Design of Study and Protocol

Tangible interaction with everyday objects for home-based upper-limb stroke rehabilitation

Study Summary

This project is a study to develop and assess interactive design prototypes that can be used by stroke survivors in a self-directed way outside the clinical environment (e.g. their home). The interactive design prototypes are based on everyday objects in combination with digital technology to enhance the use of the affected body part. The outcome of this research is to determine what kinds of activities of daily living stroke survivors enjoy participating in while living at home. Based on these outcomes digital, interactive design prototypes will be developed that can be used by stroke survivors in activities of daily living. These interactive design prototypes encourage the use of the affected hand and arm. A further outcome of this study is the usability assessment of these design prototypes to validate the clinical usability and alignment with therapeutical goals. The research will be carried out by Mailin Lemke, PhD student at the School, Victoria University of Wellington. Clinical guidance will be provided by academic clinical physiotherapists with specialist research experience in the field of stroke rehabilitation. The research participants are survivors of stroke who will provide information about activities of daily living that they enjoy taking part in and feedback on their experience (i.e. the usability) of the design prototypes. This will enable iterative changes to be made and re-evaluated within this research.

Study question

Stroke causes significant morbidity and mortality in New Zealand (Feigin et al., 2014). Survivors of stroke can have limited access to rehabilitation therapies following their discharge from hospital and there is limited availability of stroke rehabilitation in the community (Gommans et al., 2008; McNaughton et al., 2014a). One strategy is to introduce self-directed rehabilitation. This has been defined as "a stroke person's goal-directed journey of recovery following stroke, totally or largely independent of professional rehabilitation clinician input" (McNaughton et al, 2014b). One of the risks of self-directed rehabilitation is that it can be conducted incorrectly at standards, which are below the therapists' expectations. To avoid this, sensor technology and software developments have allowed computerized systems to establish goal setting, feedback and performance measurement specifically for lower-limb rehabilitation post stroke (Mawson et al., 2014; Parker et al., 2014).

Stroke causes significant morbidity and mortality in New Zealand (Ministry of Health, 2013). Stroke rehabilitation of the upper limb primarily focuses on the first six months post stroke and stroke rehabilitation in the community to improve the affected body side is rare. One strategy is to introduce self-directed rehabilitation. This has been defined as "a stroke person's goal-directed journey of recovery following stroke, totally or largely independent of professional rehabilitation clinician input" (McNaughton et al, 2014b). Doing a repetitive movement without getting the impression that it is repetitive is a core element in stroke rehabilitation. Among the different rehabilitation approaches is the constraint-induced therapy proven to be beneficial in the rehabilitation process but it is labour intensive and expensive. Using this therapy approach in combination with everyday objects and digital technology in the rehabilitation process would benefit from the patient's motivation to engage with the object. The focus would be on the interaction with the everyday object rather than on the pure delivery of rehabilitation. Using digital technology with those objects provides the opportunity to enhance the use of the affected arm by restricting the functionality of the object to a specific part of the body (Reiss, Wolf, Hammel, McLeod, & Williams, 2012; Taub et al., 2000: Wolf, Lecraw, Barton, and Jann, 1989) .

The overall research aim is:
To investigate the potential of tangible interfaces to facilitate self-delivered home-based CIT (constraint-induced therapy) for upper-limb stroke rehabilitation.

The research questions are

1. How can everyday objects that the stroke patient use during activities of daily living be used for the rehabilitation process?
2. How can constraint-induced therapy be incorporated in a tangible interface that involves activities of daily living?
3. Does the design facilitate CIT and how can it be improved?

Study design

The study is to develop interactive design prototypes based on everyday objects that the stroke survivors use during activities of daily living and incorporate them in the rehabilitation process. These design prototypes offer a self-directed rehabilitation to stroke survivors who are living at home. The intended setting for these objects is the home where the objects can contribute to the recovery of the impaired arm and hand.

The study includes interviewing stroke survivors about activities of daily living that they enjoy participating in. The inclusion criteria for this study are: the experience of a stroke at least 6 months prior to the interview, living at home, an active wrist and finger, the ability to walk independently, an age of 40-75 years, and good general health. Exclusion criteria are signs of severely impaired verbal communication, inability to give consent, severe neurocognitive deficits, excessive pain in any joint of the paretic arm, terminal illness, or life-threatening comorbidities (Wolf et al., 2006; Barzel et al.,2015). The exclusion criteria ensure that the stroke survivors are able to take part in the interviews and testing of the design prototypes. There is no formal screening process involved in this study. The anticipation is that stroke survivors who are impaired and fit the inclusion criteria are the ones who will make contact with the researchers. The inclusion criteria will be outlined on the recruitment flyer.

The study includes three different methods to answer the research questions: interviews with stroke survivors prior and after the development of the interactive design prototypes, design ethnography in the form of observation of therapy sessions, and cultural probes which will be provided to the stroke survivors.

Interviews:

The stroke survivors will be interviewed twice during this study.
The first semi-structured interviews investigate how stroke survivors engage in rehabilitation at home, and what kinds of objects they like to use during everyday tasks and if they receive a home-based rehabilitation. The interview may last up to 30 minutes and can be split in sections based on the participant's abilities and fatigue. For the interviews the research will go to the stroke survivors home. The researches will work in pairs for this interviews and the Co-Investigators will be contactable as minders.

The second interview is taking place after the design prototypes are completed.
This method includes the stroke survivors as research participants providing their feedback and suggestions to the designers (Mawson and Mountain, 2011; Williamson et al., 2015)
The stroke survivors will be asked to test the devices and invited to give feedback and recommendations. The interview may last up to 30 minutes and can be split in sections based on the participant's abilities and fatigue. For the interviews the research will go to the stroke survivors home. The researches will work in pairs for this interviews and the Co-Investigators will be contactable as minders. Clinicians will assess the testing undertaken by the stroke survivors to secure the therapeutic validity and usability of the prototypes.

Testing of design prototypes will not involve participants taking part in rehabilitation activities, such as assisted walking, that require direct expert clinical supervision. The therapeutic activities will focus on the control of one affected limb and will be performed to ensure the safety of the participants. It is intended that the use of the design prototypes will be tested while participants are seated to avoid falls or other injuries. Participants have the right to withdraw their consent and discontinue their involvement at any stage.

The interactive design prototypes will be evaluated by the stroke survivors to ensure that limb movements and tasks align to therapeutic goals and translate into controllable movements for the return of useful function to an affected limb. These are activities of daily living such as the ability to turn a tap on and off or to turn a door handle and open a door. The usability testing ensures that users can achieve their goals with effectiveness, efficiency and satisfaction in a specified context of use (Wasserkrug et al., 2009).

Ethnography

In order to determine what kinds of objects stroke survivors use in activities of daily living the method of ethnography in the form of observations will be used. Observations offer the possibility to gain a deeper understanding of what kinds of objects are used by the stroke survivor during activities of daily living (Hubbard, Parsons, Neilson, & Carey, 2009; Pollock et al., 2014). The observations will take place in the environment of the participant's home. During the observations the stroke survivor conducts activities of daily living. The aim of this method is to get a better understanding what kinds of objects play an essential role in activities of daily living. The researches will work in pairs for these observations and the Co-Investigators will be contactable as minders.

Cultural probes

The stroke survivors will further be provided with a cultural probes kit. Cultural probes offer the opportunity to collect data that has a documentary and life-realistic character. Participants are provided with a self-documentary probe kit, consisting of, for example, a disposable camera with instructions on what to photograph, diaries or postcards to write down feelings and thoughts that are valuable to the research. Using probes requires the participants to be creative, to think about what they take for granted. Careers and family members can help the stroke survivor using the cultural probes. Their involvement is an essential part in the CIMT approach and should be taken account of. The outcome of the cultural probes helps to determine what kind of activities stroke survivors like to do on a regular basis. Those activities can as well be facilitated by family members and careers (Graspemo et al., 2004; Hassling et al., 2005; Hemmings et al., 2002).

Participants will be recruited through local occupational therapist and physiotherapist working with stroke patients, as well as stroke clubs and can be considered representative of the stroke survivors in the community who would use self-directed rehabilitation. The interviews and ethnography study will take place at the participant's home. The researchers will work in teams of at least two persons when visiting the stroke survivor at their home. The therapeutic goal of the each of the design prototypes will be described to potential participants.

Participant data collection will include non-identifying demographic information and relevant clinical information relating to the stroke, physical disabilities and rehabilitation goals. The experience of the participants using the design prototypes will be collected using audio-recorded semi-structured interviews. Participants' use of the design prototypes will be recorded with using video and photography to ensure use is clinically appropriate. This recording will just focus on the hands of the participant and the design prototypes. The comments and the way the participant interacts with the object is beneficial to improve the functionality of the design prototypes and helps to make sure that the functionality suits the intended purpose. The video recording will made with equipment provided by the School of Design, Victoria University, and purely be used to analyse the interaction with the devices. The recording will not be used in presentations or teaching lessons.

Scientific Justification

Worldwide, stroke affects 15 million people and is the third most likely cause of death (McKay and Mensah, 2004). While the worldwide rate of stroke is declining, this rate is four times slower in New Zealand where it is a leading factor for long-term disability and a topic of particular concern (Feigin et al., 2014). In addition the different ethnic groups in New Zealand are affected in different ways by

stroke; with some groups, for example Pacific Islander and Māori, being more affected or having long-term dependence on care (McNaughton et al., 2011).

Stroke survivors are most likely to suffer from physical and cognitive limitations and impairments caused by their stroke. Around 20% of all new stroke survivors are limited in their mobility and require institutional care while 30% of stroke patients can return to their homes (McNaughton et al., 2014). Approximately 70% of patients experience altered arm function after a stroke. 40% of stroke patients are left with a persistent lack of function in the affected arm (Intercollegiate Working Party for Stroke and Royal College of Physicians of London, 2012).
The 'Stroke Foundation of New Zealand' and the 'New Zealand Guidelines Group' (2011) recommends that all stroke patients should be offered a rehabilitation service after hospital discharge. The rehabilitation continues after discharge and community rehabilitation services, as well as home-based rehabilitation, are recommended whenever those services are needed and available to overcome motor impairment and increase the rehabilitation process (Stroke Foundation of New Zealand and New Zealand Guidelines Group, 2011).
The tasks that get trained during the rehabilitation vary. Task specific training rather than conventional stroke rehabilitation is associated with an increased improvement of motor functionality. The emphasis is on training a specific task rather than remediating impairment such as muscle weakness. The training induces neuroplastic changes at several levels in the brain using spared regions, which have not been affected by the stroke (Arya et al. 2012; Hubbard et al. 2009). Task specific training often uses 'real world' tasks or everyday tasks as the therapeutic medium in functional recovery (Hubbard et al. 2009). Essential elements of this form of rehabilitation are that the tasks are specific to the patient, randomly assigned, positively reinforced and lead to the relearning of the whole task (Hubbard et al. 2009).

Among the different therapy approaches is the constraint-induced therapy (CIT) form mentioned as being the one with the most potential to improve motor functionality (Langhorne et al., 2011). This therapy method does not yet use external devices or digital technology and is provided in a clinical setting. It is recommended by the New Zealand clinical guidelines for stroke management that patients with difficulties using their upper limb should receive constraint-induced therapy. The therapy can be provided as a single therapy or in combination with others. Patients are encouraged by their caregivers and therapists to use the affected arm and hand as much as possible (Stroke Foundation of New Zealand and New Zealand Guidelines Group, 2011)

Task practice is an important component of the CIT (Barzel et al., 2015), however some of the tasks are relatively less meaningful and they are performed just with the affected arm. 'Task specific' is defined as a training or therapy where patients 'practice context-specific motor tasks and receive some form of feedback' (Teasell et al., 2008). Neuroplastic changes were found to be greater when the task was important to the individual, that is, meaningful in nature (Daly and Ruff, 2007). The 'task specific' training can restore motor function by using spared regions of the brain, which are usually next to the lesion and recruiting accompanying parts of the brain (Nudo et al., 2000).

An example of a 'task specific' training is the lifting and bringing of a water glass towards the mouth with the impaired arm while using the non-affected arm to stabilize the water bottle (Arya et al. 2012). Other examples are household tasks such as 'eating, opening and closing jars and spring-loaded clothespins' (Hamzei et al., 2006).

This emphasis of task specific training in constraint-induced therapy does not focus on the object that plays an important role in it. Using those objects in combination with digital technology to deliver constraint-induced therapy is a promising foundation to facilitate self-directed rehabilitation (Giaccardi, 2015; Pollock et al., 2014; Van Peppen et al., 2004).

The approach of this research is to ensure that the devices and software systems will be designed to align clinical therapeutic goals to the goals of the participants and achieving goals is measurable and can be disclosed to the participants and can be assessed by clinicians. Observations of use will be made to ensure that achieving goals is not influenced by the use of any unaffected limb.

The engagement of Māori and Pacific island participants in this research will be undertaken by the recruitment invitation process. Invitations for participant involvement will be made through the stroke clubs from Wellington South through to Upper Hutt and the Kapiti Coast.
For Pacific Islanders and Māori is the risk to experience a stroke compared to European New Zealand inhabitants 1.4 higher (McNaughton et al., 2011). The importance to this study of including Māori participants is that there is not just an increased risk of experiencing a stroke for but also disparities in the outcomes of rehabilitation for Māori affected by stroke (Dyall et al., 2008) and self-directed rehabilitation can improve medium-term stroke outcomes in both Māori and Pacific people (Harwood et al., 2012).

Skills and Resources.
Supervising Investigators:

Dr Brian Robinson, Senior Lecturer, Graduate School of Nursing, Midwifery & Health, Victoria University of Wellington
Dr Edgar Rodriguez, Associate Professor, School of Design, Victoria University of Wellington
Dr Denise Taylor, Associate Professor, Health & Rehabilitation Research Centre, Auckland University of Technology
Dr Nada Signal, Senior Research Fellow, School of Clinical Sciences, Auckland

The supervising investigators experience and expertise is a mix of industrial design, media design, clinical therapies and clinical research. Clinical research expertise relating to stroke and rehabilitation is provided by Associate Professor Taylor and Dr Signal who are physiotherapists with considerable research experience. Dr Robinson has clinical research experience, including neurological conditions, and in addition has experience in the usability and design of medical devices. Associate Professor Rodriguez has expertise in the design and usability of interactive devices and qualitative research methods.

Protocol
Study Aim:
To investigate the potential of tangible interfaces to facilitate self-delivered home-based for upper-limb stroke rehabilitation based on the constraint induced therapy approach.

Data Required:
Demographic data.
Rationale. The data will be collected to describe the research participant groups.
Data will be collected by self-reporting at interview, cultural probes and ethnography. Clinical notes will not be accessed.
Data collected. Age, gender, ethnicity, time since stroke, side of brain affected, physical disability (i.e. limb affected and how it is affected), any other affects (e.g. speech, memory), use and access to computers before and after stroke.

Performance data.
Rationale. The data will be collected to include factors such as time to set-up devices for use, speed and accuracy of movements, percentage of tasks or movements meeting clinical therapy expectations and duration of involvement with devices and games.
Data collected. Quantifiable data will be collected by software imbedded within the computer systems. Data relating to usability, ergonomics and clinical expectation will be recorded using video and still camera capture

Experience of user data
Rationale. User experience informs the usefulness of the devices and software from a user-behaviour perspective. This allows changes to be made and reassessed.
Data collected. Participants will be invited to describe their experience using the design prototypes and will be asked questions regarding ease or difficulty of use, comfort or discomfort relating to use, and also invited to make suggestions for improvement. Data will be collected by video or audio recording and still images showing just the hands and design prototypes may also be used.

Data Storage and confidentiality.
All data will be securely stored as digital files within the Victoria University data system for 5 years after collection.
All data stored will have any identifiable information removed. Given the research methods used in ergonomics, images are likely to be included in either thesis, publications or presentations. This will be with the agreement of participants and images will be altered so that participants are not identifiable. Images and videos will be recorded using cameras provided by the School of Design, Victoria University of Wellington. Any images and videos will be deleted from the cameras afterwards.

Participant numbers
Qualitative analysis and usability research requires smaller numbers of participants, typically between 6 to 10, compared to quantitative research, where 30 to 40 participants are required. As a result, this study will require around 8 participants.

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