it’s not really something you see that often. When you’re working on activities like pinning stuff on a washing line... …your patient is not going to be engaged for forty-five minutes.”

Furthering this point, a practitioner also noticed that this level of engagement was obvious even when they were not working directly with the patient stating that “He seemed very excited in that treatment, like I could hear him in the office. Shouting, laughing and having fun.” It was also observed that this therapy also allowed a participant’s family to facilitate further engagement:

“I think the nice side as well was that his whole family could be involved. So he had his friends and his family, and they would all stand around while he was playing. And they would be encouraging him or laughing with him about the game.”

Contributions to Flow

Flow was a theme communicated by all three parties, the participant stated that, “You get thoroughly immersed, in the challenge, that’s easily done.” And when asked if he ever forgot that he was participating in treatment he responded affirmatively. The patient’s partner

elaborated on this sentiment stating:

"It was just something that was a bit different, it was interesting, you know it wasn't just doing exercises, it was doing something without actually knowing you were doing it."

The therapist reported:

"Yeah it's flow. There was one time when we were practicing the virtual reality, so the swimming. And the patient made the comment, this is what I would normally be doing, this is how I would normally be staying fit and training. So, he felt like he should be doing a couple of laps each day on the Diego."

Contributions to Motivation

It was made clear that the Diego was something that the participant looked forward to more than traditional therapy and that even when fatigued, the Diego had the ability to motivate the participant. When asked about to compare the Diego with more traditional therapies the participant gave the following response:

"It was Monday, I had a big weekend and I was really shattered Monday. But I only got out of bed to do the Tyromotion and the [other therapy]. Because that is what I committed to, and I was part of your trial so... And I look forward to the Tyromotion a [expletive] more than the other… …and I only did that because of the benefits that I am getting."

When asked about the Diego the practitioners described the same instance but from a different perspective:

"Definitely motivation, he actually enjoyed participating in the Tyromotion therapy… …there was one day when he wouldn't have gotten out of bed, he felt bad, he had spent the whole weekend out and about and he was absolutely exhausted. And he got out of bed on the Monday just to come to Tyromotion. So, I think that says something. That level of motivation when you're not feeling well, and really wouldn't have gotten out of bed for any other reason and you did get out of bed because you wanted to be involved in Tyromotion therapy."

Negatives of the Diego

Although most of the comments about using the device were positive the participant and the practitioners did state some negatives. Although the entertaining the games involved in the machine do not present the best graphics. The participant reported that it was more akin to playing a primitive arcade game than a modern video game communicated, “I think it [may] need potentially an upgrade on the games, the graphics, they are very basic graphics, all be it, again [the] theory kept me immersed, and they did challenge [me] and that’s the objective really.” Furthermore, the participant expressed that if more sessions had been added he may have grown tired of the games that he had already played because he had gotten to the highest level of the game, effectively beating it.

When communicating the possible negatives of this and other robotic devices the practitioners communicated concerns that patients at times grew bored with traditional therapies and only wanted to participate in the robotic therapy. And even though robotic therapy is more than likely beneficial there have been no randomised control trials done with spinal cord injury to prove its effectiveness. Specifically, the practitioners communicated, “there are limitations to [the Diego], it’s only working on reach, you have to be able to use your hand once you reach.”

The practitioners also voiced that the lack of a continuum of a care with the device is problematic. They stated that the participant was concerned that he would not have access to the Diego in his next care setting. Additionally, to fully gain the benefit of robotic treatment it was stated that the whole suite of Tyromotion products would be necessary, which target various parts of a participant’s anatomy. However, this was perceived to be unrealistic considering the limited financial resources of the hospital.

Discussion

This study sought to determine how feasible computer assisted robotic therapy is in the acute rehabilitation setting with individuals with incomplete cervical spinal cord injury. In answering the question "Can it work?", based on design principles found in the literature, the acceptability, demand, implementation and practicality of using such device [15]. The findings suggest that even though the device shows great promise and generates a tremendous amount of interest, the practicality in implementing such a device in the acute inpatient setting can be difficult.

It's hard to find the time

One of the most difficult aspects of the acute phase of spinal cord injury is intense schedules of the patients and the practitioners. It is difficult to fit any new treatment in and robotic therapy is no different [4]. Practitioners indicated that it was difficult to fit the desired number of sessions into a participant's schedule and that the length of stay for acute patients was shorter than anticipated resulting a failure to complete the desired protocol. Furthermore, post injury individuals need time to recover before participating in treatments due to their vulnerable nature[24], and some patients do not feel well enough emotionally at this stage to fully engage in therapy[10]. This further reduces the amount of time that an individual can participate in treatment in the acute setting because patients start treatment closer to discharge. Subsequently, such a treatment may be more easily implemented in the rehabilitation setting where there is larger timeframe to implement therapy. However, additional evidence supporting the Diego's implementation in a shorter time frame closer to injury, may indicate that a shorter treatment program is justifiable and justify the need for the Diego in the acute setting.

Looking forward to treatment

One of the more positive aspects of the machine was its ability to take advantage of patient's competitive nature. The game like nature of computer assisted robotic therapy provided a unique way to implement a competitive component to acute rehabilitation. This contributes to other findings that state that athletic identity can play a key role in helping individuals recover from spinal cord injury[25]. Furthermore, the participant in this study communicated that the device did well to take advantage of his athletic identity [26].

Furthermore, it is important to motivate patients to participate in treatment at a time when they may feel unwilling [27]. The device did well to accomplish this in at least one occasion and it was communicated by the participant that he did look forward to the using the device over others. However, it cannot be said with certainty that this was due to the device itself or the individual's desire to recover. The participant was clear that his biggest motivating factor in recovering was personal improvement.

Forgetting about the injury

Gamified physical interventions and therapies often serve to increase the engagement of individuals [28, 29]. However, the extent to which technology facilitates engagement in the inpatient setting is not well documented[30]. The finding of this study indicated that the Diego did increase feelings of engagement. The participant and practitioners felt he was able to do more than he might in traditional therapy in terms of time of therapy and the range of movement of his limbs. This may have contributed to the devices ability to contribute to flow, or a participant's ability to take part in therapy without being mindful of it and losing track of time and space [31, 32]. Videogames have shown great promise in this area [33], however this area has not been comprehensively examined regarding robotic therapy. The findings of this study indicate that CART has a significant ability to enable participants to become fully immersed in therapy and forget about their injury. This may allow participants

to extend their reach further than they knew was possible and prolong their therapy sessions. After such accomplishments it was reported that this translated into possible functional gains.

People are interested

The demand for CART is clear, although not articulated in the literature, therapists and participants are very interested in the possibilities of using robotic therapy. The participants wanted to continue treatment and the practitioners reported that the demand for such treatment is prevalent outside of care. However, it was also reported that previous patients have preferred to only do robotic therapy in leu of more proven treatment. A possible biproduct of the lure of technology in the modern medical context [34]. Further investigation would help determine if the demand for robotic therapy is justified over traditional therapies.

Study Limitations

The qualitative nature of this study's findings limits their generalizability due to lack of sabermetric properties. Furthermore, although participant and practitioners offered insightful information, this study's small sample size limits its rigor and the findings cannot be attributed uniformly across the populace.

Conclusion

The Diego by Tyromotion is a promising treatment for individuals with incomplete cervical spinal cord injury in the acute inpatient rehabilitation setting. Initial findings suggest interest in the machine and indicate more global demand. Interviewees also indicated that CART is an acceptable treatment and that the Diego might be well suited as an early intervention. However, implementing a full course of treatment based on the suggested protocol has proven to be difficult in the acute setting. Initiating treatment is difficult due to the vulnerable condition of participants and discharge to offsite rehabilitation centers has been quicker than anticipated. Furthermore, the practicality of the Diego is complicated by it cost ($130,000)

and the time commitment it requires. Justifying its price and gaining ethical approval to implement such a treatment is difficult due to lack of evidence regarding its beneficence.

Consequently, determining the feasibility of the Diego in the acute rehabilitative setting has resulted in mixed findings. More rigorous investigation is recommended to justify the Diego's use. This may be accomplishable within acute rehabilitation however, an additional unit placed at the rehabilitation center of discharge might allow a more thorough investigation and ensure a larger group of participants. In conclusion, CART is an exciting and innovative treatment modality that presents many potential benefits for individuals recovering from incomplete cervical spinal cord injury. However, its prohibitive cost and the time it consumes make justifying the treatment difficult for practitioners. Clear indications of its benefits may empower therapists both in acquiring and implementing such a therapy.

List of Figures

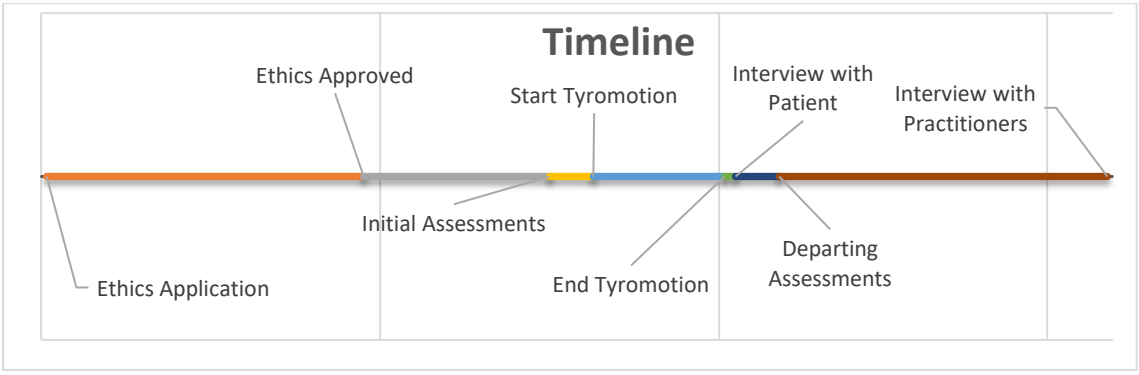
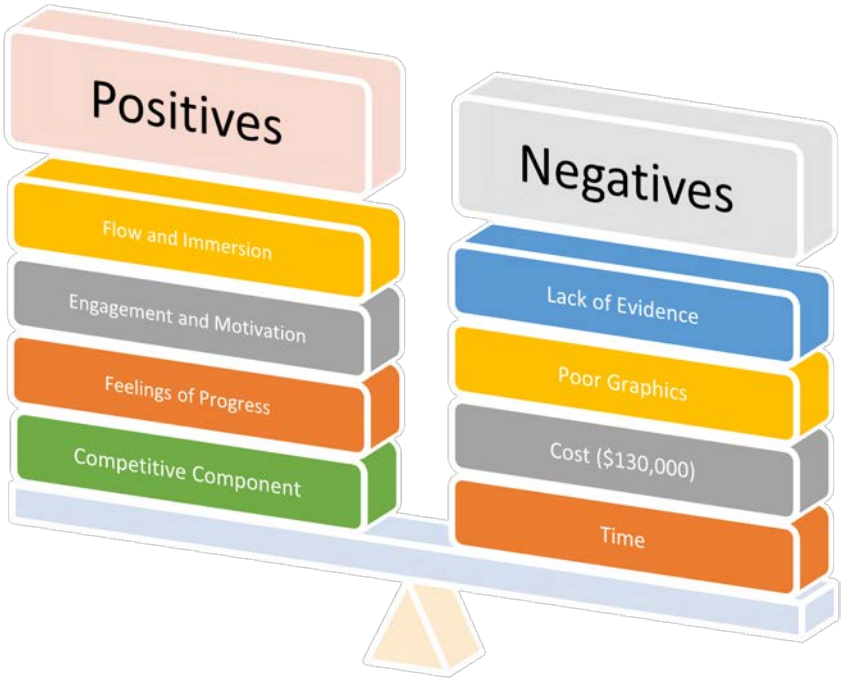


Figure 3. Positives and Negatives as revealed through thematic analysis. Discussion and Conclusion.



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Appendices

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Ethical Clearances and ANZCTR Number

Research Office
Kolling Building, Level 13
Royal North Shore Hospital St Leonards NSW 2065
Tel (02) 9926 4590 Fax (02) 9926 6179

NSW GOVERNMENT Health
Northern Sydney
Local Health District

7 May 2018

Emma Tan
Building 30
Royal North Shore Hospital
Reserve Road
St Leonards
NSW, 2065

Dear Emma

NSLHD reference:

Study Title: 'Evaluation of the Feasibility and Clinical Utility of Computer Assisted Robotic Devices for Upper Limb Therapy For Patients With Cervical Level Spinal Cord Injuries'

HREC reference: HREC/18/HAWKE/35

Thank you for your letter responding to the Northern Sydney Local Health District HREC's request for additional information/modification for the above project, which was first considered by the HREC at its meeting 12 February 2018. This HREC has been accredited by NSW Ministry of Health as a Lead HREC under the model for single ethical and scientific review and Certified by the NHMRC under the National model for Harmonisation of Multicentre Ethical Review (HoMER). This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. No HREC members with a conflict of interest were present for review of this project.

I am pleased to advise that the Committee at an Executive meeting has granted ethical and scientific approval of the above **single centre** project. The HREC were satisfied that this project meets the requirements of the National Statement.

The project is approved to be conducted at**:**

- **Royal North Shore Hospital**

You are reminded that this letter constitutes *ETHICAL* and *SCIENTIFIC* approval only. You must not commence this research project at a site until a completed Site Specific Assessment Form/Access Request and associated documentation have been submitted to the site Research Governance Officer and Authorised. A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

If a new site(s) is to be added please inform the HREC in writing and submit a Site Specific Assessment Form (SSA) to the Research Governance Officer at the new site.

The following documentation has been reviewed and approved by the HREC:

Document	Version	Date
National Ethics Application Form (NEAF) AU/1/0BA3315	V2.2	24/01/2018

Invitation Letter	V2.0	24/1/18
Participant Information Sheet, Consent Form and Consent Revocation Form - PATIENTS	V3.0	08/03/18
Participant Information Sheet - CLINICIANS	V2	
Consultant Information Sheet	V2.0	08/03/18
Consent Form - CONSULTANT	V1.0	

Consent Form – CLINICIANS	V2	
Copy of the research protocol	V2	5/12/17
Interview Schedule: PATIENTS	V2	
Interview Schedule: CLINICIANS	V2.0	

The following documents have been noted:

The National Ethics Application Form reviewed by the HREC was **NEAF AU/1/0BA3315**

If the study is a clinical trial, please include the appropriate statement from below. If the study does not require a CTN, please delete.
Please note that it is the responsibility of the Sponsor to submit the Clinical Trial Notification (CTN) to the Therapeutic Goods Administration (TGA) online. The Research Office recommends that CTN submission is completed only once HREC approval *and* site governance authorisation are granted.

Please note the following conditions of approval:

- HREC approval is valid for **5 years** from the date of approval and expires on **May 7, 2023.** The Coordinating Investigator is required to notify the HREC 6 months prior to this date if the project is expected to extend beyond the original approval date at which time the HREC will advise of the requirements for ongoing approval of the study.
- The Co-ordinating Investigator will provide an annual progress report to the Institution beginning in **August 2019** as well as a final study report at the completion of the project using the template available on the Research Office website. An annual report is due **every year on 30 August**.
- The Co-ordinating Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project and any complaints made by study participants regarding the conduct of the study.
- Proposed changes to the research protocol, conduct of the research, or length of HREC approval will be provided to the HREC for review, in the specified format.
- The HREC will be notified, giving reasons, if the project is discontinued before the expected date of completion.
- Investigators holding an academic appointment (including conjoint appointments) and students undertaking a project as part of a university course are advised to contact the relevant university HREC regarding any additional requirements for the project.

Please note it is the responsibility of the sponsor or the co-ordinating investigator of the project to register this study on a publicly available online registry (eg Australian New Zealand Clinical Trial Registry www.anzctr.org.au) if applicable.

Should you have any queries about your project please contact the Research Office, Tel: 9926 4590, email NSLHD-Research@health.nsw.gov.au.

Please quote **NSLHD reference HREC/18/HAWKE/35** in all correspondence.

The HREC wishes you every success in your research.

Yours sincerely

Jodi Humphreys
Research Manager
NORTHERN SYDNEY LOCAL HEALTH DISTRICT
Research Office
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Royal North Shore Hospital St Leonards NSW 2065
Tel (02) 9926 4590 Fax (02) 9926 6179

Health
Northern Sydney
Local Health District

August 2018

Ms Emma Tan
Royal North Shore Hospital
St Leonards NSW 2065

Dear Ms Tan,

NSLHD reference: RESP/17/361 Title: Evaluation of Feasibility and Clinical Utility of Computer Assisted Robotic Devices for Upper limb Therapy for Patients with Cervical Level Spinal Cord Injuries HREC reference: HREC/18/HAWKE/35

Thank you for submitting an application for authorisation of this project. I am pleased to advise that the delegate of the Chief Executive for Northern Sydney Local Health District has granted authorisation for the above project to commence at **Royal North Shore Hospital.**

The version of the SSA reviewed by NSLHD RGO was: **AU/2/1BA3312.**

Ethical approval for this study was granted by the **Northern Sydney Local Health District HREC** at a meeting of the Executive Committee held on **7 May 2018.**

The documents authorised for use at this site are:

Document	Version	Date
National Ethics Application Form	AU/1/0BA3315	24 January 2018
Invitation Letter	2	24 January 2018
Participant Information Sheet - Patients	3	8 March 2018
Consent Form – Participants	2	8 March 2018
Consent Revocation Form – Patients	1	22 October 2017
Participant Information Sheet – Clinicians	2	8 March 2018
Consent Form – Clinicians	2	8 March 2018
Consultant Information Sheet	2	8 March 2018
Consent Form – Consultant	2	8 March 2018
Consent Revocation Form – Consultant	1	8 March 2018
Research Protocol	2	5 December 2017
Interview Schedule: Patients	2	24 January 2018

Interview Schedule: Clinicians	2	24 January 2018

The NSLHD RGO Notes:

- CVs – Lisa Benad, Emma Tan, Lynette Mackenzie.

Site authorisation will cease on the date of HREC expiry **7 May 2023.**

You are reminded that, in order to comply with the Guidelines for Good Clinical Research Practice (GCRP) in Australia, and in accordance with additional requirements of NSLHD, the Chief Investigator is responsible for ensuring the following:

1. The HREC is notified of anything that might warrant review of the ethical approval of the project, including unforeseen events that might affect the ethical acceptability of the project.

2. The HREC is notified of all Serious Adverse Events (SAEs) or Serious Unexpected Suspected Adverse Reactions (SUSARs) in accordance with the Serious Adverse Event Reporting Guidelines.
3. Proposed amendments to the research protocol or conduct of the research which may affect the ethical acceptability of the project, and are submitted to the lead HREC for review, are copied to the Research Governance Officer.
4. Proposed amendments to the research protocol or conduct of the research which may affect the ongoing site acceptability of the project are to be submitted to the Research Governance Officer.
5. The Institutional annual report for all Human Research is due to the NSLHD Research Office on the 30 August. In addition, annual report acknowledgment from the Lead HREC should be submitted to the Research Governance Officer.

Standard forms and additional guidance documents are available on the Research Office Website:
http://www.nslhd.health.nsw.gov.au/AboutUs/Research/Office

Yours sincerely

Jodi Humphreys
Research Manager
Research Office
Northern Sydney Local Health District

Thank you for submitting the above trial for inclusion in the Australian New Zealand Clinical Trials Registry (ANZCTR).

Your trial has now been successfully registered and allocated the ACTRN: ACTRN12618001546246

Web address of your trial: http://www.ANZCTR.org.au/ACTRN12618001546246.aspx
Date submitted: 12/09/2018 9:08:15 PM
Date registered: 17/09/2018 9:08:01 AM
Registered by: Lynette Mackenzie
Principal Investigator: Lynette Mackenzie

If you have already obtained Ethics approval for your trial, please send a copy of at least one Ethics Committee approval letter to info@actr.org.au or by fax to (+61 2) 9565 1863, attention to ANZCTR.

Note that updates should be made to the registration record as soon as any trial information changes or new information becomes available. Updates can be made at any time and the quality and accuracy of the information provided is the responsibility of the trial's primary sponsor or their representative (the registrant). For instructions on how to update please see http://www.anzctr.org.au/Support/HowToUpdate.aspx.

Please also note that the original data lodged at the time of trial registration and the tracked history of any changes made as updates will remain publicly available on the ANZCTR website.

The ANZCTR is recognised as an ICMJE acceptable registry (http://www.icmje.org/faq.pdf) and a Primary Registry in the WHO registry network (http://www.who.int/ictrp/network/primary/en/index.html).

If you have any enquiries please send a message to info@actr.org.au or telephone +61 2 9562 5333.

Kind regards,
ANZCTR Staff
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F: +61 2 9565 1863
E: info@actr.org.au
W: www.ANZCTR.org.au

ANZCTR
Australian New Zealand Clinical Trials Registry

Interview Guides and Consent Form

Interview Guide

Researchable Question

How does computer assisted robotic intervention influence the acute rehabilitation experience of people with cervical spinal cord injury?

Introduction

Introduce myself – who I am, why I am there

Gain Consent

Becoming acquainted

Can you tell me about your experience working with patients with spinal cord injury?

- How long have you been working here?
- Have you worked with robotic therapy before?
- Where were you trained?
- How did you first find out about the Diego?

Topic One: What were the instructional barriers to implementing such a treatment?

- Did you have good support from management?
- What were there concerns? Financial, liability etc.
- Were your co-workers supportive?
- How difficult was ethics?
- What would have been helpful during the approval process?

Topic Two: What is the rehabilitation experience like for a person with an SCI?

- How was the rehab experience going for the participant involved?
  - What was challenging for them?
  - What did they find rewarding?
  - Were they the typical user?

Topic Three: What influence does utilizing computer assisted robotic intervention have on SCI rehabilitation.

- How do you think the patients therapy changed after using the Diego?
  - Was anything challenging?
  - Is there anything about Diego that you really like?
  - Are there things about Diego that you dislike?
- What were the main strengths of the Diego?

How the Diego assisted with your day to day work on the ward?

What challenges were there?

Topic four: How feasible is using the device in the acute setting?

What do you feel like the **demand** is for such a device? (from patients, yourselves etc)

What was the process of **implementation** like?

Were you able to facilitate the treatment as planned?

How **practical** was using the device?

Did you have enough time and resources?

How comfortable would you be asking for the money to buy one?

Conclusion

If you have the opportunity would you continue to use the Diego for UL therapy?

Any other general advice or comments about the project going forward?

Created by:

Aram Simsar

Associate Investigator

Interview Guide

Cervical Spinal Cord Injury and Computer Assisted Robotic Therapy: Interpreting User Experience in Acute Rehabilitation

Researchable Question

How does computer assisted robotic intervention influence the acute rehabilitation experience of people with cervical spinal cord injury?

Introduction

Introduce myself – who I am, why I am there

Explain the study – what we are assessing, how it will help

Gain Consent

Becoming acquainted

I would like to learn about your life can you tell me a little about yourself?

What is your family like? Siblings, Children, Parents, Partner

What do you like to do in your free time? Sports, video games, music, tv, movies

Where do you live? City or Rural, House or apartment

Topic One: What is the experience of person with a cervical spinal cord injury like in the acute rehabilitation setting?

I am a little curious about what your day is like, can you tell me what about that?

What are your mornings like?

What do you do between meals?

Who do you see on a regular basis?

Do your really look forward to anything?

Do your really dread anything?

Topic Two: What is the rehabilitation experience like for a person with an SCI?

I am interested in how your rehab has gone so far, can you tell me how physio and OT sessions have been going?

Is there anything that has been difficult for you?

Are there things that are easier than others?

Are there activities you find more useful than others?

Topic Three: What influence does utilizing computer assisted robotic intervention have on SCI rehabilitation.

Can you tell me how your experience with Diego has been going?

What is it like using Diego?

Is there anything about Diego that you really like?

Are there things about Diego that you dislike?

How do you feel using Diego compares to doing other rehab activities?

Conclusion

Is there anything you would like to add questions we just went over?

Are there any questions you have for me?

Is there anything else you think we should cover?

Created by:

Aram Simsar

Associate Investigator

PARTICIPANT CONSENT FORM

Pilot Study to Investigate the Feasibility and Clinical Utility of Computer Assisted Robotic Devices for Upper Limb Therapy For Patients With Cervical Level Spinal Cord Injuries

1. I,.....
   of.....
   agree to participate as a subject in the study described in the participant information statement attached to this form.

2. I acknowledge that I have read the participant information statement, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.

3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.

4. I understand that I can withdraw from the study at any time without prejudice to my relationship to The University of Sydney or Royal North Shore Hospital.

5. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

6. I understand that if I have any questions relating to my participation in this research, I may contact Emma Tan or Lisa Benad on telephone 94632737, who will be happy to answer them.

7. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.

8. I understand that if I consent to participate in the therapy program I can cease participation at any time if I do not wish to continue and the information provided will not be included in the study.

9. I understand that if I consent to an interview I can stop the interview at any time if I do not wish to continue, the audio recording will be erased and the information provided will not be included in the study.

10. I consent to:
    - Implementation of an upper limb therapy program YES ☐ NO ☐
    - Participation in an interview YES ☐ NO ☐
    - Audio-recording YES ☐ NO ☐

- Receiving Feedback YES ☐ NO ☐

If you answered YES to the "Receiving Feedback" question, please provide your details i.e. mailing address, email address.

Feedback Option

Address: _____

_____

Email: _____

Complaints may be directed to The Research Ethics Manager, Kollings Institute/Northern Sydney Local Health District who is the person nominated to receive complaints from research participants. You should contact them on 9926 4592 and quote [HREC project number].

Signature of subject **Please PRINT name** **Date**

_____

Signature of investigator **Please PRINT name** **Date**

_____