

Augmented Community Telerehabilitation Intervention to
improve outcomes for people with stroke

ACTIV: A Randomised Controlled Trial and Qualitative Enquiry

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ABSTRACT

For people to achieve and maintain the best possible outcomes after stroke, a level of rehabilitation input is required that cannot be met by current services. Telerehabilitation, the provision of rehabilitation at a distance using telecommunication technology, has been proposed as a way to extend the reach of rehabilitation, particularly to those for whom geography, poverty or disability preclude easy access to rehabilitation facilities. The difficulty with many potential modes of delivering telerehabilitation, is that they are expensive and complex, requiring significant technical input for satisfactory use. The use of readily-accessible telecommunication technology (landline telephones or mobile phones) to deliver stroke rehabilitation remotely was mooted as a possible solution, based on findings of feasibility and acceptability of use, in a number of small-scale studies in other populations. The idea was investigated using a systematic review, which showed that while mobile phones were almost ubiquitous in New Zealand, there had been minimal investigation of their use in stroke rehabilitation.

A novel intervention was developed, based on the literature review and the clinical experience of the research team. Augmented Community Telerehabilitation Intervention (ACTIV) is a structured 6-month programme, delivered by physiotherapists using a combination of face-to-face sessions, telephone contact and text message reminders to support rehabilitation for people following stroke after standard rehabilitation has ended.

A randomised controlled trial was undertaken, to compare the effectiveness of ACTIV with a usual care control, to improve outcomes for people with stroke. Measures of physical function and self-efficacy were taken immediately after ACTIV and 6-months after the end of the programme. A qualitative enquiry was also undertaken with a sample of those who had completed ACTIV, to explore the participant experience.

The results of the trial showed that ACTIV improved physical function in people undertaking ACTIV as long as they undertook at least 50% of the programme.

However, the significant improvement in physical function immediately after the programme was not sustained 6-months after cessation. A significant improvement was found in participation immediately after ACTIV, which also was not sustained at 6-months post-intervention.

The qualitative enquiry showed that despite the first impression of ACTIV not being proper physiotherapy, there was a strong message that participants felt they had not been left to struggle alone and gained a number of benefits from the therapeutic relationship they developed with the physiotherapist during ACTIV. Participants also communicated strong feelings of making progress and a very clear impression of knowing what they wanted from rehabilitation. This was not the participant-generated goals, decided with the physiotherapists at the start of the programme, but a desire to keep on making small forward steps towards normality.

Findings from the ACTIV study showed that a small input can make a significant difference for people after stroke but that the longed for behaviour-change leading to absolute independence from any support may be an unrealistic expectation. ACTIV may need to be extended in partnership with non-governmental agencies to continue a level of support that ensures benefits are maintained.

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ATTESTATION OF AUTHORSHIP

I hereby declare that this submission is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person (except where explicitly defined in the acknowledgments) nor material which to a substantial extent has been submitted for the award of any other degree or diploma of a university or other institution of higher learning.

PUBLICATIONS AND PRESENTATIONS

- Saywell, N. Taylor, D. Vandal, A. (2016). Telerehabilitation to improve outcomes for people after stroke (overview and results). *Physiotherapy New Zealand Annual conference* invited speaker.
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AUTHOR’S CONTRIBUTION TO THE RESEARCH

Denise Taylor and Nicola Saywell developed the ACTIV programme in consultation with a number of other clinicians and researchers. They applied for and were successful in gaining a substantial Health Research Council grant, which allowed a trial to be fully funded. They sought partners to join the team who were consulted and gave feedback on trial design. Nicola undertook all the recruitment and training of staff employed on the trial. She project-managed the trial and was a major contributor to the direction and decisions made around statistical analysis. Nicola led the interpretation of both qualitative and quantitative data with input from team members where she requested it. Nicola had a major part in the intellectual development of the concept of ACTIV and in the management of the trial.

CHAPTER 1 INTRODUCTION

1.1 STATEMENT OF THE PROBLEM

A significant consequence of improved management of chronic disease is a reduction in mortality, increasing the number of people living with disability (Robine & Michel, 2004). Stroke is a major causes of disability and in many developed countries is the number one cause of adult disability (Ovbiagele & Nguyen-Huynh, 2011). Stroke incidence in economically developed nations is decreasing but stroke mortality is falling at a greater rate (Feigin et al., 2014; Stegmayr & Asplund, 1996; Tobias, Cheung, Carter, Anderson, & Feigin, 2007), attributable in part to better acute management. Once a patient is medically stable following an acute stroke, the mainstay of management is rehabilitation, to restore function and return people to enjoyable and productive lives. Inpatient and outpatient rehabilitation, sometimes followed by community therapy is a well-established pattern of service-provision in many developed countries. In recent years early supported discharge has been found to improve function and independence (Brewer & Williams, 2010) and has clear guidance for its implementation (Fisher et al., 2011).

An increased survival and earlier discharge from hospital are creating a consumer demand for community rehabilitation services that vastly outstrips the ability of the health service to provide them (Aziz, 2010). Research has shown that to gain the best possible results, rehabilitation should not only continue until all agreed goals have been reached, but that regular reassessment should also be undertaken to ensure gains are maintained (Intercollegiate Stroke Working Party, 2008; National Stroke Foundation, 2010). To meet demand and reach best practice guidelines, new ways need to be investigated to provide adequate rehabilitation within existing health budgets.

Telehealth, the use of telecommunications to provide health information and care at a distance, has been gaining credibility as a way of extending the reach and availability of health care. Telehealth has been used with good effect in acute stroke management. Teleconferencing between rural doctors and specialist neurology centres for evaluation and diagnosis of acute stroke has been found to be as valid and reliable as traditional face-to-face consultation (LaMonte et al., 2008). Telehealth has also been shown to be effective in increasing access to, and speed of delivery of tissue plasminogen activator tPA, a thrombolytic therapy used in the management of acute ischaemic stroke (Audebert & Schwamm, 2009). There has been an increase in the use of telehealth in the last decade (Schwamm et al., 2013), with a number of studies showing that it is feasible and has similar levels of safety to face-to-face treatment (LaMonte et al., 2003; Pervez et al., 2010). More recently there has been growing interest in telerehabilitation after stroke, defined by Hailey and colleagues as “the provision of rehabilitation services at a distance using telecommunications technology as the delivery medium” (2011, p. 281). Telerehabilitation was first described in 1998 (Burns et al.) but its adoption to extend therapy for people with sub-acute and chronic stroke, has not seen the same growth as telehealth for acute stroke. The reason for this appears to be twofold; firstly, there are concerns about the remote delivery of rehabilitation, leading to some resistance from delivering therapists and secondly there are significant challenges in the development of delivery systems that have utility for widespread dissemination. Therapists delivering rehabilitation post-stroke have traditionally viewed it as inherently ‘hands-on’ (Levin & Panturin, 2011). The possibility of using technology to deliver telerehabilitation has raised some concerns about the safety, efficacy and cost of remote rehabilitation (C. C. Chen & Bode, 2011). The safety concerns may be valid for people in the acute stage of stroke or for people with severe disability; provision of telerehabilitation in these groups of patients has not been undertaken for that reason.

However, some of the concerns about efficacy may be perceived rather than real.

Increasingly research supports the use of active practice to drive neural reorganization and improve functional performance (Bosnell et al., 2011; Rensink, Schuurmans, Lindeman, & Hafsteinsdóttir, 2009; Shepherd, 2001). Telerehabilitation offers a vehicle for the provision of encouragement to maintain active practice with the option of regular brief contacts to enhance motivation. Some research suggests the hands-on nature of practice can overshadow any attempt to encourage patients to practice independently (Tyson, Connell, Busse, & Lennon, 2009) and some of the manual techniques that are a recognized part of post-stroke rehabilitation have minimal supporting evidence (Winter, Hunter, Sim, & Crome, 2011).

The cost and complexity of systems is frequently raised as a valid potential barrier to implementation when considering using technology for the purpose of telerehabilitation. Chen and Bode (2011) surveyed therapists working in stroke rehabilitation to investigate factors which influenced acceptance of technology. Although the survey was investigating technology in general, some implications for telerehabilitation can be drawn. The cost, acceptability to patients and the ability to continue use after discharge were significant factors in the therapists' decision to use any technology.

Technologically complex and novel systems are often heralded as the next frontier in rehabilitation with little consideration of the factors found to be significant to therapists who have to use them (Guidali et al., 2011; Li & Song, 2008). Krebs and colleagues (2008), discussing the development of robots in rehabilitation suggested a cautious approach and pointed to a need for their thoughtful integration into the clinical domain, to ensure rehabilitation and technical requirements are fulfilled. Investigation of programmes to deliver telerehabilitation have mainly been small-scale feasibility and acceptability studies, frequently with no comparative control population (M. Holden, Dyar, & Dayan-Cimadoro, 2007; Piron, Tonin, Trivello, Battistin, & Dam, 2004). The

few trials investigating effectiveness (Lo et al., 2010; Piron et al., 2009) have not shown a significant benefit of telerehabilitation over traditional therapy. For the general population, the high cost and technical support requirements of many of these telerehabilitation systems, means they are not currently a viable, widely available alternative to traditional rehabilitation (Carignan & Krebs, 2006; Rogante, Grigioni, Cordella, & Giacomozzi, 2010).

The difficulties encountered using complex delivery systems to deliver stroke rehabilitation, may not be a barrier to telerehabilitation. The ubiquity of mobile phone ownership in New Zealand, with one in almost every household (Statistics New Zealand, 2009) has enabled their use to increase the scope and reach of several health-related interventions. To date the use of mobile phones to deliver support and encourage behaviour-change in New Zealand, has been investigated mainly in ‘technological natives’; the generation who have grown up with technology and for whom it is a normal aspect of everyday life. There have been studies investigating the use of prompts and reminders via texts and video message to quit smoking (Whittaker et al., 2011) and help prevent depression in adolescents (Whittaker et al., 2012). These studies both found the remote delivery of an intervention to be acceptable to and feasible for the participants. There is growing evidence that older people are adopting new technology (Conci, Pianesi, & Zancanaro, 2009) which may widen the use of mobile phones to become a vehicle for telerehabilitation. The ubiquity and relative low-cost of readily-accessible telecommunication devices may facilitate translation to practice. The ACTIV trial was initiated as a direct consequence of the need to investigate the clinical effectiveness of using technology most people already own, to deliver the rehabilitation they need (McCue, Fairman, & Pramuka, 2010).

An intervention has been designed by the author and colleagues, based on evidence from research in stroke rehabilitation and clinical practice. ACTIV (Augmented

Community Telerehabilitation Intervention) is a structured 6-month programme, using a combination of face-to-face sessions, telephone contact and text message reminders to deliver rehabilitation to people following stroke after standard rehabilitation has ended.

1.2 AIM AND OBJECTIVES

The overarching aim of the study was to investigate whether telerehabilitation, delivered in the form of ACTIV, improved outcomes for people with stroke compared to usual care. The objectives of the study were as follows:

1. To measure the effect of ACTIV on physical function
2. To measure the effect of ACTIV on health outcomes and quality of life
3. To record the impact of ACTIV on hospital and residential care admission rates
4. To explore participant experience of and satisfaction with ACTIV

1.3 STRUCTURE OF THE THESIS

The study investigated the quantitative and qualitative impact of ACTIV, on outcomes for people with stroke. The structure is shown in Figure 1-1 below:

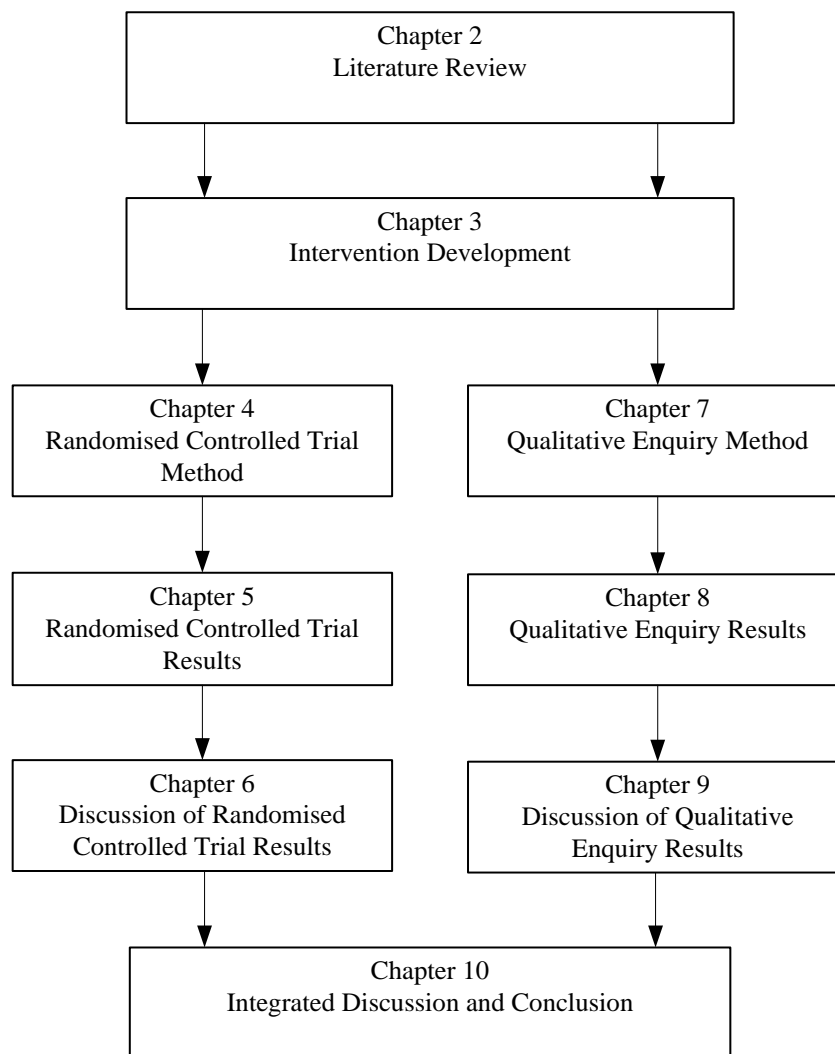


Figure 1-1: Structure of the Thesis

1.3.1 Chapter 2 - Literature Review

The literature review investigated research focused on the use of readily-accessible telecommunication devices in stroke. A search strategy was used to find studies that investigated the use of telecommunication technology to deliver rehabilitation, whether or not the authors explicitly identified the intervention as telerehabilitation.

The literature review helped inform ACTIV development and included literature available at the time of intervention development, up to the end of 2011. To establish whether the use of readily-accessible technology had gained traction as a useful tool for telerehabilitation in the time since the start of ACTIV, an updated review of the literature was undertaken. The results are included at the conclusion of the chapter.

1.3.2 Chapter 3 – Intervention Development

The intervention, ACTIV was developed partly in response to the findings of the literature review, which revealed a dearth of affordable telerehabilitation for people with stroke. The increase in numbers of studies using mobile phones and telephones to deliver interventions or support long-term management also influenced the development of ACTIV. Research in populations with other health conditions, have demonstrated that this delivery method was acceptable, feasible and had shown some evidence of effectiveness (Dick et al., 2011; Krishna, Boren, & Balas, 2009; Whittaker et al., 2011; Whittaker et al., 2012). This chapter will outline how each of the elements of ACTIV was derived, including mode of delivery and structure and content of the programme.

1.3.3 Chapters 4-6 - Randomised Controlled Trial

The following three chapters focused exclusively on the randomised controlled trial. The method, results and discussion of the results outlined the investigation into the effectiveness of ACTIV to improve outcomes for people with stroke.

1.3.4 Chapters 7-9 - Qualitative Enquiry

The next three chapters focused on the qualitative enquiry, which explored participants' experience of a new way of receiving rehabilitation. The in-depth interviews included discussion of programme-related factors that influenced engagement in ACTIV.

Individual participant factors that influenced perception of ACTIV were also canvassed.

1.3.5 Chapter 10 –Integrated Discussion and Conclusion

The final chapter synthesised the findings from the quantitative and qualitative studies. Recommendations for future research using readily-accessible telecommunication technology were discussed. Implications for practice were considered, informed by the findings of the ACTIV randomised controlled trial and qualitative enquiry.

1.4 DELIMITATIONS OF THE STUDY

The focus of this thesis was whether readily-accessible telecommunication devices used to deliver telerehabilitation for people following stroke could improve outcomes when compared with usual care. There is a number of emerging technologies currently being investigated for their utility in delivering telerehabilitation to people with stroke once they leave hospitals and rehabilitation centres e.g. iPads and smart-phones. There has been no attempt in this study to investigate these devices as a potential vehicle for ACTIV. It is possible that emerging technologies may be used in the future with ACTIV but the particular aim of this research was to investigate the use of readily-accessible telecommunication devices, the ones already owned by the majority of people in New Zealand, to augment and increase access to treatment. In the current study, readily-accessible devices referred to landline telephones and basic mobile phones only. There was limited information on the use of telerehabilitation in stroke, so literature investigating telerehabilitation in other populations also informed the development of ACTIV.

It is acknowledged that many groups of health professionals are involved in rehabilitation for people following stroke. The programme delivered via telerehabilitation in this study, was investigating the effect of exercise prescription on physical outcomes. In New Zealand rehabilitation using exercise prescription is commonly undertaken by physiotherapists, usually as part of an interdisciplinary team. This role may be undertaken by other health professions in other countries and there is no implication that the rehabilitation offered in ACTIV is solely the domain of physiotherapists. The co-operative relationship that exists within an interdisciplinary team means that no single profession has proprietary rights over the exercises or goal-setting discussed in this work.

People living in the community following stroke are a potentially vulnerable population, so no attempt was made to remove all face-to-face contact to test a wholly remote telerehabilitation programme. Physiotherapists have a responsibility to ensure safety and therefore some direct contact was required. Direct contact during ACTIV was used to provide a thorough initial assessment, established the constraints imposed by the environment the participant would be using and to ensure exercises were done correctly. Therefore, in the trial of ACTIV, telerehabilitation augmented and did not completely replace, face-to-face interaction as part of rehabilitation.

1.5 SIGNIFICANCE OF THE STUDY

There have been many studies showing that physical rehabilitation after stroke can help improve and maintain functional ability (Cramp et al., 2010; Dean, Richards, & Malouin, 2000; Gordon et al., 2004). The increase in numbers of people with stroke, combined with the pressure on health providers to contain costs, means that rehabilitation frequently ends prematurely. There is evidence to show that left without support many people after stroke do not maintain their level of activity (Landi et al., 2006) and have a gradual decline in physical performance (Kernan et al., 2005). The negative physical consequences of stroke lead to a reduced participation in meaningful activities, which often leads to depression (Mayo, Wood-Dauphinee, Cote, Durcan, & Carlton, 2002) social isolation (Hinojosa, Haun, Hinojosa, & Rittman, 2011), frustration and a continued decline in physical abilities (Noone et al., 2001). It is therefore important to continue to explore all practical avenues to increase the availability of rehabilitation to maintain activity, improve participation and prevent decline and hospital readmission.

If interventions delivered via readily-accessible telecommunication devices can improve outcomes for people with stroke, it may increase the proportion of people who can

continue rehabilitation in the community. As innovation and refinement occur in robotic and haptic technology and they become cheaper and more widely available, ACTIV could be delivered using more interactive mediums. This would increase synchronous communication allowing on-line correction, and may reduce the requirement for face-to-face therapy. Currently the use of such sophisticated technology is limited to clinical trials and although significant progress has been made, telerehabilitation will need to use what is available to the general population now, to widen access to treatment and continued rehabilitation. ACTIV is a framework, which can be transferred to tablet devices as they become ubiquitous in the way mobile phones have done.

Utilising relatively low-cost, widely available technology may have application in low and middle-income countries. Text messaging to improve access and adherence to a tuberculosis treatment programme has been investigated in Malawi (Mahmud, Rodriguez, & Nesbit, 2010). Results showed a significant cost saving from factors such as a reduction in wasted visits and a reduction in travel time. The consequence of this was that more patients were able to be enrolled. There is potential for the benefits of adherence to treatment and an increase in activity to be applied in post-stroke care, in countries such as southern India and rural South Africa where one of the main problems is the lack of even the most basic rehabilitation and follow-up programmes (Norrving & Kissela, 2013) with consequent high rates of disability. The current study investigates whether widening the availability of stroke rehabilitation using what most people already have, is effective in improving outcomes for people with stroke.

CHAPTER 2 LITERATURE REVIEW

2.1 INTRODUCTION

The background to the Augmented Community Telerehabilitation Intervention (ACTIV) study was a broad investigation of the area of stroke and telerehabilitation. The lack of consistency as to what constituted telerehabilitation and the limited research of its use in stroke, led to the focus of the systematic review. The review investigated the evidence for the use of readily-accessible telecommunication devices to deliver telerehabilitation to people with stroke. The results were used in the development of a novel intervention (ACTIV). The original literature review was updated at the end of 2015 and focused on studies published since end of 2011. The aim was to ascertain whether there had been significant changes in the use of readily-accessible telecommunication devices in the delivery of telerehabilitation for people with stroke, since the start of the ACTIV study.

2.2 BACKGROUND

2.2.1 *Stroke*

Stroke presents a significant health burden worldwide, accounting annually for as many as 44 million disability-adjusted life-years lost (Mukherjee & Patil, 2011). It is a disease associated with aging (R.-L. Chen, Balami, Esiri, Chen, & Buchan, 2010), so it is predicted that as populations age, the incidence of stroke will increase. In 2010, an estimated 8% of the world's population was aged over 65 years, by 2050 that is expected to double to 16%. The rate of increase in the number of older people is significantly higher in less developed countries than developed countries. In some less developed countries such as Brazil and South Korea, it is predicted that the percentage of people over 65 will rise from 7% to 14% in the next two decades, contrasting with

countries such as France and Sweden where a similar percentage change took over 100 years (World Health Organisation, 2011). The rapid aging of populations will lead to increasing demand for stroke care in all countries and the demand will be placed disproportionately on poorly resourced health services. In New Zealand the increase in stroke incidence from an aging population is exacerbated by stroke incidence in Pacific Island people increasing at a higher rate and stroke occurring at a younger age in Māori (indigenous New Zealanders) compared to people of European origin (Feigin, McNaughton, & Dyll, 2007).

2.2.2 Stroke rehabilitation

In New Zealand as in most developed countries, rehabilitation after stroke is delivered as part of a usual-care package. Rehabilitation usually begins as soon as a patient is medically stable (Askim, Bernhardt, Løge, & Indredavik, 2012), lasts during the hospital inpatient stay and is often continued after discharge (Baskett, Broad, Reekie, Hocking, & Green, 1999). Pressure on hospital beds and an acknowledgement that rehabilitation can be administered effectively in a home environment (Brewer & Williams, 2010), has led to a reduction in length of inpatient stay following stroke. Shorter hospital stay and earlier discharge has meant that a larger percentage of a person's total rehabilitation takes place in the community than was previously the case (Langhorne & Holmqvist, 2007). Well-structured programmes, designed to facilitate early supported discharge have reduced dependency and the consequent need for institutional care (Fisher et al., 2011).

Best practise guidelines consistently state that on-going therapy is vital to gain and maintain optimal levels of physical recovery (Stroke Foundation of New Zealand and New Zealand Guidelines Group, 2010). Options for continuing treatment after hospital discharge, have traditionally required the patient to attend hospital outpatient services

or for a community therapist to visit their home. Delivery of treatment by either of these means is expensive for healthcare providers and is frequently problematic for patients. Those who live a significant distance from a main centre need access to private or public transport so those in financial hardship are disadvantaged. Patients with significant impairments may find travel difficult even if it is relatively accessible (Mohd Nordin et al., 2014). In less developed countries, many of these disparities are magnified and on-going rehabilitation after hospital discharge may not be routinely offered. For example, in South Africa only 39% of old and 56% of young patients with stroke attend outpatient physiotherapy after hospital discharge. The haphazard and inconsistent provision of outpatient rehabilitation in less developed and poorer countries can be detrimental to outcome following stroke. This is compounded by a very short inpatient stay in many countries; in Pakistan for example, the average inpatient stay after stroke is three days (Brainin, Teuschl, & Kalra, 2007).

The difficulties associated with access after discharge from hospital do not seem to reduce patients' desire for ongoing rehabilitation. There is evidence that people are frustrated and disappointed at discharge from therapy, irrespective of when it occurs (Wiles, Ashburn, Payne, & Murphy, 2002) and feel bewildered and abandoned at the cessation of input (Martin, Yip, Hearty, Marletta, & Hill, 2002). These feelings appear to be associated with the failure to reach a level of ability to allow a return to previously valued activities. The withdrawal of therapy often precipitates a steady decline in physical ability (Kernan et al., 2005; Wottrich, Aström, & Löfgren, 2012).

The aging population worldwide, the scarcity of resources for stroke care and rehabilitation and the clear need for on-going support post-stroke has given significant impetus to finding new ways to deliver effective treatment at a manageable cost, to people with stroke. One promising area of investigation is telehealth.

2.2.3 *Telehealth*

Telehealth refers to the use of telecommunications to provide health information and care across distance. Three sub-groups have been described under the general umbrella of telehealth; telemedicine, telehealthcare and e-health/education, (Winters, 2002) see Figure 2-1 below. The sub-groups deliver different services to a range of populations and use a variety of telecommunication devices. The first sub-group, telemedicine, refers to the remote delivery of clinical services and encompasses a wide range of medical specialisations for example, teleneurology, telepsychiatry and telesurgery. Patient-specific information and clinical expertise are shared by medical professionals, to improve patient care and management often in the acute phase of illness or injury. An example would be a doctor in small rural hospital accessing clinical expertise to guide drug administration and assist in clinical decision-making, or direct interaction of a specialist with a patient to deliver information or an intervention. In a systematic review of reviews in telemedicine Ekeland, Bowes and Flottorp (2010) found clear evidence of the effectiveness of telemedicine, with 20 reviews finding positive effects, comparable in some cases to face-to-face interventions. The second sub-group, telehealthcare refers to the remote management of disability and health often involving a longer-term relationship that extends beyond a specific period of treatment or rehabilitation, to sub-acute and chronic health conditions. The final sub-group, e-health and education is harder to define. The term e-health was coined and initially used in marketing (Eysenbach, 2001). It aimed to convey the wide possibilities of using electronic media to access high-quality health information. E-health implied unfettered access to health information by the consumer, often independent of healthcare-provider guidance or advice. In the decade since Winters proposed this structure, e-health has become synonymous with anything health-related accessed via electronic means and has become a broad and non-specific term, meaning different things to different people

(King et al., 2011). Recently it has been used interchangeably with telemedicine (Eland-de Kok, van Os-Medendorp, Vergouwe-Meijer, Bruijnzeel-Koomen, & Ros, 2011).

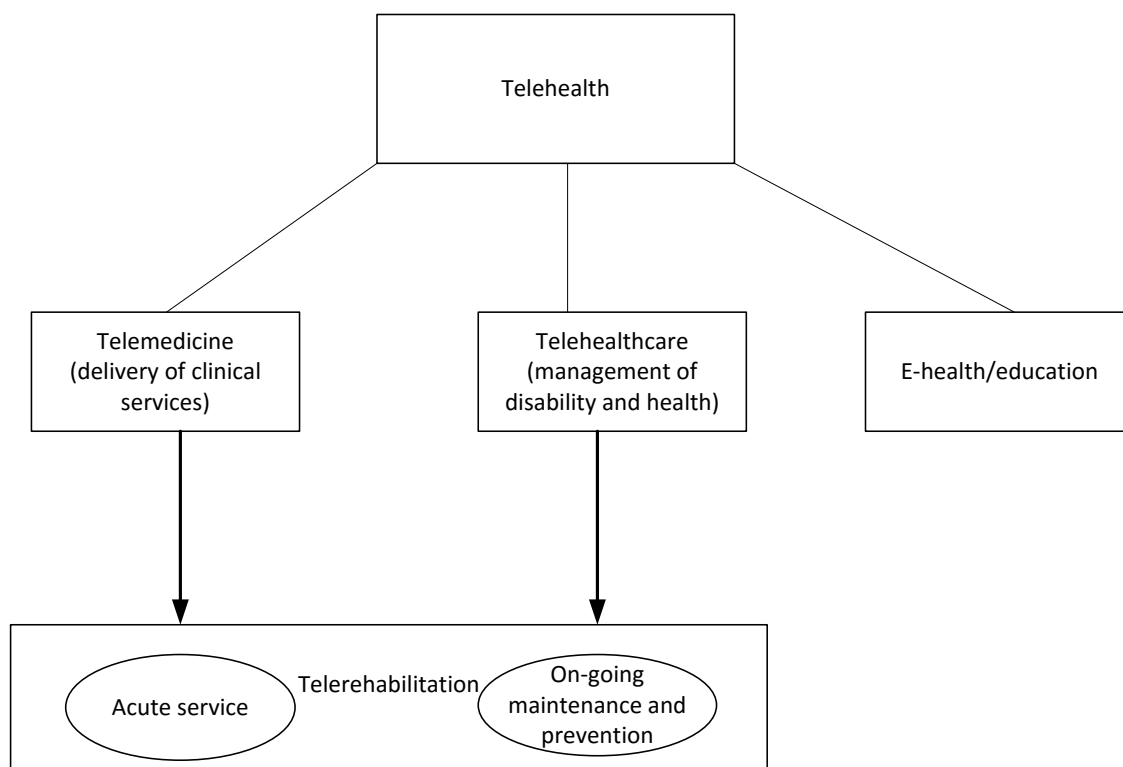


Figure 2-1: Conceptual View of Telehealth Indicating the Position of Telerehabilitation: adapted from Winters (2002, p. 290)

2.2.4 Telerehabilitation

The particular speciality of interest in this thesis is telerehabilitation, the use of telecommunication to provide rehabilitation across distance. Telerehabilitation can be considered as a sub-group of both telemedicine and telehealthcare (see Figure 2-1).

Telerehabilitation in the context of telemedicine includes acute or sub-acute rehabilitation following injury or illness, usually provided for a finite period, focussed on reduction of impairments and a return to function. Viewed in the context of telehealthcare, telerehabilitation may include on-going support to maintain function, facilitate participation in enjoyable pastimes and return to work. In clinical practice, these distinctions may be artificial but they highlight the broad range of activities that may be encompassed under the term telerehabilitation.

Telerehabilitation was first documented in 1959, when mental health services were delivered by interactive video (McCue et al., 2010) but it was not widely viewed as a viable option to deliver rehabilitation until close to the end of the Millennium. In 2000, Palsbo and Bauer published a paper outlining the opportunity telerehabilitation offered to increase reach and reduce the cost of providing therapy to an ever increasing number of people. Telerehabilitation was greeted enthusiastically as part of the solution to overcome a shortage of rehabilitation specialists, avoid some of the problems of access and increase provision of rehabilitation (Gregory, Alexander, & Satinsky, 2011). As practitioners became aware of telerehabilitation, hopes were expressed that interactive communication devices would transform rehabilitation (Peifer & Hopper, 2000). A range of devices and modes of communication was mooted for use between therapist and individuals or groups of patients. Potential devices fitted in to one of two categories, asynchronous or synchronous. Asynchronous communication systems provide a 'store and forward' communication system and initially included e-mail, web-based programmes and text message. Synchronous communication systems allowed real-time communication and included videophone, video conference and telephone (landline or mobile).

Modes of delivery

Rapidly changing technology has seen significant development of novel modes of delivery for telerehabilitation. Brochard and colleagues in 2010 noted that there seemed to be a greater focus on developing new technologies than studying their effectiveness. There has been a remarkable growth in robotic systems to increase opportunities to maximise rehabilitation (Krebs et al., 2008) and there are now hopeful signs that these can be used remotely. Virtual reality telerehabilitation allowing a therapist based in a hospital or clinic, to give on-line feedback to participants in their own home, has also shown promising results (Piron et al., 2009). However, these state-of-the-art systems are

at an early stage of development and as such are expensive and require considerable set-up and ongoing support. The rapid development of technology has led to difficulties interfacing with existing systems and participant difficulties with new technology are common. Chumbler and colleagues undertook a trial investigating use of an in-home messaging device to augment rehabilitation after stroke. In a paper reviewing the lessons learned from the trial (2010), they advised having engineering and information technology staff on-call during implementation of telerehabilitation using new technology, in view of the problems they encountered. Cost-effectiveness and cost-reduction are often cited as key drivers of telerehabilitation. The cost advantage of being able to offer rehabilitation remotely may be lost if systems are expensive, difficult to install and require significant ongoing personal and technical support. Despite exciting and rapid advance of potentially useful tools to deliver telerehabilitation, their use in standard stroke rehabilitation is still some way from being realised in developed countries and not even on the horizon for less developed countries.

In contrast to studies investigating cutting-edge technology, there has been investigation of the effectiveness of using cheap readily-accessible devices to support an increase in activity, a significant part of rehabilitation. The use of text message and telephone calls as modes of delivery has shown some promising early results. Elley and colleagues (2011) found that a written exercise prescription with telephone support for nine months, was more cost-effective than an exercise prescription alone in raising activity levels in middle aged and older women from sedentary to active. Prestwich, Perugini and Hurling (2009) also found that sending text messages to a patient who already had an intention to exercise, increased the likelihood of success more than if patients only had the intention to exercise without any reminders.

2.2.5 Telerehabilitation in stroke

There has been little investigation into the use of telerehabilitation to deliver services for people with stroke. Only one systematic review was found that focussed solely on post-stroke care. This review by Johansson and Wild (2011), identified nine studies, three addressed the impact on caregivers and the remaining six were small studies investigating acceptability and feasibility. There was a high reported level of acceptance of interventions delivered remotely and telerehabilitation was found to be feasible. Conclusions about the effectiveness of telerehabilitation were limited by low levels of evidence and low quality studies, with the majority of studies not powered to detect a change in functional outcomes.

Several other reviews of telerehabilitation have been identified that included people with stroke. A review by Kairy and colleagues (2009) included studies investigating clinical outcomes in people with physical disabilities. A review by Steel and colleagues (2011) included studies that used videoconferencing in long term conditions including stroke. Both reviews excluded studies if telephone was the only delivery method of telerehabilitation. In contrast reviews by Reynolds and colleagues (2009), investigating applications of telerehabilitation in speech and language therapy, and Hailey and colleagues (2011) investigating telerehabilitation in routine care, both included studies that used telephone contact. Hailey and colleagues (2011) noted that although new technology was being used to deliver telerehabilitation, telephone-based interventions were used more frequently than any other technology and remained a vital mode of delivery. The lack of consensus on what constitutes telerehabilitation meant that the use of readily-accessible delivery modes had been overlooked in a number of reviews.

2.2.6 The use of technology by people with stroke

The remote delivery of rehabilitation is a new concept for most people and use of new technology can be daunting, particularly for older adults. The cognitive and physical

impairments that frequently follow stroke may further exacerbate the difficulty of remote delivery. For many older adults the main form of telecommunication is still the telephone although there is an increasing trend towards the use of mobile phones (Conci et al., 2009). Due to its long history and consequent familiarity, the telephone may be an ideal tool for delivery of telerehabilitation after stroke. Further evidence of the feasibility of this was provided by Mayo, Wood-Dauphinee, Cote, Durcan and Carlton (2002) who carried out a study investigating outcomes that affected quality of life for people six months post-stroke. More than half the participants reported significant impairments in at least one important activity of daily living but less than 15% of the respondents had difficulty using the telephone.

The ubiquity and relative low-cost of landline telephones and mobile phones, the paucity of literature in the area of telerehabilitation for people with stroke and the lack of consensus about what constitutes telerehabilitation, led to a decision to investigate this further. A systematic review was undertaken to investigate the use of the landline telephone and mobile phones, to deliver or augment rehabilitation after stroke.

2.3 METHOD

2.3.1 Objective

To undertake a systematic review of peer-reviewed literature to investigate the use of telephones or mobile phones to deliver or augment the delivery of rehabilitation for people with stroke.

2.3.2 Design

A systematic search was undertaken for literature to investigate the use of telephones or mobile phones to deliver or augment the delivery of rehabilitation for people with stroke. This was based on an *a priori* plan of inclusion and exclusion criteria.

2.3.3 Inclusion criteria

Study characteristics

Randomised controlled trials, comparative studies, case series or case studies were included in the review. Designs without a comparison group were not excluded due to the paucity of both number and quality of papers published in this area. Retrospective or descriptive studies with no intervention were excluded. Studies that were coded A, B or C on the strength of recommendation taxonomy (SORT) were included (Ebell et al., 2004) (Table 2-1).

Study participants

Studies were included if they included adult participants (≥ 18 years old) with sub-acute or chronic stroke (at least 6 weeks post-stroke) or if they included participants who had been discharged earlier than 6 weeks post-stroke with at least a proportion of their rehabilitation delivered by telephone or text. Studies that included participants with stroke and participants with other pathologies were included, where data from the participants with stroke could be extracted and viewed separately.

Table 2-1: The Strength of Recommendation Taxonomy (SORT)

Code	Definition
A	Consistent, good-quality patient-oriented evidence
B	Inconsistent or limited-quality patient-oriented evidence
C	Consensus, disease-oriented evidence, usual practice, expert opinion, or case series for studies of diagnosis, treatment, prevention, or screening

Intervention

Studies were included if the intervention or the control was delivered by telephones or mobile phones alone or in addition to face to face rehabilitation and was provided by a healthcare professional. The intervention had to involve rehabilitation intended to impact a body structure or function, an activity or participation, as defined in 'The International classification of functioning, disability and health' (ICF). (Stucki, Ewert, & Cieza, 2003). The study setting had to be distant from the delivery of the intervention and included participant's home, rest homes, work places or other community settings.

Outcome measures

Studies were only included if at least one of the measured outcomes pertained to a body structure or function, an activity or participation, as defined within the ICF.

2.3.4 Exclusion criteria

Study

Studies without ethical approval and studies published in languages other than English were excluded. Publication status was considered and conference abstracts and grey literature were excluded as it was not possible to assess the level of evidence or risk of bias.

Participants

No study was included if the therapeutic contact was with a caregiver or if any of the study participants were <18 years.

Intervention

Studies were excluded if the contact by accessible devices was, for assessment purposes only such as administration of a questionnaire; limited to only one occasion; communication solely between health professionals or for the management of acute

stroke. Studies that utilised any other form of technology other than mobile phone and landline telephone, were excluded.

2.3.5 Identification of studies

Eleven databases were searched: Scopus, Medline via Ebsco, Cinahl via Ebsco, Web of Science, Cochrane via OVID, AMED: Allied and complementary Medicine, PsychINFO, Sports Discus, Evidence based Medicine reviews, Cochrane via Wiley and PEDro. No restriction was placed on date of publication and the search was completed on 30th September 2011. The search strategy combined terms that referred to the population in question, stroke (CVA, hemiparesis, hemiplegia) the intervention (telerehabilitation, distance rehabilitation) and the mode of delivery (telephone, mobile phone, SMS). The search strategy used in the Scopus database is presented in Appendix A. The reference lists of articles that met the inclusion criteria were hand-searched for further articles.

2.3.6 Data extraction and management

All extracted references were downloaded and saved in Endnote X4. Once duplicates were removed, the titles of all articles were reviewed by NS. A conservative approach to inclusion was taken so if doubt existed the article was included for review of the abstract; a similarly conservative approach was taken with review of abstracts, which were reviewed by two independent assessors. The final articles were then read in full and eligibility assessment was performed by two independent assessors. Where a disagreement existed, the inclusion and exclusion criteria were referred to, with the opportunity to discuss discrepancies with a third reviewer not involved directly in the study. Where agreement could not be reached the third reviewer made the final decision. A data extraction form was created based on the template for a data extraction form (Cochrane, n.d.). The following information was extracted from included studies:

study author and date, study design, number and characteristics of participants, intervention and control if applicable, outcome measure of interest and main result.

2.3.7 Quality assessment

The two reviewers independently critically appraised each included article to ascertain the level of evidence using, The Centre for Evidence Based Medicine, Oxford (OCEBM Levels of Evidence Working Group, 2011). Risk of bias was then assessed for the RCT's using the Cochrane collaboration's tool for assessing risk of bias (Higgins et al., 2011).

2.4 RESULTS

2.4.1 Selection process

In total 4558 articles were retrieved in the search, (see Figure 2-2 for selection of studies). After duplicates were removed 1911 remained. Articles were screened by title against the inclusion and exclusion criteria, 145 remained. All 145 abstracts were reviewed and 132 were excluded with the reason for exclusions documented. Thirteen full text articles remained but despite searching and endeavoring to contact the author, no results could be found for the study by I. W. Miller (2003) and this was therefore excluded.

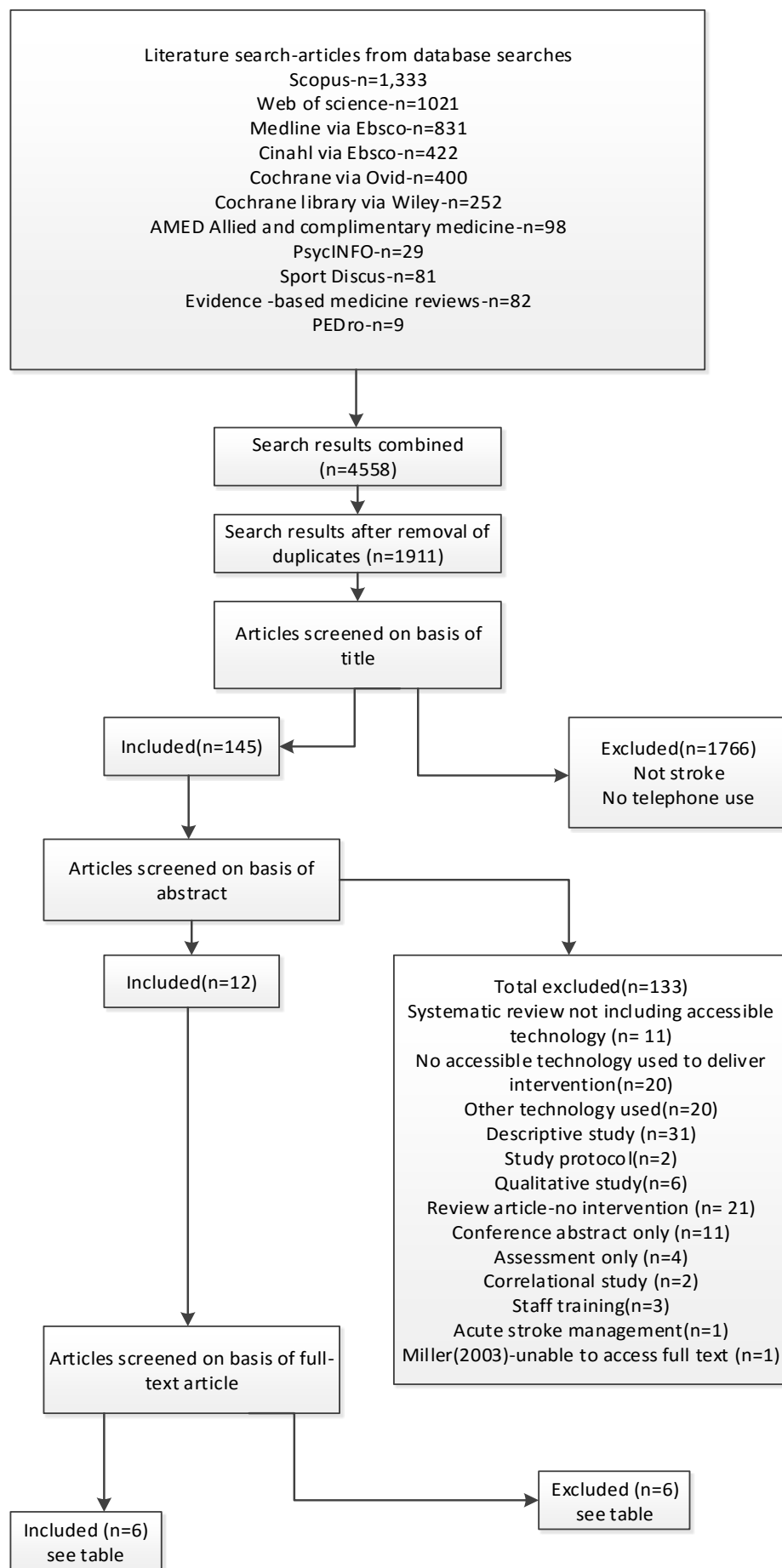


Figure 2-2: Selection of Studies for the Review

Twelve full-text articles were read, six studies met the inclusion criteria (see Table 2-2). Six studies were excluded and the criteria against which they were excluded were taken from the data extraction section of the Cochrane website (Cochrane, n.d.) (see Table 2-3 page 29). Communication was undertaken with authors to ascertain any details about the intervention that was unclear from the published study. Results for levels of evidence and risk of bias were recorded for the included articles (see Table 2-4, page 30).

Table 2-2: Included Studies after Full Text Review

Author and date	Study design	Participants		Intervention		Outcome measure of interest*	Results
		Number	Characteristics	Treatment	Control		
Ada 2003	RCT	29	Age 50-85 years, ambulatory discharged from rehabilitation, living in the community, stroke > 6 months and < 5 years prior to inclusion.	30 min treadmill and overground walking program., x3 weekly/4 weeks	Low-intensity home exercise program instructed to do x3/week/4 weeks, plus advice for a daily walk and phone contact x1/week to progress exercise.	Measures- Walking speed (over 10m), walking capacity (6-min walk), handicap (SA-SIP30). Timing- Pretest, posttest and 3-months after cessation of training.	Compared to control group, intervention group had significant improvements in walking speed (p=.02) and walking capacity (p<.001), but not handicap (p=.85)
Boter 2004	RCT	536	Age ≥18 years, 1 st admission for stroke, independent or a Rankin grade 0-3 on discharge from hospital, discharged home.	Standard care plus 'Outreach care program'-(3 phone contacts , one home visit, support and advice to actively solve problems faced) in the 5 months after discharge from hospital.	Standard Care	Measures- (Secondary OM), ADL (BI 0-20), Independence (modified Rankin scale), use of healthcare services. Timing- 6 months post-discharge	No statistical differences between groups.

Burton 2005	Pragmatic RCT	176	Clinical diagnosis of stroke. Absence of pre-stroke clinical depression, dementia.	One F/U visit from nurse within 2 days of D/C. Participant initiated phone contact as required.	Usual care consisting of 'best practice' from a multidisciplinary team.	Measures- Patient dependency (BI), patient perceptions of health (NHP), performance of daily activities (FAI). Timing- 3 months and 12 months post-stroke	Significantly larger number of control participants became physically dependent over 12-month study period. Intervention group reported significantly less social isolation
Chalermwannapong 2010	Experimental pretest-posttest design	67	1 st stroke with moderate to severe disability. No M/S disorders, psychiatric history or alcoholism. Included only those with a caregiver.	Routine hospital care and 'Transitional Care Program' ('hospital period'- D/C planning and 'home period'- F/U within 24-48 hours of D/C and x2 phone visits and additional participant initiated phone visits as required.	Routine Hospital care	Measures- Modified B I Timing- Baseline and week 12.	Significant improvement in functional ability in intervention group compared to control.

Helm-Estabrooks 1986	Case study	1	Aphasia following stroke	Phone delivery of speech language therapy. HELPSS experimental program.113 sessions during 34 weeks	N/A	Measures- NWSST and BDAE Timing- Baseline and post-programme (34 weeks)	Improvement in both outcome measures. No indication of the extent or significance of the improvement.
Mayo 2008	Randomised clinical trial	190	Patients D/C home from acute care post-stroke and at least one of the following : living alone, mobility problems, mild cognitive deficit, dysphagia, incontinence or need for post discharge management of co-morbidities	6 weeks of case management from nurses.(Home visits and participant initiated phone contact as needed)	Usual care - participant instructed to make appointment with physician or community health centre as soon as possible	Measures- Physical component summary of the SF-36, EQ5D, Reintegration to normal living index, B I, Gait speed and TUG. utilisation of health services. Timing- Post-intervention (6 weeks) and 6 months post-stroke	No significant between-group differences in any OM

BDAE: Boston Diagnostic Aphasia Examination; BI: Barthel Index; D/C: discharged; FAI: Frenchay Activity Index; NHP: Nottingham Health Profile; NWSST: Northwestern Syntax Screening Test; OM: outcome measure; SA-SIP30: Stroke-adapted 30-item version of the Sickness Impact Profile.

***Only outcome measures of constructs measured by the ICF, identified in the inclusion criteria of this review were tabulated**

Table 2-3: Excluded Studies after Full Text Review

Author and date	Study design	Criteria used to exclude	Reason for exclusion
Adie 2010	RCT	Were the participant's diagnosed with the pathology of interest?	This trial investigated TIA and stroke there was no separation of the results, so information about people with stroke could not be extracted.
Gillham 2010	RCT	Were the participant's diagnosed with the pathology of interest?	This trial investigated TIA and stroke there was no separation of the results, so information about people with stroke could not be extracted.
Johansson 2009	Systematic review	Did the study include the intervention of interest?	Only two of the studies included investigated 'accessible technology' and of those one of them investigated outcomes in the caregivers only. The decision was made to include the remaining study separately (Boter 2004 in included studies)
Lutz 2009	Non-randomised open trial, mixed methods design	Did the study include the intervention of interest?	The communication device, although it was attached to the landline telephone did not fall into the category of 'accessible technology' as it is not widely commercially available to the majority of people in the developed world.
McClellan 2004	RCT	Did the study include the intervention of interest?	The author was contacted for clarification and the control intervention only included one phone call
Smith 2008	Modified random assignment, matched pair control group design with repeated measures	Did the study include the intervention of interest?	The two reviewers were unable to reach consensus so a 3 rd independent reviewer was asked to comment and decided that the telephone communication was used to assist participants in filling in a weekly log and asking about their life, it didn't include anything that could be described as rehabilitation in the physical sense.

Table 2-4: Level of Evidence and Risk of Bias

	Level of evidence	Selection bias		Performance bias	Detection bias	Attrition bias	Reporting bias	Other bias
Study Author and date		Random sequence generation	Allocation concealment	Blinding of participants and study personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Any other sources of bias
Ada 2003	1c	Coin toss	L	L	L	L	L	L
Boter 2004	1c	Not specified	L	L	L	L	L	L
Burton 2005	1c	Stratified by centre, level of function, discharge destination	L	H	L	L	L	U
Chalermwannapong 2010	2b	Not specified	L	H	L	H	L	L
Helm-Estabrooks 1986	5							
Mayo 2008	1c	Random blocks	L	H	L	L	L	L

Risk of bias was classified by the researcher as: L: low; H: high; U: unclear; Shaded area indicates inability to assess risk of bias (single case study).

2.4.2 Levels of evidence

Four of the included studies were randomised controlled studies either with no confidence intervals specified or wide confidence intervals reported for results (Ada, Dean, Hall, Bampton, & Crompton, 2003; Boter, 2004; Burton & Gibbon, 2005; Mayo et al., 2008) and so are level 1c. The only included RCT that was judged to be level 2b had a large number of randomised participants that were not included in the data collection or results (Chalermwannapong, Panuthai, Srisuphan, Panya, & Ostwald, 2010). The other included article was a historical article a single case study with reporting at the level of expert opinion and therefore judged to be level 5 evidence (Helm-Estabrooks & Ramsberger, 1986).

2.4.3 Participants

Two of the studies included participants with chronic stroke; more than 6-months post-stroke in the trial by Ada (2003) and over 11 years post-stroke in the case study by Helm-Estabrooks (1986). The remaining four studies included participants with sub-acute stroke admitted to the trial prior to discharge from hospital (Boter, 2004; Burton & Gibbon, 2005; Chalermwannapong et al., 2010; Mayo et al., 2008). The time since stroke, which corresponded to length of stay, varied between 12 ± 11.7 days and 48.8 ± 36.6 days, the age of participants ranged from $51-75 \pm 9.6$ years. Excluding the one case study the total number of participants was 479 in the intervention groups and 490 in the control groups.

2.4.4 Intervention

The intervention of interest in this review was telecommunication contact to assist in delivering rehabilitation. One trial was included because the intervention, treadmill and over-ground walking, was compared with a telephone contact control (Ada et al., 2003). This involved a low-intensity exercise home programme, which was progressed using

phone instruction once per week. The remaining studies had telephone contact as at least a part of the intervention of interest. In the trial by Boter (2004), three telephone contacts over a period of five months were included as part of a programme to help participants actively solve problems including physical difficulty with tasks. In the trial by Mayo and colleagues (2008) telephone contact of unspecified number was used to help co-ordinate services and facilitate participation. In both these studies the contact by phone was used for a variety of purposes; encouraging physical activity was a small part of each intervention however, the consensus agreement was that they fitted the inclusion criteria. The intervention by Chalermwannapong and colleagues (2010) involved education and environmental improvements to facilitate independence and included two standard phone calls with additional calls initiated by the participant if required. The intervention described by Burton and Gibbon (2005) had a physical, educational and emotional elements focused on maximising recovery and used both home visits and phone calls with the frequency decided on a case by case basis. In contrast to the other studies, Helm-Estabrooks and Ramsberger (1986) investigated the provision of speech therapy but the study was included as it fitted the stated inclusion criteria for the review. In this study the entire speech and language therapy programme was undertaken by telephone in the case study by Helm-Estabrooks and Ramsberger (1986). Three of the six studies included phone contact initiated by the participant (Burton & Gibbon, 2005; Chalermwannapong et al., 2010; Mayo et al., 2008).

2.4.5 Setting

All the interventions were delivered to participants who had returned to living in the community, which for five of the studies meant living at home. Only the trial by Burton and Gibbon (2005) included participants who had been discharged to institutional care. The trial by Chalermwannapong included an inpatient aspect to the intervention.

2.4.6 Control Group

For the purpose of this review the control group was the group that did not receive the telephone intervention, so in the case of the trial by Ada the group receiving treadmill training.

2.4.7 Outcomes measured

Under each category of the ICF, the outcome measure will be reported followed by the construct it measures if it is not self-explanatory. None of the studies measured changes in body structure or function. All studies measured an activity and all used outcome measures that were valid and reliable and might commonly be used in clinical practice. Only one trial measured participation.

Measurement of an activity

Activities of daily living (ADL) measures

- Modified Barthel Index (mBI) - performance of self-care (Chalermwannapong et al., 2010).
- Barthel Index (BI) - performance of activities of daily living (Boter, 2004; Burton & Gibbon, 2005; Mayo et al., 2008).
- Frenchay Activities Index (FAI) - performance of everyday activities (Burton & Gibbon, 2005).
- Modified Rankin Scale (mRS)- ADL(Boter, 2004).

Gait and balance measures

- Gait speed (Ada et al., 2003; Mayo et al., 2008).
- Walking capacity (Ada et al., 2003).
- Step length, cadence and step width (Ada et al., 2003).
- Timed up and Go (TUG) - speed during sit to stand, walking and turning, may challenge low level balance (Mayo et al., 2008).

Speech and language measures

- Northwestern Syntax Screening Test (NSST)- language impairment (Helm-Estabrooks & Ramsberger, 1986).
- Boston Diagnosis Aphasia Examination (BDAE)- language skills including some non-verbal such as signing (Helm-Estabrooks & Ramsberger, 1986).

Measurement of participation

- The Stroke-adapted 30-item version of the sickness impact profile (SA-SIP30) (Ada et al., 2003).

2.4.8 Quality of studies

Risk of bias

Risk of bias could only be assessed in the randomised controlled studies so the study by Helm-Estabrooks was excluded from this process. Two of the five randomised controlled studies did not state how they generated a random sequence (Boter, 2004; Chalermwannapong et al., 2010) but all studies concealed group allocation from participants. All trials used blinded assessors but three of the five trials did not blind other trial personnel or participants (Burton & Gibbon, 2005; Chalermwannapong et al., 2010; Mayo et al., 2008). All except one trial accounted for participants in their analysis, the trial by Chalermwannapong (2010) failed to account for a considerable number of participants who dropped out after randomisation. The results all reported the primary and relevant secondary outcomes between groups with no evidence of selective reporting. There was potential for an increased risk of bias in the pragmatic trial by Burton and Gibbon (2005) as no attempt was made to standardise delivery of the intervention, possibly leading to more variability. They also noted that despite efforts to retain blinding, the majority of assessors correctly guessed group allocation. No other sources of bias were noted.

2.4.9 Results of outcomes of interest

All the studies used telephone contact for verbal communication. None of the studies in this review utilized text or SMS contact. A positive result in favour of the use of telephone to improve outcomes was reported in three of the studies (Burton & Gibbon, 2005; Chalermwannapong et al., 2010; Helm-Estabrooks & Ramsberger, 1986). For the remaining three studies (Ada et al., 2003; Boter, 2004; Mayo et al., 2008) there were no between-group differences recorded for any of the outcomes of interest to this review.

Outcomes pertaining to an activity

ADL measures

Burton and Gibbon (2005) reported that the participants who received continued support to maintain physical function reduced their deterioration in physical independence significantly when compared with the control group as measured by the BI. However, no difference was found between groups in the ability to undertake everyday activities as measured by the FAI. Chalermwannapong and colleagues (2010) found physical independence measured by the mBI, was significantly better in the intervention than the control group. In the trial by Boter (2004) investigating an outreach nursing support programme, no difference was found in ADLs measured by the BI or in the degree of independence measured by mRS. Mayo and colleagues, used the Barthel index as a secondary outcome and found no between group differences.

Gait and Balance measures

The telephone contact group in the trial by Ada and colleagues (2003) received regular contact combined with a low-intensity exercise programme. This produced significantly less improvement in step length, walking speed and walking capacity than in the treadmill and over-ground walking group. Between-group difference in step width was not significant and cadence increased equally in both groups although the within group increases were not specifically reported. Mayo and colleagues (2008) measured gait

speed and balance (using the TUG) as secondary outcome measures, in a trial to investigate whether the addition of a stroke co-ordinator would confer extra benefit for vulnerable patients returning home after rehabilitation. There were no between group-differences for either measure.

Speech and language measures

Helm-Estabrooks and Ramsberger (1986) reported significant improvements in both language outcomes measured, in the single participant.

2.5 DISCUSSION

It is clear from the comprehensive literature search that there has been little investigation in to the use of landline telephones or mobile phones to either augment or replace traditional physiotherapy rehabilitation that occurs after stroke. The next section looks at the two groups of studies separately, studies that reported changes from the use of the accessible devices and those that did not.

2.5.1 Studies that demonstrated improvement in outcomes of interest using telephone support:

Of the three studies that found an improvement in outcomes of interest there was no consistent pattern to the amount of telephone contact with participants. Helm-Estabrooks and Ramsberger (1986) in the single case study used 113 telephone calls, which is the highest number of telephone contacts found in any of the literature on telerehabilitation and may represent the historical nature of the study, undertaken in an era when resources were less constrained. In this study the treatment programme was delivered by telephone with no face-to-face contact. This differs from all other included studies where telephone contact was part of the intervention, not its entirety. The intervention may still have been an efficient use of resources, as there would have been no travel time or travel costs; often a significant portion of the cost of treatment if a

participant lives a long distance from the treatment facility. There was no cost comparison made with other methods of therapy provision but it was noted that this participant previously had a trial of traditionally delivered therapy with limited success. The participant in this study also had significant co-morbidities and disabilities which would have made travel difficult. Looking at the amount of telephone contact used in the other two studies (Burton & Gibbon, 2005; Chalermwannapong et al., 2010) there were infrequent telephone contacts with participants. Chalermwannapong and colleagues (2010) included two planned calls and but allowed participants to initiate telephone contact as required, there is no record of the number or content of calls initiated by participants but the guidelines for participants state they could contact the investigator twice a week for two weeks after discharge. Burton and Gibbon (2005) also permitted participant initiated telephone contact but the actual number of calls initiated by participants was not possible to ascertain as visits and telephone calls are reported together as contacts (range 0-28). Telephone calls initiated by participants may be considered to represent support but some question whether they fall into the category of telerehabilitation. There has been contention about whether a passive receipt of contact or actively seeking help are superior and a study is currently underway investigating this in a population with mild stroke (Rochette et al., 2010), however both have the potential to be part of a wider definition of telerehabilitation.

The trial by Chalermwannapong included a feature not evident in the other studies, this being the addition of significant discharge planning for participants in the intervention group, compared with the control group so it is difficult to compare the findings with other telephone-augmented rehabilitation. It would not be possible to isolate whether the pre-discharge education or post-discharge intervention accounted for the between-group differences.

From the studies that found improvement, using landline telephones or mobile phones to deliver rehabilitation there is little homogeneity between the studies. It appears that the addition of contact in this way may be useful in maintaining or improving function but so few studies have used this method of augmenting activity that little more can be drawn from the results.

2.5.2 Studies that did not demonstrate improvement in outcomes of interest using telephone support:

In the trial by Ada, the telephone reminder group was the control and was compared to a group who received face-to-face intervention. The intervention group received 30 minutes of walking practice over 12 sessions, so it is not surprising that they improved significantly more than the group receiving encouragement by telephone to complete low-level exercises. However, the telephone group had a good level of compliance with the low-level exercise they had been prescribed, with an average of 11/12 of the sessions completed. Therefore, although the intensity of exercise in the telephone group had been designed as a credible sham, insufficient to produce a meaningful change in gait parameters, the reminders to exercise were effective in supporting engagement with the exercise programme. In addition, Ada noted that despite seeing changes in gait parameters during the programme, only one person in the treadmill-training group made a behavioural change to a regular exercise routine after cessation of the trial. Ada concluded that longer term programmes were needed to encourage ongoing activity and these would need to be accessible and affordable to make them viable. The trial by Mayo and colleagues (2008) and the trial by Boter (2004), both delivered an intervention which used a telephone to support participants, although there was a ‘tele’ component, the rehabilitation aspect of the intervention was limited. Boter noted that there was a focus on participants actively solving problems with support but the encouragement of activity seemed to be restricted to maximizing daily living activities

and encouraging independence. Similarly, in the trial by Mayo it was noted that the interventions delivered were passive, including surveillance, medication management and risk identification. There is no evidence of patients working collaboratively with the healthcare professionals to reach a goal, indeed it was stated that this was not the purpose of the intervention. The authors suggested that to have made a difference to function, the intervention may have needed to include a degree of specific functional training, not just assist in problem-solving and mitigation.

There are a number of tentative conclusions possible from studies that found no improvement that may help inform further research. The reflection that neither phone contact nor intensive therapy over a four-week period was enough to effect any behavioural change suggests that a longer period of intervention may be required, irrespective of delivery method. Mayo (2008), stated that cost is an important factor to consider in longer term programmes; the compliance achieved using a low-level intervention in the telerehabilitation group of the trial by Ada (2003) suggests that low-level (presumably less expensive) contact may still have a beneficial effect on engagement in exercise and activity. The important element of an intervention seems to be that it encourages or supports an increase in exercise or activity that persists beyond the duration of the programme.

2.6 SUMMARY

At the start of the study, at the end of 2011, there had been little investigation into the use of telephone to deliver therapy to people following stroke. There was some early evidence that it is possible to augment or replace at least some of an intervention using telephone support, however the evidence was of an extremely low level. There had been no investigation of the use of text messages to deliver any portion of a post-stroke rehabilitation programme. Of particular interest was the possibility of extending the

length of current rehabilitation by using phone calls and text messages. The proposal was to recruit patients who had been discharged from rehabilitation services and investigate if the addition of 6-months of remotely delivered rehabilitation would improve outcomes compared with current practice. The decision was made to develop an evidence-based intervention, which used the technology available to most people. Chapter 3 details the development process.

2.7 UPDATED LITERATURE REVIEW

ACTIV was developed at the end of 2011, following a review of the literature up to the end of September 2011. An updated literature review was undertaken to review changes that have occurred during the intervening period. The same methods were used as in the previous literature review with dates from the beginning of October 2011 until the end of December 2015.

2.7.1 Results

No additional studies were found which fitted the inclusion criteria at initial search. A systematic review of the efficacy of self-management programs for increasing physical activity in community-dwelling adults with acquired brain injury (T. M. Jones, Dean, Hush, Dear, & Titov, 2015) was excluded on review of abstracts, but as it included the population of interest, physical activity and self-management, a hand search of references was undertaken. One trial met the inclusion criteria for the systematic review (see Table 2-5 page 43).

The included trial was a pilot RCT by Damush and colleagues (2011), which investigated the feasibility of using a self-management programme to improve self-efficacy and healthy behaviors post-stroke. The intervention was designed to encourage self-management and increase healthy behaviour, aimed at stroke prevention and was delivered via telephone and face-to-face contact. The attention-matched control group

received a general phone call and no between group differences were found. However, this was a pilot study, designed to investigate feasibility and was therefore not powered to detect a between-group difference. The outcome measure of interest to this review was self-reported aerobic exercise. The risk of bias in this trial is low and detailed in Table 2-6 page 44. The only obvious source of bias was that all the participants were male, which was acknowledged by the authors. One trial protocol has been published recently (Merchan-Baeza, Gonzalez-Sanchez, & Cuesta-Vargas, 2015), which investigates using mobile phone reminders to help people regain independent function in important ADL s at home after discharge from hospital. This study investigates the use of a mobile phone application, based on an initial assessment from a therapist and does not appear to be personalised. The stated randomisation plan is problematic, as allocation will be blinded but also dependent on whether a participant owns a phone that can accept the planned application. This calls in to question the trial quality, as there will be clear allocation bias; the intervention group will need to own a suitable phone and it is not possible to know if they might be wealthier, better educated or more technologically literate than the control group. No other protocols were found that investigated using landline telephones or mobile phones to increase activity in a stroke population.

2.8 SUMMARY

In the four years, since ACTIV began there had been a steady increase in levels of mobile phone ownership. There had also been increased access to more sophisticated personal communication devices, as the price of smart phones and iPads has reduced. The increase in access to telecommunication devices had not resulted in any significant increase in the investigation of their utility and effectiveness to deliver telerehabilitation after stroke. There had been research using landline telephones and mobile phones in a number of other health populations. Some of the studies, particularly where the stated

aim was to encourage behavior change, may help inform ongoing research and practice in the arena of stroke rehabilitation. Several of these studies are discussed in Chapter 10 where they are used to inform the discussion on implications for practice and potential areas for future research.

Table 2-5: Additional Studies since Initial Literature Review

Author and date	Trial design	Participants		Intervention		Outcome measure of interest	Results
		Number	Characteristics	Treatment	Control		
Damush 2011	RCT pilot	63	Age ≥ 18 years, 1 st admission for stroke in the past month,	A 12 –week intervention: Six sessions of self-management (3 in person and 3 by telephone) bi-weekly telephone sessions to re-inforce, adjust goals and self-management strategies	Placebo call	Measure -Self-management behaviour- minutes spent doing aerobic exercise. Timing -3 months post-enrollment (after intervention) and 6 months (retention)	No statistically significant differences between the groups at baseline, 3 or 6 months.

Table 2-6: Level of Evidence and Risk of Bias

	Level of evidence	Selection bias		Performance bias	Detection bias	Attrition bias	Reporting bias	Other bias
Trial Author and date		Random sequence generation	Allocation concealment	Blinding of participants and trial personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Any other sources of bias
Damush 2011	1c	Coin toss	L	L	L	L	U	All male cohort

Risk of bias was classified by the researcher as: L: low; H: high; U: unclear

CHAPTER 3 INTERVENTION DEVELOPMENT

3.1 INTRODUCTION

In light of the findings from the literature, review the decision was made to develop an intervention delivered in part using landline telephones or mobile phones, for people with stroke. The intervention employed exercises to improve physical function and utilised strategies to support behaviour-change.

Behaviour-change is vital to ensure that functional gains from rehabilitation are maintained or improved upon after discharge from rehabilitation services. Newly acquired skills need to be used regularly to become embedded. ACTIV was developed by NS and DT with input from a number of healthcare professionals and researchers and used principles of Bandura's social cognitive theory, which acknowledges that behaviour is influenced by the individual's perceived competence to manage a task in their environment (Bandura, 1989). While the complexity of the interaction between these factors was not the primary focus of this thesis, specific strategies that have been shown to support behaviour-change were used to inform the development of ACTIV. The influence of current literature on the development of the final programme is discussed.

3.2 GOAL ACHIEVEMENT

Snyder and colleagues (1991) suggested that goal-directed behaviour leading to achievement involves two interrelated but distinct components, the determination and focused belief in goal achievement which they describe as 'agency' and a clear understanding of the practical steps a person can use to achieve those goals, described as 'pathways'. Snyder and colleagues developed and validated a scale based on these two constructs, the Hope Scale. Increased scores in the Hope scale correlated with levels of success and coping strategies in a range of populations including people

following stroke. The following two sections discuss how literature was used to develop two important elements in ACTIV; the facilitation of focused belief in goal achievement and the practical steps to achieve those goals.

3.2.1 Focused belief in goal achievement

It is unknown the extent to which treatment interventions can alter agency for an individual. However agency is strongly affected by and closely related to self-efficacy; a core tenet of behaviour-change as discussed by Bandura and Locke (2003), who affirmed that people are motivated by anticipation of achievement and belief in their ability to effect it. People are proactive and aspirational, so planning to achieve challenging goals increases effort. Early evidence suggests that personalising a goal to an easily understood next step such as ‘what do you want to do next?’ has a positive effect on self-efficacy in people with stroke (Leach, Cornwell, Fleming, & Haines, 2010). During ACTIV each assessment form used by the physiotherapists and the manual given to each participant were designed to have an area clearly highlighted to record the participant goal. The words used on each assessment sheet were “What do you want to do most?” This used the concepts from Leach and colleagues to make the idea of goal-setting easily understood, but also used information from a study by F. Jones and colleagues (2008) that found participants who were given the opportunity to lead and direct their treatment and select important goals, had enhanced self-efficacy. Goal setting is frequently discussed in the literature and has been found to be an essential element in any rehabilitation programme (Stroke Foundation of New Zealand and New Zealand Guidelines Group, 2010). However it is a complex (Barnard, Cruice, & Playford, 2010) and relatively little understood process and frequently appears to be an alien concept to patients. (Siegert, 2010). Research undertaken by Leach and colleagues (2010) investigating patient-centred goal-setting found that patients rarely focused on an impairment when discussing future goals, but frequently identified a

return to activities they had previously enjoyed. Hafsteinsdottir and Grypdonck (1997) agree, finding that patients often measured success by the re-gaining of valued activities with less emphasis placed on the skill of task performance. This frequently leads to difficulties in the goal-setting process. Rosewilliam, Roskell and Pandyan (2011) in a systematic review of patient-centered goal-setting practices discovered that goals were frequently not patient-centred. In several of the reviewed studies, a patient goal appeared to have been hijacked by health professionals. They frequently focused on impairment and basic functional limitations, ignoring significant patient concerns about their re-integration into their previous social and participatory roles (Bendz, 2003; Ewan, Kinmond, & Holmes, 2010). A study by Wade (1999) found such basic functional goals were frequently seen by patients as medium-term objectives. They were considered stepping-stones to the overarching goal of fulfilling your role in the family, in the environment you have chosen to live; they were perceived only as achievable sub-steps. Ewan and colleagues (2010) exploring peoples response to rehabilitation after stroke, found that physiotherapy seemed to be of most benefit when working towards goals that were perceived by the patient as important. These were often enjoyable activities that were valued before the stroke. If working towards an important goal is not clearly addressed and evident to the patient, they may be indifferent to any intervention regardless of its merits (Pound, Bury, Gompertz, & Ebrahim, 1994). The disparity between a patient's desire to return to a meaningful life and a therapist's focus on basic functions can limit the goal-setting process. In training delivered to the ACTIV intervention physiotherapist, the emphasis was on ensuring each physiotherapist understood the process of goal-setting, Emphasis was placed on the importance of the goal being participant-generated. Patient scenarios were used to give examples of aspirational goals and how exercises could be tailored to work towards them. Several included examples of goals that could be described as unrealistic; to give

physiotherapists a chance to explore how to prescribe exercises that avoided coercing participants to choose a more realistic goal. This approach is supported by findings from a study by Levack and colleagues (2011). They found that patients' response to a disparity between their goals and therapists' objectives may be to claim not to have a goal or to hide goals from healthcare professionals. Patients feared being accused of being unrealistic or wanting to achieve things that were not relevant to their current stage of recovery. In the paper by Levack and colleagues, the authors found patients had been given spoken and unspoken messages about goals that were considered valid because they fulfilled basic functional requirements, and those that were not.

The main message from recent literature is that goal-setting is a vital component of rehabilitation. Goals need to be specific to each patient, and should focus on incremental gains, allowing people to select activities of their choice to allow progress towards fulfilling life roles.

The process of goal-setting has often been considered with little mention of goal-achievement. In literature that focused on patients achieving their goals, there was still considerable controversy, with little consensus on the best way to evaluate success (Playford, Siegert, Levack, & Freeman, 2009; Turner-Stokes & Williams, 2010). The difficulty in measuring goal-achievement has been compounded by changes in goals over time. A study by Wood, Connelly and Maly (2010) found that working towards a goal was not a linear process. Goals set by participants changed several times in the year following stroke and establishing a degree of independence was needed before participants felt ready to focus on more real-life goals. The ACTIV physiotherapy training scenarios included examples of goals changing over the course of ACTIV, either because a goal had been achieved or because the participant found a different goal more motivating or important. The physiotherapists who were going to deliver ACTIV used role-play to stimulate discussion and encourage problem-solving.

Wood and colleagues (2010) in a qualitative study of re-integration in to the community after stroke found that when activities were first attempted there was an initial loss of self-efficacy, which returned once some success had been experienced. This suggested that early success may encourage persistence with ACTIV exercises. For this reason, the physiotherapists were encouraged to select at least one exercise at the initial assessment that the participant had a high likelihood of being able to improve quickly. The first follow-up physiotherapy visit was then scheduled within two weeks, to check that some success had been achieved before the face-to-face interactions became less frequent.

Goal-setting has been shown to increase self-efficacy and perseverance (Bandura & Locke, 2003) and it has been known for over 20 years that self-efficacy can alter health behaviours and improve performance (G. Holden, 1991). What is still not clear is whether increased self-efficacy can lead to the behaviour-change, so vital to ongoing rehabilitation. The ACTIV outcome measures undertaken by the blinded assessors, aimed to increase understanding of the success of goal-setting and included self-efficacy and functional outcomes. These were undertaken after the intervention and 6-months after cessation of the intervention to establish if any changes had been more permanent. There were also questions related to the goal-setting process in the qualitative study. In this way we hoped to capture a range of changes and responses related to the programme.

3.2.2 Practical steps to goal achievement

The process of working in an active way towards a goal has been identified as assisting in retaining hope (Bright, Kayes, McCann, & McPherson, 2011). The practical steps used to achieve a goal are the pathways described by Snyder and colleagues (1991) and as such form a component of the Hope Scale. Working actively towards a goal is a circular process, an increase in hope has been identified as a factor which leads to an

increase in participation which in turn is important for both physical progress and psychological well-being (Bays, 2001).

Physical exercise has been demonstrated to have a significant beneficial effect on outcomes for people with a variety of pathologies, including stroke (Smidt et al., 2005) and was chosen as the basis of the ACTIV intervention. The use of exercise as the main component of stroke rehabilitation has increased over the past two decades with a gradual move away from isolated strengthening exercise to task-related practice (Rensink et al., 2009; Shepherd, 2001). This has been driven by evidence that repetitive, meaningful practice is essential to drive neuroplasticity and hence recovery following stroke (Bosnell et al., 2011; Kleim & Jones, 2008). The principles of motor learning have been increasingly applied to rehabilitation practice to maximise physical gains. Research shows that without ongoing support to maintain meaningful practice after discharge from rehabilitation services, people with stroke experience a gradual reduction in activity levels and physical fitness (Langhammer & Lindmark, 2012).

A systematic review and meta-analysis which focused on people with chronic stroke, found that task-related rehabilitation had a significant positive effect on functional outcomes (Rensink et al., 2009). The movement towards more task-orientated therapy (Eng, 2010) and away from arbitrary exercise, unrelated to real life activities has meant that post-stroke rehabilitation is becoming more engaging for individuals (Hubbard, Parsons, Neilson, & Carey, 2009). In ACTIV the prescribed exercises were task-related, but there was also encouragement to be more active. Some of the prescribed exercises involved walking or climbing stairs or using your arm, so participants were encouraged to integrate these exercises in to enjoyable activities such as going out with friends or returning to hobbies or crafts.

In a study investigating impressions of physiotherapy after stroke, participants reported there were other important factors in addition to the purely physical benefits of doing exercise (Pound et al., 1994). They reported that doing exercises kept them busy and encouraged them to ‘keep going’. The same authors also found participants believed exercises gave a structure to the day (Pound, Gompertz, & Ebrahim, 1999). The regularity of contact via text in ACTIV, aimed to help exercises at home become part of the normal structure of a participant’s day. One of the ways to improve the quality of a trial is to clearly document the exercises undertaken by participants. To make ACTIV reproducible and to improve clarity, each physiotherapist was given a menu of basic exercises from which to select a range appropriate for the individual participant. This would also help in translation of ACTIV to clinical practice by guiding exercise choice. It was important to ensure that ACTIV exercises were challenging enough for participants with a range of impairments, so modifications to alter the level of challenge were available for each exercise. Tailoring of the exercises would allow them to be appropriate to the individual, taking account of their level of impairment and environment. To ensure that ACTIV physiotherapists had clinical support a physiotherapist who was an expert in the field of neurological physiotherapy was employed as part of the study. ACTIV physiotherapists were encouraged to seek help from her if they were having difficulty selecting appropriate exercises or adapting them to an individual participant’s needs.

3.3 LENGTH AND STRUCTURE OF ACTIV

When deciding on the length and structure of ACTIV several competing concerns needed to be balanced:

3.3.1 The need for a programme to continue long enough for the participant to change behaviour

Behaviour-change has been studied in rehabilitation literature but there are no clear guidelines on the length of time required to achieve the change. Results from a study of 96 young adults attempting to gain automaticity in a desired behaviour, demonstrate large variability between individuals in the time taken to achieve a change in behaviour (Lally, van Jaarsveld, Potts, & Wardle, 2010). The results point to an asymptotic relationship of behaviour over time, with a levelling off (95% of the asymptote) in automaticity occurring at a mean of 66 days (range 18-254 days). Interestingly the authors noted that despite the participants being volunteers and self-selecting the desired behaviour, approximately half of them failed to repeat the task often enough to form a habit. The authors suggested that regular reminders may be required to support behaviour-change. The authors also noted that more complex behaviour, such as engaging in exercise appeared to take longer to become a habit than simple habits such as alteration of a food or drink choice. Based on the information from available literature a 6-month programme was designed. This is longer than the mean time shown by Lally and colleagues (2010) for participants to achieve behaviour-change but accounted for the fact that the participants in the current study were addressing complex behaviours, were older and had had a stroke.

3.3.2 The need to limit face-to-face contact to contain costs, so a publicly funded health system is able to consider its use as an adjunct to existing rehabilitation.

The cost of stroke to the healthcare system is well known to be high, the estimate of the annual cost of stroke, excluding the high-cost of the first year, in Australia in 2004 (Cadilhac, Carter, Thrift, & Dewey, 2009) was between AU\$3977 and AU\$6022. A study undertaken in the USA detailed direct costs of outpatient rehabilitative stroke services and medication between 2001 and 2005 in the first year after discharge from

hospital following stroke and found it was over US\$17,000. Interestingly the cost of outpatient rehabilitation constituted approximately 70% of that total. (K. M. Godwin, Wasserman, & Ostwald, 2011). Cost data are very specific to the country of collection, and change yearly with inflation, so figures from literature need to be viewed as a guide only. However, a large proportion of cost post-stroke, especially after the acute hospitalisation, is attributable to rehabilitation.

The high cost of outpatient rehabilitation in general has led to an increased interest in the use of telerehabilitation applications in a wide variety of populations, with the expectation that remote delivery of treatment will reduce costs. Significant economic benefits have been claimed using telerehabilitation post-injury rehabilitation, to enable employees to continue therapy whilst remaining at work (Dhurjaty, 2004). A programme designed to contain cost must therefore consider the most expensive aspects of that programme. The majority of the cost of community physiotherapy in New Zealand is the therapist's time used for both patient treatment and travel to the patient. Any programme designed as an adjunct to current practice needs to limit the amount of physiotherapy time required.

3.3.3 The need to consider participant preference

Ascertaining patients exercise-preference following stroke was investigated in a study by Banks, Bernhardt, Churilov and Cumming (2012). One significant finding was that people with stroke wanted to have exercises clearly demonstrated by a skilled person to optimise performance. The decisions on the structure of ACTIV were initially based on clinical experience. It was clear that a small number of face-to-face visits were going to be needed to ensure an in-depth initial assessment of the participant, an accurate evaluation of the participant's environment and an ability to oversee and correct exercises over the course of the programme. Results from an earlier qualitative study

undertaken by the current author and colleagues, were used to refine the development of ACTIV, including considering participant preference. Participants in that study indicated that a proposed number of three face-to-face visits and four phone calls may be too few (Saywell & Taylor, 2014). Consequently, the number of visits was increased to four and phone calls increased to five. A consumer forum in 2010, which included people with stroke, rehabilitation specialists and stroke foundation field officers (Stroke Foundation of New Zealand and New Zealand Guidelines Group) asked participants to name their top ten priorities for rehabilitation and life after hospital discharge. The top priority was to have access to ongoing services to achieve optimum recovery. This was not a novel finding, the desire for more therapy following hospital discharge particularly when patients expectations of recovery have not been met, has previously been documented (Wiles, Ashburn, Payne, & Murphy, 2004). ACTIV was designed to be an addition to usual rehabilitation and as such needed to be of a reasonably low cost to allow the possibility of future widespread use, this necessitated a trade-off between cost and patient preference. The average total physiotherapy hours were estimated to be 14 hours per participant for ACTIV. Any programme that has a small amount of face-to-face contact and the degree of standardisation of ACTIV may fall short of expectation for a number of people. Information from the planned qualitative study after the intervention ascertained participant experience. A cost-effectiveness study and a survey to rank patient preference for various aspects of ACTIV (discrete choice questionnaire) being undertaken by other members of the research team, in parallel with the current study, will further address the question of what people want most from therapy after stroke.

3.4 USE OF TELEPHONE CALLS AND TEXT MESSAGES

In the systematic review of effectiveness of exercise therapy by Smidt and colleagues (2005) they concluded that it would be useful for future research interventions to

include ways of increasing motivation to continue exercises. A study conducted by Yap and Davis (2008) found evidence that personalised messages had a beneficial effect on physical activity in sedentary adults. Use of both phone reminders and text messaging has been shown to be feasible and acceptable in several population groups with some evidence of effectiveness in improving health outcomes (Elley et al., 2011; Mahmud et al., 2010; Whittaker et al., 2011).

Mobile phone ownership and acceptability of its use to augment rehabilitation had been investigated in New Zealand involving focus groups of community dwelling people with stroke. Results showed that many people owned and used a mobile phone, with others having access to one if needed. Participants expressed an interest in the use of mobile phones to augment rehabilitation (Saywell & Taylor, 2014). However, it is acknowledged that some people do not have access to a mobile phone, so in order to increase the opportunity to participate in this study, we provided a mobile phone to all those undertaking ACTIV, who did not own a phone.

The physiotherapists were given training to use the text messaging system and given examples of a range of message types to send. Discussions prior to the training with the authors from a previous trial undertaken in Auckland, using text messaging, (Whittaker et al., 2011) clarified some key parameters they had found useful in their trial, to avoid misunderstanding. These included ensuring when calling or texting that the physiotherapist clearly identified themselves, avoiding text contractions of words, keeping the message short, using the minimum punctuation required for clarity and never asking questions. Questions were avoided as the intervention was intended to remind participants to keep persevering; questions inevitably encourage reply, which was not the desired outcome in this programme.

Ongoing reminders seem to be important to help people to make behavioral changes (Lemoncello, Sohlberg, Fickas, Albin, & Harn, 2011; Pascucci, Leasure, Belknap, & Kodumthara, 2010; Shaughnessy, Resnick, & Macko, 2006) and despite a number of other options for providing reminders to continue exercising, it has been noted that:

“Even though it is important to use the correct tool to perform a given task, the simplest and least expensive technology that meets the need is almost always the best solution.”(Peifer & Hopper, 1999)

At the time ACTIV began the most logical choice of communication device to deliver exercise reminders was landline telephone and text message, due to the ease of use and low cost of doing so. ACTIV had been designed to be easily adapted to use smart phones or tablets as these became more available and used by the stroke population. There may be reluctance to trial technological solutions in older populations due to the assumption they would have difficulty with the technology or would be reluctant to try it. However a study in England by Gilleard, Hyde and Higgs (2007), four years before the start of the current study, showed that use of a mobile phone was over 60% in 60-69 year olds and 45% in 70-79 year olds. Furthermore on average 50% of people even in the most deprived areas had use of mobile phone, significantly more than had access to an internet connection for e-mail. There is evidence that older people are adopting new technology at a rapid rate (Conci et al., 2009), so mobile phone ownership percentages may reasonably be expected to rise.

3.5 HOME AS THE ENVIRONMENT

The majority of people in hospital following a stroke place the highest importance on returning home (F. Jones, Mandy, et al., 2008; Pound et al., 1994). However, many patients express a fear of becoming a burden and of not being able to care for themselves or re-gain their previous roles once they are discharged. These contradictory

feelings were described in a study by Wottrich and colleagues (2012). Participants expressed difficulty reconciling the excitement of going home and the reality of the difficulties they faced once they were there. Despite these concerns, evidence supports the intuitive belief that people do better when they undertake a home-based rehabilitation programme. A systematic review by Novak (2011) concluded that home programmes are as effective as face-to-face provision of physiotherapy for adult rehabilitation, unless specific clinic-based equipment was required. They found that for stroke rehabilitation, equal gains could be made in physical function using an expert-guided home programme, or expert-provided therapy. Results showed some consistent features that differentiated programmes with favourable and unfavorable outcomes. Very few programmes had unfavourable outcomes, so the findings need to be viewed with caution, but they do represent current best evidence. Successful home programmes actively involved patients in planning the programme, around specific goals that were individualised to the patient, this required expert physiotherapy input at the start of the programme to prescribe activities that encompassed aspects of the participation domain of the ICF and did not focus only on impairments of body structure and function. Successful programmes were planned by therapists who ensured that the participant was able to manage the exercises independently and then gave feedback to the participant about their progress, either by visit, phone call or clinic visit.

Another advantage of a home programme was that problems achieving activities while negotiating the home environment were hard to predict in hospital and often became evident some weeks after discharge. Pound, Gompertz and Ebrahim (1999) investigated the experiences of patients after stroke and concluded that the home should be seen as the central place of stroke management and rehabilitation. ACTIV has been designed to assist in re-integration to normal life after discharge from hospital, to allow physiotherapists to see participants in the environment where challenges may be

experienced. New Zealand stroke guidelines echo this, advising that rehabilitation should be offered in the home if community services are available (Stroke Foundation of New Zealand and New Zealand Guidelines Group, 2010). There is a need for treatment immediately following discharge but also for ongoing feedback on progress and ideas to maintain motivation (Pound et al., 1994). In the study by Wottrich and colleagues (2012) participants expressed concern about being left to manage self-directed exercise, they felt that if left to their own devices, exercise could be easily postponed and may well be less effective. The significant challenge addressed in rehabilitation literature is how to make the transition from therapist-driven, to patient-driven activity. Turner and colleagues (2008) in a systematic review of the transition from hospital to home environment for people with acquired brain injury found some evidence of a reduction in hospital readmission and functional improvement for people with stroke who received post-discharge follow-up support. The authors identified a need to investigate the effectiveness of ongoing support, using innovative tailored approaches.

3.6 ENCOURAGEMENT OF FAMILY-MEMBER INVOLVEMENT

There are references to involvement of family in rehabilitation after stroke, including involvement in goal-setting and development of a post-discharge care plan, in several clinical guidelines (Intercollegiate Stroke Working Party, 2008; National Stroke Foundation, 2010). A home exercise programme may seem like an ideal time to include family members in ongoing rehabilitation, however there are competing interests involved in the decision. The participant has a right to support from a person of their choice but the physiotherapist has a legal duty to maintain the participant's right to privacy. This means physiotherapists need express permission to share participant details with a family member and the participant needs to decide the extent to which they would like family involvement (Health and Disability Commissioner, 1996). In

training for the ACTIV physiotherapists it was emphasised that care should be taken to ask participants to invite family and friends of their choice to attend and be involved in the sessions, with no necessity to include anyone if they preferred not to. A study exploring physiotherapy after stroke in Ireland revealed that physiotherapists felt family member involvement in rehabilitation sessions needed to be considered carefully as family members were sometimes found to be too enthusiastic, emotional or critical of the participant's performance (Galvin, Cusack, & Stokes, 2009a). In contrast a study by the same authors explored the attitude of family and friends of people following stroke (n=100) to being involved in delivering a prescribed exercise programme. Of those surveyed, 90% felt that they should be actively encouraged to participate in the physiotherapy and 86% responded that they would like to be more involved than they were (Galvin, Cusack, & Stokes, 2009b). To take in to account the possibility of family and friends being invited by participants to be involved in ACTIV, all prescribed exercises and information about ACTIV were collected in a manual. This included diagrams and instructions for each exercise and clear safety messages to increase the confidence of family or friends to be part of ACTIV if the participant wished. Interviews from the qualitative study after the intervention, included an invitation to family and friends who had been part of helping or supporting a participant, to understand the impact of ACTIV on all who were involved.

3.7 SUMMARY

ACTIV was designed to provide a low-cost follow-on programme to help with the transition from hospital to living independently. Decisions about the structure and content of ACTIV were made based on best available evidence, expert clinical opinion from a number of clinicians with research experience and the resources available. This necessitated making some compromises to allow a low-cost programme to be

developed. The following chapter details the method used to investigate the effectiveness of ACTIV.

CHAPTER 4 RANDOMISED CONTROLLED TRIAL METHODS

4.1 INTRODUCTION

The investigation of telerehabilitation for people with stroke is at an early stage and some way from widespread implementation. In contrast, landline telephones or mobile phones are being used in other populations for health delivery now, with promising results. Establishing whether this mode of delivery could be applied to stroke rehabilitation was an important next step in extending the reach of rehabilitation beyond standard practice. The systematic review revealed six studies where landline telephones or mobile phones were used to deliver or augment stroke rehabilitation. Little could be concluded about effectiveness due to the heterogeneity of the interventions investigated. To date there have been no large trials to investigate the effectiveness of delivering stroke rehabilitation using landline telephones or mobile phones to improve outcomes for patients. Augmented Community Telerehabilitation Intervention (ACTIV) is a 6-month standardised programme delivered in a participant's home and was developed to address this gap. This chapter details the method used to investigate effectiveness using a multi-centre randomised controlled trial.

4.2 AIMS

The overarching aim of this trial was to investigate the effectiveness of a method of delivering stroke telerehabilitation to people following stroke, once their initial period of rehabilitation had finished. ACTIV aimed to improve the transition from hospital treatment to community living, using landline telephones or mobile phones to augment rehabilitation delivery. The control group condition chosen for the trial was usual care, with no limits put on access to other exercise, activity or rehabilitation. The research team wanted to know if the addition of a small amount of input, much of which was

delivered remotely, would be enough to make a significant difference to physical function. The specific aims were to:

1. Determine the effect of ACTIV on physical function, compared to usual care control.
2. Determine the effect of ACTIV on health outcomes and quality of life, compared to usual care control.
3. Determine the effect of ACTIV on admission rates, compared to usual care control.

4.2.1 Aim 1: Determine the effect of ACTIV on physical function, compared to usual care control.

Primary research question

At the end of the 6-month intervention, did ACTIV improve physical function in people with stroke compared to a usual care control group, as measured by the physical sub-component of the Stroke Impact Scale (SIS 3.0)?

Secondary research questions

Question 1

At the 12-month follow-up, were any physical gains achieved by the intervention group at the end of the intervention maintained, as measured by the physical sub-component of the SIS 3.0?

Question 2

At the end of the 6-month intervention, did ACTIV improve physical function in people with stroke, compared to a usual care control group as measured by the physical performance measures and the stroke self-efficacy questionnaire?

4.2.2 *Aim 2: Determine the effect of ACTIV on health outcomes and quality of life, compared to usual care control.*

Question 3

Over the trial period, did ACTIV improve health outcomes and quality of life in people with stroke compared to a usual care control group as measured by the whole SIS 3.0?

4.2.3 *Aim 3: Determine the effect of ACTIV on admission rates, compared to usual care control.*

Question 4

Over the trial period, did participation in ACTIV result in a reduction in hospital or residential care admissions compared to the usual care control group?

4.3 TRIAL DESIGN

This trial was a two-arm, assessor blinded, parallel randomised controlled trial.

Enrolment occurred in four sites across New Zealand (North Auckland (North Shore Hospital), South Auckland (Middlemore Hospital), Christchurch (The Princess Margaret Hospital), and Dunedin (Dunedin Hospital)). People were eligible for inclusion in the trial at the time of discharge from standard physiotherapy. Standard physiotherapy included inpatient rehabilitation either in general medical or specialist stroke care facilities, and outpatient or community physiotherapy post-discharge from hospital. Participants undertaking other interventions provided by the hospital, such as occupational therapy or speech therapy were not excluded from the trial. Outcome assessments were conducted at baseline, immediately after the six-month intervention and at six months post-intervention, by an assessor blinded to group allocation.

Minor changes were made to the trial design in May 2013, nine months after recruitment had begun. Recruitment for the trial was extremely slow and the researcher

identified two possible and ameliorable reasons for this. Many potential participants' response to the initial invitation were a lack of interest at that time, or that they were too busy or stressed following discharge from hospital. Secondly some potential participants did not have adequate English to meet the inclusion criteria, but had relatives or close friends who spoke excellent English and wanted their family member to be part of the study. To address these problems the researcher applied for ethical approval for two changes to be made to recruitment, (see Table 4-1).

Table 4-1: Amendments to Study Design May 2013

	Previously approved	Requested amendment	Reason for change
Recruitment	Participants will be recruited via hospital based stroke and rehabilitation services. In all four hospitals, potential participants will be identified predominantly via the Community Based Rehabilitation Team or Community Stroke Rehabilitation Team.	In addition to the recruitment already approved we requested that newspaper advertisements and information via Stroke foundation field officers could be used to recruit people who had a stroke up to 18 months prior to recruitment.	We found that many of the participants who fit the criteria for the study were not ready to undertake more rehabilitation immediately on discharge from hospital or outpatient therapy. They found the transition back home stressful and adapting to their disability tiring. The functional deterioration and disappointment associated with not reaching goals that is discussed in the literature may not have happened until a later date and we wanted to give people the opportunity to join the study within the first 18 months following their stroke.
Inclusion criteria	People will be eligible if they understand English	We wanted to include people who understood minimal English but who had a family/whānau member, who was available to assist them to read the text messages and assist them to understand the exercises.	Particularly within the counties Manukau DHB there were many people who were ineligible, despite being keen to be involved and having family/whānau who were very happy to help with understanding and translating the instructions for exercise etc.

Whānau- Māori-language word for extended family

4.4 ETHICAL APPROVAL

The New Zealand Multi-regional Ethics Committee gave ethical approval for this study (see Appendix B [MEC 11/11/089]) and each of the centres where recruitment was to take place approved the study. The study had no intent to investigate efficacy in any particular ethnic group but Māori are New Zealand's indigenous population and it is a legal responsibility under the Treaty of Waitangi to ensure partnership, participation and protection. Partnership and participation were particularly important concepts in the recruitment phase of the study to ensure that Māori were represented as far as possible in the final sample. To ensure that we were as inclusive as possible, Māori consultation was undertaken in each centre to ensure that cultural values that may differ between Iwi (tribe) were given appropriate consideration. All participants had a written information sheet (see Appendix C) and were given an opportunity to ask questions about the study prior to the baseline assessment. Each participant gave written informed consent (see Appendix D) prior to participating in the study. Ethical approval was given for the amendment, discussed in section 4.3 (MEC/11/11/089/AM01).

4.5 TRIAL SAMPLE

4.5.1 Sample size

Sample size computations were based on a 5% per comparison significance level and a two-tailed critical region. Two previous studies have indicated consistent baseline standard deviations for the physical sub-component of the SIS, for a pooled baseline standard deviation of approximately 21.7. A naïve combination of the clinically important differences (CID) from Lin and colleagues (2010), based on a geometric mean of the elements, yields a CID for the SIS physical sub-component score of 5.3, corresponding to an effect size of about 0.25.

Marsden and colleagues (2010) in their rehabilitation trial obtained standard errors for the mean differences in measurement of 9.5 and 6.6 for their control and treatment groups respectively. Using these values 38.4 participants per arm were required to detect the target effect size with 80% power, based on Welch's (1947) t-distribution for the difference of two such changes from baseline. A total sample size of 96 was required, allowing for an attrition rate of 20% over the 12-month research period. With these numbers, the probability was approximately 80% that the trial would detect a treatment difference, if the difference between the changes in ACTIV and usual care control group was at least 5.4 points in the physical sub-component of the SIS3.0.

Due to the variation in response to physiotherapy intervention after stroke a conservative approach was taken with the assumption that no correlation existed between baseline measures and final outcome. Under a positive correlation, the sample size computation underestimated the true power provided by the statistical analysis plan, according to which analyses were to be adjusted for baseline values and other covariates.

4.5.2 Recruitment

From hospital data obtained prior to the start of recruitment, based on figures from previous years, it was estimated that approximately 150 patients satisfying the inclusion criteria for this trial would be discharged to their own home from each of the Auckland sites. Approximately half that number were estimated to be discharged from each of the South Island sites, meaning a potential pool for recruitment of 450 patients per year. Participants were recruited via hospital-based stroke and rehabilitation services. In all four hospitals, potential participants were identified via the Community-Based Rehabilitation Team or Community Stroke Rehabilitation Team. In addition, discharges from acute medical wards and rehabilitation wards were checked for people discharged

directly from these services. To access people with stroke who were under 65 years in the Christchurch area, discharges from Burwood Brain Injury Service were checked. Randomisation was stratified by centre (4 locations) with recruitment targets of 32 participants from North Auckland and South Auckland and 16 from Christchurch and Dunedin, proportional to the number of stroke admissions expected in each location. Eligibility of participants was established in a two-step process. Firstly, patients who had been discharged from hospital care and who fitted the inclusion and exclusion criteria below were mailed an information sheet and an invitation letter (see Appendix E) to be part of the study. After a period of seven to ten days a follow-up telephone call was made. Potential participants who identified as Māori or who expressed a need for more information were given the opportunity for a face-to-face discussion of the information sheet. If no further information was required and they were interested in being part of the study, telephone screening was undertaken to ensure that inclusion criteria unable to be ascertained from the initial referral, had been met. If the potential participant was interested but had not concluded their rehabilitation (for example was still having community physiotherapy), a note was made to re-contact them one month later. Following the amendment approved in June 2013, participants were also recruited via newspaper advertisements placed in local papers (see Appendix F) in each of the recruitment areas. Participants recruited in this way still underwent the same screening process as detailed above.

Inclusion criteria

People were eligible for inclusion if they:

- experienced a first ever hemispheric stroke of haemorrhagic or ischaemic origin
- were over the age of 20 years

- had been discharged from inpatient, outpatient and community physiotherapy services to live in their own home (participants involved in other forms of therapy such as Tai Chi or community exercise programmes were not excluded) (From June 2013 broadened to include people up to 18 months post-stroke)

Exclusion criteria

People were excluded if they:

- experienced a confirmed brain stem or cerebellar stroke
- were unable to understand and speak basic-level English¹ (from June 2013 this criterion was widened to include participants with a family member who had basic-level English and who was regularly available to the participant).

Telephone Screening

Participants who fulfilled the initial inclusion and exclusion criteria and expressed an interest in participating were screened. The telephone screening was undertaken to establish eligibility (see Appendix G). If they met the additional inclusion criteria the recruiter referred the person to an assessor in their area, who made an appointment for the baseline assessment to be carried out. All assessments took place in the participant's home. Participants needed to:

- understand the English language at the level required for participating in ACTIV²
- score at least 3 on a telephone cognitive screening questionnaire (Callahan, Unverzagt, Hui, Perkins, & Hendrie, 2002)
- have a limitation in physical function of leg, arm or both

¹ Involvement in ACTIV required frequent communication with a physiotherapist, in person, by telephone and by text message (SMS message) so using an interpreter was considered impractical.

² Inclusion and exclusion criteria prior to telephone screening had been verified from hospital discharge information, which was not always explicit about language facility.

- have had medical clearance from their general practitioner to participate in a low to moderate level activity programme

Limitation in physical function of the leg was established if the person had a score between 4 and 6 on the Functional Ambulation Category (FAC) (Mehrholz, Wagner, Rutte, Meissner, & Pohl, 2007). In order to be eligible potential participants who scored 6 on the FAC (corresponding to independent ambulation on a variety of surfaces), also needed to answer 'No' to at least one of the 2 walking parameter questions below:

1) Can you get across the road at the traffic lights, in the time the green man is showing?

2) Are you able to walk 400m (i.e. ¼ mile, 1-2 blocks)?

Physical function of the arm was investigated using the questions below. To fit the inclusion criteria for arm exercises, participants needed to have some arm function, established using section A, but some impairment, established using section B. These questions were easy to explain during the phone screen and quickly gave a very good indication of arm function.

A. With your affected arm are you able to:

1. Switch on a light?
2. Bring a glass of water to your mouth?
3. Move your fingers and thumb independently?

B. Are you able to:

1. Use a keyboard equally with both hands?
2. Holding a pencil with your affected hand, make rapid dots on a piece of paper?
3. Take a spoonful of liquid to your mouth without spilling it or bending your neck?

ACTIV was a low-intensity programme, offered to participants in their own home, after all other rehabilitation had concluded; as such it was considered to be a low-risk intervention. For that reason, a standard letter was sent to the general practitioner of each participant who fulfilled the criteria for inclusion in to the study (see Appendix H), informing them of the study and requesting that they contact one of the researchers by phone or e-mail if they had any concerns about the person's fitness to participate.

4.5.3 Randomisation and concealment

Randomisation occurred after the baseline assessment and participants were assigned to one of two groups, ACTIV or usual care control. Stratified block randomisation was used according to geographic centre and baseline mobility. Baseline mobility was decided by the FAC: either 'less mobile' if they had a level of five or below or 'more mobile' if they had a level of six. Random block sizes were used (size four with 85% probability, size six with 15% probability) according to a plan that ensured, based on simulations, a probability smaller than 0.1% that balance would be broken across strata by four participants or more. All details of the block distribution were disclosed to investigators only at the end of follow-up to promote concealment. The randomisation software was coded and tested by the trial statistician, then handed over to a third independent party for random number generator seeding, execution of allocation, and day-to-day management of the randomisation. The recruiters, assessors and personnel involved in data management and analysis were blinded to treatment assignment. Participants were contacted by the blinded assessor for baseline assessment. The intervention physiotherapist contacted those randomised to ACTIV and the recruiter those randomised to the control, to inform them of their group allocation. (See Figure 4-1 for participant progress through the study).

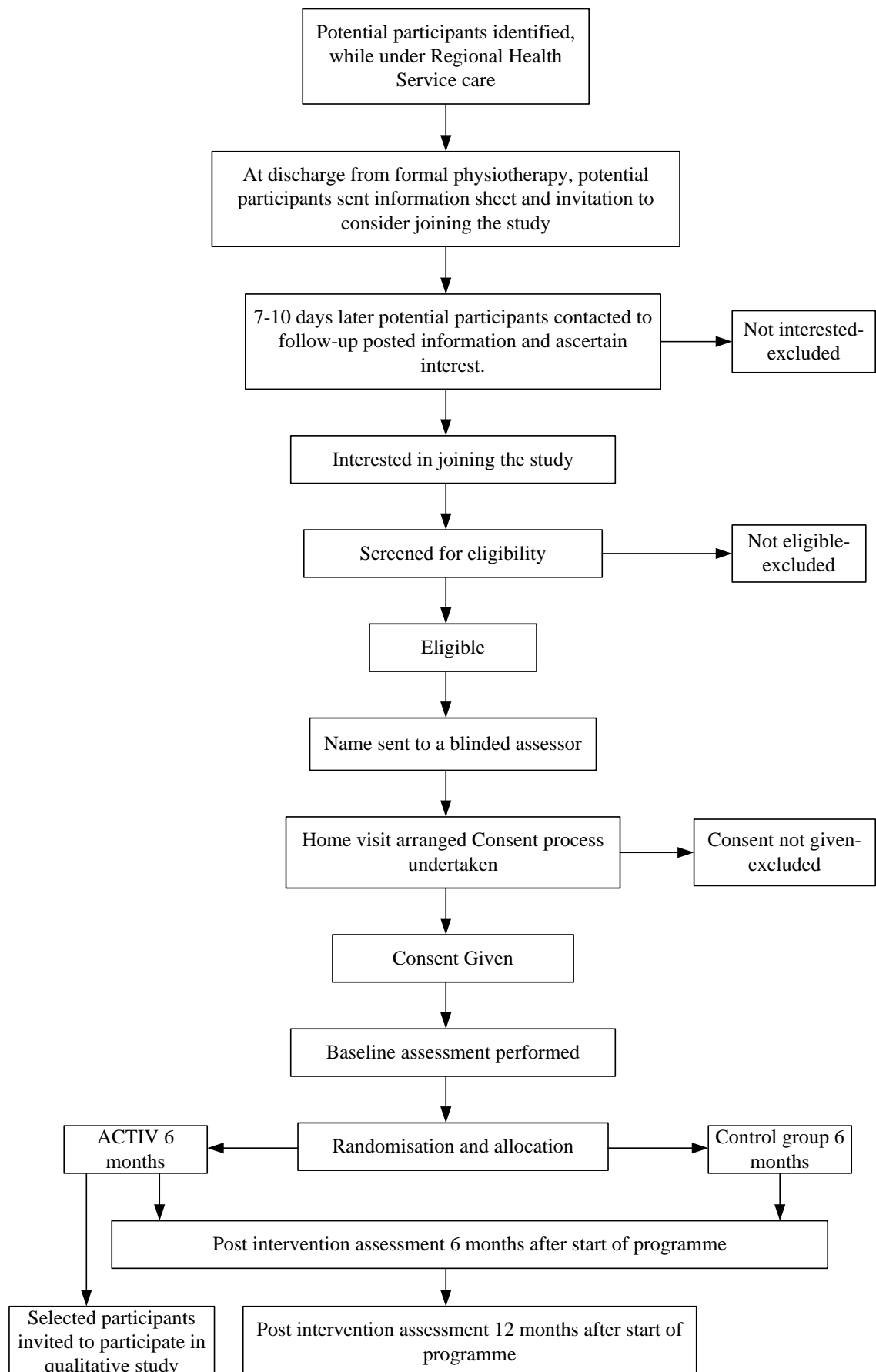


Figure 4-1: Participant Progress through the Study

4.6 INTERVENTION-ACTIV

The description of the intervention followed the Template for Intervention Description and Replication (TIDieR) checklist and guide (Hoffmann et al., 2014). This standardised information about ACTIV to improve understanding of the content of both the intervention and control arms.

4.6.1 Programme

ACTIV focused on two functional categories, ‘staying upright’ and ‘using your arm’. Within each functional category there are standard exercises addressing key components of the defined function. For example, when addressing ‘using your arm’, exercises could be chosen from eight possible exercise areas, ranging from a focus on gross arm movements to fine hand function and from bi-manual tasks to improving stereognosis. For each component there are parameters to select and modify, allowing the programme to be tailored to individual needs. The parameters that can be changed include the support received during an exercise, the number of exercises prescribed and the environment in which the exercise took place. ACTIV was delivered by a physiotherapist who had completed a 2-day training package that provided information on the rationale of ACTIV, a menu of exercises with guidelines for treatment selection, information on goal setting and information to facilitate patients in the transition to increased independence.

Patient-centred goals were ascertained at the first home visit (initial assessment); the physiotherapist then selected exercises and activities aimed at incremental attainment of these goals. The physiotherapists had telephone and internet access to an expert physiotherapist who had been part of the original planning group for the development of ACTIV and had extensive experience in stroke rehabilitation. She was employed to be a

point of contact for physiotherapists, to discuss any concerns or questions with the provision of the programme.

ACTIV consisted of four home visits at week 1, week 2, week 12 and week 26; five structured telephone calls at the end of week 1, week 4, week 8, week 16 and week 20; and text messaging, twice weekly for the first 10 weeks and once weekly for the following 16 weeks (see Figure 4-2). Some people with stroke re-accessed services following discharge from standard therapy. No effort was made to prevent the intervention group receiving additional care either publicly or privately.

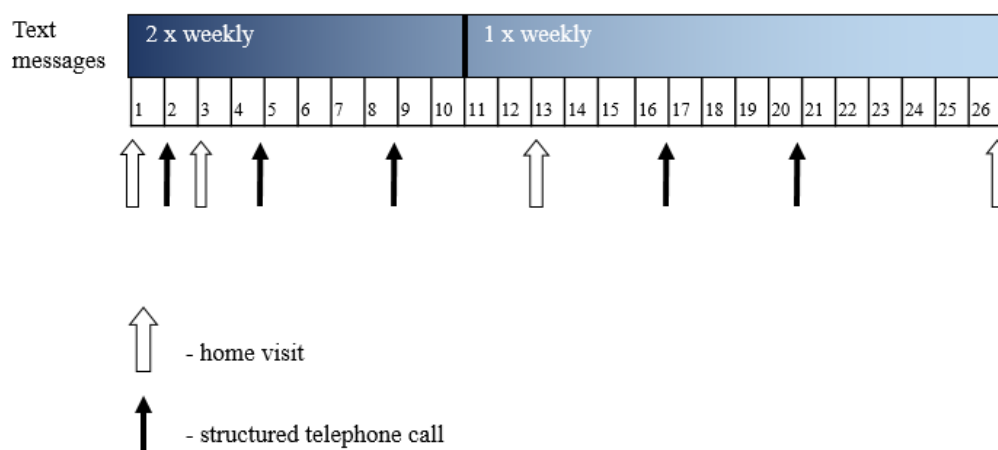


Figure 4-2: Timeline for Physiotherapy Contact with Participants in the Intervention-arm of ACTIV

Initial assessment and exercise prescription

The physiotherapist worked with the participant to identify a goal using the phrase “What do you want to do most?” No attempt was made to ensure this goal was achievable or realistic as the aim initially was to encourage an aspirational goal.

However, as the programme was an exercise-based programme, the participants were encouraged to choose a goal that was activity-based not an exclusively cognitive goal. Once this had been selected, the therapist explored the participant’s perception of why they were unable to complete the activity. The next step was to observe the chosen

activity to assess the aspects the participant was unable to complete and where they were experiencing difficulty. If the goal was distant or aspirational, the participant was encouraged to complete a part of it. For example, if the goal was to go tramping (trekking), the therapist would ascertain from the participant useful interim steps needed to achieve it, such as getting out of the house, getting in the car, walking further or faster. If the goal was a significant distance from their current ability the therapist used interim steps to act as a bridge between their current ability and their goal. The evaluation of the observed activity allowed the therapist to select appropriate exercises and level of difficulty which was recorded on the Initial assessment sheet (see Appendix I). Exercises were selected from a standard menu for the lower limb (see Appendix J) and the upper limb (see Appendix K) and modified by mutual agreement of participant and therapist, to pursue and attain the desired activity. The therapist retained a copy of the exercise chart detailing the prescribed exercises and parameters for each participant, to facilitate future progressions. This resulted in an individualised programme based on the assessment of the participant's goals and ability. One sheet for each selected exercise was left with the participant in a manual. An example of a lower limb exercise (see Appendix L) and an upper limb exercise (Appendix M) shows details of the parameters and a diagram of the exercise. There was a designated area to write, 'this exercise works on...' 'and helps you improve your...' to ensure a clear link to the next step of their goal. Basic safety information was included in every sheet. The physiotherapists were instructed not to leave more than four exercises in the participant manual.

Follow-up visits

At each follow-up visit, the physiotherapist checked that prescribed exercises were being performed effectively and safely (see Appendix N). If the participant was able to perform the prescribed exercises with ease, the therapist could choose to change the

parameters of the current exercises or change to a different exercise to maintain challenge, however there was still a maximum of four exercises. If the selected activity had been achieved the participant was encouraged to consider another desired activity. Information was recorded on the follow-up assessment sheet, about exercise completion and facilitators and barriers to exercise. This helped personalise subsequent communication by phone and text messaging. The participant was encouraged incrementally to take control over deciding on a desired activity and selecting exercises to help them reach that activity, to reduce reliance on the physiotherapist over the 6-month intervention.

Telephone calls

A structured telephone call (see Appendix O) was used to check on progress, satisfaction with the programme and the occurrence of any barriers to completion of the exercises. Information from each interview was used to help formulate a strategy to maximise participation in the programme. For example, if a participant reported that they were unable to complete the exercises because they did not understand the instructions, the physiotherapist would clarify or change the exercise instructions or parameters. The physiotherapist had a copy of the participant's exercise chart and could refer to the type and level of exercise the participant was doing at their last contact. No new exercises were prescribed by phone but if a participant reported that they were finding the programme too easy or too hard, the physiotherapist would provide modifications to alter the difficulty level. The participant could then note the alterations prescribed, in the table provided on each exercise sheet.

Telecommunication devices

A basic mobile phone was given to those participants who did not own one. The Nokia 100 was selected because it was low-cost and had large keys and an easy-to-read screen.

Participants who were not regular mobile phone users received instruction and were given plain English written instructions (Flesch-Kincaid readability score 80%). A small credit (\$20) was put on all participants' phones, to ensure that cost of messaging was not a barrier to continuation of the programme.

Text messages

Text messages were sent via MessageMedia, a web-based messaging programme (<http://www.messagemedia.co.nz/business/products/features>), accessed by each physiotherapist with a unique user name and password. Participants' name and mobile number were entered and stored securely for the length of the programme, the physiotherapist was then able to send messages of up to 160 characters. Physiotherapists were given instructions for use and suggestions for text messages. Text messages were designed to encourage continuation of exercises and to acknowledge progress so far, focusing on what the participant had identified they wanted to work on most. Participants were encouraged to receive messages via mobile phones if possible, but messages were sent to their e-mail address if this was not possible. Text messages were used to suggest modifications of exercises already prescribed but not to prescribe new exercises. Simple checks on progress were undertaken and those able to use text messaging confidently could reply but there was no expectation that anyone should do so.

Participant manual

Each participant was left with a participant workbook to support their progress (see Appendix P). This consisted of an introduction to the programme, a schedule of contact with the physiotherapist and the assessor, a page to write a goal and encouragement to fill out steps towards attaining it. Information about the normal response to exercise, including mild muscle soreness was also included. There was also written

encouragement to keep persisting with the exercises. The manual had clear sleeves to allow space for four exercises, which was the maximum recommended for the physiotherapists to prescribe.

Additional support

If the participant requested information about stroke-related issues beyond the exercise programme, the physiotherapist had information sheets commonly in use, provided by the Stroke Foundation (a not-for-profit organisation supporting and representing people with stroke in the community). These were kept in the folder used by the physiotherapist for assessment forms and other paperwork and could be provided as required. Participants were requested to contact the physiotherapist at any stage if an adverse event occurred, if there was confusion about the programme and instruction, or if they were unable to perform the exercises.

Contingency planning

In the event of a concern about the participant's health or wellbeing and prior to starting the programme, the physiotherapist gained consent from the participant to contact their emergency contact person or general practitioner. Contact details from both had been collected as part of the initial assessment. As a registered healthcare professional, the physiotherapist was able to access appropriate medical assistance, as they would in any other clinical setting.

Discharge visit

The physiotherapist checked on goal achievement. If the goal had been reached the participant was encouraged to consider the next thing they would like to achieve. If the original goal had not yet been reached the physiotherapist encouraged the participant to note the steps that had been achieved and plan the next steps needed. Encouragement

was given to continue with the exercise programme independently, focusing on exercises in ACTIV that had been useful.

4.6.2 Usual care control group

Some people with stroke re-access services following discharge from standard therapy, no effort was made to prevent the control group receiving additional care either publicly or privately. Participation in physical activity was ascertained at the same time as the check for adverse events, during the monthly phone call by a research assistant independent of the study and blinded to group allocation. Participants in the control group had the three assessments from the blinded assessor at baseline, six months and 12-months.

4.6.3 Data monitoring

A Data Monitoring Committee (DMC) monitored the progress of the study. The DMC consisted of the trial statistician, and two researchers independent of the study. The Health Research Council of New Zealand, as the funders of this research, reviewed the proposal at their Data Monitoring Core Committee and agreed that as a low-risk study, a wholly independent DMC was not required and the partial un-blinding of the trial statistician was acceptable.

4.7 OUTCOME MEASURES

4.7.1 Baseline data

Baseline demographic data was collected from all participants at the initial assessment by the blinded assessor.

All quantitative outcome measures were collected at baseline, immediately after the intervention (approximately six months after randomisation) and 12 months after randomisation.

4.7.2 Primary outcome measure

The primary outcome measure was the physical sub-component of the (SIS 3.0) (Duncan et al., 1999). The SIS 3.0 is a stroke-specific, self-report health status measure administered as a questionnaire, which can be completed by the participant or a proxy if reading or writing is impaired. It takes approximately 15 minutes to complete and consists of 59 questions divided into eight domains; strength, hand function, mobility, activities of daily living, emotion, memory, communication and social participation. The physical sub-component score can be used as a stand-alone tool. It comprises the four physical domains (strength, hand function, mobility and activities of daily living) which are summed to generate the score and reported as a normalised summary score which is calculated from the SIS database. The SIS has been shown to be responsive to change in this population (Duncan et al., 1999). Rasch analysis of the SIS indicated that the items are unidimensional, investigating a range of physical functions that people with stroke commonly find difficult (Duncan, Bode, Lai, & Perera, 2003).

4.7.3 Secondary outcome measures

Physical performance measures

Simple physical performance measures of hand grip strength and balance were undertaken. A Jamar® hand-held dynamometer (Sammons Preston, Rolyan, Bolingbrook, IL, USA) was used to measure grip strength. Grip strength measurement has been shown to have a significant ($p=0.05$) and strong correlation with elbow flexor and shoulder abductor strength, on the weak ($r=0.753-0.937$) and strong sides ($r=0.735-0.876$) in people with stroke, making it useful tool to record changes in arm strength (R. W. Bohannon, 2004). The reliability coefficient for grip strength in the paretic arm of people with stroke is >0.80 (Bertrand, Mercier, Bourbonnais, Desrosiers, & Gravel, 2007). These two findings and the ease of use and portability of the Jamar dynamometer

made it a good tool for the home-based assessment required in this trial. The Step Test was used to assess balance, by requiring repetitive stepping on and off a 7.5cm step while remaining in single-leg stance on the test leg. The test takes approximately 15 seconds on each leg and has been shown to have good test-retest reliability in people with stroke, with an ICC of 0.88 (Hill, Bernhardt, McGann, Maltese, & Berkovits, 1996). It has been used in previous RCTs of stroke-related interventions (Askim et al., 2010; Dean et al., 2000).

Self-efficacy

The Stroke Self-Efficacy Questionnaire (SSEQ) was used to collect data relating to the participants' confidence in their ability to undertake daily tasks. The 13-item questionnaire was presented to participants and they were asked to rate the strength of their belief in their ability on a 10-point scale (0= not at all confident and 10= very confident). Items include activities that may have been difficult since their stroke and more abstract achievements, such as the ability to 'persevere to make progress from your stroke after discharge from therapy'. The SSEQ has been shown to have good face validity and its criterion validity was 0.80 when compared with the Falls Efficacy Scale. It was also found to have good utility when used in the recovery period following stroke; initial testing was with participants from 39-94 years who found it took under 15 minutes to complete (F. Jones, Partridge, & Reid, 2008).

Health outcomes and the impact of stroke

The SIS 3.0 measures changes in both body structure and activity and was used to ascertain changes in health outcomes and the impact the stroke has had in various areas of the participant's life. All eight domains and the overall stroke recovery rating were used (K. C. Lin et al., 2010) Its test-retest reliability is excellent (ICC >0.90) for all but the emotion domain which has an ICC of 0.68.(Duncan et al., 2005).

The EQ-5D was used in the parallel economic analysis of the cost-effectiveness of ACTIV undertaken by other members of the research team. The Visual analogue scale of the measure EQ-5D VAS was used to understand the participant's perception of their health status at each assessment point. The scale requires participants to draw a line from a box to a vertical 'thermometer' to rate how good or bad they think their health is at that point in time. The scale runs from 0, 'worst imaginable health state' to 100, 'best imaginable health state'. The EQ-5D VAS has been found to have acceptable test-retest reliability, with ICC values ranging from 0.81 (baseline to post-intervention) to 0.67 (post-intervention to follow-up) in an investigation of patients undergoing rehabilitation following stroke.(Hunger, Sabariego, Stollenwerk, Cieza, & Leidl, 2012).

Hospital and residential care admission rates

Acute or emergency admission to hospital and respite or permanent admission to residential care was collected from electronic records and stroke participant/carer responses.

4.8 ADVERSE EVENTS

Every participant in the intervention and the control arm of ACTIV was telephoned monthly by a research assistant, independent of the study and blinded to group allocation. The research assistant had a comprehensive understanding of the meaning of adverse events in the context of this study. An adverse event was defined as any untoward medical occurrence that did not necessarily have a causal relationship with the study treatment (Zhao et al., 2010) and that had occurred in the previous four weeks. The research assistant noted all unique events on a form (see Appendix Q) and asked the date of the event, whether there were any lasting problems associated and if the participant had sought medical treatment or had needed hospital treatment. A report of all adverse events was collated by a senior research officer, who reported to the Data

Monitoring Committee (DMC) monthly, to ensure that any significant increase in adverse events in the intervention group as compared with the control group was able to be assessed. Adverse events were coded according to the Common Terminology Criteria for Adverse Events version 4.0 (U.S. Department of Health and Human Services, 2010). Each event was adjudicated for severity (on a scale of 1 to 5, with 1 being mild, requiring no medical intervention and 5 being death) and relatedness to the intervention (yes or no) in the absence of knowledge of allocation by NS and DT independently with any disagreement resolved by consensus. The number of adverse events was expected to be small due to the low-risk nature of the intervention.

4.9 STAFF RECRUITMENT

Four research assistants were employed, one at each site to recruit participants. The recruiter in North Auckland also undertook all the adverse events phone calls. Six assessors (two each in North and South Auckland, one each in Christchurch and Dunedin) were employed to assess all the participants at each time-point. Six physiotherapists (in the same distribution as the assessors) were employed to deliver ACTIV to the participants. A senior physiotherapist Suzie Mudge (SM), who is an expert in the area of neurological rehabilitation was employed to support and advise the physiotherapists. There was a requirement for the assessors and the physiotherapists to have an undergraduate physiotherapy qualification. In addition, the physiotherapists needed to have had at least two years' clinical experience in any area of physiotherapy practice and had to hold a current annual practicing certificate for NZ.

4.10 TRAINING AND EDUCATION

A clear procedure and a comprehensive package of resources for each research role was developed by NS and DT. These were given to staff during the training programmes which were mandatory for all staff employed in each role in the ACTIV study. Venue

and mode of delivery of each training programme was dependent on the role; see below for details. The training programmes for the assessors and the physiotherapists were held at Auckland University of Technology. All staff undertaking the same role were invited to attend together to ensure consistency.

4.10.1 Training for research assistants to undertake recruitment

The training programme for recruiters was delivered individually by the researcher (NS). She visited each recruiter in the centre where they worked, in order to understand and work constructively with the regional differences in process in different DHBs. The researcher went through the procedure (see Appendix R) step by step giving the research assistant time to ask questions. The researcher then modelled the recruitment procedure. All the recruiters were contacted regularly to monitor progress and any difficulties encountered.

4.10.2 Training for research assistant to undertake adverse events monitoring

The recruiter who undertook all the adverse events calls received training from NS once several participants had been recruited, so the research assistant could learn and demonstrate skills in a realistic way. NS went through the procedure step by step (see Appendix S) giving time for further questions. She then modelled an appropriate phone call, then monitored two phone calls. Over the course of the study NS undertook an audit of calls by monitoring occasional calls for length and content to ensure that they interfered as little as possible with the intervention.

4.10.3 Training for blinded assessors

All staff employed as assessors undertook a training programme lasting a half day (see Appendix T). During the training programme, each step of the procedure (see Appendix U) was discussed in detail and the assessors had time to practice administering the standardised outcome measures on each other and to gain feedback on performance. NS

and DT were present at the training to ensure that individual questions could be addressed and that there was sufficient checking of technique. Each assessor was given the equipment required to undertake the outcome measures, a file with all relevant forms and a laminated procedure. They were encouraged to contact the researcher (NS) with any queries or problems and were given alternate contact details for an assistant who could also assist and who would be the recipient of their completed assessments.

4.10.4 Training for physiotherapists delivering the intervention

All staff employed to deliver the intervention undertook a two-day training programme (see Appendix V). Prior to the training, pre-reading was sent to each physiotherapist to introduce the underlying rationale for, the decision to deliver ACTIV as a home programme (Novak, 2011); encouraging a sense of hope in participants and helping them to consider a wide range of possible activities (Bright et al., 2011); and setting achievable steps on the way to a larger goal (F. Jones, Mandy, & Partridge, 2009). The training programme began by enlarging on some of the concepts covered in the pre-reading, introduced the study's overall goals and the role of each of the staff. The procedure (see Appendix W) was reviewed in detail with an opportunity to discuss all aspects of delivery of the programme.

A significant feature of the physiotherapist's initial assessment of the participant in ACTIV was a focus on regaining or working towards a valued activity. The emphasis in the training for the initial visit was to encourage the physiotherapist to practice translating a participant's hopes directly to a goal. Case scenarios (see Appendix X) were used, facilitated by the researchers NS and DT. There was considerable time dedicated to discussion of the case scenarios and documentation. The subsequent three visits and five structured phone calls were focused around using exercise to achieve small steps on the way to their desired activity. The procedure for the follow-up visits

and structured phone calls were worked through step-by-step, emphasizing key points. There was an introductory and practical teaching session on use of MessageMedia and an introduction to the contact person for any technical queries that may occur during intervention delivery.

The expert physiotherapist (SM) was introduced and was available to answer any questions; she was the contact person for the physiotherapists throughout the programme if they had any queries. The researcher (NS) and the expert clinician were in close contact, but because NS was blinded to group allocation SM was the first point of contact. Each therapist was given a folder with a comprehensive package of all resources, including all forms required, exercise sheets, envelopes for return of patient data sheets, five participant manuals and two low-cost mobile phone to be given to participants who did not own one.

4.11 DOCUMENTATION

All data regarding each aspect of recruitment, assessment and intervention were kept on password-protected Excel spreadsheets. Only two research assistants directly involved in the study were able to view and access the spreadsheets. The researcher NS had access to the spreadsheets that did not show allocation.

4.11.1 Recruiter documentation

When details of potential participants were received from the contact person within the community stroke team, relevant details were transferred to the spreadsheet. Date of contact was recorded and a series of drop-down menus were used to document the screening process including reason for any exclusion.

4.11.2 Assessor documentation

The recruiter sent details of each participant to the assessor by e-mail, which the assessor recorded on the spreadsheet. The assessor completed a baseline assessment form for each participant and recorded the date on the spreadsheet. Baseline assessment included completion of two consent forms, one to remain with the participant and one returned with the baseline assessment. At the end of intervention, the assessor repeated the assessment and recorded the date on the spreadsheet. The baseline and post-intervention assessment forms were posted to a research officer who checked for completeness of information and filed the sheets in a locked cabinet in a room in the university.

4.11.3 Physiotherapy documentation

Carbon copies of the initial and follow-up assessment sheets and the exercise chart used to record the parameters of each exercise were sent to the expert physiotherapist SM. This process ensured she was aware of the specific exercises prescribed to each participant and allowed her to offer appropriately informed assistance if it was requested. The date of each visit, phone call and text message were recorded on the spreadsheet. This information allowed SM to monitor the schedule for each participant. The data was also used to assist measurement of intervention fidelity.

4.12 DATA ANALYSIS

4.12.1 Quantitative Analysis

The difference between the two groups in the primary outcome at 6 months was obtained using analysis of covariance, adjusting for baseline, and accounting for centre using random effects. Secondary analyses examined all efficacy outcomes over time in a mixed-effects model with centre-associated random effects. For each outcome, covariates were selected at blind review from among a core set of pre-specified

variables, and were retained for adjustment purposes on the basis of their partial R^2 , in the presence of all covariates from the core set but in absence of treatment effect.

Observations with missing outcome data were not included in the main analysis, on the assumption of being Missing at Random. Multiple imputation of missing baseline data was used for the production of final results and was effected on the basis of the full conditional specification of all baseline covariates (including outcomes measured at baseline). Primary and secondary outcomes were analysed in an intention-to-treat analysis set. No interim analysis for efficacy took place. Some secondary analyses were carried out on a per protocol basis, with participants who had withdrawn prior to completing 50% of the intervention assigned to the control arm, unless they had withdrawn because they judged they had achieved all their goals. Sensitivity analyses were undertaken to assess the effect of missing data, by singly imputing all missing outcome data according to four distinct schemes and producing point estimates only.

4.12.2 Adverse events analysis

Contingency tables displaying the following information were produced:

1. The numbers of adverse events recorded by arm, severity and relatedness
2. The number of participants by arm and number of adverse events
3. The total adverse events follow-up time by arm and number of adverse events

Modelling of incidence

In all three cases of Poisson modelling described below, incidence and incidence ratio estimation was carried out by using the appropriate number of adverse events as the dependent variable in a log-linear Poisson model. The model included an offset equal to the natural logarithm of the follow-up for adverse events monitoring in years.

For the first successful telephone call, the follow-up time was computed as four weeks.

For each subsequent completed telephone call, the follow-up time was computed as the

smallest of either four weeks or the number of weeks elapsed since the previous completed telephone call. The overall follow-up time for a participant was the sum of the follow-up times for each completed telephone call, expressed in years.

Incidence of adverse events by arm

A Poisson model was fitted to the data using the allocation as the explanatory variable to test the hypothesis that adverse event incidence differed between the arms. The estimate and 95% confidence interval of the incidence ratio was obtained from the exponentiation of the original estimate and 95% confidence interval, and the p-value obtained from the model.

Incidence of adverse events by severity

Deaths were reported separately and otherwise removed from severity analysis to avoid small numbers. The number of adverse events at each other severity level was included in a single Poisson mixed effects model to test the hypotheses of differing adverse event incidence between arms at each severity level, as well as an overall difference between the arms. The model fitted the effect of the allocation in interaction with the severity level as a fixed effect and the participant as a normally distributed random effect. The results reported were the estimates and 95% confidence intervals of the severity-specific incidence ratios as well as their individual p-values. An overall p-value for allocation was also reported, testing the model above against a null involving severity only.

Adverse events relatedness

A Poisson model was used to consider only those adverse events adjudicated as being related to the intervention. Under the assumption that the probability of misclassifying an unrelated event as related was the same in both arms, an estimate of the incidence of intervention-related events was produced using the difference between the incidences of adjudicated related adverse events in the intervention and in the control arm (in number

of events per person-year) as a point estimate and 95% confidence interval and a p-value. The estimate was obtained by exponentiating and subtracting the appropriate combinations of parameter estimates from the Poisson model; the standard error by the use of the bivariate delta-method.

Overdispersion

In analyzing the incidence of adverse events by arm and by relatedness status, overdispersion was not expected to occur due to the small numbers involved. (The mixed model accommodates extra-Poisson variability through the random effects.) Nevertheless, quasi-Poisson models were fitted: the Poisson-based standard errors were retained if the estimated dispersion was less than 1, and the quasi-Poisson-based standard errors retained otherwise.

4.13 INTERVENTION FIDELITY

The cause and effect relationship between an intervention and specified outcomes is reliant on an intervention having consistency between participants. Gearing and colleagues (2011) identified four key areas that can impact treatment fidelity: intervention design, staff training, intervention delivery and intervention receipt. Each of these four key areas were considered in the planning and execution of ACTIV. Table 4-2 below, shows how intervention fidelity was defined at each stage of the research and the evidence collected in ACTIV to monitor fidelity achieved.

Table 4-2: Evidence of Intervention Fidelity in ACTIV (adapted from Gearing (2011))

Stage of research	Definition	Evidence of fidelity
Intervention design		
1. Framework	Underlying theory, programme goals and intervention delivery are clear	Physiotherapy programme based on social cognitive theory (overarching). Used current research to support programme development see Appendix V
2. Established training protocols	Training protocol clear for all staff.	Physiotherapy procedure clearly set out for each aspect of the process see Appendix W
3. Manual	All aspects of the programme are clearly set out in a manual.	All resources required were presented in a fully indexed folder with procedure included.
Staff training		
4. Training protocols	Protocols are standardised and include didactic sessions, role play and modelling	Training protocol outlined see Appendix V
5. Supervision protocols	Frequency and duration of supervision set out	Frequency of supervision was not planned <i>a priori</i> but was left to individuals due to the very wide geographical spread
6. Maintenance protocols	Ongoing supervision corrective feedback, ongoing training	Drop box entries of contact were monitored but no on-going training occurred.
7. Measurements	Establishing compliance with delivery of intervention	SM expert physiotherapist viewed returned physiotherapy contact information (copy sent after each visit and phone call)

Intervention delivery

8. Differentiation	Understanding features unique to programme	The unique features of ACTIV were clearly articulated to physiotherapists and text delivery was practiced during the training.
9. Interventionist behaviours	Adherence to core elements	Dose and content of the core elements that were delivered, were recorded see details below 4.13.1
10. Interventionists competence	Experience and competence	Years of experience and previous clinical practice was recorded.
11. Monitoring drift	Ensure programme delivered correctly throughout programme	Physios filled out and returned paper copies of each contact and filled in a drop-box register of contact.
12. Corrective feedback	Feedback procedures in place	Ongoing support was offered by a research assistant if there were problems with text messaging.

Intervention receipt

13. Protocols for dose received	Monitor dose received	In ACTIV dose delivered and dose received were recorded see details below 4.13.1
14. Participant comprehension	Establish participant comprehension	Participant comprehension was not measured systematically but was explored in the qualitative study.
15. Participant adherence	Establish participant adherence to programme	Asked about and documented at each telephone contact. Strategies were suggested for participants who expressed difficulties with ACTIV, see details below 4.13.2

To ensure each area was considered in enough detail, work by Carroll and colleagues (2007) was used to augment the framework developed by Gearing and colleagues (2011) and adapted to establish the degree to which ACTIV was delivered as per protocol. Adherence is the most basic level for assessing intervention implementation fidelity (Carroll et al., 2007). It establishes whether the core elements of the intervention were delivered; frequency and duration (dose) and programme content.

4.13.1 Adherence to delivery as per protocol

Dose

For ACTIV the important measures of dose were different from many physiotherapy interventions where the duration of contact with the participant was measured. In ACTIV duration of each contact was dependent on need and not specified in the programme protocol. Regular contact to encourage and support exercise and activity was an important element of ACTIV, with three types of contact (face-to-face, telephone call and text message), scheduled to occur at specified intervals. All physiotherapists recorded the date of contact with each participant on a spreadsheet. The number and timing of contacts were considered to be the important metrics to establish dose. These were reported as the number of participants who received the specified number of contacts and contacts at the prescribed time.

Content

Content of the programme was hard to quantify due to individual exercise prescription, so key features vital to the programme and common to all participants were agreed by consensus between NS and SM the expert physiotherapist. Data were taken from the sheets detailing each physiotherapy contact and documentation of the structured telephone calls. The results were reported as the number of participants who received

the specified component. These included the key elements of goal setting, prescription of exercise and ongoing monitoring.

4.13.2 Exercise completion: self-report

In ACTIV, where much of the exercise was self-directed, one way of measuring exercise completion was self-report. At the start of each physiotherapist phone call, participants were asked: ‘Since we last talked, have you managed to do any of your exercises?’ The options for response were ‘None / Some / All’. The response to the question was recorded for each of the five phone calls.

4.14 SUMMARY

The randomised controlled trial was undertaken in a rigorous manner across four centres in New Zealand, to investigate the effectiveness of ACTIV to improve outcomes for people with stroke. The protocol was published prior to the start of the trial to increase transparency (Saywell et al., 2012). The trial design, intervention, outcome measures, data analysis and intervention fidelity have been documented in sufficient detail to allow trial replication. The results of the trial can be found in the following chapter.

CHAPTER 5 RANDOMISED CONTROLLED TRIAL RESULTS

5.1 INTRODUCTION

In this chapter participant recruitment, results of primary and secondary outcomes and adverse events are reported. The results of the randomised controlled trial were reported according to CONSORT guidelines (Schulz, Altman, & Moher, 2010) with specific reference to the extension for reporting non-pharmacological trials (Boutron, Moher, Altman, Schulz, & Ravaud, 2008). The extension required additional details to be included in reporting of results: the number of care providers or centres performing the intervention in each group, the number of participants treated by each care provider at each centre, details of the experimental treatment and comparator as they were implemented, a description of care providers (case volume, qualification, expertise, etc.) and centres (volume) in each group (Boutron et al., 2008, p. 296). The detailed description of intervention delivery, content and the degree to which participants were able to continue with prescribed exercises was used to evaluate intervention fidelity.

5.2 PARTICIPANT RECRUITMENT

5.2.1 Identification of potential participants

The participant recruitment from each centre is outlined in Figure 5-1. It identifies the criterion on which each potential participant was excluded and how the number eligible for randomisation was derived. To ensure no potential participant was missed, each recruiter identified and kept a record of all patients, who at admission were classified as having had a stroke, unless it was explicit in the admission documentation that they had had at least one previous stroke. Four hundred and twenty-four people, initially identified with stroke, died before they were even approached to be assessed for eligibility.

	North Auckland	South Auckland	Christchurch	Dunedin	Total
Potential participant	N=1166	N=973	N=1531	N=456	N=4126
	Died prior to D/C N=111	Died prior to D/C N=88	Died prior to D/C N=170	Died prior to D/C N=55	Died prior to D/C N=424
Assessed for inclusion criteria	N=1055	N=885	N=1361	N=401	N=3702
	Not 1 st stroke N=198 Under 20 years N=0 Not D/C home N=163	Not 1 st stroke N=19 Under 20 years N=0 Not D/C home N=121	Not 1 st stroke N=290 Under 20 years N=0 Not D/C home N=299	Not 1 st stroke N=35 Under 20 years N=0 Not D/C home N=61	Not 1 st stroke N=542 Under 20 years N=0 Not D/C home N=644
Assessed for exclusion criteria	N=694	N=745	N=772	N=305	N=2516
	BS /cerebellar N=103 Insuff English N=0	BS /cerebellar N=102 Insuff English N=0	BS /cerebellar N=135 Insuff English N=0	BS /cerebellar N=32 Insuff English N=0	BS /cerebellar N=372 Insuff English N=0
Received telephone screen	N=591	N=643	N=637	N=273	N=2144
	Insuff English N=3 Cogn impair N=9 Physical(G) N=73 Physical (S) N=12	Insuff English N=28 Cogn impair N=18 Physical(G) N=50 Physical (S) N=1	Insuff English N=4 Cogn impair N=3 Physical(G) N=280 Physical (S) N=16	Insuff English N=0 Cogn impair N=3 Physical(G) N=118 Physical (S) N=20	Insuff English N=35 Cogn impair N=33 Physical(G) N=521 Physical (S) N=49
Consent requested	N=494	N=546	N=334	N=132	N=1506
	Not interested N=244 Poor health N=28	Not interested N=145 Poor health N=43	Not interested N=139 Poor health N=28	Not interested N=24 Poor health N=4	Not interested N=552 Poor health N=103
Other	N=222	N=358	N=167	N=104	N=851
	Unable to contact N=90 Other research N=78 Live outside area N=11	Unable to contact N=116 Other research N=201 Live outside area N=23	Unable to contact N=35 Other research N=28 Live outside area N=69	Unable to contact N=59 Other research N=0 Live outside area N=25	Unable to contact N=300 Other research N=307 Live outside area N=128
Eligible after telephone screen	N=43	N=18	N=35	N=20	N=116

Figure 5-1: Recruitment in all Centres

5.2.2 Inclusion criteria

The early identification of potential participants meant some people were ineligible because subsequently it was established they had not suffered a first ever stroke (N=542). This group included those diagnosed with a transient ischaemic attack (TIA), delirium, other neurological disease such as multiple sclerosis and those who had already had a stroke previously which had not been noted at admission. No person under 20 years of age was identified in any centre. The discharge destination needed to be a participant's own home, which included independent living in a retirement village or living with family members; those discharged to rest home or private hospital were excluded (N=644).

5.2.3 Exclusion criteria

The number of potential participants excluded due to brainstem or cerebellar strokes was recorded (N=372). The reason no-one was excluded on language facility prior to the telephone screen was that it was too difficult to establish the level of English from admission information. In addition, once the decision was made to include people without English (if a family member could assist), a telephone call was required to establish this.

5.2.4 Telephone screen

The people who were excluded based on language at the telephone screen had inadequate English to participate and no family member or friend able to assist with translation (N=35). Cognitive impairment and physical ability was established as per the method outlined in Chapter 4 section 4.5.2. The establishment during the telephone screen of an appropriate physical level for inclusion was interpreted broadly, blinded assessors excluded potential participants at the face-to-face baseline assessment if criteria were not met at that point.

5.2.5 Consent

Those who were asked for consent fitted all the inclusion criteria. The majority of those who did not consent were not interested in being part of the research study (N=552).

People were not asked to give reasons for this, to avoid coercion (Savage, 2006). Some participants did not consent because they were too unwell to be part of the study (N=103).

5.2.6 Other reasons

There was a significant number of potential participants who were uncontactable (N=300). For some none of their contact numbers were connected, some never answered the phone and some phones were answered by people who did not know the participant. No participant was deemed uncontactable until at least 4 separate calls had been made on separate days at different times of the day, including some at weekends or evenings. The majority of potential participants who were involved in other research (N=307), were involved in one study which recruited in both Auckland centres and which had very similar inclusion criteria to ACTIV. A large number (N=128) who fitted the inclusion criteria lived too far outside the study area to be practical for assessment and intervention home visits.

5.2.7 Eligibility

One hundred and sixteen participants were deemed eligible for the study after telephone screening. Confirmation of eligibility was then undertaken by the blinded assessor at baseline assessment, 21 were deemed ineligible at that point; the reasons for exclusion are outlined in Table 5-1. Ninety-five patients were randomised in to the trial. The predominant reason for the exclusion was being found to be too good for the inclusion criteria when assessed in person. The aim had been to randomise 96 patients but an error

occurred in participant identification numbers meaning that only 95 were included. (See Figure 5-2: Consort Diagram page 100).

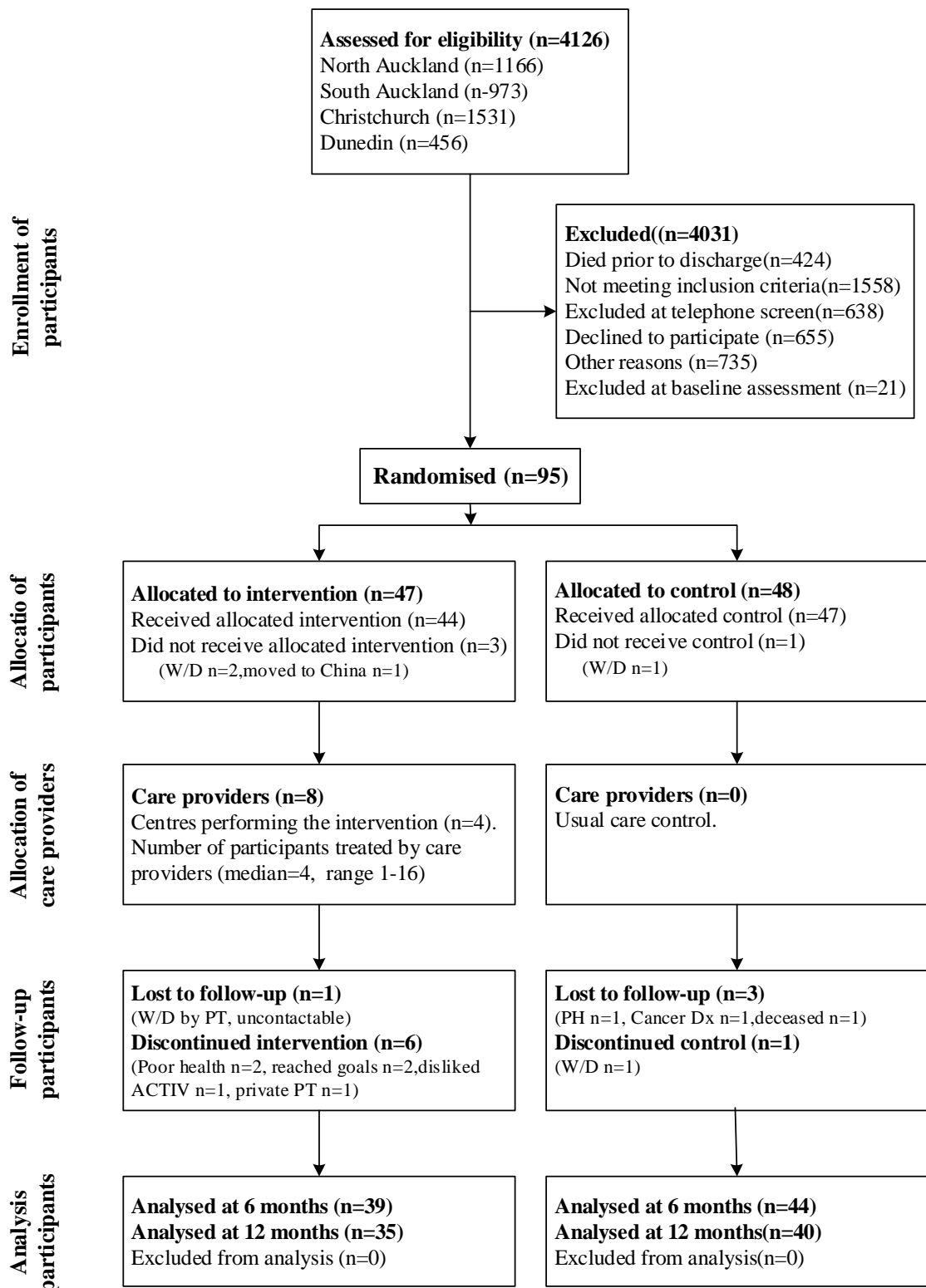
Table 5-1: Number Randomised in ACTIV after Assessor Visit

	North Auckland	South Auckland	Christchurch	Dunedin	Total
Eligible after telephone screen	43	18	35	20	116
Too good (physical)	6	3	3	5	17
Too severe (physical)	0	0	0	1	1
Problems not due to stroke	0	1	2	0	3
Randomised	37	14	30	14	95

5.2.8 Analysis set

The intention-to-treat analysis set included all randomised participants, regardless of whether they remained in the study beyond randomisation or not. The ACTIV (intervention) set, N=47 and the control set, N=48.

The per protocol analysis excluded from the ACTIV set all participants who had not received at least 50% of the intervention components, two visits; three phone calls and half the text messages. Four participants fit this category, none of whom had withdrawn from ACTIV because they had achieved all their goals, so all were consequently moved to the control group for analysis. Under these conditions the ACTIV set became N=43 and the control set N=52. For the division in to these analysis sets only adherence to the number of components was considered, content of the intervention and participant self-report of exercise completion was not.



W/D: withdrawn; PT: physiotherapist; Dx: diagnosis; PH: private hospital.

Figure 5-2: Consort Diagram

5.3 PHYSIOTHERAPIST DELIVERING THE INTERVENTION

This research study employed eight physiotherapists on a part-time basis over the duration of the study. Slow recruitment meant that study duration was longer than initially expected, leading to some staff turn-over. Three of the physiotherapists (P2, P3, and P6) were available for the entire study. Recruitment was slow initially so at the beginning of the trial P3 covered North and South Auckland. P4 was employed to cover South Auckland as the number of participants increased and when she moved out of the district, P5 was employed. P1 was employed to cover North Auckland and South Auckland when P3 became busy with family commitments. In Dunedin P7 worked until she was offered a job overseas and was replaced by P8.

All the physiotherapists were female and all had been qualified for at least eight years. They had a range of clinical experience and not all were currently employed in the area of neurological rehabilitation. Five of the eight had current or recent experience of being involved in a research study. To minimise travel, in the areas where there were two physiotherapists the physiotherapist closest to each participant was asked to deliver ACTIV. This was only varied if one physiotherapist was unavailable due to workload, holiday or family-related factors. On this basis each physiotherapist saw between one and 16 participants, details of the ACTIV physiotherapists can be found below in Table 5-2.

Table 5-2: Characteristics of Physiotherapists Delivering the Intervention

	Sex	Time since qualification (years)	Area covered during ACTIV	Number of participants seen during ACTIV	Recent areas of employment and experience
P1	F	12	North Auckland	7	Clinical supervisor in private musculo-skeletal practice. Physiotherapy advisor on research study
P2	F	28	North Auckland	9	Community physio with an area health board Private hospital orthopaedics Private community physio-owns business
P3	F	23	South Auckland	3	University teaching in the area of neurological practice. Blinded assessor on previous research studies
P4	F	14	South Auckland	1	Community physio with an area health board
P5	F	8	South Auckland	2	Research assistant, private physiotherapist in gait clinic
P6	F	12	Christchurch	16	Private community physio, blinded assessor on another research study
P7	F	23	Dunedin	1	Undertaking PhD during ACTIV study
P8	F	12	Dunedin	5	Private practice, musculo-skeletal and breathing disorders. Demonstrating anatomy at university. Clinical education

F: female.

5.4 USE OF THE EXPERT PHYSIOTHERAPIST

The expert physiotherapist was available for the ACTIV physiotherapists to discuss any part of the physiotherapy intervention. This included practical questions about the day-to-day running of the trial and clinical advice about ways to progress treatment to ensure an appropriate level of difficulty. In total the physiotherapy advisor was contacted 35 times. All physiotherapists contacted her at least twice, (median 5, range 2-9 occasions) and the majority of contacts (28) were made via e-mail and resolved quickly. Two contacts were initiated by the advisor to follow-up a small discrepancy in data recording. Most of the contacts involved enquiries about programme structure and function, only two of the contacts were regarding programme content (see Table 5-3).

Table 5-3: Contact with Expert Physiotherapist

Reason for contact	Number of contacts
Discrepancy with documentation	6
Discussion about participant withdrawal/discharge	6
Problems with technology	2
Checking continued eligibility after changes in participant	5
Programme variation to accommodate participant differences	4
Alterations in timing of input due to external influences	6
Physio relating a question by the participant.	3
Professional discussion about programme content	2
Practical issues such as travel and reimbursement	1

5.5 BASELINE DATA OF INCLUDED PARTICIPANTS

Participants were randomised to either the intervention (ACTIV) or control group after baseline assessment. The characteristics of the participants at baseline can be seen in Table 5-4 below.

Table 5-4: Baseline Data of Included Participants

		ACTIV	Control
Age (years)	Mean (SD)	74.1(11.7)	72.9(11.7)
Sex	Male	23	26
	Female	24	22
Side of stroke	Right	22	26
	Left	25	22
Type of stroke	Ischaemic	40	45
	Haemorrhagic	7	3
Time since stroke (months)	Mean (SD)	7.2(3.3)	6.1(2.8)
Centre	North Auckland	18	19
	South Auckland	7	7
	Christchurch	16	14
	Dunedin	6	8
Living situation	Accompanied	34	35
	Alone	13	11
	Missing	0	2
Ethnic group	European	43	43
	Non-European	3	4
	New Zealand Māori	1	1
Mobility level	more mobile	23	21
	less mobile	24	27
Depression	moderate depression	20	22
	no depression	27	26

5.6 OUTCOME MEASURES

In the following section outcomes are reported in line with the statistical analysis plan.

Table 5-5 shows the unadjusted scores of all outcomes at baseline, 6 months

(immediately post-intervention) and 12 months (6 months after the end of intervention).

Table 5-5: Unadjusted Scores of Outcome Measures at each Time-point by Group

		ACTIV			Control		
		Baseline	6-months	12-months	Baseline	6-months	12-months
SIS3.0 physical	mean(SD)	69.4(16.0)	72.5(15.8)	68.5(17.4)	63.3(19.4)	64.4(18.8)	63.5(22.8)
	N	47	39	35	48	44	40
Grip strength (affected)	mean(SD)	14.4(9.2)	16.3(9.3)	16.1(10.5)	16.7(10.4)	18.5(10.5)	18.3(11.6)
	N	47	39	35	48	44	40
Grip strength (unaffected)	mean(SD)	24.0(12.0)	25.2(11.5)	24.1(13.1)	27.2(14.3)	28.5(13.3)	26.4(13.3)
	N	47	39	35	48	44	40
Step number (affected)	mean(SD)	7.4(4.5)	7.9(4.9)	7.4(5.6)	7.1(5.4)	7.4(6.1)	7.2(5.9)
	N	47	39	35	48	42	39
Step number (unaffected)	mean(SD)	8.2(5.1)	8.5(5.2)	7.9(5.5)	8.0(5.3)	8.5(5.9)	7.5(6.2)
	N	47	39	35	48	42	39
SSEQ	mean(SD)	99.9(20.1)	105.5(19.9)	99.8(27.0)	90.7(30.9)	93.9(28.3)	94.6(28.7)
	N	47	39	35	48	44	40
SIS-strength	mean(SD)	64.1(16.9)	64.1(16.9)	61.6(22.8)	54.0(19.5)	54.3(18.7)	56.9(22.5)
	N	47	39	35	48	44	40
SIS- memory	Mean (SD)	74.6(17.5)	80.6(14.9)	77.8(15.4)	71.2(18.9)	72.7(19.9)	73.7(23.9)
	N	47	39	35	48	44	40
SIS-emotion	mean (SD)	75.8(15.0)	77.0(16.9)	77.5(14.3)	71.2(16.5)	70.4(18.8)	70.3(21.7)

	N	47	39	35	48	44	40
SIS-communication	mean (SD)	81.7(16.7)	84.9(16.3)	83.8(17.9)	78.3(19.2)	80.6(20.1)	82.7(18.6)
	N	47	39	35	48	44	40
SIS-ADL	mean (SD)	72.8(16.1)	75.4(17.4)	73.0(18.1)	70.8(19.1)	69.4(20.0)	70.5(22.5)
	N	47	39	35	48	44	40
SIS-mobility	mean (SD)	71.8(17.8)	74.6(17.0)	70.4(20.2)	63.2(22.4)	66.9(21.7)	61.7(25.0)
	N	47	39	35	48	44	40
SIS-use of hand	mean(SD)	62.7(31.9)	68.8(26.9)	61.7(29.5)	55.9(32.7)	58.1(29.9)	58.3(31.9)
	N	47	39	35	48	44	40
SIS-participation	mean(SD)	62.1(21.3)	72.4(22.0)	67.7(24.5)	56.5(22.6)	57.9(29.9)	61.3(24.1)
	N	47	39	35	48	44	40
SIS-recovery rating	mean(SD)	58.5(19.5)	67.3(21.3)	64.9(20.4)	53.5(20.1)	61.8(19.6)	61.8(22.7)
	N	47	39	35	48	44	40
EQ5D-VAS	mean(SD)	69.9(18.0)	76.2(17.8)	62.9(25.6)	60.3(19.7)	62.4(25.7)	69.2(20.4)
	N	45	38	35	48	41	40

SD: standard deviation; N: number of participant data sets included; SIS: Stroke impact scale; SSEQ: stroke self-efficacy questionnaire; EQ-5D VAS: visual analogue scale to measure health status; ADL: activities of daily living.

5.6.1 Blind review: selection of families and transformation

During the blind review, carried out without any knowledge or account of the allocation, residuals for each outcome from models including all potential covariates were assessed for normality using graphical methods and estimation of skewness and excessive kurtosis. Some queries were generated in regard to visual outliers, but no observation removed due to their outlier status. Moderate leptokurtosis was evidenced in all continuous outcomes but deemed insufficient to steer away from a normal model (Judkins & Porter, 2016).

5.6.2 Covariates selected for adjusted analysis

Before analysis a blind review was undertaken and factors that reached significance on adjusted partial R^2 for each outcome measure were selected as covariates. ‘Mobility’ identified the randomised strata described earlier. ‘Depression’ was a dichotomous covariate identified from the fifth item of the baseline EQ-5D measurement: an answer of 1 corresponds to ‘no depression or anxiety’ and an answer of 2 or 3 to ‘moderate or severe depression and anxiety’. ‘Living situation’ was a dichotomous variable taking values ‘living alone’ and ‘living accompanied’, identified from a free-form report. ‘Age group’ at baseline was age at randomisation, dichotomised according to ‘less than 75’ and ‘75 or older’. These are shown in Table 5-6.

Table 5-6: Covariates used for Individual Outcome Measure Adjustment

	Baseline value	Mobility	Depression	Living situation	Sex	Age group
SIS (physical)	x	x				
Grip strength	x	x	x		x	
Step test	x	x				
SIS(strength)	x	x	x	x		
SIS(memory)	x					
SIS(emotion)	x			x		
SIS(communication)	x					
SIS(ADL)	x	x				
SIS(mobility)	x	x				
SIS(use of hand)	x					
SIS (participation)	x	x	x			
SIS (recovery rating)	x	x	x		x	
SSEQ	x					
EQ-5D VAS	x					
Admission	N/A					x

SIS: stroke impact scale; EQ-5D: a generic health status instrument; ADL: activities of daily living; N/A: not applicable.

5.6.3 Estimated effect of ACTIV: intention-to-treat analysis

The estimated effect of ACTIV on all outcome measures at 6 months and 12 months, adjusted for the covariates detailed above, is presented below in Table 5-7. All results are rounded to 2 decimal places or 2 significant digits.

Table 5-7: Estimated Effect of ACTIV at 6 and 12 months, adjusted for Covariates (Intention-to-Treat Analysis).

	6 months				12 months			
	Effect estimate	Standard error	95%CI	p-value	Effect estimate	Standard error	95%CI	p-value
SIS3.0 physical	4.51	2.50	-0.46, 9.48	0.07	1.72	2.89	-4.04, 7.48	0.55
Grip strength (A)	-0.29	1.02	-2.32, 1.73	0.77	0.04	1.22	-2.40, 2.47	0.98
Grip strength (U)	0.20	0.88	-1.56, 1.96	0.82	-0.71	1.31	-3.33, 1.92	0.59
Step number (A)†	0.06	0.08	-0.11, 0.23	0.50	-0.047	0.10	-0.25, 0.16	0.65
Step number (U)†	-0.02	0.08	-0.18, 0.14	0.79	0.0063	0.10	-0.19, 0.21	0.95
SSEQ	6.15	3.78	-1.37, 13.67	0.11	2.42	4.67	-6.88, 11.72	0.61
SIS-strength	4.63	3.38	-2.11, 11.38	0.18	2.09	4.28	-10.65, 6.46	0.63
SIS-memory	4.43	2.78	-1.11, 9.97	0.12	1.72	3.38	-5.01, 8.45	0.61
SIS-emotion	4.59	3.03	-1.44, 10.62	0.13	4.86	3.69	-2.50, 12.23	0.19
SIS-communication	1.88	2.83	-3.76, 7.52	0.51	-0.21	2.72	-5.64, 5.21	0.94
SIS-ADL	5.26	2.89	-0.50, 11.02	0.073	3.54	3.02	-2.48, 9.56	0.24
SIS-mobility	2.67	2.88	-3.06, 8.40	0.36	3.00	3.03	-3.05, 9.04	0.33
SIS-use of hand	6.43	4.42	-2.37, 15.22	0.15	0.12	4.87	-9.60, 9.84	0.98
SIS-participation	11.34	4.42	2.54, 20.14	0.012*	4.41	5.28	-6.13, 14.95	0.41
SIS-recovery rating	2.68	4.03	-5.35, 10.70	0.51	0.64	4.22	-7.79, 9.07	0.88
EQ5D-VAS	10.09	4.79	0.53, 19.65	0.04*	-10.76	4.55	-19.86, -1.67	0.02*
Admissions †	0.63	0.50	-0.37, 1.62	0.21	N/C	-	-	-

SIS: stroke impact scale; A: affected; U: unaffected; SSEQ: stroke self-efficacy questionnaire; ADL: activities of daily living; EQ-5D VAS: visual analogue scale to measure health status; †: natural logarithmic scale; *: statistically significant at 5% level; CI: confidence interval; N/C: not collected.

5.6.4 Estimated effect of ACTIV: per protocol analysis

Outcome measures identified in the statistical analysis plan were analysed at 6-months to establish the estimated effect of ACTIV in the per protocol analysis set, defined in Chapter 4. The results of the analysis can be seen in Table 5-8.

Table 5-8: Estimated Effect of ACTIV at 6 months, adjusted for Covariates (per Protocol Analysis)

	Effect estimate	Standard error	95% Confidence interval	p-value
SIS3.0 physical	5.28	2.49	0.33, 10.23	0.037*
Grip strength (A)	0.02	1.02	-2.01, 2.06	0.98
Grip strength (U)	0.26	0.90	-1.53, 2.04	0.77
Step number (A)†	0.06	0.08	-0.11, 0.23	0.50
Step number (U)†	-0.02	0.08	-0.18, 0.14	0.79
SSEQ	6.58	3.77	-0.93, 14.08	0.085
SIS-recovery rating	2.81	4.05	-5.26, 10.87	0.49
EQ5D-VAS	9.76	4.79	0.20, 19.32	0.046*
Admissions	0.63	0.50	-0.37, 1.62	0.21

SIS: stroke impact scale; A: affected; U: unaffected; SSEQ: stroke self-efficacy questionnaire; EQ-5D VAS: visual analogue scale to measure health status; †: natural logarithmic scale; *: statistically significant at 5% level.

5.6.5 Sub-group analysis

A sub-group analysis was undertaken to investigate differences in the estimated effect of ACTIV, dependent on a participant's mobility level at baseline. The Functional Ambulation Classification was used to differentiate mobility levels, with a score of five or below being defined as 'less mobile' and a score of six as 'more mobile'. There was a significant ACTIV effect only for the EQ-5D in participants who were more mobile and no significant difference in ACTIV effect between the two sub-groups for any outcome, seen Table 5-9 below.

Table 5-9: Sub-group Analysis (6 months post-randomisation)

	Mobility level	Effect estimate	Standard error	95% Confidence interval	p-value ACTIV	p-value interaction
SIS3.0 physical	less mobile	4.12	3.44	-2.74, 10.97	0.24	
	more mobile	4.94	3.65	-2.33, 12.21	0.18	0.87
Grip strength (A)	less mobile	1.55	1.43	-1.29, 4.39	0.28	
	more mobile	-2.27	1.49	-5.24, 0.70	0.13	0.07
Grip strength (U)	less mobile	-1.10	1.20	-3.49, 1.28	0.36	
	more mobile	1.93	1.31	-0.68, 4.54	0.14	0.09
Step number (A)*	less mobile	0.19	0.14	-0.10, 0.48	0.19	
	more mobile	-0.01	0.16	-0.33, 0.31	0.95	0.25
Step number (U)*	less mobile	0.06	0.13	-0.20, 0.31	0.67	
	more mobile	-0.07	0.16	-0.38, 0.25	0.66	0.46
SSEQ	less mobile	4.36	5.24	-6.07, 14.79	0.41	
	more mobile	8.16	5.53	-2.86, 19.18	0.14	0.62
SIS-recovery rating	less mobile	0.90	5.52	-10.11, 11.91	0.87	
	more mobile	4.71	5.99	-7.23, 16.65	0.43	0.64
EQ5D-VAS	less mobile	6.61	6.51	-6.39, 19.61	0.31	
	more mobile	14.12	7.04	0.08, 28.17	0.05*	0.43
Admissions	less mobile	0.69	0.65	-0.60, 1.97	0.29	
	more mobile	0.54	0.83	-1.10, 2.19	0.51	0.89

SIS: stroke impact scale; A: affected; U: unaffected; SSEQ: stroke self-efficacy questionnaire; EQ-5D VAS: visual analogue scale to measure health status; p-value ACTIV: the observed significance level of ACTIV in each sub-group; p-value interaction: the observed significance level of the difference in ACTIV effect between sub-groups.

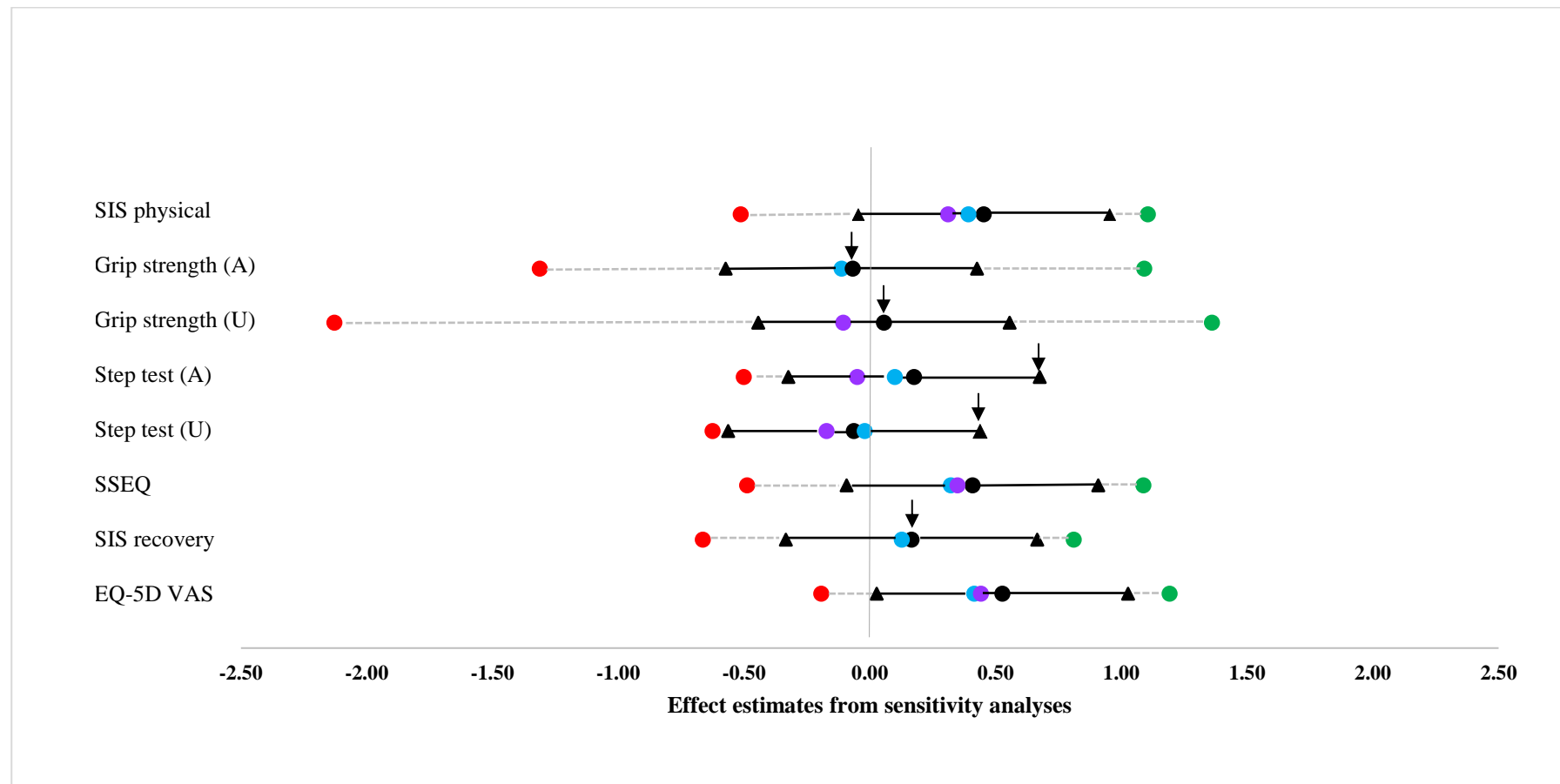
5.7 SENSITIVITY ANALYSES

Sensitivity analyses were undertaken for outcome measures selected *a priori*, to understand the possible importance of missing data and to test the confidence that could be placed in the ACTIV effect estimate. They involved imputing selected values into missing values using a range of alternative assumptions to Missingness at Random. Because sensitivity analyses were based on single imputations, only the point estimates which they produced were reported.

Return to baseline (RTB): assumed that all missing outcome values were returned to their baseline values. Worst case for intervention (WCI): all missing outcome values were imputed with the least favourable value within the same cluster and time point in the ACTIV arm and with the most favourable value in the control arm. Best case for intervention (BCI): all missing outcome values were imputed with the most favourable value within the same cluster and time point in the ACTIV arm and with the least favourable value in the control arm. Intention-to-treat extension (ITT_e): the control arm average was imputed to missing values in the control arm and in ACTIV participants who had withdrawn, and the ACTIV arm average was imputed to other missing values for current ACTIV participants. Only the point estimates were retained for the sensitivity analyses.

The results are displayed in Figure 5-3 below; all effect estimates have been standardised to the width of the intention-to-treat 95% confidence interval. Seven points can be seen on each line; the upper and lower bounds of the 95% confidence interval around the original ACTIV effect estimate and one effect estimate for each of the four described sensitivity analyses. The exception to this was when two values were too similar to be able to be represented separately. For grip strength (affected) and the SIS(recovery), the ITT(ext) and ACTIV effect values; for grip strength (unaffected), the

RTB and ACTIV effect values; and for step test (affected) and (unaffected), the BCI and the upper bound of the 95%CI values, all fit this situation.



● : worst case for intervention; ● : intention-to-treat extension; ● : return to baseline; ● : ACTIV effect estimate ; ● : best case for intervention; ▲ : upper and lower bounds 95% CI. A: affected; U: unaffected; SIS: stroke impact scale; A: affected; U: unaffected; SSEQ: stroke self-efficacy questionnaire; EQ-5D VAS: visual analogue scale to measure health status; ↓ : two points overlaid.

Figure 5-3: Effect Estimates from Sensitivity Analyses for each Outcome Measure.

5.8 PRIMARY RESEARCH QUESTION

At the end of the 6-month intervention, did ACTIV improve physical function in people with stroke compared to a usual care control group, as measured by the physical sub-component of the Stroke Impact Scale (SIS 3.0)?

The physical sub-component of SIS 3.0 is a composite score of the four physical domains (strength, hand function, mobility and activities of daily living). In the intention-to-treat analysis, the estimated effect of ACTIV at 6-months (4.51), did not reach significance ($p=0.07$), and was somewhat smaller than the hypothesised effect of 5.3, suggesting that our study may have been underpowered. The imbalance in this outcome at baseline, favouring the intervention arm with a higher mean SIS physical sub-component score, was an unfortunate chance event that increased heterogeneity between arms, potentially masking a true effect. The estimated effect from the per protocol analysis (5.28) was significant ($p=0.037$) and showed that ACTIV was significantly effective in improving physical function after stroke for those who received at least 50% of the intervention.

5.9 SECONDARY RESEARCH QUESTIONS

5.9.1 Question 1

At the 12-month follow-up, will any physical gains achieved by the intervention group at the end of the intervention be maintained, as measured by the physical sub-component of the SIS 3.0?

At the 12-month follow-up the estimated effect of ACTIV on the physical sub-component of the SIS 3.0 (1.72, 95%CI [-4.04, 7.48], $p=0.55$), suggested that there was no retention of gains made during the intervention.

5.9.2 Question 2

At the end of the 6-month intervention, did ACTIV improve physical function in people with stroke, compared to a usual care control group as measured by the physical performance measures and the stroke self-efficacy questionnaire?

The estimated effect of ACTIV on grip strength in the hand affected by stroke (-0.29, 95%CI [-2.32, 1.73], $p=0.77$) and the unaffected hand (0.20, 95%CI [-1.56, 1.96], $p=0.82$) was not significant. The estimated effect of ACTIV on the step test, stepping with the leg affected by stroke (0.06, 95%CI [-0.11, 0.23], $p=0.50$) and stepping with the unaffected leg (-0.02, 95%CI [-0.18, 0.14], $p=0.79$) was not significant. The estimated effect on the stroke self-efficacy questionnaire (SSEQ) (6.15, 95%CI [-1.37, 13.67], $p=0.11$) was not significant.

5.9.3 Question 3

Over the study period, did ACTIV improve health outcomes and quality of life in people with stroke compared to a usual care control group as measured by the whole SIS 3.0?

At the end of intervention (6 months) the effect estimates for the participation sub-scale of the stroke impact scale (11.34, 95%CI [2.54, 20.14], $p=0.012$) was found to be significant. However, this effect was not sustained and at the 12-month assessment none of the sub-scales of the SID3.0 were found to be significantly different between the two arms.

The EQ-5D VAS was also used to understand the health effects of ACTIV. The estimated effect was found to be significant at 6 months for both the intention-to-treat analysis (10.09, 95%CI [0.53, 19.65], $p=0.04$) and the per protocol analysis (9.76, 95%CI [0.20, 19.32], $p=0.046$). The results from the sub-group analysis showed that a significant effect was found only for participants who were more mobile at baseline

(14.12, 95%CI [0.08, 28.17], $p=0.049$). The estimated effect for those who were less mobile at baseline was non-significant (6.61, 95%CI [-6.39, 19.61], $p=0.31$). The estimated effect of ACTIV on the EQ-5D at 12 months (-10.76, 95%CI [-19.86, -1.67], $p=0.02$) was also significant, in the opposite direction. Participants in the intervention arm had significantly lower EQ-5D VAS scores than the control arm.

5.9.4 Question 4

Over the study period, did participation in ACTIV result in a reduction in hospital or residential care admissions compared to the usual care control group?

Hospital admission data was only collected for the period of the ACTIV intervention (6 months). Despite having a positive odds ratio (OR 1.80) of ACTIV increasing hospital or residential care admissions, the confidence interval (95%CI [0.67, 4.88]) includes 1 and therefore the effect failed to reach significance ($p=0.24$). ACTIV had no impact on the level of hospital admissions compared to the control arm.

5.10 ADVERSE EVENTS

Adverse event information from all ACTIV participants was collected over the 6-month intervention period, using monthly telephone calls. Presented below are the frequency of adverse events and the incidence inferred from analysis.

5.10.1 Adverse event frequency

The following Table 5-10 details all the adverse events that occurred during the study with their relatedness to ACTIV and severity detailed. During the intervention period there was one death in the control arm, there were no adverse events in either arm adjudicated to be severity level 4, corresponding to a life-threatening event requiring urgent medical attention.

Table 5-10: Number of Adverse Events by Arm, Adjudicated for Relatedness and Severity

Arm	Related	Severity					Total
		1	2	3	4	5	
ACTIV	Yes	5	1	0	0	0	6
	No	14	16	11	0	0	41
	Total	19	17	11	0	0	47
Control	Yes	0	1	0	0	0	1
	No	19	9	15	0	1	44
	Total	19	10	15	0	1	45
Overall	Yes	5	2	0	0	0	7
	No	33	25	26	0	1	85
Total		38	27	26	0	1	92

The documentation for adverse event telephone calls showed attempted follow-up for all participants, but four were unable to be contacted, despite several attempts. The missing data corresponds to those not contacted in the ACTIV (N=3) and control (N=1) groups. Table 5-11 details adverse events for all other participants ACTIV (N=44) and control (N=47). The majority of participants had two or fewer adverse events over the study period. A small number of participants had multiple adverse events, in the ACTIV group (N=3) and the control group (N=6).

Table 5-11: Number of Participants by Arm and Number of Adverse Events Reported

Arm	Number of adverse events reported						Total
	0	1	2	3	4	6	
ACTIV	16	15	10	2	0	1	44
Control	21	14	6	5	1	0	47
Overall	37	29	16	7	1	1	91

Over the course of the intervention period the average length of follow-up time was equal in each groups and corresponded to approximately four months. The reduction from the planned six months was accounted for by the missing data and some delays longer than four weeks between phone calls due to unavailability of participants.

5.10.2 Adverse events incidence

Interferential analysis was undertaken to ascertain whether the incidence of adverse effects differed between groups. Table 5-12 below shows that there was no significant difference.

Table 5-12: Incidence Ratio of Adverse Events (ACTIV to Control)

Estimated incidence ratio	Lower 95% confidence limit	Upper 95% confidence limit	p-value
1.09	0.64	1.85	0.76

Table 5-13 below shows that there was also no significant difference between the groups in incidence of adverse effects at any severity level (the one death was removed prior to analysis, as planned). The overall p-value for allocation when all severity levels were combined was 0.47.

Table 5-13: Incidence Ratio of Adverse Events by Severity (ACTIV to Control)

Severity	Estimated incidence ratio	Lower 95% confidence limit	Upper 95% confidence limit	p-value
1	1.038	0.52	2.09	0.92
2	1.765	0.77	4.07	0.18
3	0.761	0.33	1.75	0.52

Under the assumption of equal probability, in both arms, of misclassification of an adverse event as being related to the intervention, the adjustment was made as detailed

in the methods section. The Table 5-14 below shows the estimated incidence of adverse events related to the ACTIV intervention.

Table 5-14: Incidence Ratio of Adverse Events by Relatedness (ACTIV to Control)

Estimated excess incidence (adverse events per person-year)	2.50%	97.50%	p-value
0.115	-0.0017	0.232	0.053

5.11 INTERVENTION FIDELITY

5.11.1 Adherence to delivery as per protocol

The measurable elements of the dose and content of ACTIV, were agreed *a priori* by consensus of the research team NS, DT and SM and are reported below.

Dose

The two key components of dose were the number of contacts, and their delivery within a specified timeframe. Contact refers to a face-to-face contact, a telephone call or a text sent by the physiotherapist. An intervention was considered to be complete if it included all the face-to-face contacts, at least four of the five telephone calls and at least 80% of the text messages. The number of contacts was retrieved from spreadsheets filled in by the physiotherapist. The timely delivery of the contacts was verified by a comparison with the specified timeframes shown in the ACTIV method in Figure 4-2. A contact was considered to have been delivered on time if it was within a week of the designated date. The number of participants who received the dose as per protocol, is shown in Table 5-15.

Table 5-15: Dose of ACTIV Delivered to Participants in the Intervention arm (N=47)

Contacts	Number of participants who had specified number of contacts delivered.	Number of contacts delivered within specified time-frame.
Four face-to-face visits	34	34
At least four phone calls	37	35
At least 28 text messages	37	37
Number of Participants who received dose as per protocol		34

Content

The content of ACTIV comprised key components shown in Table 5-16 with the number of participants who received each one as specified. Each component corresponds to an identifiable action on the forms filled out by the physiotherapists which were sent to the expert physiotherapist after each visit. No attempt was made to make a judgement on the quality of each component, as long as the goal was identified, an analysis of difficulty was recorded, the exercises targeted the selected function and instructions on the parameters and dose of each exercise was included.

Table 5-16: Content of ACTIV Delivered to Participants in the Intervention arm (N=47)

Key component	Number who received component
Goal identified and difficulty investigated	44
Exercises prescribed appropriate to goal	44
All 3 follow-up visits made with completed detail	34
At least 4/5 telephone follow-up visits with completed detail	37
Number of Participants who received content as per protocol	34

Three participants withdrew from the ACTIV intervention group immediately after randomisation, so the intervention was delivered to 44 participants. Seventy-two percent of the participants randomised to ACTIV received the intervention as per protocol and

77% of the participants who began the intervention, received it as per protocol. Of the ten participants who did not receive ACTIV dose and content as per protocol, eight had withdrawn during the intervention (two had reached their goals, three withdrew for other health reasons, one was attending private physio, one disliked the texting and one was transient and uncontactable); all of these participants had received the ACTIV protocol up to the time that they withdrew. The other two participants had completed all but one home visit due to scheduling difficulties with the physiotherapist.

Seven participants did not receive the full 28 text messages; five of these were participants who had withdrawn (three of the eight who withdraw received at least 28 texts). Two participants were not able to manage the text messages, one found them too difficult to see, due to poor eyesight and instead received brief (under 2 min) phone encouragement on the same schedule as texts would have been sent. One participant found it too difficult to get used to the phone and received the same type of message by e-mail instead.

5.11.2 Exercise completion: self-report

The dose and content of the intervention was recorded as above but equally important was the degree to which the participants were able to undertake the intervention and complete the exercises. The results of the 47 participants' response are summarised in Table 5-17.

Table 5-17: Participant Self-report Exercise Completion (N=47)

Phone call number	All exercises competed	Some exercises completed	No exercises completed
1	33	11	0
2	32	9	1
3	26	15	0
4	23	10	2
5	25	8	3

Three participants withdrew before ACTIV delivery began, so the first phone call was made to 44 participants. By the 5th phone call 33 participants were still completing some or all of their exercises. Of the 11 who stopped between first and last phone calls, three had stopped exercising but were still part of ACTIV and one phone call was missed by an assessor due to difficulty contacting the participant. The seven who had withdrawn have been outlined above regarding receipt of content.

5.12 SUMMARY

This chapter detailed how the participants were recruited and allocated to one of two trial arms. Information about the physiotherapists delivering the intervention and the strategies put in place to support them were also outlined. The results of the analysis of all outcome measures were used to answer the five research questions posed at the start of the trial. They showed that ACTIV was effective in improving outcomes for people with stroke during the 6-month intervention, for those who received at least 50% of the planned protocol. The results of measures of intervention fidelity show a high level of adherence to the protocol, which increases confidence in the results of the outcomes of interest. There are a number of important questions that arise from the results, which will be discussed in the following chapter.

CHAPTER 6 DISCUSSION OF RANDOMISED CONTROLLED TRIAL RESULTS

6.1 INTRODUCTION

This chapter is a discussion of the findings of the randomised controlled trial. Recruitment of participants, the selection of physiotherapists to undertake the intervention and the use of the expert physiotherapist were considered. The results of the trial have been scrutinised and discussed in light of literature in the area of stroke rehabilitation. The results of the investigation of intervention fidelity are also discussed and suggestions made to further enhance protocol adherence. The strengths and limitations of the trial helped to inform the degree to which the results could be generalised to the population.

6.2 PARTICIPANT RECRUITMENT

The difficulties experienced recruiting participants to the ACTIV study are common to many research studies (Provencher, Mortenson, Tanguay-Garneau, Bélanger, & Dagenais, 2014). Key strategies suggested in previous studies involving people with stroke (Blanton et al., 2006; Hadidi, Buckwalter, Lindquist, & Rangen, 2012) were adopted to improve recruitment and retention during the ACTIV trial. The way in which each of the suggested strategies was enacted during recruitment is detailed.

6.2.1 Careful consideration of inclusion and exclusion criteria

Significant discussion and negotiation of inclusion and exclusion criteria occurred during study design, prior to publication of the study protocol (Saywell et al., 2012). The team involved in ACTIV were aware of the potential difficulties recruiting from a sub-acute and chronic stroke population. Only people who had suffered a first stroke were included, as recovery from a subsequent stroke often is significantly slower compared to a first stroke (Alexander, Bugge, & Hagen, 2001). Brain stem or cerebellar

strokes were also excluded as deficits experienced after these strokes are less likely to be unilateral and some outcomes measured in this study are focused on the weaker side. Exclusion of cerebellar and brainstem stroke has also occurred in other exercise intervention studies (Langhammer, Stanghelle, & Lindmark, 2009). These criteria were intended to improve internal validity but naturally reduced the number of potential participants considerably. In hindsight, differences between stroke type and expected speed and extent of recovery would have been managed by randomisation at the possible expense of increased heterogeneity and including subsequent strokes and strokes with lesions in the cerebellum and brain stem would have increased external validity. The decision to exclude potential participants because they were outside the geographical area was considered carefully and participants were included from as wide an area as possible. However, some people were discharged to locations that were over 150km from the centre, which would have made the assessment of outcomes and physiotherapy visits impractical. Some potential participants had suffered a stroke while on holiday and returned to another country or city, not involved in the study. The remainder of the group had moved house to an area outside the study area soon after their stroke. One potential participant was in prison and therefore was not able to be included because the study requirement of mobile phone use conflicted with prison regulations.

6.2.2 Early feedback and support from involved medical and administration staff

NS visited the medical team and administration staff at each site, prior to the start of ACTIV. The contact helped enlist support of the staff at each site and minor changes were made to accommodate regional differences. Particular attention was paid to the two Auckland sites, as a study recruiting a very similar cohort was due to complete recruitment as ACTIV began. Despite clarification of the planned end of recruitment, the other study's recruitment was extended for an additional year due to insufficient

numbers. This compromised recruitment as ACTIV was given access to one in every seven potential participants in these two sites.

6.2.3 Planning of recruitment procedures

The recruiter and research assistant collecting adverse event data had a job description and an outline of procedures. NS undertook all training for consistency and was available if problems occurred. Several visits were made to each centre to observe procedure and give support and encouragement. ACTIV was able to include participants with minor disability so establishing eligibility by phone was difficult when deficits were subtle. Recruiters were advised to apply the inclusion criteria liberally, so if eligibility was in doubt but a participant was interested, confirmation was able to occur at baseline assessment. The variation in experience of the recruiters helps explain differences between centres, in numbers lost between eligibility at telephone screen and baseline assessment.

6.2.4 Consideration for participants' schedules

Approximately 30% of potential participants who fitted the inclusion criteria were not interested in being part of the research; many people did not give a reason for this but where a reason was volunteered many cited a lack of time, feeling too tired or not having the ability to commit to the length of the study. This group was lost to the study but the same concerns can significantly impact retention (Blanton et al., 2006). To help circumvent problems, participants in the intervention group had a manual with space to record physiotherapy visits and phone calls, which were scheduled and altered by mutual consent. A common problem for intervention trials is the inability to vary treatment to best suit an individual: ACTIV used a protocol which enabled tailoring of exercises to participant needs which made it more responsive to individual goals.

If agreement was gained from a participant, phone calls and text messages could still be used when they were on holiday, even if this was overseas. The home-based nature of ACTIV meant that there were no transport difficulties which is a common problem for study participants. All Participants had an information sheet, consent sheet and clear contact information. This allowed changes to appointments, information to be given and questions to be answered.

6.2.5 Encouraging participants in the control group

Recruiters frequently reported that information about randomisation discouraged potential participants. The 50:50 chance of being in the usual care control group was a disincentive. When a participant was randomised to the control group, a letter was sent to confirm (see Appendix Y) and the recruiter made a follow-up phone call. They explained the value of a control group in research, acknowledging that this allocation may be disappointing and reiterated that all participants would be assessed at the start and finish of ACTIV. There is a common belief that people are motivated by an altruistic desire to be part of research, however McCann, Campbell and Entwistle (2010) found that this only applied to an interest in research. The feature that most people considered before committing to being part of a research study was that there was no obvious significant disadvantage to themselves. ACTIV is a programme offered when standard treatment has finished. People who are receiving physiotherapy at that stage are usually self-funded. It was hoped that participants in the control group would perceive no significant loss, as ACTIV had very few face-to-face sessions and the remainder were delivered remotely. The researchers who developed ACTIV, all maintained equipoise during the study, having no certainty whether ACTIV would deliver a significant physical benefit or not. It was testimony to the level perceived and real needs of people after discharge from stroke rehabilitation services that a number of participants recruited to the study, expressed bitter disappointment when randomised to

the control group. Funding constraints prevented the ability to offer ACTIV to the control group at the completion of the study. As with all randomised controlled studies, the selection of intervention for the control group was carefully considered. There was discussion about whether a dose-matched control, such as receiving a sham treatment might be used, but because the ACTIV intervention used phone calls and text to encourage, it is difficult to imagine how you could ensure that a control intervention was not achieving some of the active ingredient of ACTIV. Indeed, one of the main themes identified by participants was that simply someone making contact was a valuable aspect of the intervention.

6.3 PHYSIOTHERAPISTS DELIVERING THE INTERVENTION

The decision not to limit ACTIV physiotherapists to those with neurological experience meant we recruited physiotherapists with a broad cross-section of clinical experience. Employing each therapist part-time meant that only physiotherapists who were not already in full-time employment could apply for the positions. This may account for the all-female, older work-force; male physiotherapists and younger physiotherapist were frequently the family's sole wage-earner and so worked full-time. Working as a physiotherapist on ACTIV drew those who had young children, other part-time work or were involved in post-graduate study. Our intention was to employ physiotherapists at least two years' post-graduation, to ensure that we employed physiotherapists who had gained some clinical experience. When the positions were advertised, no physiotherapist who had less than eight years of post-graduation experience applied for a position. This may have implications for implementation to clinical practice, as ACTIV has not been delivered by more recent graduate physiotherapists. However time since qualification is no guarantee of experience and competence is now maintained in the physiotherapy profession in New Zealand by the regular audit of physiotherapists to ensure continued professional development (Physiotherapy Board of New Zealand). If ACTIV is

implemented in clinical practice in the future, physiotherapists with two years' experience will also be supported by its well-structured programme with clear steps and a comprehensive training schedule. A structured schedule of quality checks and feedback will also be instigated. (See Intervention fidelity 6.7 page 141).

6.4 USE OF THE EXPERT PHYSIOTHERAPIST

A surprising finding in the results was the use of the expert physiotherapist (SM). Contact between SM and the physiotherapists had been established during initial training and maintained throughout the intervention with e-mail and telephone calls. Ensuring practical questions were addressed quickly and minor documentation discrepancies were resolved was important to the smooth running of the study. It was anticipated that advice about content from a physiotherapist with extensive experience would be helpful, to guide individual tailoring of ACTIV. Some clinicians in the study had had many years of practice in neurological physiotherapy and may have felt no need of the support offered. For clinicians with less recent neurological experience the Dunning-Kruger effect may in some part account for the minimal contact of physiotherapists with the expert clinician. The effect refers to the state of not knowing what you don't know and was proposed as a reason help is not sought in many situations. The state of being unaware about your lack of knowledge was posited to co-exist with a high level of confidence in your ability (Kruger & Dunning, 1999). It is not clear the extent to which this occurred as we did not have a way of measuring the quality of the intervention delivery directly. However, we gained insight into intervention delivery using two complementary sources; the fidelity checks ensured that specified elements were delivered as proposed and the qualitative study explored the extent to which the intervention was satisfactory to participants. There remain the unknown elements: whether the intervention was delivered optimally and whether more

opportunities to discuss treatment planning and reflect on performance could have further enhanced delivery by the ACTIV physiotherapists.

6.5 DISCUSSION OF THE RESULTS

6.5.1 Confidence in the effect estimates

The sensitivity analyses were intended to assess the consequences of departure from the basic assumption of Missingness at Random (MAR) using simple single imputation schemes. The worst case for intervention (WCI) and best case for intervention (BCI) schemes produced an interval representing the plausible range of all possible sensitivity analyses of the MAR assumption. These intervals were comparable to the 95% confidence intervals, if somewhat larger, except for both Grip Strength outcomes, indicating higher sensitivity to departure from the MAR assumption in these cases.

The width of the plausible sensitivity range in the case of all other outcomes can be partially explained by the unrealistic nature of the WCI and BCI imputation schemes. WCI was unlikely to be close to the true difference between arms, as a number of participants withdrew having reached their goals, meaning they would be more likely to have a better score than predicted by the imputation under that assumption. BCI was also unlikely to yield a value close to the truth, as some participants withdrew due to poor health, did not like the intervention or did not find it useful.

The return to baseline and intention-to-treat extension analyses are somewhat less extreme, although still conservative and yielded very similar values to the original ACTIV effect estimates, increasing the confidence that they consisted in a fair representation of effect.

6.5.2 Primary research question:

At the end of the 6-month intervention, did ACTIV improve physical function in people with stroke compared to a usual care control group, as measured by the physical sub-component of the Stroke Impact Scale (SIS 3.0)?

The finding of a significant estimated effect of ACTIV for the participants who completed the 6-month programme was encouraging. The threshold for including participants in the per protocol analysis was low: they had to have completed half the intervention, so only three participants were switched from the ACTIV to the control arm in this instance. It was a surprising finding that the input of just 14 hours over six months for each ACTIV participant had such a significant effect, given that no limitations to engaging in exercise or activity was placed on the control group. The control group could still access exercise classes or purchase a gym membership, available to anyone regardless of health status, or seek private stroke-specific treatment. The results suggested that they did not and agreed with literature around activity after stroke, which has shown that after discharge from rehabilitation people are very sedentary (Tieges et al., 2015) and experience a steady decline in mobility in the months and years after discharge from stroke services, if they do not have access to post-discharge rehabilitation (Paolucci et al., 2000; Van De Port, Kwakkel, Van Wijk, & Lindeman, 2006). The barriers to engaging in self-initiated exercise after stroke have been documented (Rimmer, Wang, & Smith, 2008) and include the cost of the programme, transport to the facility, access to appropriate services and the fear or embarrassment of being in a mainstream facility, combined with the perception that staff may not have the requisite skills to manage their particular needs (Salbach, Howe, Brunton, Salisbury, & Bodiam, 2014). The message from this finding seemed to be an important yet self-evident one. In order to gain benefit from ACTIV, participants had to actually do it but given a little support and encouragement, people after stroke were able

to engage in exercise and activity of a sufficient level to have significantly better physical function than the control group. The results from ACTIV demonstrate how a small amount of input made a large difference and further, that without some input people did not maintain activity. ACTIV could be extended to a wide variety of people, including those who were geographically isolated or unable to travel and could make a significant difference to function after stroke. The results from the analysis of outcomes at 12-months support the view that after stroke the complete withdrawal of support can lead to a failure to maintain or improve function.

6.5.3 Secondary research questions

6.5.4 Question 1

At the 12-month follow-up, will any physical gains achieved by the intervention group at the end of the intervention be maintained, as measured by the physical sub-component of the SIS 3.0?

ACTIV was a programme that emphasised participant-selected, valued activities as goals, supported problem-solving and gave participants small behavioural nudges to encourage behaviour change. A reduction in the frequency of face-to-face visits, telephone contact and text messaging over the course of the intervention, was designed to encourage a gradual return to autonomy. The findings suggested that participants had not internalised strategies to allow a true behaviour-change that would allow independence from ACTIV input and that the exercises and activity were not sustained once the reminders stopped. Langhammer, Lindmark and Stanghelle (2014) conducted a follow-up 3 years after the end of a year-long randomised controlled trial comparing an intensive exercise intervention with regular monitoring and an encouragement to keep activity levels high. A number of the less mobile patients in this study had died and some were lost to follow-up, never-the-less they found that at four years post-stroke

there was no difference between the groups, emphasising the importance of regular monitoring and encouragement to stay active in the year following stroke. It seems that a level of interest in progress and regular encouragement to maintain exercise or activity during the year following stroke was very important. There is a possibility that the ACTIV intervention was too short to achieve the hoped-for change in behaviour and that a longer intervention may have lifted people to a threshold, to allow independence from any input. It is also possible that relative autonomy may have been attained.

Brawley and colleagues (2003) have pointed out that older adults with chronic disease or disability are much more prone than the general population, to events such as an injurious fall or illness, which often have the effect of reducing activity and preventing engagement in exercise. They highlighted that people frequently need help in the process of identifying problems and planning a course of action to re-institute activity and exercise after a hiatus. An ongoing low level of support may be required to maintain what has been gained or to re-gain momentum after a set-back. At present the majority of stroke services are unable to offer the ongoing follow-up for people in the community after stroke, (Tyson & Turner, 2000) and the advice to continue rehabilitation until improvements are no longer being noted (Stroke Foundation of New Zealand and New Zealand Guidelines Group, 2010) and to monitor at least six-monthly for signs of deterioration (Aziz, 2010) rarely taken. People who may require services beyond the acute phase, possibly due to co-morbidities limiting early gains, can rarely be accommodated. Despite rhetoric to the contrary, people who fail to respond well to early rehabilitation by improving function, specifically activities of daily living, are effectively shut-out of ongoing rehabilitation (Egan, Kessler, et al., 2016).

6.5.5 *Question 2*

At the end of the 6-month intervention, did ACTIV improve physical function in people with stroke, compared to a usual care control group as measured by the physical performance measures and the stroke self-efficacy questionnaire?

The primary outcome measure for the ACTIV trial was the physical sub-component of the SIS 3,0 which included a self-report measure of hand function. However it has been suggested in the literature that upper limb measures should be undertaken as a combination of capacity and self-perception (van Delden, Peper, Beek, & Kwakkel, 2013). There are always difficult decisions to be made when adding secondary outcome measures in a clinical trial. The need to gain information about a large range of domains needs to be carefully balanced against the participant burden of undertaking numerous assessments. Strength is an important determinant of upper limb function (Burridge, Turk, Notley, Pickering, & Simpson, 2009) and grip strength is well correlated with strength in other important upper limb muscles. For those reasons and due to its simplicity and reliability grip strength was chosen as a measure of an impairment (Bertrand et al., 2007). There was a reasonable expectation that some changes in grip strength might be found but the absence of a between-group difference in grip strength does not necessarily mean there was no difference in any impairments in the ACTIV group. Upper limb exercises were included in the exercise menu used by the ACTIV physiotherapists and included exercises to address a range of impairments in strength, dexterity, proprioception and co-ordination, all impairments that have been identified as valid to measure during neurological physiotherapy assessment (Tyson et al., 2008). The decision not to test every impairment means that a change in a specific impairment may have occurred. The primary outcome measure gave a far wider view of physical recovery, including hand function reported over a 2-week period, giving a more complete view of use of the hand affected by stroke than a single impairment measure at

a single time-point. The results for the primary outcome demonstrated a significant change between groups. In addition, it is possible that the pooling of results masked changes in grip strength as a number of participants focused more on lower limb than upper limb exercises and consequently may have had no change in strength.

The other physical performance measure used in ACTIV investigated the function of balance. Balance is a vital function; controlling your body in a space is necessary for the completion of almost every other function. Consequently, there was a balance component to almost all the exercises in ACTIV and many incorporated activities in standing or walking with reduced base of support and secondary tasks which have the capacity to improve balance. However as the majority of exercise completion was done by the participant without physiotherapy supervision, and control of balance is often significantly impaired in people post-stroke (Ioffe, Ustinova, Chernikova, & Kulikov, 2006), the physiotherapists would have been conservative in their prescription of exercises with a high challenge, being aware of the possibility of increasing the risk of falls. In section 6.6 below, it can be seen that the conservative approach was successful, as there were only two adverse events that were even possibly associated with the intervention. To improve balance significantly, activities need to be undertaken at or very close to the limit of stability (Nitz & Choy, 2004) and this may not have been achieved consistently enough during ACTIV. However, it can be seen, when looking at the raw score results that the lack of a between-group difference may also be partially explained by a small improvement in both groups for the Step Test using affected and unaffected legs to step. This finding has been found in previous trials measuring balance and Langhammer and colleagues (2009) attributed this in part to the regular checks and re-assessment of both groups. Certainly several of the control group participants in ACTIV related to the research assistant who informed them of their group allocation

that having a monthly adverse-events phone call and assessments at 6 and 12 months would act as a real encouragement to do more.

Although improvements in the physical performance measures could have translated to real-life changes, Langhammer and colleagues (2009) suggest that a return to meaningful activity can be better assessed using measures of participation; this issue is addressed below in the discussion of question 3.

The decision to measure self-efficacy was closely related to a need to understand the factors which increase the likelihood of a return to a satisfying life post-stroke. Self-efficacy has been shown to be an important predictive factor in on-going physical activity post-stroke (Shaughnessy et al., 2006) and strategies which increase self-efficacy have been shown to improve factors such as health-related quality of life and mobility, and also to reduce depression (Korpershoek, van der Bijl, & Hafsteinsdóttir, 2011). ACTIV aimed to increase self-efficacy using the strategies of skill mastery and verbal encouragement by a professional, both of which were deemed important by Korpershoek and colleagues. The results did suggest that ACTIV may have increased self-efficacy. The trial was not powered to detect an effect on the SSEQ and indeed did not detect one at the 5% level, but the confidence interval is consistent with a positive effect. In a similar intervention investigating the use of telerehabilitation in people after stroke, Chumbler and colleagues (2014) measured falls self-efficacy and did not find a between-group difference. Theirs was a more specific scale than was used in ACTIV but investigated the consequence of fear of falling on participant's confidence in managing daily activities. The findings from ACTIV and the study by Chumbler and colleagues when viewed together suggested that self-efficacy was not altered over a short period of time and people may need more input to build self-efficacy, which in turn may drive ongoing physical activity.

6.5.6 *Question 3*

Over the study period, did ACTIV improve health outcomes and quality of life in people with stroke compared to a usual care control group as measured by the whole SIS 3.0?

The two measures of health outcome used in the trial tell a remarkably consistent story. Both the participation sub-scale of the SIS3.0 and the EQ-5D VAS show significant improvement at the end of the intervention period (6-month assessment). The improvement in participation was lost once the intervention was withdrawn and the EQ-5D showed an even more significant change, with participants feeling that their health was worse than before they started the intervention. People who had experienced the support of ACTIV and then had it withdrawn may have simply transferred the disappointment that regularly attends the discharge from outpatient physiotherapy, to the discharge from ACTIV. The fact that it happened later made no difference. The loss of gains made during any intervention and the reduction in hope, were consistent with research in the area of rehabilitation and recovery (Wiles et al., 2004). Discharge after a period of rehabilitation marks, for many, the time after which they could not really expect any further improvement. Ironically this may be particularly distressing if a vague non-specific hope for recovery, has been transformed into more of an expectation of improvement by the achievement of significant interim steps (Wiles, Cott, & Gibson, 2008). This may well have been the case during ACTIV as the concomitant improvement in the physical sub-component of the SIS for the per protocol 6-month analysis suggests.

The sub-group analysis revealed that the significant improvement in perception of health at the end of ACTIV was restricted to those who entered ACTIV with a higher mobility level, which suggests that there may be a threshold that allows exercises to have a larger effect on a person's sense of health and wellbeing. This finding did not

extend to a between-group difference in any other outcome measure, which was contrary to other research. An exercise programme for frail elderly was found to have a protective effect on physical function, preventing deterioration but only in people with moderate frailty, not in the very frail (Gill et al., 2002).

6.5.7 Question 4

Over the study period, did participation in ACTIV result in a reduction in hospital or residential care admissions compared to the usual care control group?

The trial was not powered to investigate a change in hospital admissions so the non-significant finding was expected. Looking at individual admissions during ACTIV the majority were for planned surgery or medical admissions not primarily associated with the stroke, so many of the readmissions would not have been influenced by rehabilitation services, however it is important to consider whether readmission after stroke could be influenced by rehabilitation.

Readmission in the first year following discharge from hospital after stroke has been estimated to be as high as 62% when all causes of readmission are taken in to account, and 31% when only stroke-related factors are considered (Lichtman et al., 2010). This represents a significant financial cost to the health system and considerable distress to the person with stroke, their family and friends. Predicting the reason for these readmissions may help identify modifiable factors on which to base interventions. A systematic review undertaken by Lichtman and colleagues in 2010 found that the heterogeneity in reporting of both patient factors and process factors associated with re-admission made it difficult to draw firm conclusions. However, there were a number of included studies identifying factors which increased the risk of readmission. A number were unmodifiable factors, such as age, gender, type of stroke and co-morbidities, however lower physical function was found by Bohannon and Lee (2004) to be a

significant predictor of readmission. Physical function can be improved with appropriate rehabilitation and maximising physical function during the acute hospital stay has been shown in a recent study to reduce the risk of readmission. Andrews, Li and Freburger (2015) found the risk of readmission was reduced in people who received more rehabilitation during their acute hospital stay. This retrospective cohort analysis of all acute care hospitals in Arkansas and Florida found an association between increased dose of inpatient stroke rehabilitation and a reduction in risk of 30-day and 90-day readmission rates. This applied even when the results were adjusted for stroke severity and the presence of co-morbidities. The suggestion from this study is that rehabilitation may be able to reduce the risk of hospital admissions, but the study did not investigate post-discharge rehabilitation. A study by Andersen and colleagues (2000) in Denmark investigated the effect of post-discharge interventions, in addition to usual care, on hospital readmissions. The study compared follow-up from either a physiotherapist or a physician, offering education, problem identification and resolution, with usual care. A significant reduction in hospital readmissions was found in both intervention groups compared to the usual care control. This finding is not backed up by findings from ACTIV but there are possible explanations for the differences. The Danish study had a larger sample size and participants were recruited at discharge from acute services. This meant that Danish participants were on average three months and ACTIV participants over six months post-stroke at the time of recruitment. Research has shown that people are most vulnerable to readmission within the first 60 days after discharge (H.-J. Lin, Chang, & Tseng, 2011), so the Danish study may have been able to make a bigger impact, whereas early medical support (and some readmissions) would have occurred prior to recruitment to ACTIV, making ACTIV a more medically stable cohort.

6.6 ADVERSE EVENTS

ACTIV was a low-risk intervention delivered to people who had been discharged to the community. Safety advice was added to each exercise sheet and the DMC monitored for accidents and incidents regularly. The number of adverse events potentially related to the intervention was very low, but did approach significance. Further investigation reveals that relatedness was higher in ACTIV in severity category 1, corresponding to a low-level event, asymptomatic or with mild symptoms requiring no intervention.

Ethical approval was contingent on all possible risks being assessed and mitigated, so there was a low threshold for reporting adverse events. Several of the category 1 events were mild muscle soreness or a low level of fatigue following an increase in activity. These both fit the category of an adverse event and so were recorded as such, but they are actually the expected and even intended consequence of an unaccustomed increase in activity. The participant workbook given to everyone in the intervention group explicitly states:

“The following are some normal responses to exercise which you may experience:

- Stiffness
- Sore muscles / body
- Increased tiredness / sense of fatigue after exercising

These should pass in 2-3 days and are a healthy sign you are challenging your body.”

By following the strict guidelines laid down by the ethics committee we can be sure that ACTIV was not putting participants in the intervention group at a higher risk of injury than those in the control group. However, a number of the adverse events may not accurately reflect unintended or unwelcome consequences. It is interesting to note that such a high level of risk aversion may in fact be a hazard in rehabilitation. Egan and colleagues (2016) have discussed how the risk-averse culture within stroke

rehabilitation limits autonomy and can actively prevent the resumption of valued activities. The risk aversion which keeps people safe unwittingly opens up new and potentially larger risks. Patients are encouraged to concentrate on a narrow range of important activities so they do not become a burden, with little interest and even less emphasis on regaining what is important to them. It would not be desirable or even conscionable to expose patients to high risk when they are discharged from hospital, but in our efforts to remove risk entirely, we may unwittingly be depriving patients of the possibility of a more satisfying life (Egan, Laliberté Rudman, et al., 2016).

6.7 INTERVENTION FIDELITY

This section discusses the extent to which the intervention achieved fidelity across all aspects of planning and execution. Intervention fidelity is a measure of how closely a delivered intervention conformed to the research plan (Santacroce, Maccarelli, & Grey, 2004). Historically there has been limited consideration and inconsistent reporting of intervention fidelity (Devito Dabbs et al., 2011) and the use of vague descriptions to describe fidelity measures, has added to the confusion (Gearing et al., 2011).

Intervention fidelity is particularly difficult to ascertain when an intervention is complex (Hasson, 2010), which may partly explain the scant reporting of fidelity for investigations of exercise in people following stroke. This difficulty significantly affects the confidence that can be placed in results (Resnick et al., 2011) and the use of strategies incorporated in the design, training and delivery of ACTIV sought to address this problem. The following sections will discuss measures put in place during ACTIV to increase the level of intervention fidelity achieved.

6.7.1 Intervention Design

In addition to the systematic literature review the clinical input to intervention design was extensive. Five experienced physiotherapists, all of whom were academics, were

involved in the initial intervention design. It was refined by DT, SM and NS, all of whom have had clinical experience, the majority of which has been in neurological rehabilitation (SM currently divides her time between her academic position and a neurological rehabilitation practice).

6.7.2 Staff Training

The training protocols which came directly from the design of the intervention were clear and physiotherapists found them easy to follow. However the planned frequency of supervision and feedback was not able to be achieved in the ways suggested by Gearing and colleagues (2011). ACTIV was delivered by physiotherapists in four centres over a wide geographical area, so having a supervisor attending face-to-face sessions was impractical. In hindsight it may not have been explicit enough that one of the purposes of the contact with the expert physiotherapist was to encourage reflection and ensure that ACTIV was delivered as closely to the intention as well as the procedure as possible. It is clear from other research that clinical supervision was often not as successful as it could be due to a misunderstanding of its purpose (Hall & Cox, 2009). In the case of ACTIV most contact was about practical aspects and very little focused on the underlying principles of intervention delivery. The research conducted by Hall and Cox found that physiotherapists often were not really sure what to discuss in sessions of supervision and the self-generated nature of the contact for ACTIV physiotherapists may have exacerbated this concern. An investigation in the UK of supervision of physiotherapists delivering a trial intervention confirmed that therapists liked to have regularly scheduled contact with a structured agenda (Cox & Araoz, 2009). The researchers in ACTIV had felt that seeking assistance as needed would be helpful and would avoid an excess load on both physiotherapy staff and the expert physiotherapist but it may be that a more structured and regular supervision would have been helpful.

6.7.3 Intervention delivery

The ACTIV physiotherapists did not have opportunities to meet with each other during the trial which could have led to ‘drift’ away from protocol (Resnick et al., 2011). The finding that over 70% of all participants had both the dose and content of ACTIV delivered as per protocol shows this was not the case in ACTIV. The delivery of dose and content of ACTIV were relatively easy to monitor but the degree to which the physiotherapists enacted the philosophy and intent of ACTIV was harder to ascertain. Alteration of exercises by physiotherapists was dependent on two factors, the response of the participant to questions about exercise and activity and the observation of exercise execution. It was very difficult to establish the degree to which ACTIV was personalised to the participants to assisted goal attainment. These less measurable aspects of intervention fidelity are dependent on the interplay between participant and the person delivering the intervention (Devito Dabbs et al., 2011)

6.7.4 Intervention receipt

The degree to which the participants completed the prescribed exercises was monitored using self-report. Home exercise programmes are commonly prescribed for people with stroke on discharge from inpatient stay but it is not known how many people complete these exercises as adherence has rarely been reported (K. K. Miller, Porter, DeBaun-Sprague, Van Puymbroeck, & Schmid, 2016). In a cross-sectional study by Miller and colleagues, 89% of the 55 participants reported having been given a home exercise programme and 65% reported doing at least some of the exercises. The cohort of participants included in the study had to be within 6 months of concluding a physiotherapy programme, so had a similar time since stroke to the participants in ACTIV. By the end of ACTIV over 70% of participants reported maintaining at least some of the prescribed exercises and over 50% were still completing all the exercises. The degree of adherence to a post-stroke exercise programme, as opposed to just a

dichotomous report of the presence or absence of exercise, has to the best of our knowledge not previously been reported. By maintaining regular contact throughout the 6-month intervention ACTIV may have encouraged increased persistence with exercises.

6.8 STRENGTHS OF THE RANDOMISED CONTROLLED TRIAL

ACTIV had broad inclusion criteria, including a low threshold for cognitive ability and therefore recruited participants who often are excluded from intervention studies. A recent study found the prevalence of cognitive deficits following even a mild stroke was almost 50% (Jacquin et al., 2014). Exclusion of such a large number of the population, means that a potentially useful intervention may have no supporting evidence in people with cognitive deficits.

Approximately one third of the stroke population has some language deficit and although this is not usually an explicit exclusion criterion, interventions and assessment often require a level of language that means this group of potential participants is excluded at pre-screening (Ali, Bath, Lyden, Bernhardt, & Brady, 2014). During ACTIV intervention-development it was determined that participants had to understand and speak basic English and this criterion was broadened to include people with speech and language deficits (or English as an additional language) who had access to assistance from family or friends. Some participants with expressive dysphasia in the qualitative study which informed ACTIV (Saywell & Taylor, 2014) found the use of text messages beneficial for effective communication and in some cases better than face-to-face.

Despite ACTIV being a complex intervention, the combination of clear guidelines and procedures and comprehensive resources supported physiotherapists. It was designed as a stand-alone programme to be the next step after discharge from standard

physiotherapy and could be incorporated in to clinical practice with little alteration from its current form. The ACTIV physiotherapists appreciated the ability to personalise the programme within clear guidelines, having professional autonomy allowed clinical reasoning to ensure responsiveness to the participant. Previous research in implementation of complex interventions has emphasised the need to be able to include a degree of personalisation of any widely disseminated programme, to take account of the needs and personal preference of the recipient (Brady et al., 2011). Brady and colleagues (2011) also point out the importance of using quantitative and qualitative investigation of new complex interventions, to ensure the participant's experience was taken in to account.

6.9 LIMITATIONS OF THE RANDOMISED CONTROLLED TRIAL

Prior to the start of recruitment several steps were made to reduce barriers to Māori participants. The Māori health committee made suggestions to encourage Māori recruitment and retention in the trial including, offering a face-to-face explanation of trial information rather than an information sheet, explicitly inviting whānau³ and rewording some of the written information to reflect iwi⁴ differences among regions. One of the recruitment areas was a south Auckland district where 16% of the population identified as Māori (Winnard, Lee, & Macleod, 2015). Despite these steps only two participants recruited into the trial identified as Māori. This was disappointing but the difficulties of recruiting Māori participants has been previously documented. Selak and colleagues (2013) noted that additional recruitment strategies needed to be employed in a study of medication for cardiovascular disease to ensure good Māori representation. In their study the recruitment period was extended for Māori alone and lower thresholds were used for Māori in the screening process. This was not something that was able to

³ Maori term for extended family

⁴ tribal

be done in ACTIV, due to funding constraints and the already extended recruitment period. There has been discussion since the 1970's that non-Maori may not be best placed to understand the particular needs of Maori. Research by Maori for Maori has been frequently exhorted and would enable a more nuanced exploration of cultural factors that could improve Maori engagement in rehabilitation (Smith, 1999). There was not sufficient funding to allow the use of multilingual text which may have broadened the reach of ACTIV. We addressed that by the use of family and friends to translate but there may have been a small number of people who could have benefitted from ACTIV but did not have the requisite support.

When considering the low level of contact between the physiotherapist and the expert physiotherapist and the minimal advice requested about practice, it may have been better to have had a fixed schedule of contacts. A scheduled meeting with the expert physiotherapist would have required reflection and the ACTIV physiotherapist would have needed to articulate progress in intervention delivery. This would still have needed to happen remotely but the regularity of contact would have ensured more dialog with the expert; especially for the therapists who made contact less frequently.

ACTIV was not a multi-disciplinary intervention, the purpose of the study was to establish the degree a 6-month tailored exercise intervention could influence outcomes for people with stroke. The added complexity of managing an interdisciplinary team was considered to be too large an undertaking considering the mode of intervention delivery was relatively untested. This did mean that a number of potential goals may have fallen outside the remit of a physiotherapist. Interdisciplinary team goal-setting and management may have allowed participants to select from a broader range of activities.

A systematic audit of participant understanding of the programme could have been undertaken to establish participant receipt of ACTIV. Such an audit lay beyond the resources of this study but some assessment of participant understanding can be drawn from the qualitative findings.

6.10 GENERALISABILITY

Using a range of ages, both sexes and a range of disability levels, cognitive levels and language ability means that the results of this study apply to a wide group of people with stroke. The tension between internal and external validity is always present when selecting inclusion and exclusion criteria (M. Godwin et al., 2003). The results can be generalised to people with first-time stroke of the cerebral cortex; the most common lesion site for stroke. The use of four geographically separate locations and physiotherapists with a broad range of skills and experience means that results from ACTIV can be applied to a range of people from both rural and urban locations, whether they live alone or have support from family members at home. As discussed only two Māori were recruited; the lack of a Māori voice needs to be considered in the generalisability of the results in the wider New Zealand context.

6.11 SUMMARY

The randomised controlled trial has been discussed in light of current research. The approach to recruitment detailed the way challenges were planned for and managed. Characteristics of the physiotherapists showed that delivery of ACTIV during the trial was undertaken by physiotherapists with a broad range of experience who used the skills and resources from ACTIV training to achieve excellent intervention fidelity. For future use of ACTIV a structured approach to professional support from an expert physiotherapist will ensure fidelity is maintained as ACTIV is disseminated widely. Exploration of the data showed that participants experienced a significant and

meaningful change to their function, as measured by SIS3.0. The apparent contradiction between the primary outcome and the secondary outcomes of physical function may be explained by the SIS3.0 assessing changes over a 4-week period, as opposed to a single point in time. The randomised controlled trial yielded important information about effectiveness of ACTIV and the inclusion of participants who have previously been excluded from rehabilitation trials increased the generalisability of the benefit of ACTIV.

CHAPTER 7 QUALITATIVE ENQUIRY METHOD

7.1 INTRODUCTION

The qualitative study was undertaken for the purpose of understanding ACTIV from a participant's viewpoint. There has been very little investigation of the use of landline telephones or mobile phones for stroke rehabilitation. The exploration of participant experience of this delivery method has been virtually non-existent. The only authors who have investigated more than just physical changes after telerehabilitation using landline telephones or mobile phones as a delivery mode were Boter (2004) and Chalermwannapong, Panuthai, Srisuphan, Panya and Ostwald (2010). Both authors used questionnaires to investigate the impact of their intervention on quality of life. Questionnaires allowed participants an opportunity to offer feedback, but detail was limited by the narrow range of possible responses. It was important to ascertain if engagement in ACTIV was affected by the remote communication and relatively limited face-to-face contact with the physiotherapist. ACTIV was designed using established treatment principles but the method of delivery was new, so participants' impressions were important. Experiences from participants will enable programme refinement to better suit the needs of people after stroke either in subsequent research or in translation to practice. The study has been reported in line with the Consolidated Criteria for Reporting Qualitative Studies (COREQ) a 32-item checklist designed to promote complete reporting to increase rigour and subsequent trustworthiness of the findings of in-depth interviews and focus groups (Tong, Sainsbury, & Craig, 2007).

7.2 AIMS

The aims of the qualitative study were:

- To gain the participants perspective of the programme, to improve and refine the programme for use in practice.

- To understand the impact on participants of being part of a programme that relied largely on telecommunications to maintain their rehabilitation.
- To give context to the quantitative study findings.

7.3 RESEARCH QUESTION

What are the experiences, in particular the perceived benefits and challenges for participants in ACTIV?

7.4 STUDY DESIGN

A qualitative descriptive approach was selected to investigate ACTIV. Qualitative descriptive methods are ideally positioned to assist in intervention development and refinement and to inform dissemination and implementation (Pearson, 2004). They are frequently used in conjunction with quantitative investigation (Neergaard, Olesen, Andersen, & Sondergaard, 2009) to allow triangulation of information from multiple sources.

7.5 METHOD

7.5.1 Participants

Participants were eligible if they had completed ACTIV or had withdrawn from the intervention arm of the study for any reason including difficulty with the technology or dissatisfaction with the intervention. Participants were purposively sampled, to capture as wide a range of views as possible. The aim was to include people with a range of demographic factors, levels of disability and satisfaction with the intervention.

7.5.2 Recruitment

As each participant approached the end of ACTIV a research assistant recorded their participant ID number under each criteria that applied, in a grid shown below as Table 7-1. The decision-making grid had been designed by the principle researcher (NS) to

include participant characteristics of interest ensuring a diverse population was invited to participate in the study. NS was then able to stay blinded to allocation while purposively selecting participants. Selected participants were then invited to take part in an interview about their experience of ACTIV. If they agreed a letter (Appendix Z) was sent to arrange the date and time of the interview, at a venue of their choice. Due to the large number of variables across four sites, the initial aim was to recruit approximately 20 participants, with at least two participants from each geographical area. This ensured recruitment of participants who had been seen by a range of ACTIV physiotherapists. Exact numbers were finalised when data saturation was reached.

Table 7-1: Decision-making Grid to Ensure Diversity of Participants

Centre	Severity		Functional Category		Location		Age		Ethnicity	
	FAC 5	FAC 6	Upper limb	Lower limb	Rural	Urban	Over 65	Under 65	Other ethnicity	Māori
North Auckland										
South Auckland										
Christchurch										
Dunedin										

7.5.3 Data collection and management

Semi-structured in-depth interviews were conducted by a neurological physiotherapist who was an experienced qualitative researcher and she had not been involved in the intervention provision or outcome assessment of ACTIV. At the time of the interviews she was employed as a research fellow, following completion of a PhD and also worked as a neurological physiotherapist at a private clinic. Interviews took place in the participant's home or at a mutually convenient alternate location e.g. university or hospital outpatient department. The interviewer was not previously known to the participants and was able to reassure them that the interview was solely for the purpose

of information-gathering, to encourage frank disclosure. They were reminded that information would be useful in future planning for stroke services, whether or not they had found ACTIV helpful or not and regardless of whether they had continued any of the exercises (Braun & Clarke, 2006). Participants were encouraged to include family or close friends in the interview, particularly if they had had a role in supporting or facilitating their progress during ACTIV. Each interview lasted between .5 and 1.5 hours and all interviews were audio-recorded using a digital recorder. The interviewer used open-ended questions to ensure the participants had an opportunity to discuss all aspects of the programme (see Appendix AA, for indicative questions). Topics in the interview guideline included: what the intervention meant for the participant, any benefits derived from the intervention, interest in and barriers to continuing the exercises and ideas that would improve the intervention. The use of telecommunication to assist intervention provision was the feature that was new to all participants, so there was a focus on positive and negative aspects of its use during the programme. At the conclusion of each interview the participant was given an opportunity to add information not already covered. After each of the first four interviews the principle researcher (NS), listened to the interview and adjusted the subsequent questions to ensure themes of interest could continue to be explored and that there had been broad capture of new important information. After the first six participant interviews, theoretical sampling was used to guide further recruitment and interviewing to capture the stories of participants with different experiences and to challenge themes the researcher was finding in the early data (Charmaz, 2006). All interviews were transcribed verbatim; the principle researcher then reviewed each transcription whilst listening to the audio recording to ensure accuracy. Any unintelligible words or phrases were checked with the interviewer. Any references to visual material in the home at the time of interview such as “I’ll show you the manual...I did this exercise”, were checked

with the interviewer as soon as possible after the interview. Additional information gained in this way was stored as memos.

7.5.4 Data Analysis

Choice of analysis

Thematic analysis was selected to analyse the data set. An important distinction between content and thematic analysis in descriptive research, is the weight given to context in thematic analysis (Vaismoradi, Turunen, & Bondas, 2013). The context of answers was important in this study, as differences in experience may be dependent on non-ACTIV related factors such as living situation, previous life-roles and interests. It was important to put answers about the intervention in context, to assist in understanding who may benefit from this delivery method. The insights were viewed for factors that would allow a better match between the mode of delivery and individual patients. The data in this study were accounts of an experience of ongoing stroke rehabilitation, an area of practice which already has a significant research base, but delivered in a way that was new for the participants. Thematic analysis allowed findings from these data to add new information that will be important if telerehabilitation is to be used in practice. The choice of analysis meant that the resultant themes remained close to the data with a low–inference interpretation; the data were viewed as being accurate renditions of participant’s views on the topic. This does not mean there was no interpretation of the participants’ experiences, as interpretation-free analysis is not possible (Sandelowski, 2000b). The researcher’s background and beliefs influenced the choice of both method and type of analysis as discussed below.

Researcher bias

The process of analysis of the data was unavoidably influenced by the epistemological background of the researcher. The researcher conducting the analysis was a

physiotherapist and had a realist's world view which naturally influenced the selection of the study design and data analysis. For many years the physiotherapy profession was bounded by the construct of the body-as-machine, viewing people as little more than their component anatomical and physiological parts. In recent decades this has been criticised for allowing a careless disregard for the "subjective elements of human experience" (Nicholls & Gibson, 2010, p. 501). This has led to a gradual move away from a purely bio-mechanical view of body function and dysfunction. Despite the changing view within the profession, the majority of physiotherapy training is still entrenched in physical sciences with relatively little philosophical debate, which influenced the choice of study design and analysis. The ontological beliefs of the researcher required a method of analysis that stayed close to the original meaning of the participants' words and presented them in plain language. The results needed to be a rendition of events which stayed relatively 'at-face-value', increasing the likelihood of gaining general consensus among researchers (Sandelowski, 2000a). The plain English rendition of findings also made them more likely to be accessible to clinicians to help inform practice (Braun & Clarke, 2006).

Analysis process

The researcher listened to the interviews and read the transcription, noting down initial ideas, observations and impressions of each interview. The researcher then listened repeatedly to the audiotapes whilst re-reading the transcripts becoming familiar with the data. Interviews were then imported in to QSR International's NVivo 10, qualitative data analysis software, to assist with data management and coding. Very little was known about the area of using landline telephones or mobile phones in any form of rehabilitation and even less known in the stroke population. However, there was a significant body of research investigating stroke rehabilitation. Consequently, the process of coding data was primarily inductive and at a semantic level when participants

were discussing the use of the technology. Some deduction was used for parts of the data concerning patient experience of rehabilitation following stroke, a previously well-explored topic. Coding was done line by line, or in meaningful segments of text where a single line yielded incomplete information. This was done systematically across each data set. The entire data set was coded, with codes added as new phenomena of interest were found. Codes were then investigated for overlapping ideas or areas where the text was not quite captured by the code, some text was initially put under two codes. Each code was then clearly described to allow segments of data to be interrogated for fit. The data in each code were then checked and re-coded if they were not coherent with the description.

The codes were then viewed for broader overarching themes that may link them.

Themes were not selected solely on frequency of appearance of a coded idea. They were also selected if the idea captured an important issue related to the research question.

Due to the background of the researcher, themes were influenced by coded segments which were identified as being particularly pertinent to practice.

Rigour

During coding and re-coding there was a process of constant comparison with the original data sets and reference memos, to ensure that the meaning of the data within the context of the participants' interview fitted the description of the code.

The codes within each theme were checked for context, to ensure original meaning had not been lost and to ensure that the theme represented all the coded sections. Themes were named and defined and the relationship between themes was explored to ensure it was consistent with the original interviews (Vaismoradi et al., 2013). A researcher not involved with the study was asked to verify the categorisation of data (consistency check). The method and code definitions were given to the interviewer and an

independent qualitative researcher working in the area of neurological rehabilitation a week prior to an oral presentation of the findings to allow discussion and critique. This helped verify believability and congruence of the codes within the themes therefore improving rigour.

Following the presentation of findings and subsequent discussion there was some re-coding to ensure that each code reflected the participant data accurately. The process of writing the results yielded a number of iterations and refinements to the themes which were agreed upon by the researcher, the interviewer and the independent qualitative researcher.

7.6 SUMMARY

The qualitative descriptive data collection and thematic analysis was undertaken in a rigorous manner to establish participant's views of ACTIV, to refine the programme and to give context to the quantitative findings. The results of the analysis are outlined in the following chapter.

CHAPTER 8 QUALITATIVE ENQUIRY RESULTS

8.1 INTRODUCTION

The analysis of data from this study was subjected to a rigorous peer-review process to increase the confidence with which the results can be viewed. The chapter outlines characteristics of the participants recruited for the qualitative study and the themes drawn from the interview data. Each theme was presented in detail with quotes from participants that best illustrate the findings.

8.2 PARTICIPANTS

In total 21 people were approached to give their views and impressions of ACTIV and all consented to be interviewed. Characteristics of the participants can be seen in Table 8-1 below; characteristics that may influence the acceptability and utility for participants were collected. Ten of the participants were male and eleven female, the median age was 72 years (range 40-91 years), the majority of the participants identified as New Zealanders, despite the significant effort made to include a range of ethnicities. One participant was from Asia, one from Africa and two from Europe. Twelve of the participants had a function ambulation classification (FAC) of 6, representing independent ambulation. The remaining nine had an FAC of 5, indicating assistance or supervision needed with ambulation. No participant who had a FAC lower than 5 was included in the sample as there were very few participants in this category and none had completed the intervention at a time when the interviewer was available to travel. There were two broad categories of exercise, upper limb and lower limb and participants were eligible to work on one or both based on the criteria discussed in chapter 3. Once the criteria for one or both categories were met, participant and physiotherapist would work together to plan the exercises best aligned to the selected goal. Three fitted the criteria to work only on upper limb and three only on lower limb. Fifteen fitted the inclusion

criteria for both categories and all chose to engage in exercises from both categories.

Only three participants lived in rural locations and eighteen in urban areas. Ten of the participants lived alone and the remainder lived in a range of living situations, including living with a spouse, family members and friends. One of the included participants had withdrawn from the intervention due to a dislike of the text messages.

Table 8-1: Participant Characteristics Recruited in the Qualitative Enquiry (N=21)

Age (years)	Mean(SD)	72 (12.4)
Sex	male	10
	female	11
Centre	North Auckland	7
	South Auckland	2
	Christchurch	8
	Dunedin	4
Living situation	accompanied	11
	alone	10
Ethnic origin	European	19
	Non-European	2
Mobility level	more mobile	12
	less mobile	9
Eligible for ACTIV	both	15
	lower limb only	3
	upper limb only	3
Addressed with ACTIV exercises	both	12
	lower limb only	4
	upper limb only	5

8.3 FINDINGS FROM THE INTERVIEWS

8.3.1 Overview of the themes

The interviews elicited participant's perception of ACTIV and how it had influenced their rehabilitation. Four main themes were drawn from the data. Although each theme described unique insights from participants, we found the following interrelationships between the themes. The first theme, *not what I call physio*, expressed participant reaction to the different mode of rehabilitation delivery and provided insight into their understanding of what constituted physiotherapy. It portrays participants' initial response to ACTIV and highlights how the intervention differed from their expectation. The second theme, *there's someone there*, identified an almost universally expressed experience of a relationship which started in person and continued remotely. Despite a significant proportion of ACTIV being delivered remotely, an important and positive therapeutic relationship between participant and physiotherapist still existed which ameliorated potential disappointment at the reduced contact. The sub-themes identified the ways the physiotherapists demonstrated support and how participants benefitted from the relationship. The third theme, *making progress*, explored factors that moderated participants' ability to maintain and increase activity. The sub-themes revealed strategies which participants reported had helped them to continue rehabilitation and those they believed had hindered progress. The consideration of progress led many to consider longer term aspirations of *what I really want*. This theme revealed participants sometimes hidden or unexpressed hopes and plans for the future. The following section discusses each theme in detail with supporting quotes from participants who are identified by pseudonym. (Square brackets were used to enclose any text inserted by the researcher to clarify participant meaning).

8.3.2 *Theme 1: Not what I call physio*

The first theme relates to participant perception of the content and delivery of ACTIV. The overriding sentiment was that it was not what people were used to. The response to the mostly remote delivery of rehabilitation reflected participants' beliefs and preconceptions of physiotherapy and physiotherapists. The unfamiliarity was not necessarily viewed negatively but the lack of any hands-on treatment was reiterated by several participants as being a cause for concern; for some this meant it was simply not physiotherapy. George was happy with the programme he received and reported benefitting from it during the 6-month intervention and in his subsequent progress, but he did not recognise ACTIV as being physiotherapy delivered by real physiotherapists.

The girl who came and saw me there, she was not a physio as such.... she never did any physio with me but showed me the pamphlets and everything like that, what I'm supposed to do and how many [exercises] I should do (George).

For some participants, not having the hands-on element of physiotherapy was unacceptable, the perception was that unless you got an intensive manual work-out or were seen in-person regularly, the programme could not possibly work, self-directed exercises were seen as unimportant and unlikely to be effective:

...nothing beats the fact of a physio... coming to visit or you going to a centre, because it's more hands-on, this [ACTIV] it's not going to solve the problem because sitting at home doing your exercises without more input is not going to get you anywhere (Jenny)

None of the participants ever named a technique or particular therapy that was not possible because of the lack of physical contact. Some participants found the alternative forms of contact helpful, but despite this there was a sense of missing the face-to-face contact.

It's just too long between the physical contact, the phone, texts and things is a great idea (Clare)

The expectation of physiotherapy and rehabilitation post-stroke being hands-on in nature, was a view shared by many participants. However once there had been some experience of the differences involved in the remote provision of rehabilitation, there was often an acceptance. Many participants could see that even though it was not what they knew as physiotherapy, it did not necessarily detract from the effectiveness or acceptability of the programme.

Well, I'm quite a fan of more hands-on stuff but that's just me, I wouldn't say.... the lack of hands-on therapy made it less effective. (Alan)

I quite understand the alternative of a phone call and I don't mind that being there, I don't find it impersonal or anything like that. (John)

It was not a universal belief that physiotherapy needed to be delivered face-to-face to prescribe exercises and ensure rehabilitation was progressing. Many people welcomed a brief personalised communication that spoke directly to them and did not involve a complete treatment. It provided an input that was often all that was needed at the time; sometimes unexpectedly personal and relevant without being intrusive. Far from missing the personal contact and constant input, one participant stated:

it was an ideal situation rather than having to go all the time down to a physiotherapy department... one of the programmes was to pick out chocolate sultanas out of the bowl with the fingers, you know [to work on fine hand function], and the text... come through – 'hope you're not getting too fat' or something like that (laughs). (Jeff)

He valued the freedom and autonomy he gained from getting personalised physiotherapy in small amounts very regularly. Many of the participants expressed the

satisfaction of being able to be at home and ACTIV fitting in to their lives in a way they could control. It was convenient to have input that could be used as required.

...if someone is visiting occasionally and that constant contact you know, to me it worked really well....if.it [the text message] was right on teatime, I'd sort of just ignore it and then you know, look later. (Jane)

The novelty of the mode of provision uncovered how participants perceived physiotherapy and revealed a range of views about how well ACTIV could provide rehabilitation, despite not conforming to those preconceptions. Possibly the most vivid example of the way people view physiotherapy was from the previous participant who had stated throughout her interview that she found ACTIV very helpful and effective, and yet still did not quite accept that it was actual therapy.

...having someone on the end of a phone or the text message or visits, and that to me I found that really helpful and supportive because it was like ongoing therapy. (Jane)

The message was that ACTIV was not what people thought of as physiotherapy. Whether it could be useful for rehabilitation post-stroke appeared partly dependent on whether people could put aside preconceptions and accept a different delivery system. Some participants did not really like the remote contact but almost all were able to find an aspect of ACTIV that helped them feel that there was someone there to help. The next theme explores how participants related to the physiotherapists in different ways.

8.3.3 *Theme 2: There's someone there*

The next theme has four sub-themes, *encouraging me*, *get off your bottom*, *someone who cares*, and *learning something new*. They each deal with a different aspect of the role the physiotherapist fulfilled for participants in their rehabilitation. The overwhelming impression from the participant interviews was of a sense of not being

left to struggle-on alone but instead having someone they could continue to relate to in a variety of ways.

Sub-theme 1: Encouraging me.

The knowledge that there was someone who was encouraging your efforts and sharing satisfaction in your successes, seemed to be very valuable. The participants often remarked that the encouragement applied to more than just the simple encouragement to do prescribed exercises or activities. It seemed to have the wider application of being generally encouraging. Encouragement in this context fits with the dictionary definition of encouragement, as ‘something that makes someone more determined, hopeful, or confident in their ability to achieve’. Participants suggested that the hope and confidence the physiotherapists instilled, increased the chance that they would continue to stay active. Julie, found the encouragement from the regular contact, helped her maintain the motivation she had to continue.

...right from the start I was determined to achieve certain things... but I found that by having somebody either text and sort of, ‘keep up the good work’ or visiting um it did encourage me to keep going. (Julie)

Ongoing problem-solving was one way physiotherapists showed encouragement, looking for different ways to help the participant keep persevering. Jeff’s wife noticed the way the encouragement was enacted.

She [the physiotherapist] was terribly patient and she all the time gave encouragement like if he was struggling with something... she would say, well look let’s just try this again and hold it this way or pick it up that way. Little things but, you know, and like those little things that count. Never ever once made him felt inadequate, which I thought was such an important thing. (Jeff’s wife)

Sub-theme2: Get off your bottom

There was a sense from several participants that, left to their own devices they tended to get lazy or sit on their backsides and that regular reminders were necessary. Participants talked of the texts inducing a bit of guilt but this did not appear to be viewed negatively by participants. The feeling expressed by participants was of having in some way ‘let the side down’ if they didn’t exercise.

...if I missed exercises that day I felt a bit guilty, you know, ‘the girls are waiting for me to do my exercise and I haven’t done anything’ there so. (George)

Frequent text messages reminded the participants to continue to be active. Something as simple as a single text acted as a spur to complete an agreed activity for some.

...it was a good thing because it sort of got me off me bum and done these things, otherwise I wouldn’t have done it. I’m a lazy bugger, if you can excuse my language, but I always have been and things like that got me motivated. (Martin)

There was no evidence that the regular contact and occasionally slightly guilt-inducing texts were seen as too much. On the contrary, several participants and more particularly participant’s families, would have liked more of a ‘big-stick’ approach.

They were too easy and too nice to put it bluntly. I should have got a kick up the arse and told to get on with it. (Dan)

This participant felt that a large amount of external pressure was required to induce him to move. There was sometimes a belief that family and friends could act as the motivator and reminder but many found that extremely difficult. Dan’s wife expressed the sentiment of a number of other participants’ family members; they found it too much of a burden to be the caregiver and the person who ensured the exercises were done. Having someone else who was able to take over those regular reminders was a

relief. She expresses her concern about being the only one who was trying to help her husband maintain his activity level:

I mean I sit here and say to him, ‘you can’t sit here’ and I can’t keep trying to find things for him to do because then I feel as though I’m nagging. (Dan’s wife)

The feeling that the internal motivation for exercise and general activity seemed to have deserted them, led many of the participants to value the external reminders of the text messaging. However, there was a sense in some that this could not be relied on forever and that eventually it would stop and then they would be thrown back on their own resources. The same participant who described needing ‘a kick up the arse’ to motivate him to act, found it was hard to sustain and internalise the motivation between contacts:

Yeah it [your motivation] dies a natural death very quickly [referring to the time after any physiotherapy contact] (Dan).

There were a number of participants who finished the programme and ruefully admitted that what they had suspected would happen, had happened; the end of ACTIV was the end of their exercise regime. When asked by the interviewer if he knew why he had stopped the exercises John replied:

Because there wasn’t the same incentive and guilt, the guilt phone calls, you know, to keep me going. (John)

Participants needed varying levels of external motivation to maintain an exercise programme. For some the extra six months of ACTIV just deferred their eventual inactivity, for others it provided ongoing support and ideas that helped them find strategies that worked, to continue rehabilitation after ACTIV had stopped. The problems and difficulties that slowed or even halted progress, and the strategies that helped continuation of exercise and activity are both explored in 8.3.4 Theme 3: Making progress.

Sub-theme3: Someone who cares

Apart from any practical help or advice the therapists gave participants, there was a feeling of being cared for and supported. This was mentioned in the context of the personal qualities of the therapist who were often described as lovely, caring or sincere. For participants the knowledge that they hadn't been forgotten and that someone genuinely cared and was taking notice of them, seemed to be a very important part of ACTIV. Jane described the effect the text messages had on her:

I'd describe it as being very helpful from the sense that you feel as if you're in contact with somebody um, and so you're getting that support... emotional support as well... they [the texts] come through when you're feeling a bit down...so that would help sort of make you feel better and think, yeah there is somebody there. (Jane)

Many participants expressed a general sense of being remembered or cared for. The care was communicated using telephone calls and texts as well as face-to-face communication and was not necessarily particular to any part of the programme:

That was good, being contacted with each month, giving us a ring, saying how am I going, having a chat. That helped a hell of a lot, a hell of a lot yeah. (Martin)

Some of the participants had extremely caring and supportive family members who were with them a lot of the time, but even in those circumstances, the added care from a professional still seemed to be valued. The wives of two of the participants expressed the sentiment:

It was just nice for Sam know that somebody cared about him. (Sam's wife)

Wife [talking to Jeff]: So it wasn't just the exercises – it was just the overall support you were getting? [Jeff was agreeing with this strongly]. (Jeff's wife)

The physiotherapist was perceived by some, to have empathy in addition to a caring disposition. One participant had quite significant dysphasia and had difficulty speaking during the interview, but she very clearly expressed her perception that physiotherapists, with their experience of people with disability were in a position that perhaps family members were not:

It's someone who cares.....someone who knows [what you are] going through. (Clare)

For a few participants the situation was very different, the care and support shown by the physiotherapist was valued because they perceived there was very little from family members at home:

Interviewer: You didn't feel like your wife needed to be involved?

No well she's out Monday, Wednesdays, Fridays and Sundays. Golf, golf, golf, golf... (Peter)

...they [family living in the same house] never even asked what exercises or anything like that because they're busy with their own life. (Jenny)

Sub-theme 4: Learning something new

Some participants saw the programme as a time to learn new things, including more about exercises they could do, their stroke and other things that cropped up during the time they were alone. For many of the participants, outpatient or community physiotherapy had been of short duration. Their stroke still felt quite new, they were coming to terms with changes to their activity levels and still had a lot of questions:

...every time a physio person came I learnt something more...it was to me free knowledge because this is all a new ball game to me. (Dave)

Dave expressed a keenness to do exercises and had been trying to stay active between hospital discharge and starting ACTIV. He found the addition of regular contact from a

physiotherapist helped him find new ways of doing exercises. He was motivated and was exercising by himself but was unsure how he could progress his exercises:

If I've been sort of come home and that was it, left on me own I'd be scratching my head...sometimes if [the physiotherapist] would say something to me – god why didn't I think of that, you know. (Dave)

In addition to learning new exercises there was ongoing help to learn how to alter the exercises. One of the aims of ACTIV was to provide a transition from hospital physiotherapy to living independently, so it was also important that participants could try altering exercise for themselves with guidance as needed.

And that again was probably the beauty of having the communication process between the physio and me in that if I was finding things hard then she'd suggest other things.... (Jeff)

This suggests that for many the opportunities to continue learning were present not only in the face-to-face contacts but also remotely. Many of the learning occasions allowed participants the freedom to try things out with small amounts of input. They were able to develop strategies for themselves to help continue progress. The next theme discusses some of the strategies.

8.3.4 Theme 3: Making progress

This theme has five sub-themes. The first two expressed what participants believed had hindered progress. *I can't I can't I can't*, articulated a feeling of being unable to do things as before, and *things get in the way*, identified a series of health and external factors that seemed to conspire to stop progress. The other three sub-themes were all positive ways the participants had found to maintain progress. The third *success matters* expressed the idea that identifying even small improvements can encourage you to continue to make progress. The fourth *weaving it in* identifies progress made when

exercises and therapy become recreation or part of your everyday life. The final sub-theme, *keeping on keeping on* describes an attitude of determination to keep active no matter what.

Sub-theme 1: I can't, I can't, I can't

This sub-theme expresses the frustration and bewilderment many participants felt when not able to do things they could do before the stroke. For some this feeling did not spur them on to try to overcome the problem, it seemed to have the opposite effect, making them feel disconnected and incapable.

When you're struggling with something sometimes you actually shut off, you feel like I can't, I can't, I can't, I can't. (Jeff)

It was often difficult for family members to understand what the participants were feeling especially if they had made quite a good recovery. There was a sense that if you looked alright everyone forgot that you still had limitations. Several participants talked about hoping others would notice they needed extra help, until finally frustration overwhelmed them when no-one did. One participant talked about trying to manage some basic household tasks:

...and other bits and pieces where I physically can't and that...he [husband] forgets very easily because I look normal...and that's how it is. There have been a few melt downs on my part. (Jane)

For some participants there was a sense of thinking they were going to be able to do something, planning to do it and then just not being able to. This often curtailed social interaction and participation in activities they enjoyed:

I think I had the ability before the stroke, but what I'm finding now quite difficult to handle is, I will say to my friends 'yes I'll go with you to such and such a thing', and then when the time comes, I have to let them down. (Sylvia)

Sylvia was talking about physical limitations, especially a sense of tiredness but not all participants got overwhelmed because of physical limitations, sometimes it was the emotional toll of finding everything more difficult than prior to the stroke that led to the inability to do anything.

That was the last month, I wasn't able to do anything. I sort of got weighed down with things. (Bob)

Sub-theme 2: Things get in the way

There were several accounts of initial good progress in activity and exercise, which were stopped or even set back by external factors. One of the centres in the study was Christchurch in the South Island of New Zealand, which suffered a devastating earthquake early in the study. Christchurch participants found that the stress and practical considerations seemed to stop them doing exercises:

...it's why I wasn't able to do exercises, you know, we had so many engineers and things coming around testing things, drilling holes and.... the earthquake thing that's time consuming, you know. (Bob)

Some participants identified actual physical impediments to exercise, with one participating enthusiastically until a flare up of arthritis made any exercise so painful that he lost all interest in rehabilitation.

So for start off I quite enjoyed it then you get the pain, the shoulder it minimise to do the exercise...when you get constant pain all the time it restricts you from exercise. I got less and less interested... I couldn't concentrate, the pain took it away. (Jack)

Another participant had a serious infection and once recovered, found the progress he had made previously had been reversed.

...just before Christmas I had a kidney infection and that laid me low for, well I spent seven days in bed, 12 days on antibiotics and I couldn't even sit up,

couldn't stand, I couldn't walk, I couldn't do a darn thing and I'm just slowly coming right now. It's been put back several months at the moment I would think. (Peter)

With the majority of the participants being over 65, it was not surprising that they often have co-morbidities that interfere with rehabilitation after stroke. However, a number of participants who did experience setback from a variety of causes, still managed to use some of the strategies in the following three sub-themes, to overcome difficulty and continue to make progress.

Sub-theme 3: Success matters

Participants who acknowledged the improvements they gained seemed to gain a boost to their morale, which encouraged them to go on. There seemed to be an advantage in stopping to mark each small gain:

I found it very, very good, good back up good support, as I said I actually baked a banana cake just a wee while ago and some scones, now I haven't done baking for a long time. (Sylvia)

For many the incremental improvements kept them going on the exercises, it was a method to encourage exercise from an internal rather than external source.

It was good because it kept me motivated to do the exercises with the thought that improvement would result, you know. (John)

The opposite also applied, participants who had not seen improvement found that they did not want to return to previous activities. Bowling was a popular activity for many of the interviewed participants and the difference between a participant who was able to see evidence of success and someone who was not, was clearly illustrated. The first participant quoted below, Dan, chose not to return to bowling because he was not as

good as he had been previously, the second George enjoyed modest success on his return to bowling after his stroke which increased his motivation to improve further:

Interviewer: Was there some kind of plan for you to go back to bowls...?

Oh yeah, yeah I went back but I pulled out of the all the club stuff because I just be dead meat.

Interviewer: Are you saying that you're not very good at it or that it's difficult for you to go?

I never was a world-beater but I certainly never disgraced myself.

Interviewer: Do you feel like your bowling's got a lot worse and so it's not so fun anymore?

No that's exactly right. (Dan)

And they came and saw me there and slowly, slowly and the first month actually was very quick. I maybe my hand maybe was a bit like that [very flexed], not so quite like that but came there and after about six weeks I could hold the bowl and bowl and at the moment there I'd be about 80%.... I bowl there and do a bit of exercise and so on there. I'm getting better and better. (George)

Sub-theme 4: Weaving it in

This sub-theme expresses that for some, specific exercises became far less important once an activity was good enough to be reintegrated to normal life. The activity was not necessarily as skilled as it had been prior to the stroke, nor was it effortless. Participants seemed to have reached a threshold that allowed a degree of normalcy to be achieved. There were differences between participants but the common theme was that they were living their lives and the rehabilitation was subsumed in living.

For some participants this occurred when an activity that had started as therapy became enjoyable. Jane had re-gained a hobby she had enjoyed prior to her stroke. She had been encouraged as part of ACTIV to return to some basic knitting as an exercise to improve hand function, she describes here how it was not the same as before her stroke but has progressed as she persevered during her rehabilitation:

It's the different thicknesses of the wool, it's different patterns that type of thing [that were being used to progress rehabilitation] um and that, whereas I could say do a pair of booties in 4 hours [before the stroke], um now it sort of takes say 2 nights.

Interviewer: Right so is that double the amount of time?

Yeah, yeah, it's a lot slower but we actually do it without making any mistakes.

Interviewer: Yeah good and when you're doing that do you feel like that's a leisure activity for you?

Yeah, it's not an exercise

Interviewer: Right, OK that's interesting

No it's just leisure it's something I enjoy doing. (Jane)

A number of participants talked about phasing out particular exercises as functional activities became easier to manage. They transferred their efforts to something that was useful in daily life. Stopping their exercises was seen as a progression as the therapy became part of daily activity:

Interviewer: So can you tell me why you're not doing those exercises?

Because I didn't feel as though I want, need to do it.

Interviewer: So you feel like they're too easy for you do you?

Well no not really but I just felt as though I've completed that.

No I think with my walking stick I find, I think I'll be able to do more exercises. (Martin)

A slight variation on the strategies explained above was participants who were still doing exercises but were fitting them in to their ordinary lives. They no longer set a time to exercise but did a few repetitions weaved into their day. The following two participants used slightly different ways to incorporate exercises into their daily life, in a way that worked for them, without taking too much time or being an addition to their normal life:

...sometimes when I'm at the bench preparing a meal, I will try to stand on one leg. (Sylvia)

If you can incorporate it, like even say reach and grabs every time you want to pick up a pen or door handles, by the time a day's gone by I would have reached up and grabbed those door handles ...I'd hate to think how many times. (Alan)

Sub-theme 5: Keeping on keeping on

Those who expressed this strategy appeared to have made a decision to continue exercising and were simply sticking to it without regularly giving themselves the choice to give up. Some of these participants expressed a long-standing work-ethic. One participant used a metaphor from his working life as a contractor to describe his attitude to being part of ACTIV:

You agreed to work for that price; you have to do your best. And that's my theory. (Martin)

Some participants were extremely determined and continued with an activity with no thought of stopping, one of the participants had started the exercise programme and now stated:

I still do them every day, regardless. (Dave)

For others it was a case of dogged determination despite not really having very much faith in the eventual outcome.

Interviewer: And so although you don't sort of feel like they're that useful to you or that you don't really see how they're linked to those, why are you continuing with them?

Faint hope. (Keith)

The strategy of just keeping going no matter what, seemed to work for several participants. Later in the interview this particular man admitted that the strategy for sticking to exercise on the basis of faint hope had paid off for him:

They were about right because there was an improvement. It was slow but there was an improvement. (Keith)

Participants who employed one or more of these strategies seemed to maintain activity. Almost all the participants expressed a desire to improve, whether they were actively working on it or feeling overwhelmed by circumstance or ill health and managing to do very little. The final theme discusses what participants really wanted as their rehabilitation progressed.

8.3.5 *Theme 4: What I really want*

There was a very specific emphasis to the physiotherapists delivering ACTIV to focus on a participant's goal. The training programme for the physiotherapists focused on ensuring that as much as possible they found out what might motivate each participant, asking 'what do you want to do most?' We hoped to encourage participants to select an activity that would motivate them to complete exercises, specifically designed to work towards achieving the activity. Phone calls and text messages were designed to re-focus their attention regularly on efforts to attain their valued activity. It was therefore a very surprising finding that on direct questioning about the activity they had selected as being meaningful to them, many of the interviewed participants could not recall what it was, this participant gave a very typical response:

Interviewer: So as part of the programme you had something called "what I want to do most"? Can you remember what your, "I want to do most" was?
No, quite honestly. (John)

This does not mean that participants did not have goals nor that they were not working towards something. Several participants remembered what they wanted to achieve in very general terms but were not able to articulate where they were heading, by identifying an activity. A constant process of improvement was such a generalised hope

that it had not been registered by the participant or recorded as a goal by the physiotherapist:

Um, if I persevere, just perhaps next year, it might be better. (Sylvia)

I was all the time looking for something better in my physical exercises that would take me a step up, so always looking for a new way to improve this hand..... (Dave)

I'm planning to sort of until January or February I think, to be nearly 100% by February. (George)

What participants often expressed was a desire to return to how they were before or at least steady progress towards a more normal life. One participant who did recall his valued activity admitted to manufacturing what he wanted to do most so it fitted the programme, to get what he really wanted:

When they asked me what sort of activity I'd like to do and that, I deliberately picked the sport of cricket.... I only have one goal, I want to get back fit and healthy and doing everything I used to do before..... All I did was pick one aspect of that [returning to a previously enjoyed sport], coz they couldn't target the programme to an overall goal as unfocussed as that ... (Alan)

As already seen in the literature goal setting is far from straightforward and the vast majority of participants spoke with huge interest and enthusiasm about making small improvements, an equally large majority had no memory of the goal so carefully negotiated 6 or so months before.

8.4 SUMMARY

The four themes drawn from the data investigate participant perceptions of a new way of delivering physiotherapy. Preconceptions of what physiotherapy should be, meant that many participants found that *ACTIV* was *not what I call physio*. This was not

necessarily a negative feeling. Some participants missed the hands-on treatment but there was also an acceptance and appreciation of a delivery method that fitted in well with their lives and which gave them a ‘little and often’ encouragement to exercise. ACTIV had the effect of making most participants feel that they had a relationship with a physio and that, *there’s somebody there*. This was helpful in a number of different ways, depending on what the participant needed at the time. The contact helped many participants to find strategies to continue *making progress*, although some people found a variety of internal and external obstacles limited their progress. All participants had a view of what they wanted for the future but very few were able to articulate it as a specific goal. The notion of *what I really want* was often far less specific and had more to do with forward movement and continued improvement than any ultimate goal. The results helped the researchers understand the experiences of participants. It became clearer which parts of the programme were the most help in encouraging activity and which may need modification. The results are discussed in the following chapter.

CHAPTER 9 DISCUSSION OF QUALITATIVE ENQUIRY RESULTS

9.1 INTRODUCTION

Four clear themes were found in the results of the qualitative study exploring participants' impressions after participating in ACTIV. In this chapter the results were discussed and each theme viewed in the light of current research in the area of stroke rehabilitation. Where relevant literature could not be found in stroke rehabilitation, a broader view of the literature was taken.

9.2 PARTICIPANTS

Use of a sampling grid ensured recruitment of a representative sample of ACTIV participants. The recruitment of 21 participants also ensured a rich and varied exploration of participant experiences, gaining not just code saturation but meaning saturation (Hennick, Kaiser, & Marconi, 2016). The age range of included participants was broad and spanned the five decades (40-90 years of age) during which stroke prevalence increases in the New Zealand population (Tobias et al., 2007). There was ethnic diversity in the study sample, including participants from Europe, Africa and Asia. One group who were not represented were participants with a low FAC of 4 or below. This represents participants who were unable to walk or who needed supervision to manage safely. There were very few people who fit this criterion in the ACTIV cohort, as the majority of people with this level of mobility require rest home care and ACTIV did not recruit from rest homes. The participants who did fit this criterion had not finished the programme when the interviews were scheduled.

Whilst only three participants came from a rural location, several of the locations within the urban environment were still a significant distance from services and were not necessarily close to other amenities or public transport. No attempt was made to

ascertain the exact living situation for participants, beyond asking if anyone else lived in the property with them. People who were supported by helpful neighbours or friends still fitted the ‘lives alone’ category and those who lived with family members with whom they had minimal contact were not categorised as living alone. No attempt was made to quantify the impact location and living situation may have on an individual, rather the aim of the qualitative enquiry was to gain a wide range of perspectives as possible. As the study progressed, people with differing perspectives to those we had already interviewed were sought. The credibility of the results was considerably improved by all invited participants giving consent and being interviewed. The inclusion of people who had found the intervention unsatisfactory in any way was important. Inclusion of one participant who had not found ACTIV beneficial due to a dislike of texting and one who had withdrawn early due reaching all their goals, added to the diversity of experiences captured.

9.3 THEME 1: NOT WHAT I CALL PHYSIO

9.3.1 Perception of physiotherapy

The use of telerehabilitation is relatively new in the area of stroke rehabilitation and may be a natural next step for the profession. Given the novelty of the delivery method, it was not a surprising finding that there appeared to be some resistance to its adoption. The beliefs about what physiotherapy is and what physiotherapists do when treating patients, seemed to lie behind some of the participants’ negative perceptions.

Physiotherapy was founded in 1894 by the formation of the Society of Trained Masseuses (STM). Prior to that time massage was frequently associated with prostitution and the STM legitimatised and sanitised massage, bringing it into the arena of medically sanctioned healthcare practices. The STM was the forerunner of the Chartered Society of Physiotherapists (CSP) (Nicholls & Cheek, 2006) and the

association with massage has ensured that physiotherapy has its roots in hands-on treatment. Many physiotherapy organisations world-wide, use hands on their branding and logos, so it is logical for the general public to believe that manual physiotherapy techniques are synonymous with physiotherapy. Although in many physiotherapy practices massage has lost its position as the mainstay of treatment, manual therapy remains a significant part of many physiotherapist's practice (Evans, Yeung, Markoulakis, & Guilcher, 2014). Recently there has been considerable discussion on the appropriate balance between manual therapy and a hands-off approach, particularly in the treatment of musculo-skeletal disorders, with differing viewpoints expressed (Jull & Moore, 2012; Lluch Girbés, Meeus, Baert, & Nijs, 2015; Zusman, 2013). Many physiotherapists feel the profession is in danger of completely discarding a core skill but the opposing view contends that a balance is required between hands-on and hands-off treatment. In the area of neurological physiotherapy there has also been a gradual move away from 'the laying on of hands' towards more focus on restoration of movement and function using task-related training (Rensink et al., 2009; Salbach et al., 2005) and strengthening (Dibble et al., 2006; Pak & Patten, 2008). The general move away from relying heavily on manual techniques in many areas of physiotherapy practice, has been reflected in our national professional body. Physiotherapy New Zealand recently re-branded, replacing the image of a person superimposed on a hand with an abstract image and using the slogan 'movement for life'. International professional organisations also reflect the primacy of activity, with the World Confederation of Physical Therapy (2011) having the stated aim of restoration of movement and function. Hands-on therapy is not physiotherapy, it is one modality used to reduce impairments in an effort to improve function and participation.

For patients with neurological disorders, there have been concerns expressed that manual techniques are not always warranted or effective in achieving improved function

or participation (Winter et al., 2011) and that a greater emphasis on helping patients with self-management and problem solving would be beneficial to long term progress (F. Jones, Livingstone, & Hawkes, 2013). There is clearly a need to offer physical support and assistance during acute stroke treatment (Askim et al., 2012) but as treatment progresses there needs to be an increasing emphasis on problem-solving and a return to autonomy; the provision of treatment remotely seems a logical next step after face-to-face treatment to continue to encourage these skills.

In direct contrast to the move towards increased patient autonomy being debated in current literature, many participants in the ACTIV study viewed physiotherapy as synonymous with hands-on therapy. The initial belief of some participants was that the preferable or best therapy was hands-on and that remote assistance to encourage independence and autonomy could only ever be a compromise. The opinion was not universally held and changed for some as they experienced ACTIV, however if remotely delivered physiotherapy is going to be considered for use in clinical practice as part of the continuum of care, it is important that we do not unwittingly set patients up for disappointment by limiting the opportunity for independence early in rehabilitation.

The provision of physiotherapy in the acute stage following stroke, is when strong impressions of post-stroke physiotherapy are formed. A recent review of patient's hospital rehabilitation experiences, showed that at the start of their inpatient stay many patients viewed opportunities to practice activities as very important (Luker, Lynch, Bernhardsson, Bennett, & Bernhardt, 2015). This frequently could not be accommodated by the hospital staff, who discouraged activity without supervision. The resultant inactivity tended to reduce motivation and left many patients feeling bored and unstimulated. Participants in this study expressed feelings of disempowerment which were frequently a result of "restrictions on participants' acts of independence or access to information..." (Luker et al., 2015, p. 1705). This review pooled the results from

thirty-one studies, suggesting limited encouragement of self-management and autonomy in acute stroke services may be widespread. The early experience of independence being discouraged may be reinforced during a hospital stay. Hospital policies are designed to ensure patient safety and minimise the risk of falls. Patients have to wait for staff to accompany them to the toilet or bathroom (Gustafsson & Bootle, 2013). Reduced staff numbers means that wheelchairs are frequently used for those trips to reduce time taken, when independent mobility would be possible and preferable. There is evidence of a correlation between mobility and self-efficacy (Korpershoek et al., 2011), so it is possible that limiting mobility may have a deleterious effect on self-efficacy for regaining independence. Additional support for this view can be found in a qualitative enquiry which explored participant perceptions of their rehabilitation (Dixon, Thornton, & Young, 2007). Participants talked of pushing their limits and several voiced a reluctance to ask staff for help, finding small increases in independence hugely significant and satisfying.

9.3.2 The balance between remote intervention and meaningful contact

The design of ACTIV included a combination of face-to-face contact, telephone calls to allow synchronous communication and texting nudges to encourage on-going behaviour-change. The timetable of each element included more contact initially to ensure safety and to foster a relationship with the physiotherapist. For that reason, two face-to face visits (the initial visit for assessment and exercise prescription and the first follow-up visit, to check progress of those exercises) were scheduled within the first two weeks of starting ACTIV, the relationship could then be built-on via the two remote communication modes. Frequency of contact was reduced as the end of the programme approached to limit dependency. Each participant had one physiotherapist for the 6-month intervention, who conducted all phone calls and sent all the text messages manually. This helped maintain an important focus of ACTIV, to tailor all

communication towards achieving a valued activity. The consistency of physiotherapist ensured accurate and up-to-date knowledge of exercises and activity levels, so each text was pertinent to the participant. There were several discussions when developing ACTIV, about the choice between automated and customised text messages. Some previous text messaging interventions had used automated text messages (Schwerdtfeger, Schmitz, & Warken, 2012; Whittaker et al., 2011), which would increase convenience for a therapist and reduce cost to the service if the intervention was rolled-out as standard practice. For the purpose of this study, the decision was to use manual personalised text message. This decision was supported by a systematic review by deJongh, Gurol-Urganci, Vodopivec-Jamsek, Car and Atun (2012), who investigated studies using text messaging to encourage self-management in long-term illness. The only study in the review to show improved health status from text messaging, encouraged personalised two-way communication. Whilst ACTIV did not have an explicit plan for two-way text communication, some participants did reply to messages because the messaging was meaningful. Texting was part of a two-way communication process, because a relationship had already been established by face-to-face contact and was also maintained by the telephone calls. The decision to personalise the text messages appeared justified by the many ways that participants referred to roles the physiotherapists were able to fulfil during the programme. Automated text messages have to be generic and take a mid-ground position, to ensure they could not be misunderstood or be unwittingly offensive. An automated text message service could not add the level of personalised humour or empathy obvious in some of the encounters in ACTIV; two examples related in the results, illustrated this well:

1. Text messages from the physiotherapist, telling the participant she hoped he wasn't getting fat because she had prescribed an exercise picking up chocolate raisins to improve hand function.

2. Text messages very firmly reminding a participant to exercise because he had already identified to the physiotherapist that he considered himself lazy and in need of a ‘bit of a kick’.

Both examples were related by the participants as evidence of the excellent understanding the therapist had of their situation and progress. Theoretically it would be possible to replace all but the initial physiotherapy assessment in ACTIV with automated text messages. Any change to the intervention which reduced physiotherapy input and replaced it with automated messaging, would reduce cost. A recent study investigating the provision of text messages to participants with coronary heart disease, reported that the cost for automated text messages, four times per week for six months was around \$10US (\$15NZ) per participant (Chow et al., 2015), considerably cheaper than any intervention requiring a physiotherapist’s time. For ACTIV there was a trade-off between the low cost of minimal personal contact and continuation of meaningful personal communication to enhance the relevance of the messages. An approach was selected to maintain a relationship whilst providing only four face-to-face contacts, this included an emphasis on personalising the text messages. The next theme highlighted some aspects of the relationship that were important to participants.

9.4 THEME 2: THERE’S SOMEONE THERE

9.4.1 The person who is there, really matters

The connection with the physiotherapist was very important to almost all participants. The value they saw in the connection did not seem to be dependent on either their initial impressions of ACTIV or reliant on physical visits. Even some participants who would have preferred more face-to-face encounters, commented favourably on the physiotherapist’s empathy and care. Many participants appreciated the pragmatic value of the physiotherapists who were able to provide such things as additional information

and reminders to keep working. However, there was a strong emphasis on human characteristics and a caring therapeutic relationship. The level of empathy with and understanding of the participant's situation was highly valued. This may have been assisted by the decision to have one therapist undertake the entire programme for each participant. The comments about specific characteristics and actions which demonstrated care to the participants also suggests that there are characteristics of individual therapists that are important in a therapeutic relationship. Besley, Kayes and McPherson (2011), investigating the therapeutic relationship in physiotherapy found a number of important themes in studies considering the patient and physiotherapist points of view. An interesting finding agreeing with the current findings, was that relational aspects of treatment such as friendliness, empathy and kindness, featured very highly in patient perception of a positive relationship. In another study of therapeutic relationship in the context of community physiotherapy, the importance of providing more than just physical input was clearly articulated. The caring aspect of the relationship was very important, leading the authors to suggest the need to be concerned with *how* we practice not just *what* we practice (Tasker, Loftus, & Higgs, 2012). In a study by Peiris Taylor and Shields (2012) the authors went further, finding participants placed a higher value on caring and empathy of physiotherapists than on either the content or the amount of physiotherapy they received during inpatient treatment. We had the perception at the start of ACTIV that having only four face-to-face visits might have meant the relationship between participant and physiotherapist would be a less important aspect of the programme, the results suggest this was not the case. Kindness, caring and empathy were encapsulated in a sub-theme in the theme *there's someone there* showing that these traits were viewed as both important and manifest in ACTIV physiotherapists. Recently Campling (2015), made a case for the application of intelligent kindness in healthcare, describing the concept as a kinship which promotes a

‘virtuous circle’. Simply, kindness builds trust and improves the therapeutic alliance, leading to better outcomes for patients. This suggests that there may be physiotherapists more or less suited to providing a remote programme, where kindness and caring will need to be clearly articulated in a short contact period. Consideration of how to increase the likelihood that those qualities will be found in future physiotherapists is addressed next.

9.4.2 Ensuring intelligent kindness in physiotherapists.

In 1990 a discussion paper identified empathy as an important characteristic for physiotherapists (Davis). The author questioned if it could be taught in physiotherapy education and argued that it may not be possible. Empathy has been shown to be extremely important in a therapeutic relationship but the contention that it is an inherent trait rather than a teachable skill suggests that some physiotherapists may be more effective than others at forging a therapeutic alliance with patients. Empathy is described as being “a therapeutic presence for patients... more than knowledge and skill alone; it is also composed of a compassionate understanding of the patient”. Davis (1990, p. 36) did go on to suggest that empathy may not be able to be taught but probably can be facilitated, so it is vital that we educate and mentor our students during their undergraduate programme of study. A study was undertaken in Norway to establish if the need for care and empathy were evident to first year undergraduate physiotherapy students. The authors found that despite an emphasis on ‘curing’ and a biomechanical focus, students were aware of times when an educator demonstrated care and empathy towards them and were able to consider how they could incorporate these skills in their own practice (Dahl-Michelsen, 2015). The unspoken messages gleaned from the way educators treated students appeared to have an impact on students. Educators need to ensure that they model behaviours that have the possibility of influencing students’ future practice. A study in England investigated a different

approach to increase student's empathy and care for patients. An on-line archive of patient narratives detailing perspectives on their experience of illness was used during education of healthcare students, including physiotherapists. Educators found this was a less contrived way of introducing difficult topics for discussion. The findings from this study suggested that hearing directly from patients with a variety of health conditions gave students an increased empathy and a clearer understanding of patients' expertise in their own condition. Educators and students both felt this could be translated into the clinical setting (Powell, Scott, Scott, & Jones, 2013).

9.5 THEME 3: MAKING PROGRESS

9.5.1 Coping with constraints

For many people stroke occurs amid a constellation of other health problems that increase with age. Forty-six percent of patients admitted for stroke rehabilitation will have evidence of coronary heart disease, 40% will have diabetes mellitus (Black-Schaffer, Kirsteins, & Harvey, 1999). However, after stroke, additional impairments may further limit previously enjoyed activities. Increased age is significantly correlated with an increased risk of falls, particularly early after stroke (Wagner, Phillips, Hunsaker, & Forducey, 2009) and approximately 30% of people post-stroke are affected by shoulder pain which limits function (Adey-Wakeling et al., 2015). The cumulative incidence of depression up to 5-years post-stroke is 39-52% with an OR of 2.94, (CI 2.37–3.64) of becoming depressed compared with healthy people of the same age and socio-economic status (Wikman, Wardle, & Steptoe, 2011). The study by Wikman and colleagues (2011) also found that stroke decreased quality of life significantly compared to other chronic health conditions such as diabetes and coronary heart disease, having a stroke with multiple other health conditions decreased quality of life even further. The results from ACTIV participant interviews indicate the presence of many of these co-

morbidities. A number of the participants discussed the ways in which health problems impacted negatively on their ability and willingness to engage in exercise. Problems encountered by the participants were both transitory infections and injuries and long-standing health conditions. For rehabilitation to be effective it is important to consider how to help people to engage in meaningful activity in daily life, despite their restrictions. There were a number of participants who expressed positive and hopeful emotions about their lives, despite significant disability and uncertain health. This accords with Ellis-Hill's model, of learning to view disability as part of life, not allowing it to dominate, and viewing rehabilitation as a transition process (Ellis-Hill, Payne, & Ward, 2008). The skills required to help people following stroke view their lives hopefully and work towards what they value will be considered in the next section and in goal setting 9.6.1.

9.5.2 Finding strategies

There is recent evidence to suggest that regularity of contact using text messages can lead to significant changes in behaviour. A large randomised controlled trial investigated the effectiveness in producing modifications in life-style, of adding four text messages per week to usual care for participants with coronary heart disease. The authors reported significant changes including a reduction in smoking and an increase in activity levels for participants in the intervention group compared to a usual care control group (Chow et al., 2015). Findings from ACTIV participant interviews concur with the findings of Chow and colleagues (2015) that regular ongoing contact helps to encourage changes in behaviour. In the case of ACTIV this meant maintenance or increase in activity in the majority of participants during the 6-month intervention. However, the importance of any intervention attempting to effect behaviour-change is to help people internalise strategies, so they are no longer reliant on external prompts. There were some hopeful signs from this study to suggest a permanent change may be

possible. Many participants in ACTIV had developed their own strategies to help sustain activity to continue making progress. None of the ways they described were explicitly taught by the ACTIV physiotherapists but each appeared to be based on either the specific prescribed exercises or advice to work at re-gaining activities. This gives some weight to the belief that the regular contact in ACTIV was at least partially responsible for the strategies that helped participants to increase activity. The quantitative results from the RCT were required to ascertain if these strategies had been effective in sustaining activity beyond the intervention phase and whether any changes persisted at the 12-month follow-up assessment.

9.5.3 Enhancing self-management

The length of time post-stroke for people to feel ready to undertake self-management varies considerably (F. Jones et al., 2013). Many people are not ready to take over their own management at discharge from inpatient treatment, hence the need for on-going input and support (Satink, Cup, de Swart, & Nijhuis-van der Sanden, 2015). A recent study highlighted that giving the right amount of support whilst allowing patients to direct their own progress is a difficult balance (F. Jones et al., 2013). The skills of the individual healthcare professionals to facilitate self-management are important and can have a significant impact on a patient's motivation and empowerment to fully participate in the direction of their rehabilitation (Satink et al., 2015). Recent research has also found the attitude of physiotherapist to self-management to be critical. Norris and Kilbride (2014) describe a reluctant sharing of information with their patients by some physiotherapists, born out of a well-meaning belief that they know best and possibly also an unwillingness to share power. These authors describe a benign dictatorship in stroke rehabilitation which can give way to a reluctant democracy, as self-management strategies become embedded. The reluctance to share power and encourage autonomy may be motivated in part by concerns for patient safety. Norris

and Kilbride (2014) found that when physiotherapists saw self-management as an abdication of responsibility for patient well-being or safety, it was unlikely to be done well if at all.

It cannot be assumed that all physiotherapists have the skills to encourage and support self-management. Programmes designed to enhance patient self-management need to undertake training and education of the staff prior to implementation. A recent study of the reflections of healthcare professionals following use of a self-management programme found a range of factors influenced its successful implementation (F. Jones et al., 2013). It was evident from the results that to achieve confidence and competence to facilitate successful self-management, staff need a clear understanding of underlying theoretical models, an appreciation of the complexities of self-management and an ability to be self-reflective after encounters with patients. Reflecting on the training given to the ACTIV physiotherapists, there was significant training prior to the start of participant contact which included theoretical underpinnings of ACTIV. Support was in place for physiotherapists to access help throughout the programme as required, however more mandatory contact may have been useful given the length of the trial. Refocusing on underlying principles by sharing case examples throughout the programme may have been beneficial to encouraged self-reflection.

9.5.4 The patient's role

In rehabilitation a significant proportion of the responsibility to maintain activity falls on the patient. This is particularly true of any remotely delivered therapy which has a small component of face-to-face contact. In ACTIV there was evidence of participants who sustained effort and motivation during the intervention and those who did not. Lack of motivation is often given as a reason why patients do not continue rehabilitation, with an acceptance that it is part of their personality (Jurkiewicz, Marzolini, & Oh, 2011). There has been considerable debate in recent years about the

construct of motivation; how much of it is dependent on an intrinsic trait and how much on external influence and social setting (Maclean & Pound, 2000). An investigation was undertaken of participant motivation during stroke rehabilitation (Maclean, Pound, Wolfe, & Rudd, 2000). Individuals were selected to participate if the professional rehabilitation staff reached consensus that they fitted in to either a high or low motivation group. Participants were interviewed to explore their attitudes and beliefs about rehabilitation. Participants with low motivation were more likely to find the process of rehabilitation unclear and not to see a link between therapy and achieving a desired goal. The results from the qualitative enquiry in to ACTIV demonstrate that therapists and patients frequently have an entirely different understanding of a goal and how it might be achieved. It is possible that this may cause misunderstanding. Patients who are confused about both the process and the end result of rehabilitation may appear unmotivated. Findings from the study by Maclean and colleagues (2000) showed support and encouragement from staff were factors that participants identified as increasing motivation. It appeared that motivation was strongly related to external influence, the complex interactions between individuals and their wider social environment. This finding aligns with results from ACTIV with participants describing increased activity and persistence with exercise, suggesting that regular short contacts may be a useful tool to encourage and motivate. An understanding of the complexity of the construct of motivation and the selection of appropriate support may reduce the tendency to ascribe so much responsibility to patients.

9.6 THEME 4: WHAT I REALLY WANT

9.6.1 Goal setting

As discussed in Chapter 3 patients have reported that having control and direction in their rehabilitation helped with self-efficacy (F. Jones et al., 2009). The question ‘what

do you want to do most?’ used in the ACTIV research, was inspired by the work done by Leach and colleagues (2010) to allow participants the freedom to select anything that might motivate them. The strategy was not wholly successful and there are several reasons that may account for this. Physiotherapists have long been exhorted to use SMART (specific, measurable, achievable, relevant and time-bound) goals; the belief has been that achievable goals increase motivation. However, in a consensus document in 2009 a working group suggested that the ‘A’ in SMART, should more appropriately denote ambitious (Playford et al.). The authors note that the process of modifying a patient’s goal to allow for achievability may remove it from their control. It has been noted that even when there is agreement about collaborative goal-setting, patient’s expressed wishes are rarely unmodified by the physiotherapist and frequently are transformed into a more realistic goal or changed to allow them to be easily measurable (Barnard et al., 2010). Healthcare providers are already in a powerful position relative to a patient (Ellis-Hill et al., 2008) so patients may be compliant with modification of their stated desire into an achievable goal, without any obvious coercion taking place. A study by Lloyd, Roberts and Freeman (2014) illustrated this, finding that physiotherapists often reported a goal-setting process to be easier with patients who were realistic. A study by Soundy and colleagues (2010) explored physiotherapists’ beliefs around hope for recovery in patients after stroke. The authors found some physiotherapists felt that allowing a patient to reach for an unrealistic goal may be detrimental to both their well-being and the trust they have in the therapist but that removing all hope was wrong and likely to reduce motivation. There was significant skill required to negotiate the ground between retaining a patient’s hope and being honest about expected outcomes. The unpredictability of achievement and the risk that some goals may mean a patient puts their life on hold in anticipation, adds to the

complexity of establishing a goal that will help motivate and encourage ongoing engagement in activities likely to improve outcomes.

In the training for ACTIV we emphasised that the physiotherapists should encourage selection of ambitious rather than achievable goals to increase motivation. The inability of the majority of participants during their interview to recall their selected goal suggested that goal-setting had not elicited a really meaningful goal. It is possible that long-held ways of working meant that physiotherapists found it hard to think beyond achievable goals, to help participants identify activities important enough to be memorable. However, it may not be a failure of the physiotherapists to elicit a goal, but the participants generalised hope of improvement, which demoted any goal to a secondary consideration. Evidence for this comes from the finding in ACTIV that all participants who were eligible to work on both upper and lower limb exercises did so, regardless of goals. This strengthens the possibility that participants simply wanted to do all they could to improve as much and in as many areas as possible, without being particularly strategic in aligning exercises with agreed goals. A few participants had hidden their goals from the physiotherapist or had dismissed a goal as unrealistic, with the physiotherapists' acquiescence. Some of the goals that participants mentioned in the interviews were goals a physiotherapist may not have all the skills required to address fully, for example returning to driving in a safe manner. ACTIV was a programme undertaken by a physiotherapist alone and as such had to confine the valued activity elicited in 'what do you want to do most?' to their scope of practice. This may have restricted participants to a secondary goal, which was not as memorable.

Previous research made it clear that linking exercises and activities directly to a meaningful activity was very important to participants (Saywell & Taylor, 2014) so strenuous attempts were made to ensure that exercises were linked to goals. The training for the physiotherapists delivering ACTIV stressed the importance of relevance. This

aim was supported by Luker and colleagues (2015) who reported that participants became discouraged if subjected to pointless therapy, which seemed to have no link to real life activities. The number of participants who could not easily or specifically recall their selected goal suggests that if we want to use a valued activity as a goal, we have not yet found a way of eliciting one meaningful enough to be memorable, let alone motivating. However, a very interesting finding was that almost all participants were interested and actively working towards improving a general area of physical function to get better or get back to normal. Neither of these aspirations can be fitted in to the parameters normally reserved for goal-setting but agree with a finding by Laver, Halbert, Stewart and Crotty (2010). These authors found that most participants who were asked about goal-setting, during acute care, rehabilitation and six months after stroke, consistently reported just wanting to get back to normal. They also reported participants having difficulty remembering goals, or their goals being very non-specific.

In light of these findings it may be tempting to suggest that the emphasis in rehabilitation should be on continuous subjective improvements. However, it is unrealistic to think that therapy funding could continue with no ability to measure improvement. Some outcome measures such as the Motor Activity Log (MAL) capture a range of day-to-day activities people consider important after stroke, using self-report and a qualitative component. Using patient report measures helps to include the sense of ongoing improvement but improvements may happen in domains that are not routinely measured in rehabilitation, such as self-efficacy.

Despite significant literature in the area of goal-setting, there is very little evidence of its effectiveness in changing the outcomes we currently measure, and no consensus on the way goal-setting should be undertaken (Sugavanam, 2013). Siegert may have hit the mark in his 2010 paper entitled 'Goal-setting in rehabilitation: perhaps it is rocket science'.

9.7 SUMMARY

The area of telerehabilitation was new and this study has explored how participants perceived ACTIV. For many participants, remote delivery was very different to their expectations of physiotherapy, which made it less acceptable for some. The impact this could and possibly should have on physiotherapy practice was considered. Some requirements for maintaining a therapeutic relationship via remote contact were considered and how that may impact physiotherapy education. The ways some participants overcame the difficulties associated with stroke was discussed and reasons suggested for why some participants had not found useful strategies to help maintain activity. Finally, the complex and sometimes contradictory role of goal-setting in rehabilitation was considered and some current practices questioned. Goal setting is widely described as an integral component to rehabilitation (Dalton et al., 2011; Scobbie, Dixon, & Wyke, 2011; Siegert, 2010), considerable further research needs to be undertaken to help goal-setting become more meaningful to patients and physiotherapists.

CHAPTER 10 INTEGRATED DISCUSSION AND CONCLUSION

10.1 INTRODUCTION

In the final chapter quantitative and qualitative findings were viewed together to examine agreement and divergence. The integration of findings shed light on the potential clinical usefulness of ACTIV and changes that may enhance its utility for practice. In addition, viewing the findings from the ACTIV study and considering other research in the area of readily-accessible telecommunication devices allowed consideration of future research. Theme or sub-theme names, as identified in the qualitative study are used in the discussion and have been italicised for clarity. This helps to demonstrate the links between the quantitative and qualitative work.

10.2 INTEGRATION OF QUANTITATIVE AND QUALITATIVE FINDINGS

ACTIV was developed based on a thorough and in-depth understanding of the literature in the areas of stroke and telerehabilitation and many decades of clinical experience. The randomised controlled trial showed that ACTIV was effective in improving physical function as measured by the primary outcome measure (SIS 3.0). The qualitative enquiry found that ACTIV had a number of benefits to participants despite it not being quite what they expected from physiotherapy. The knowledge that there was someone there was helpful in many ways, which assisted exercise completion and an overall increase in activity. Interestingly participants measured success not by the overarching goals physiotherapists had helped them plan at the outset of the study, but by the gradual improvement in everyday activities. Viewing the integration of quantitative and qualitative findings revealed a number of important points to consider when delivering a telerehabilitation intervention.

10.2.1 *Delivering an effective intervention.*

As anticipated the novel method of delivery did lead to reservations from some participants but much of the initial resistance seemed to have been dispelled by the therapeutic relationship with the ACTIV physiotherapists. The positive feeling of a therapeutic presence revealed in *there's someone there*, was enhanced by the care and encouragement the physiotherapists showed the participants, which was strongly emphasised in the qualitative findings. This helped overcome the barrier of novelty within the study. ACTIV may not have been what participants expected from a physiotherapy intervention but the programme did help the majority of participants maintain prescribed exercises and those who completed at least half the programme improved their physical function.

10.2.2 *Who should deliver ACTIV?*

When considering participant views of the importance of care and encouragement it could be asked whether skilled professionals were needed to deliver ACTIV or whether a similar programme could be run by community groups and delivered by lay-people. However, it is clear that the knowledge and skill of the physiotherapists was also a vital aspect to the intervention. Participants related *learning something new*, describing novel ideas for exercises and modifications that increased the challenge of their exercises. This suggested that a knowledge of physical rehabilitation and stroke pathology was an integral part of the effectiveness of ACTIV physiotherapists. Also pertinent to this question was the finding that some participants needed added impetus to *get off your bottom*. It may be difficult to judge how hard to push someone undertaking exercise without an underlying understanding of their general health, stroke-related impairments and expertise in exercise prescription. Someone without the knowledge that a physiotherapist has would find it more difficult to appropriately progress and modify the exercises.

10.2.3 *Measuring important gains*

There was no between-group difference in the physical performance measurements of grip strength and balance. This was at odds with the finding of a significant between-group difference in the physical sub-component of the SIS 3.0; one section including self-report of grip strength and one self-report of balance. One explanation is that there was no change in these impairments, alternatively measuring a single impairment or function at a single point in time may have failed to capture real and important changes for a participant in their daily life. In support of this assertion is the significant between-group difference in favour of ACTIV, in the participation sub-scale of the SIS3.0 measured at 6 months. The sub-scale recorded responses about areas that give life purpose, including participation in work, social and family roles. This finding suggested that during the programme participants had a significantly increased participation in roles they deemed important. This is supported by findings from the qualitative study that *success matters* and what participants really wanted was to carry on making small meaningful steps in everyday life.

10.2.4 *Why were functional gains not maintained at 12 months?*

The randomised controlled trial showed an improvement in physical function at the end of the 6-month intervention but this was not maintained at 12 months. The findings from the SSEQ measure showed that although there may have been some improvement in self-efficacy, it was small and participants did not have enough confidence in their ability to sustain physical improvements once ACTIV ended. This is supported by the feeling of frustration and inability to manage everyday tasks expressed by some participants. The combined findings suggest that regular reassurance and help may be required to boost self-efficacy and maintain progress. This does not imply that the programme failed to engender any change in behaviour because there was evidence of participants *weaving it in*; exercises were being translated in to an increase in everyday

activity. However, the loss of gains made during the programme when measured at the 12-month follow-up, combined with the significant reduction in ACTIV participants' health perception when the programme ended, suggest that the much sought-after permanent behaviour-change may be illusory. Maintenance or continued improvement of activity may need ongoing contact, our intention is to make that affordable enough to be possible.

10.3 RECOMMENDATIONS FOR FUTURE PRACTICE

Viewing the findings from ACTIV in conjunction with recent research in the use of readily-accessible technology has led to a number of recommendations for future practice.

1. Use of ACTIV to promote further recovery following discharge from standard community physiotherapy for people with stroke.

The finding that ACTIV led to improvement in physical function will make it a valuable addition to rehabilitation after hospital discharge. The improvement in participation during ACTIV was also an important outcome which was supported by findings from Chumbler and colleagues (2012). These authors undertook a randomised controlled trial similar to ACTIV, using a similar low level of contact via a combination of telephone calls and an in-home communication device. They found their programme (STeleR) conferred a significant between-group difference in favour of the intervention group, in the ability to manage important life tasks and social activities. Crotty and colleagues (2014) conducted a feasibility and acceptability study of telerehabilitation for older people including those with stroke, using a tablet computer loaded with an off-the-shelf videoconferencing application. Although not a controlled trial they reported that 75% of participants achieved their goals. There is agreement from these studies that remote delivery of rehabilitation can achieve meaningful outcomes for patients.

2. Consistent use of outcome measures in clinical practice which include the measurement of participation for people with stroke.

Quantitative and qualitative findings from ACTIV and the study by Chumbler and colleagues (2012), suggest that outcome measures of impairment and function do not always capture important changes that are meaningful to participants. Failing to measure participation may underestimate the effectiveness of a treatment. It will become increasingly difficult to maintain funding for rehabilitation without measurable effectiveness.

3. Ensure remotely delivered rehabilitation uses the simplest technology that meets the requirements of the programme and includes training and support for healthcare professionals and patients.

There are still potential barriers to use of technology for rehabilitation delivery. Crotty and colleagues (2014) reported that participants using the videoconferencing application found it easy to use but a number of potential participants refused to take part due to apprehension about the technology. Using technology that most people already owned also helped overcome this barrier in ACTIV. The initial difficulties for participants who had not texted before was overcome by clear instructions for receipt of messages.

Physiotherapists in ACTIV had access to a research assistant if problems occurred with the technology, which happened infrequently due to its simplicity. Chumbler and colleagues (2010) warned from their experience that remote delivery without such technical support can be problematic.

4. Begin the process of self-management earlier in stroke rehabilitation.

Starting the process of self-management during inpatient stroke rehabilitation (Gustafsson & Bootle, 2013) may minimise the impression that remote delivery is different from proper physiotherapy. For remote delivery of rehabilitation to succeed

people need to have had some opportunity for trial and error and self-determination during the acute hospital stay. The ability to help direct and take some control of rehabilitation has been shown to be important to patients (F. Jones, Mandy, et al., 2008; Luker et al., 2015) and to improve quality of life (Harwood et al., 2012). The experience for patients of having helped direct rehabilitation would improve the alignment between hospital rehabilitation and a remotely delivered service after discharge.

10.4 RECOMMENDATIONS FOR FUTURE RESEARCH

The ACTIV study has shown that important gains in physical function can be achieved using a relatively low-cost intervention. Below is the planned schedule of ongoing research to increase the likelihood of ACTIV being incorporated in to clinical practice.

1. A cost-effectiveness analysis of ACTIV will be undertaken.

During the randomised controlled trial data was collected to be able to complete a cost-effectiveness analysis. This will be undertaken and published to assist health funders to evaluate ACTIV.

2. Funding will be sought to undertake an implementation trial of ACTIV in one of the district health boards in the study.

Changing practice is always challenging so the first step to implementation will be sharing the results of ACTIV with the profession and exploring physiotherapy perception of the programme. A pilot study will be undertaken to investigate the uptake of ACTIV when it is offered as part of the discharge package, to all patients from one clinical centre, over an eight-week period. The results will be used in an application to fund a larger implementation study.

3. The Stroke Foundation will be approached to consider investigating a partnership for delivery of ACTIV.

The results from ACTIV confirmed that it was useful when participants actually engaged in the programme and that seemed to require ongoing support. Focus groups including people with stroke, representatives from the stroke foundation and healthcare professionals will be used to explore ways care and support could be continued after ACTIV, at a sustainable level and cost. The Stroke foundation currently run stroke clubs, which offer support and companionship and frequently include an exercise programme. Encouragement to maintain engagement after ACTIV may be able to be incorporated in their current structure.

4. A final year undergraduate physiotherapy student will investigate ways ACTIV could be made more acceptable and accessible to Māori patients.

At Auckland University of Technology every physiotherapy student is matched with a supervisor and must complete a research project during their final year. Expressions of interest for this project will be sought from Māori students in 2017. The project would include a literature review of strategies shown to improve health delivery to Māori. All aspects of ACTIV will then be inspected for alignment with these strategies.

5. The use of text messaging to deliver or augment rehabilitation for other populations will be explored.

Our research team has recently gained funding for a feasibility study of automated messages for patients discharged from community physiotherapy. This project is in collaboration with clinical staff from a district health board, a health economist and health funders. Although different from ACTIV much of the knowledge and information gained during the past four years will inform this study.

10.5 SUMMARY

Viewing quantitative and qualitative together improved understanding of the aspects of ACTIV that may account for its effectiveness in gaining improvements. Participants

found the knowledge and expertise of physiotherapists to prescribe exercises and modify them as required was very important. The feeling of being connected to someone who stays in touch and gives regular encouragement seemed to help participants persist with exercise and activity. The benefit participants gained from regular support did not engender behaviour change to sustain improvement, suggesting that some level of ongoing support may be required to account for the fluctuations in health and mobility that occur after stroke. The challenge is to continue to work towards the use of the telecommunication devices we have now, to achieve important gains for our patients. We may need to accept that complete independence from any support is too lofty-a-goal for many after stroke, but in view of the gains made with relatively small input, telerehabilitation using landline telephones or mobile phones offers a viable solution to the problem of extending stroke rehabilitation beyond standard treatment.

REFERENCES

- Ada, L., Dean, C. M., Hall, J. M., Bampton, J., & Crompton, S. (2003). A treadmill and overground walking program improves walking in persons residing in the community after stroke: a placebo-controlled, randomized trial. *Archives of Physical Medicine and Rehabilitation*(10), 1486-1491. Retrieved from <http://onlinelibrary.wiley.com/doi/10.1016/j.apmr.2014.09.007>
- Adey-Wakeling, Z., Arima, H., Crotty, M., Leyden, J., Kleinig, T., Anderson, C. S., & Newbury, J. (2015). Incidence and associations of hemiplegic shoulder pain poststroke: prospective population-based study. *Archives of Physical Medicine and Rehabilitation*, 96(2), 241-247.e241. doi:10.1016/j.apmr.2014.09.007
- Alexander, H., Bugge, C., & Hagen, S. (2001). What is the association between the different components of stroke rehabilitation and health outcomes? *Clinical Rehabilitation*, 15(2), 207-215.
- Ali, M., Bath, P. M., Lyden, P. D., Bernhardt, J., & Brady, M. (2014). Representation of people with aphasia in randomized controlled trials of acute stroke interventions. *International Journal Of Stroke: Official Journal Of The International Stroke Society*, 9(2), 174-182. doi:10.1111/ijss.12043
- Andersen, H. E., Schultz-Larsen, K., Kreiner, S., Forchhammer, B. H., Eriksen, K., & Brown, A. (2000). Can readmission after stroke be prevented? Results of a randomized clinical study: a postdischarge follow-up service for stroke survivors. *Stroke; A Journal Of Cerebral Circulation*, 31(5), 1038-1045.
- Andrews, A. W., Li, D., & Freburger, J. K. (2015). Association of Rehabilitation Intensity for Stroke and Risk of Hospital Readmission. *Physical Therapy*, 95(12), 1660-1667. doi:10.2522/ptj.20140610
- Askim, T., Bernhardt, J., Løge, A. D., & Indredavik, B. (2012). Stroke patients do not need to be inactive in the first two-weeks after stroke: results from a stroke unit focused on early rehabilitation. *International Journal Of Stroke: Official Journal Of The International Stroke Society*, 7(1), 25-31. doi:10.1111/j.1747-4949.2011.00697.x
- Askim, T., Morkved, S., Engen, A., Roos, K., Aas, T., & Indredavik, B. (2010). Effects of a community-based intensive motor training program combined with early supported discharge after treatment in a comprehensive stroke unit: A randomized, controlled trial. *Stroke*, 41(8), 1697-1703.
- Audebert, H. J., & Schwamm, L. (2009). Telestroke: Scientific results. *Cerebrovascular Diseases*, 27(SUPPL. 4), 15-20.
- Aziz, N. A. (2010). Long-term rehabilitation after stroke: Where do we go from here? *Reviews in Clinical Gerontology*, 20(3), 239-245.
- Bandura, A. (1989). Human agency in social cognitive theory. *The American Psychologist*, 44(9), 1175-1184.
- Bandura, A., & Locke, E. A. (2003). Negative self-efficacy and goal effects revisited. *The Journal Of Applied Psychology*, 88(1), 87-99.
- Banks, G., Bernhardt, J., Churilov, L., & Cumming, T. B. (2012). Exercise preferences are different after stroke. *Stroke Research And Treatment*, 2012, 890946-890946. doi:10.1155/2012/890946
- Barnard, R. A., Cruice, M. N., & Playford, E. D. (2010). Strategies used in the pursuit of achievability during goal setting in rehabilitation. *Qualitative Health Research*, 20(2), 239-250. doi:10.1177/1049732309358327
- Baskett, J. J., Broad, J. B., Reekie, G., Hocking, C., & Green, G. (1999). Shared responsibility for ongoing rehabilitation: a new approach to home-based therapy after stroke. *Clinical Rehabilitation*, 13(1), 23-33.
- Bays, C. L. (2001). Older adults' descriptions of hope after a stroke. *Rehabilitation Nursing: The Official Journal Of The Association Of Rehabilitation Nurses*, 26(1), 18.
- Bendz, M. (2003). The first year of rehabilitation after a stroke - from two perspectives. *Scandinavian Journal of Caring Sciences*, 17(3), 215-222.

- Bertrand, A. M., Mercier, C., Bourbonnais, D., Desrosiers, J., & Gravel, D. (2007). Reliability of maximal static strength measurements of the arms in subjects with hemiparesis. *Clinical Rehabilitation*, 21(3), 248-257.
- Besley, J. B. B. N., Kayes, N. M. B. M. P., & McPherson, K. M. R. N. B. A. P. (2011). Assessing Therapeutic Relationships in Physiotherapy: Literature Review. *New Zealand Journal of Physiotherapy*, 39(2), 81-91.
- Black-Schaffer, R. M., Kirsteins, A. E., & Harvey, R. L. (1999). Stroke rehabilitation. 2. Comorbidities and complications. *Archives of Physical Medicine and Rehabilitation*, 80(5 Suppl 1), S8-S16.
- Blanton, S., Morris, D. M., Prettyman, M. G., McCulloch, K., Redmond, S., Light, K. E., & Wolf, S. L. (2006). Lessons learned in participant recruitment and retention: the EXCITE trial. *Physical Therapy*, 86(11), 1520-1533.
- Bohannon, R. W. (2004). Adequacy of hand-grip dynamometry for characterizing upper limb strength after stroke. *Isokinetics & Exercise Science*, 12(4), 263-265.
- Bohannon, R. W., & Lee, N. (2004). Association of physical functioning with same-hospital readmission after stroke. *American Journal Of Physical Medicine & Rehabilitation / Association Of Academic Physiatrists*, 83(6), 434-438.
- Bosnell, R. A., Kincses, T., Stagg, C. J., Tomassini, V., Kischka, U., Jbabdi, S., . . . Johansen-Berg, H. (2011). Motor practice promotes increased activity in brain regions structurally disconnected after subcortical stroke. *Neurorehabilitation And Neural Repair*, 25(7), 607-616. doi:10.1177/1545968311405675
- Boter, H. (2004). Multicenter randomized controlled trial of an outreach nursing support program for recently discharged stroke patients [Clinical Trial. Multicenter Study. Randomized Controlled Trial. Research Support, Non-U.S. Gov't]. *Stroke; A Journal Of Cerebral Circulation*, 35(12), 2867-2872.
- Boutron, I., Moher, D., Altman, D. G., Schulz, K. F., & Ravaud, P. (2008). Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. *Annals of Internal Medicine*, 148(4), 295-309.
- Brady, M. C., Stott, D. J., Norrie, J., Chalmers, C., St George, B., Sweeney, P. M., & Langhorne, P. (2011). Developing and evaluating the implementation of a complex intervention: using mixed methods to inform the design of a randomised controlled trial of an oral healthcare intervention after stroke. *Trials*, 12, 168-168. doi:10.1186/1745-6215-12-168
- Brainin, M., Teuschl, Y., & Kalra, L. (2007). Acute treatment and long-term management of stroke in developing countries. *The Lancet. Neurology*, 6(6), 553-561.
- Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, 3(2), 77-101. doi:10.1191/1478088706qp063oa
- Brawley, L. R., Rejeski, W. J., & King, A. C. (2003). Promoting physical activity for older adults: the challenges for changing behavior. *American Journal of Preventive Medicine*, 25(3 Suppl 2), 172-183.
- Brewer, L., & Williams, D. (2010). A review of early supported discharge after stroke. *Reviews in Clinical Gerontology*, 20(4), 327-337. doi:10.1017/S0959259810000249
- Bright, F. A., Kayes, N. M., McCann, C. M., & McPherson, K. M. (2011). Understanding hope after stroke: a systematic review of the literature using concept analysis. *Topics In Stroke Rehabilitation*, 18(5), 490-508. doi:10.1310/tsr1805-490
- Burns, R. B., Crislip, D., Daviou, P., Temkin, A., Vesmarovich, S., Anshutz, J., . . . Jones, M. L. (1998). Using telerehabilitation to support assistive technology. *Assistive Technology*, 10(2), 126-133.
- Burridge, J. H., Turk, R., Notley, S. V., Pickering, R. M., & Simpson, D. M. (2009). The relationship between upper limb activity and impairment in post-stroke hemiplegia. *Disability And Rehabilitation*, 31(2), 109-117.
- Burton, C., & Gibbon, B. (2005). Expanding the role of the stroke nurse: a pragmatic clinical trial. *Journal Of Advanced Nursing*, 52(6), 640-650. doi:10.1111/j.1365-2648.2005.03639.x
- Cadilhac, D. A., Carter, R., Thrift, A. G., & Dewey, H. M. (2009). Estimating the long-term costs of ischemic and hemorrhagic stroke for Australia: new evidence derived from the

- North East Melbourne Stroke Incidence Study (NEMESIS). *Stroke; A Journal Of Cerebral Circulation*, 40(3), 915-921. doi:10.1161/STROKEAHA.108.526905
- Callahan, C. M. M. D., Unverzagt, F. W. P., Hui, S. L. P., Perkins, A. J. M. S., & Hendrie, H. C. M. B. C. (2002). Six-Item Screener to Identify Cognitive Impairment Among Potential Subjects for Clinical Research. *Medical Care*, 40(9), 771-781.
- Campling, P. (2015). Reforming the culture of healthcare: the case for intelligent kindness. *The Psychiatrist*, 39(1), 1-5. doi:10.1192/pb.bp.114.047449
- Carignan, C. R., & Krebs, H. I. (2006). Telerehabilitation robotics: Bright lights, big future? *Journal Of Rehabilitation Research And Development*, 43(5), 695-710. doi:10.1682/jrrd.2005.05.0085
- Carroll, C., Patterson, M., Wood, S., Booth, A., Rick, J., & Balain, S. (2007). A conceptual framework for implementation fidelity. *Implementation Science: IS*, 2, 40-40.
- Chalermwannapong, S., Panuthai, S., Srisuphan, W., Panya, P., & Ostwald, S. K. (2010). Effects of the transitional care program on functional ability and quality of life of stroke survivors. *Chiang Mai University Journal of Natural Sciences*, 9(1), 49-66.
- Charmaz, K. (2006). *Constructing Grounded Theory: A practical guide through qualitative analysis* (Vol. 1). London: Sage Publications.
- Chen, C. C., & Bode, R. K. (2011). Factors influencing therapists' decision-making in the acceptance of new technology devices in stroke rehabilitation. *American Journal Of Physical Medicine & Rehabilitation / Association Of Academic Physiatrists*, 90(5), 415-425. doi:10.1097/PHM.0b013e318214f5d8
- Chen, R.-L., Balami, J. S., Esiri, M. M., Chen, L.-K., & Buchan, A. M. (2010). Ischemic stroke in the elderly: an overview of evidence. *Nature Reviews. Neurology*, 6(5), 256-265. doi:10.1038/nrneurol.2010.36
- Chow, C. K., Redfern, J., Hillis, G. S., Thakkar, J., Santo, K., Hackett, M. L., . . . Thiagalingam, A. (2015). Effect of Lifestyle-Focused Text Messaging on Risk Factor Modification in Patients With Coronary Heart Disease: A Randomized Clinical Trial. *JAMA*, 314(12), 1255-1263. doi:10.1001/jama.2015.10945
- Chumbler, N. R., Quigley, P., Li, X., Morey, M., Rose, D., Sanford, J., . . . Hoenig, H. (2012). Effects of telerehabilitation on physical function and disability for stroke patients: a randomized, controlled trial. *Stroke; A Journal Of Cerebral Circulation*, 43(8), 2168-2174. doi:10.1161/STROKEAHA.111.646943
- Chumbler, N. R., Quigley, P., Sanford, J., Griffiths, P., Rose, D., Morey, M., . . . Hoenig, H. (2010). Implementing telerehabilitation research for stroke rehabilitation with community dwelling veterans: lessons learned. *International Journal Of Telerehabilitation*, 2(1), 15-22. doi:10.5195/ijt.2010.6047
- Chumbler, N. R., Rose, D., Li, X., Griffiths, P., Quigley, P., Sanford, J., . . . Hoenig, H. (2014). A home-based telerehabilitation randomized trial for stroke care: Effects on falls self-efficacy and satisfaction with care Symposium conducted at the meeting of the 2014 International Conference on Collaboration Technologies and Systems, CTS 2014 Retrieved from <http://www.scopus.com/inward/record.url?eid=2-s2.0-84906258381&partnerID=40&md5=ca5e8f50963ae42780647c5fe0eac341> doi:10.1109/CTS.2014.6867601 Retrieved from Scopus database.
- Cochrane. (n.d.). *Template- data extraction*. Retrieved from <http://chmg.cochrane.org/sites/chmg.cochrane.org/files/uploads/Template-Data%20Extraction-CHMG.pdf>
- Conci, M., Pianesi, F., & Zancanaro, M. (2009). Useful, Social and Enjoyable: Mobile Phone adoption by older people. In *Human-Computer Interaction - INTERACT 2009* (pp. 63-76). Berlin: Springer doi:10. 1007/978-3-642-03655-2_7
- Cox, D. L., & Araoz, G. (2009). The experience of therapy supervision within a UK multi-centre randomized controlled trial. *Learning in Health & Social Care*, 8(4), 301-314 314p. doi:10.1111/j.1473-6861.2009.00218.x
- Cramp, M. C., Greenwood, R. J., Gill, M., Lehmann, A., Rothwell, J. C., & Scott, O. M. (2010). Effectiveness of a community-based low intensity exercise programme for ambulatory stroke survivors. *Disability And Rehabilitation*, 32(3), 239-247.

- Crotty, M., Killington, M., van den Berg, M., Morris, C., Taylor, A., & Carati, C. (2014). Telerehabilitation for older people using off-the-shelf applications: acceptability and feasibility [Article]. *Journal of Telemedicine and Telecare*, 20(7), 370-376. doi:10.1177/1357633x14552382
- Dahl-Michelsen, T. (2015). Curing and caring competences in the skills training of physiotherapy students. *Physiotherapy Theory And Practice*, 31(1), 8-16. doi:10.3109/09593985.2014.949946
- Dalton, C., Farrell, R., De Souza, A., Wujanto, E., McKenna-Slade, A., Thompson, S., . . . Greenwood, R. (2011). Patient inclusion in goal setting during early inpatient rehabilitation after acquired brain injury. *Clinical Rehabilitation*. doi:10.1177/0269215511405230
- Damush, T. M., Ofner, S., Yu, Z., Plue, L., Nicholas, G., & Williams, L. S. (2011). Implementation of a stroke self-management program: A randomized controlled pilot study of veterans with stroke. *Translational Behavioral Medicine*, 1(4), 561-572. doi:10.1007/s13142-011-0070-y
- Davis, C. M. (1990). What is empathy, and can empathy be taught? *Physical Therapy*, 70(11), 707-711.
- de Jongh, T., Gurol-Urganci, I., Vodopivec-Jamsek, V., Car, J., & Atun, R. (2012). Mobile phone messaging for facilitating self-management of long-term illnesses. *The Cochrane Database Of Systematic Reviews*, 12, CD007459. doi:10.1002/14651858.CD007459.pub2
- Dean, C. M., Richards, C. L., & Malouin, F. (2000). Task-related circuit training improves performance of locomotor tasks in chronic stroke: a randomized, controlled pilot trial. *Archives of Physical Medicine & Rehabilitation*, 81(4), 409-417.
- Devito Dabbs, A., Song, M.-K., Hawkins, R., Aubrecht, J., Kovach, K., Terhorst, L., . . . Callan, J. (2011). An intervention fidelity framework for technology-based behavioral interventions. *Nursing Research*, 60(5), 340-347. doi:10.1097/NNR.0b013e31822cc87d
- Dhurjaty, S. (2004). The economics of telerehabilitation. *Telemedicine journal and e-health : the official journal of the American Telemedicine Association*, 10(2), 196-199.
- Dibble, L. E., Hale, T. F., Marcus, R. L., Droge, J., Gerber, J. P., & LaStayo, P. C. (2006). High-intensity resistance training amplifies muscle hypertrophy and functional gains in persons with Parkinson's disease. *Movement Disorders: Official Journal Of The Movement Disorder Society*, 21(9), 1444-1452.
- Dick, J. J., Nundy, S., Solomon, M. C., Bishop, K. N., Chin, M. H., & Peek, M. E. (2011). Feasibility and usability of a text message-based program for diabetes self-management in an urban African-American population. *Journal Of Diabetes Science And Technology*, 5(5), 1246-1254.
- Dixon, G., Thornton, E. W., & Young, C. A. (2007). Perceptions of self-efficacy and rehabilitation among neurologically disabled adults. *Clinical Rehabilitation*, 21(3), 230-240.
- Duncan, P. W., Bode, R. K., Lai, S. M., & Perera, S. (2003). Rasch analysis of a new stroke-specific outcome scale: The stroke impact scale. *Archives of Physical Medicine and Rehabilitation*, 84(7), 950-963.
- Duncan, P. W., Reker, D., Kwon, S., Lai, S. M., Studenski, S., Perera, S., . . . Marquez, J. (2005). Measuring stroke impact with the stroke impact scale: Telephone versus mail administration in veterans with stroke. *Medical Care*, 43(5), 507-515.
- Duncan, P. W., Wallace, D., Lai, S. M., Johnson, D., Embretson, S., & Laster, L. J. (1999). The stroke impact scale version 2.0: Evaluation of reliability, validity, and sensitivity to change. *Stroke*, 30(10), 2131-2140.
- Ebell, M. H., Siwek, J., Weiss, B. D., Woolf, S. H., Susman, J., Ewigman, B., & Bowman, M. (2004). Strength of recommendation taxonomy (SORT): a patient-centered approach to grading evidence in the medical literature. *American Family Physician*, 69(3), 548-556.
- Egan, M. Y., Kessler, D., Ceci, C., Laliberté-Rudman, D., McGrath, C., Sikora, L., & Gardner, P. (2016). Problematising risk in stroke rehabilitation. *Disability And Rehabilitation*, 38(23), 2334-2344. doi:10.3109/09638288.2015.1123304

- Egan, M. Y., Laliberté Rudman, D., Ceci, C., Kessler, D., McGrath, C., Gardner, P., . . . Malhotra, R. (2016). Seniors, risk and rehabilitation: broadening our thinking. *Disability And Rehabilitation*, 1-8.
- Ekeland, A. G., Bowes, A., & Flottorp, S. (2010). Effectiveness of telemedicine: A systematic review of reviews. *International Journal of Medical Informatics*, 79(11), 736-771. doi:10.1016/j.ijmedinf.2010.08.006
- Eland-de Kok, P., van Os-Medendorp, H., Vergouwe-Meijer, A., Bruijnzeel-Koomen, C., & Ros, W. (2011). A systematic review of the effects of e-health on chronically ill patients. *Journal Of Clinical Nursing*, 20(21-22), 2997-3010. doi:10.1111/j.1365-2702.2011.03743.x
- Elley, C. R., Garrett, S., Rose, S. B., O'Dea, D., Lawton, B. A., Moyes, S. A., & Dowell, A. C. (2011). Cost-effectiveness of exercise on prescription with telephone support among women in general practice over 2 years. *British Journal Of Sports Medicine*, 45(15), 1223-1229. doi:10.1136/bjsm.2010.072439
- Ellis-Hill, C., Payne, S., & Ward, C. (2008). Using stroke to explore the life thread model: an alternative approach to understanding rehabilitation following an acquired disability. *Disability And Rehabilitation*, 30(2), 150-159.
- Eng, J. J. (2010). Fitness and Mobility Exercise (FAME) Program for stroke. *Topics in Geriatric Rehabilitation*, 26(4), 310-323.
- Evans, C., Yeung, E., Markoulakis, R., & Guilcher, S. (2014). An online community of practice to support evidence-based physiotherapy practice in manual therapy. *The Journal Of Continuing Education In The Health Professions*, 34(4), 215-223. doi:10.1002/chp.21253
- Ewan, L. M., Kinmond, K., & Holmes, P. S. (2010). An observation-based intervention for stroke rehabilitation: experiences of eight individuals affected by stroke. *Disability And Rehabilitation*, 32(25), 2097-2106. doi:10.3109/09638288.2010.481345
- Eysenbach, G. (2001). What is e-health? *Journal Of Medical Internet Research*, 3(2), E20-E20.
- Feigin, V. L., Forouzanfar, M. H., Krishnamurthi, R., Mensah, G. A., Connor, M., Bennett, D. A., . . . Murray, C. (2014). Global and regional burden of stroke during 1990-2010: findings from the Global Burden of Disease Study 2010. *Lancet (London, England)*, 383(9913), 245-254.
- Feigin, V. L., McNaughton, H., & Dyal, L. (2007). Burden of stroke in Maori and Pacific peoples of New Zealand. *International Journal of Stroke*, 2(3), 208-210.
- Fisher, R. J., Gaynor, C., Kerr, M., Langhorne, P., Anderson, C., Bautz-Holter, E., . . . Walker, M. F. (2011). A consensus on stroke: early supported discharge. *Stroke; A Journal Of Cerebral Circulation*, 42(5), 1392-1397. doi:10.1161/STROKEAHA.110.606285
- Galvin, R., Cusack, T., & Stokes, E. (2009a). Physiotherapy after stroke in Ireland: a qualitative insight into the patients' and physiotherapists' experience. *International Journal Of Rehabilitation Research. Internationale Zeitschrift Für Rehabilitationsforschung. Revue Internationale De Recherches De Réadaptation*, 32(3), 238-244. doi:10.1097/MRR.0b013e32832b083c
- Galvin, R., Cusack, T., & Stokes, E. (2009b). To what extent are family members and friends involved in physiotherapy and the delivery of exercises to people with stroke? *Disability And Rehabilitation*, 31(11), 898-905. doi:10.1080/09638280802356369
- Gearing, R. E., El-Bassel, N., Ghesquiere, A., Baldwin, S., Gillies, J., & Ngeow, E. (2011). Major ingredients of fidelity: a review and scientific guide to improving quality of intervention research implementation. *Clinical Psychology Review*, 31(1), 79-88. doi:10.1016/j.cpr.2010.09.007
- Gill, T. M., Baker, D. I., Gottschalk, M., Peduzzi, P. N., Allore, H., & Byers, A. (2002). A program to prevent functional decline in physically frail, elderly persons who live at home. *The New England Journal Of Medicine*, 347(14), 1068-1074.
- Gilleard, C., Hyde, M., & Higgs, P. (2007). Community and communication in the third age: the impact of internet and cell phone use on attachment to place in later life in England. *The Journals Of Gerontology. Series B, Psychological Sciences And Social Sciences*, 62(4), S276-S283.

- Godwin, K. M., Wasserman, J., & Ostwald, S. K. (2011). Cost associated with stroke: outpatient rehabilitative services and medication. *Topics In Stroke Rehabilitation, 18 Suppl 1*, 676-684. doi:10.1310/tsr18s01-676
- Godwin, M., Ruhland, L., Casson, I., MacDonald, S., Delva, D., Birtwhistle, R., . . . Seguin, R. (2003). Pragmatic controlled clinical trials in primary care: the struggle between external and internal validity. *BMC Medical Research Methodology, 3*, 28-28.
- Gordon, N. F., Gulanick, M., Costa, F., Fletcher, G., Franklin, B. A., Roth, E. J., & Shephard, T. (2004). Physical Activity and Exercise Recommendations for Stroke Survivors: An American Heart Association Scientific Statement from the Council on Clinical Cardiology, Subcommittee on Exercise, Cardiac Rehabilitation, and Prevention; the Council on Cardiovascular Nursing; the Council on Nutrition, Physical Activity, and Metabolism; and the Stroke Council. *Circulation, 109*(16), 2031-2041.
- Gregory, P., Alexander, J., & Satinsky, J. (2011). Clinical Telerehabilitation: Applications for Physiatrists. *Pm&R, 3*(7), 647-656. doi:10.1016/j.pmrj.2011.02.024
- Guidali, M., Duschau-Wicke, A., Broggi, S., Klamroth-Marganska, V., Nef, T., & Riener, R. (2011). A robotic system to train activities of daily living in a virtual environment. *Medical & Biological Engineering & Computing, 49*(10), 1213-1223. doi:10.1007/s11517-011-0809-0
- Gustafsson, L., & Bootle, K. (2013). Client and carer experience of transition home from inpatient stroke rehabilitation. *Disability And Rehabilitation, 35*(16), 1380-1386. doi:10.3109/09638288.2012.740134
- Hadidi, N., Buckwalter, K., Lindquist, R., & Rangen, C. (2012). Lessons learned in recruitment and retention of stroke survivors. *Journal of Neuroscience Nursing, 44*(2), 105-110.
- Hafsteinsdóttir, T. B., & Grypdonck, M. (1997). Being a stroke patient: a review of the literature. *Journal Of Advanced Nursing, 26*(3), 580-588.
- Hailey, D., Roine, R., Ohinmaa, A., & Dennett, L. (2011). Evidence of benefit from telerehabilitation in routine care: a systematic review. *Journal of Telemedicine and Telecare, 17*(6), 281-287. doi:10.1258/jtt.2011.101208
- Hall, T., & Cox, D. (2009). Clinical supervision: an appropriate term for physiotherapists? *Learning in Health & Social Care, 8*(4), 282-291 210p. doi:10.1111/j.1473-6861.2009.00226.x
- Harwood, M., Weatherall, M., Talemaitoga, A., Barber, P. A., Gommans, J., Taylor, W., . . . McNaughton, H. (2012). Taking charge after stroke: promoting self-directed rehabilitation to improve quality of life--a randomized controlled trial. *Clinical Rehabilitation, 26*(6), 493-501.
- Hasson, H. (2010). Systematic evaluation of implementation fidelity of complex interventions in health and social care. *Implementation Science: IS, 5*, 67-67. doi:10.1186/1748-5908-5-67
- Health and Disability Commissioner. (1996). *The code of rights*
- Helm-Estabrooks, N., & Ramsberger, G. (1986). Aphasia treatment delivered by telephone. *Archives of Physical Medicine and Rehabilitation, 67*(1), 51-53.
- Hennick, M. M., Kaiser, B. N., & Marconi, V. C. (2016). Code Saturation Versus Meaning Saturation: How Many Interviews Are Enough? *Qualitative Health Research*.
- Higgins, J. P. T., Altman, D. G., Gøtzsche, P. C., Jüni, P., Moher, D., Oxman, A. D., . . . Sterne, J. A. C. (2011). The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *BMJ (Clinical research ed.), 343*, d5928-d5928. doi:10.1136/bmj.d5928
- Hill, K., Bernhardt, J., McGann, A., Maltese, D., & Berkovits, D. (1996). A new test of dynamic standing balance for stroke patients: reliability, validity and comparison with healthy elderly. *Physiotherapy Canada, 48*, 257-262.
- Hinojosa, R., Haun, J., Hinojosa, M. S., & Rittman, M. (2011). Social isolation poststroke: relationship between race/ethnicity, depression, and functional independence. *Topics In Stroke Rehabilitation, 18*(1), 79-86. doi:10.1310/tsr1801-79
- Hoffmann, T. C., Glasziou, P. P., Boutron, I., Milne, R., Perera, R., Moher, D., . . . Michie, S. (2014). *Better reporting of interventions: template for intervention description and*

- replication (TIDieR) checklist and guide (Vol. 348) [Journal Article]. Retrieved from <http://www.bmj.com/bmj/348/bmj.g1687.full.pdf>. doi:10.1136/bmj.g1687
- Holden, G. (1991). The relationship of self-efficacy appraisals to subsequent health related outcomes: a meta-analysis. *Social Work In Health Care*, 16(1), 53-93.
- Holden, M., Dyar, T., & Dayan-Cimadoro, L. (2007). Telerehabilitation Using a Virtual Environment Improves Upper Extremity Function in Patients With Stroke. *IEEE Transactions on Neural Systems and Rehabilitation Engineering*, 15(1), 36-42.
- Hubbard, I. J., Parsons, M. W., Neilson, C., & Carey, L. M. (2009). Task-specific training: evidence for and translation to clinical practice. *Occupational Therapy International*, 16(3-4), 175-189.
- Hunger, M., Sabariego, C., Stollenwerk, B., Cieza, A., & Leidl, R. (2012). Validity, reliability and responsiveness of the EQ-5D in German stroke patients undergoing rehabilitation. *Quality Of Life Research: An International Journal Of Quality Of Life Aspects Of Treatment, Care And Rehabilitation*, 21(7), 1205-1216. doi:10.1007/s11136-011-0024-3
- Intercollegiate Stroke Working Party. (2008). *National Clinical Guideline for Stroke (3rd Ed)*. London: Royal College of Physicians.
- Ioffe, M. E., Ustinova, K. I., Chernikova, L. A., & Kulikov, M. A. (2006). Supervised learning of postural tasks in patients with poststroke hemiparesis, Parkinson's disease or cerebellar ataxia. *Experimental Brain Research*, 168(3), 384-394.
- Jacquin, A., Biquet, C., Rouaud, O., Graule-Petot, A., Daubail, B., Osseby, G.-V., . . . Béjot, Y. (2014). Post-stroke cognitive impairment: high prevalence and determining factors in a cohort of mild stroke. *Journal Of Alzheimer's Disease: JAD*, 40(4), 1029-1038. doi:10.3233/JAD-131580
- Johansson, T., & Wild, C. (2011). Telerehabilitation in stroke care - a systematic review. *Journal of Telemedicine and Telecare*, 17(1), 1-6. doi:10.1258/jtt.2010.100105
- Jones, F., Livingstone, E., & Hawkes, L. (2013). 'Getting the balance between encouragement and taking over': reflections on using a new stroke self-management programme. *Physiotherapy Research International: The Journal For Researchers And Clinicians In Physical Therapy*, 18(2), 91-99. doi:10.1002/pri.1531
- Jones, F., Mandy, A., & Partridge, C. (2008). Reasons for recovery after stroke: a perspective based on personal experience. *Disability And Rehabilitation*, 30(7), 507-516.
- Jones, F., Mandy, A., & Partridge, C. (2009). Changing self-efficacy in individuals following a first time stroke: preliminary study of a novel self-management intervention. *Clinical Rehabilitation*, 23(6), 522-533.
- Jones, F., Partridge, C., & Reid, F. (2008). The Stroke Self-Efficacy Questionnaire: measuring individual confidence in functional performance after stroke. *Journal Of Clinical Nursing*, 17(7B), 244-252.
- Jones, T. M., Dean, C. M., Hush, J. M., Dear, B. F., & Titov, N. (2015). A systematic review of the efficacy of self-management programs for increasing physical activity in community-dwelling adults with acquired brain injury (ABI). *Systematic Reviews*, 4, 51. doi:10.1186/s13643-015-0039-x
- Judkins, D. R., & Porter, K. E. (2016). Robustness of ordinary least squares in randomized clinical trials. *Statistics in Medicine*, 35(11), 1763-1773.
- Jull, G., & Moore, A. (2012). Hands on, hands off? The swings in musculoskeletal physiotherapy practice. *Manual Therapy*, 17(3), 199-200. doi:10.1016/j.math.2012.03.009
- Jurkiewicz, M. T., Marzolini, S., & Oh, P. (2011). Adherence to a home-based exercise program for individuals after stroke. *Topics In Stroke Rehabilitation*, 18(3), 277-284. doi:10.1310/tsr1803-277
- Kairy, D., Lehoux, P., Vincent, C., & Visintin, M. (2009). A systematic review of clinical outcomes, clinical process, healthcare utilization and costs associated with telerehabilitation. *Disability And Rehabilitation*, 31(6), 427-447.
- Kernan, W. N., Viscoli, C. M., Brass, L. M., Gill, T. M., Sarrel, P. M., & Horwitz, R. I. (2005). Decline in physical performance among women with a recent transient ischemic attack

- or ischemic stroke: opportunities for functional preservation a report of the Women's Estrogen Stroke Trial. *Stroke; A Journal Of Cerebral Circulation*, 36(3), 630-634.
- King, G., Heaney, D. J., Boddy, D., O'Donnell, C. A., Clark, J. S., & Mair, F. S. (2011). Exploring public perspectives on e-health: findings from two citizen juries. *Health Expectations: An International Journal Of Public Participation In Health Care And Health Policy*, 14(4), 351-360. doi:10.1111/j.1369-7625.2010.00637.x
- Kleim, J. A., & Jones, T. A. (2008). Principles of experience-dependent neural plasticity: implications for rehabilitation after brain damage. *Journal Of Speech, Language, And Hearing Research: JSLHR*, 51(1), S225-S239.
- Korpershoek, C., van der Bijl, J., & Hafsteinsdóttir, T. B. (2011). Self-efficacy and its influence on recovery of patients with stroke: a systematic review. *Journal Of Advanced Nursing*, 67(9), 1876-1894. doi:10.1111/j.1365-2648.2011.05659.x
- Krebs, H. I., Dipietro, L., Levy-Tzedek, S., Fasoli, S. E., Rykman-Berland, A., Zipse, J., . . . Hogan, N. (2008). A paradigm shift for rehabilitation robotics: Therapeutic robots enhance clinician productivity in facilitating patient recovery. *IEEE Engineering in Medicine and Biology Magazine*, 27(4).
- Krishna, S., Boren, S. A., & Balas, E. A. (2009). Healthcare via cell phones: a systematic review. *Telemedicine Journal And E-Health: The Official Journal Of The American Telemedicine Association*, 15(3), 231-240. doi:10.1089/tmj.2008.0099
- Kruger, J., & Dunning, D. (1999). Unskilled and unaware of it: How difficulties in recognizing one's own incompetence lead to inflated self-assessments [Article]. *Journal Of Personality And Social Psychology*, 77(6), 1121-1134. doi:10.1037/0022-3514.77.6.1121
- Lally, P., van Jaarsveld, C. H. M., Potts, H. W. W., & Wardle, J. (2010). How are habits formed: Modelling habit formation in the real world. *European Journal of Social Psychology*, 40(6), 998-1009. doi:10.1002/ejsp.674
- LaMonte, M. P., Bahouth, M. N., Hu, P., Pathan, M. Y., Yarbrough, K. L., Gunawardane, R., . . . Page, W. (2003). Telemedicine for acute stroke: triumphs and pitfalls. *Stroke; A Journal Of Cerebral Circulation*, 34(3), 725-728.
- LaMonte, M. P., Bahouth, M. N., Xiao, Y., Hu, P., Baquet, C. R., & Mackenzie, C. F. (2008). Outcomes from a comprehensive stroke telemedicine program. *Telemedicine Journal And E-Health: The Official Journal Of The American Telemedicine Association*, 14(4), 339-344. doi:10.1089/tmj.2007.0062
- Landi, F., Onder, G., Cesari, M., Zamboni, V., Russo, A., Barillaro, C., & Bernabei, R. (2006). Functional decline in frail community-dwelling stroke patients. *European Journal Of Neurology: The Official Journal Of The European Federation Of Neurological Societies*, 13(1), 17-23.
- Langhammer, B., & Lindmark, B. (2012). Functional exercise and physical fitness post stroke: the importance of exercise maintenance for motor control and physical fitness after stroke. *Stroke Research And Treatment*, 2012, 864835-864835.
- Langhammer, B., Lindmark, B., & Stanghelle, J. K. (2014). Physiotherapy and physical functioning post-stroke: Exercise habits and functioning 4 years later? Long-term follow-up after a 1-year long-term intervention period: A randomized controlled trial. *Brain Injury: [BI]*, 1-10.
- Langhammer, B., Stanghelle, J. K., & Lindmark, B. (2009). An evaluation of two different exercise regimes during the first year following stroke: A randomised controlled trial. *Physiotherapy Theory And Practice*, 25(2), 55-68.
- Langhorne, P., & Holmqvist, L. W. (2007). Early supported discharge after stroke. *Journal of Rehabilitation Medicine*, 39(2), 103-108.
- Laver, K., Halbert, J., Stewart, M., & Crotty, M. (2010). Patient readiness and ability to set recovery goals during the first 6 months after stroke. *Journal Of Allied Health*, 39(4), e149-e154.
- Leach, E., Cornwell, P., Fleming, J., & Haines, T. (2010). Patient centered goal-setting in a subacute rehabilitation setting. *Disability And Rehabilitation*, 32(2), 159-172.
- Lemoncello, R., Sohlberg, M. M., Fickas, S., Albin, R., & Harn, B. E. (2011). Phase I evaluation of the television assisted prompting system to increase completion of home

- exercises among stroke survivors. *Disability and rehabilitation. Assistive technology*, 6(5), 440-452. doi:10.3109/17483107.2010.542571
- Levack, W. M. M., Dean, S. G., Siegert, R. J., & McPherson, K. M. (2011). Navigating patient-centered goal setting in inpatient stroke rehabilitation: how clinicians control the process to meet perceived professional responsibilities. *Patient Education and Counseling*, 85(2), 206-213. doi:10.1016/j.pec.2011.01.011
- Levin, M. F., & Panturin, E. (2011). Sensorimotor integration for functional recovery and the Bobath approach. *Motor Control*, 15(2), 285-301.
- Li, H., & Song, A. (2008). Force assistant master-slave telerehabilitation robotic system. *Journal of Southeast University (English Edition)*, 24(1), 42-45.
- Lichtman, J. H., Leifheit-Limson, E. C., Jones, S. B., Watanabe, E., Bernheim, S. M., Phipps, M. S., . . . Goldstein, L. B. (2010). Predictors of hospital readmission after stroke: a systematic review. *Stroke; A Journal Of Cerebral Circulation*, 41(11), 2525-2533. doi:10.1161/STROKEAHA.110.599159
- Lin, H.-J., Chang, W.-L., & Tseng, M.-C. (2011). Readmission after stroke in a hospital-based registry: risk, etiologies, and risk factors. *Neurology*, 76(5), 438-443. doi:10.1212/WNL.0b013e31820a0cd8
- Lin, K. C., Fu, T., Wu, C. Y., Wang, Y. H., Liu, J. S., Hsieh, C. J., & Lin, S. F. (2010). Minimal detectable change and clinically important difference of the stroke impact scale in stroke patients. *Neurorehabilitation And Neural Repair*, 24(5), 486-492.
- Lloyd, A., Roberts, A. R., & Freeman, J. A. (2014). 'Finding a balance' in involving patients in goal setting early after stroke: a physiotherapy perspective. *Physiotherapy Research International: The Journal For Researchers And Clinicians In Physical Therapy*, 19(3), 147-157. doi:10.1002/pri.1575
- Lluch Girbés, E., Meeus, M., Baert, I., & Nijs, J. (2015). Balancing “hands-on” with “hands-off” physical therapy interventions for the treatment of central sensitization pain in osteoarthritis. *Manual Therapy*, 20(2), 349-352. doi:<http://dx.doi.org/10.1016/j.math.2014.07.017>
- Lo, A. C., Guarino, P. D., Richards, L. G., Haselkorn, J. K., Wittenberg, G. F., Federman, D. G., . . . Peduzzi, P. (2010). Robot-assisted therapy for long-term upper-limb impairment after stroke. *The New England Journal Of Medicine*, 362(19), 1772-1783. doi:10.1056/NEJMoA0911341
- Luker, J., Lynch, E., Bernhardsson, S., Bennett, L., & Bernhardt, J. (2015). Stroke Survivors' Experiences of Physical Rehabilitation: A Systematic Review of Qualitative Studies. *Archives of Physical Medicine and Rehabilitation*, 96(9), 1698-1708.e1610. doi:10.1016/j.apmr.2015.03.017
- Maclean, N., & Pound, P. (2000). A critical review of the concept of patient motivation in the literature on physical rehabilitation. *Social Science & Medicine (1982)*, 50(4), 495-506.
- Maclean, N., Pound, P., Wolfe, C., & Rudd, A. (2000). Qualitative analysis of stroke patients' motivation for rehabilitation. *BMJ (Clinical research ed.)*, 321(7268), 1051-1054.
- Mahmud, N., Rodriguez, J., & Nesbit, J. (2010). A text message-based intervention to bridge the healthcare communication gap in the rural developing world. *Technology And Health Care: Official Journal Of The European Society For Engineering And Medicine*, 18(2), 137-144. doi:10.3233/thc-2010-0576
- Marsden, D., Quinn, R., Pond, N., Golledge, R., Neilson, C., White, J., . . . Pollack, M. (2010). A multidisciplinary group programme in rural settings for community-dwelling chronic stroke survivors and their carers: A pilot randomized controlled trial. *Clinical Rehabilitation*, 24(4), 328-341.
- Martin, B. J., Yip, B., Hearty, M., Marletta, S., & Hill, R. (2002). Outcome, functional recovery and unmet needs following acute stroke. Experience of patient follow up at 6 to 9 months in a newly established stroke service. *Scottish Medical Journal*, 47(6), 136-137.
- Mayo, N., Nadeau, L., Ahmed, S., White, C., Grad, R., Huang, A., . . . Wood-Dauphinee, S. (2008). Bridging the gap: the effectiveness of teaming a stroke coordinator with patient's personal physician on the outcome of stroke. *Age And Ageing*, 37(1), 32-38.

- Mayo, N., Wood-Dauphinee, S., Cote, R., Durcan, L., & Carlton, J. (2002). Activity, participation, and quality of life 6 months poststroke. *Archives of Physical Medicine and Rehabilitation*, 83(8), 1035-1042.
- McCann, S. K., Campbell, M. K., & Entwistle, V. A. (2010). Reasons for participating in randomised controlled trials: conditional altruism and considerations for self. *Trials*, 11, 31-31. doi:10.1186/1745-6215-11-31
- McCue, M., Fairman, A., & Pramuka, M. (2010). Enhancing Quality of Life through Telerehabilitation. *Physical Medicine And Rehabilitation Clinics Of North America*, 21(1), 195-205.
- Mehrholtz, J., Wagner, K., Rutte, K., Meissner, D., & Pohl, M. (2007). Predictive validity and responsiveness of the functional ambulation category in hemiparetic patients after stroke. *Archives of Physical Medicine and Rehabilitation*, 88(10), 1314-1319.
- Merchan-Baeza, J. A., Gonzalez-Sanchez, M., & Cuesta-Vargas, A. (2015). Clinical Effect Size of an Educational Intervention in the Home and Compliance With Mobile Phone-Based Reminders for People Who Suffer From Stroke: Protocol of a Randomized Controlled Trial [Article]. *Jmir Research Protocols*, 4(1). doi:10.2196/resprot.4034
- Miller, I. W. (2003). Efficacy of a family telephone intervention for stroke. *ClinicalTrials.gov*. Retrieved from <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/517/CN-00421517/frame.html>
- Miller, K. K., Porter, R. E., DeBaun-Sprague, E., Van Puymbroeck, M., & Schmid, A. A. (2016). Exercise after Stroke: Patient Adherence and Beliefs after Discharge from Rehabilitation. *Topics In Stroke Rehabilitation*, 1-7.
- Mohd Nordin, N. A., Aziz, N. A. A., Abdul Aziz, A. F., Ajit Singh, D. K., Omar Othman, N. A., Sulong, S., & Aljunid, S. M. (2014). Exploring views on long term rehabilitation for people with stroke in a developing country: findings from focus group discussions. *BMC Health Services Research*, 14, 118-118. doi:10.1186/1472-6963-14-118
- Mukherjee, D., & Patil, C. G. (2011). Epidemiology and the global burden of stroke. *World Neurosurgery*, 76(6 Suppl), S85-S90. doi:10.1016/j.wneu.2011.07.023
- National Stroke Foundation. (2010). *Clinical Guidelines for Stroke Management*. Melbourne, Australia.
- Neergaard, M. A., Olesen, F., Andersen, R. S., & Sondergaard, J. (2009). Qualitative description - the poor cousin of health research? *BMC Medical Research Methodology*, 9, 52-52. doi:10.1186/1471-2288-9-52
- Nicholls, D. A., & Cheek, J. (2006). Physiotherapy and the shadow of prostitution: the Society of Trained Masseuses and the massage scandals of 1894. *Social Science & Medicine* (1982), 62(9), 2336-2348.
- Nicholls, D. A., & Gibson, B. E. (2010). The body and physiotherapy. *Physiotherapy Theory And Practice*, 26(8), 497-509. doi:10.3109/09593981003710316
- Nitz, J. C., & Choy, N. L. (2004). The efficacy of a specific balance-strategy training programme for preventing falls among older people: a pilot randomised controlled trial. *Age And Ageing*, 33(1), 52-58.
- Noone, I., Fan, C. W., Tarrant, H., O'Keeffe, S., McDonnell, R., & Crowe, M. (2001). What happens to stroke patients after hospital discharge? *Irish Medical Journal*, 94(5), 151-152.
- Norris, M., & Kilbride, C. (2014). From dictatorship to a reluctant democracy: stroke therapists talking about self-management. *Disability And Rehabilitation*, 36(1), 32-38. doi:10.3109/09638288.2013.776645
- Norrving, B., & Kissela, B. (2013). The global burden of stroke and need for a continuum of care. *Neurology*, 80(3 Suppl 2), S5-S12. doi:10.1212/WNL.0b013e3182762397
- Novak, I. (2011). Effective home programme intervention for adults: a systematic review. *Clinical Rehabilitation*, 25(12), 1066-1085.
- OCEBM Levels of Evidence Working Group. (2011). *The Oxford Levels of Evidence 2*. Retrieved November 23, 2011,
- Ovbiagele, B., & Nguyen-Huynh, M. N. (2011). Stroke epidemiology: advancing our understanding of disease mechanism and therapy. *Neurotherapeutics: The Journal Of*

- The American Society For Experimental Neurotherapeutics*, 8(3), 319-329.
doi:10.1007/s13311-011-0053-1
- Pak, S., & Patten, C. (2008). Strengthening to promote functional recovery poststroke: an evidence-based review. *Topics In Stroke Rehabilitation*, 15(3), 177-199.
- Palsbo, S. E., & Bauer, D. (2000). Telerehabilitation: managed care's new opportunity. *Managed care quarterly*, 8(4), 56-64.
- Paolucci, S., Grasso, M. G., Antonucci, G., Troisi, E., Morelli, D., Coiro, P., & Bragoni, M. (2000). One-year follow-Up in stroke patients discharged from rehabilitation hospital. *Cerebrovascular diseases (Basel, Switzerland)*, 10(1), 25-32.
- Pascucci, M. A., Leasure, A. R., Belknap, D. C., & Kodumthara, E. (2010). Situational challenges that impact health adherence in vulnerable populations. *Journal Of Cultural Diversity*, 17(1), 4-12.
- Pearson, A. (2004). Balancing the evidence: Incorporating the synthesis of qualitative data into systematic reviews. *Joanna Briggs Institute reports*, 2, 45-64.
- Peifer, J., & Hopper, A. (1999). A review of current and future technology for telerehabilitation. *Topics in Spinal Cord Injury Rehabilitation*, 5(3), 1-10.
- Peifer, J., & Hopper, A. (2000). A review of current and future technology for telerehabilitation. *Topics in Spinal Cord Injury Rehabilitation*, 5(3), 1-10.
- Peiris, C. L., Taylor, N. F., & Shields, N. (2012). Patients value patient-therapist interactions more than the amount or content of therapy during inpatient rehabilitation: a qualitative study. *Journal of Physiotherapy*, 58(4), 261-268. doi:10.1016/S1836-9553(12)70128-5
- Pervez, M. A., Silva, G., Masrur, S., Betensky, R. A., Furie, K. L., Hidalgo, R., . . . Schwamm, L. H. (2010). Remote supervision of IV-tPA for acute ischemic stroke by telemedicine or telephone before transfer to a regional stroke center is feasible and safe. *Stroke*, 41(1), e18-e24.
- Physiotherapy Board of New Zealand. *Competence and recertification audit*. Retrieved 23rd February 2016, from <http://www.physioboard.org.nz/competence-and-recertification-audit>
- Piron, L., Tonin, P., Trivello, E., Battistin, L., & Dam, M. (2004). Motor tele-rehabilitation in post-stroke patients. *Medical Informatics And The Internet In Medicine*, 29(2), 119-125.
- Piron, L., Turolla, A., Agostini, M., Zucconi, C., Cortese, F., Zampolini, M., . . . Tonin, P. (2009). Exercises for paretic upper limb after stroke: a combined virtual-reality and telemedicine approach [Randomized Controlled Trial]. *Journal of rehabilitation medicine : official journal of the UEMS European Board of Physical and Rehabilitation Medicine*, 41(12), 1016-1102.
- Playford, E. D., Siegert, R., Levack, W., & Freeman, J. (2009). Areas of consensus and controversy about goal setting in rehabilitation: a conference report. *Clinical Rehabilitation*, 23(4), 334-344.
- Pound, P., Bury, M., Gompertz, P., & Ebrahim, S. (1994). Views of survivors of stroke on benefits of physiotherapy. *Quality In Health Care: QHC*, 3(2), 69-74.
- Pound, P., Gompertz, P., & Ebrahim, S. (1999). Social and practical strategies described by people living at home with stroke. *Health & Social Care in the Community*, 7(2), 120-128.
- Powell, S., Scott, J., Scott, L., & Jones, D. (2013). An online narrative archive of patient experiences to support the education of physiotherapy and social work students in North East England: an evaluation study. *Education For Health (Abingdon, England)*, 26(1), 25-31. doi:10.4103/1357-6283.112797
- Prestwich, A., Perugini, M., & Hurling, R. (2009). Can the effects of implementation intentions on exercise be enhanced using text messages? *Psychology & Health*, 24(6), 677-687. doi:10.1080/08870440802040715
- Provencher, V., Mortenson, W. B., Tanguay-Garneau, L., Bélanger, K., & Dagenais, M. (2014). Challenges and strategies pertaining to recruitment and retention of frail elderly in research studies: a systematic review. *Archives of Gerontology and Geriatrics*, 59(1), 18-24. doi:10.1016/j.archger.2014.03.006

- Rensink, M., Schuurmans, M., Lindeman, E., & Hafsteinsdóttir, T. B. (2009). Task-oriented training in rehabilitation after stroke: systematic review. *Journal Of Advanced Nursing*, 65(4), 737-754.
- Resnick, B., Michael, K., Shaughnessy, M., Nahm, E. S., Sorkin, J. D., & Macko, R. (2011). Exercise intervention research in stroke: optimizing outcomes through treatment fidelity. *Topics In Stroke Rehabilitation*, 18 Suppl 1, 611-619. doi:10.1310/tsr18s01-611
- Reynolds, A. L., Vick, J. L., & Haak, N. J. (2009). Telehealth applications in speech-language pathology: a modified narrative review. *Journal of Telemedicine and Telecare*, 15(6), 310-316. doi:10.1258/jtt.2009.081215
- Rimmer, J. H., Wang, E., & Smith, D. (2008). Barriers associated with exercise and community access for individuals with stroke. *Journal Of Rehabilitation Research And Development*, 45(2), 315-322.
- Robine, J.-M., & Michel, J.-P. (2004). Looking forward to a general theory on population aging. *The Journals Of Gerontology. Series A, Biological Sciences And Medical Sciences*, 59(6), M590-M597.
- Rochette, A., Korner-Bitensky, N., Bishop, D., Teasell, R., White, C., Bravo, G., . . . Wood-Dauphinee, S. (2010). Study protocol of the YOU CALL--WE CALL TRIAL: impact of a multimodal support intervention after a "mild" stroke. *BMC Neurology*, 10, 3-3. doi:10.1186/1471-2377-10-3
- Rogante, M., Grigioni, M., Cordella, D., & Giacomozzi, C. (2010). Ten years of telerehabilitation: A literature overview of technologies and clinical applications. *Neurorehabilitation*, 27(4), 287-304. doi:10.3233/nre-2010-0612
- Rosewilliam, S., Roskell, C. A., & Pandyan, A. D. (2011). A systematic review and synthesis of the quantitative and qualitative evidence behind patient-centred goal setting in stroke rehabilitation. *Clinical Rehabilitation*, 25(6), 501-514. doi:10.1177/0269215510394467
- Salbach, N. M., Howe, J.-A., Brunton, K., Salisbury, K., & Bodiam, L. (2014). Partnering to increase access to community exercise programs for people with stroke, acquired brain injury, and multiple sclerosis. *Journal Of Physical Activity & Health*, 11(4), 838-845. doi:10.1123/jpah.2012-0183
- Salbach, N. M., Mayo, N. E., Robichaud-Ekstrand, S., Hanley, J. A., Richards, C. L., & Wood-Dauphinee, S. (2005). The effect of a task-oriented walking intervention on improving balance self-efficacy poststroke: a randomized, controlled trial. *Journal Of The American Geriatrics Society*, 53(4), 576-582.
- Sandelowski, M. (2000a). Combining qualitative and quantitative sampling, data collection, and analysis techniques in mixed-method studies. *Research in Nursing & Health*, 23(3), 246-255.
- Sandelowski, M. (2000b). Whatever happened to qualitative description? *Research in Nursing & Health*, 23(4), 334-340.
- Santacroce, S. J., Maccarelli, L. M., & Grey, M. (2004). Intervention fidelity. *Nursing Research*, 53(1), 63-66.
- Satink, T., Cup, E. H. C., de Swart, B. J. M., & Nijhuis-van der Sanden, M. W. G. (2015). How is self-management perceived by community living people after a stroke? A focus group study. *Disability And Rehabilitation*, 37(3), 223-230. doi:10.3109/09638288.2014.918187
- Savage, T. A. (2006). Ethical issues in research with patients who have experienced stroke. *Topics In Stroke Rehabilitation*, 13(4), 1-10.
- Saywell, N., & Taylor, D. (2014). Focus group insights assist trial design for stroke telerehabilitation: a qualitative study. *Physiotherapy Theory And Practice*, 1-6.
- Saywell, N., Vandal, A. C., Brown, P., Hanger, H. C., Hale, L., Mudge, S., . . . Taylor, D. (2012). Telerehabilitation to improve outcomes for people with stroke: study protocol for a randomised controlled trial. *Trials*, 13, 233. doi:10.1186/1745-6215-13-233
- Schulz, K. F., Altman, D. G., & Moher, D. (2010). CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *BMC Medicine*, 8, 18-18. doi:10.1186/1741-7015-8-18
- Schwamm, L. H., Ali, S. F., Reeves, M. J., Smith, E. E., Saver, J. L., Messe, S., . . . Fonarow, G. C. (2013). Temporal trends in patient characteristics and treatment with intravenous

- thrombolysis among acute ischemic stroke patients at get with the guidelines-stroke hospitals. *Circulation. Cardiovascular Quality And Outcomes*, 6(5), 543-549.
doi:10.1161/circoutcomes.111.000303
- Schwerdtfeger, A. R., Schmitz, C., & Warken, M. (2012). Using text messages to bridge the intention-behavior gap? A pilot study on the use of text message reminders to increase objectively assessed physical activity in daily life. *Frontiers In Psychology*, 3, 270-270.
doi:10.3389/fpsyg.2012.00270
- Scobbie, L., Dixon, D., & Wyke, S. (2011). Goal setting and action planning in the rehabilitation setting: development of a theoretically informed practice framework. *Clinical Rehabilitation*, 25(5), 468-482.
doi:<http://dx.doi.org/10.1177/0269215510389198>
- Selak, V., Crengle, S., Elley, C. R., Wadham, A., Harwood, M., Rafter, N., . . . Rodgers, A. (2013). Recruiting equal numbers of indigenous and non-indigenous participants to a 'polypill' randomized trial. *International Journal For Equity In Health*, 12, 44-44.
doi:10.1186/1475-9276-12-44
- Shaughnessy, M., Resnick, B. M., & Macko, R. F. (2006). Testing a model of post-stroke exercise behavior. *Rehabilitation Nursing*, 31(1), 15-21.
- Shepherd, R. B. (2001). Exercise and training to optimize functional motor performance in stroke: driving neural reorganization? *Neural Plasticity*, 8(1-2), 121-129.
- Siebert, R. J. (2010). Goal-setting in rehabilitation: perhaps it is rocket science. *Journal of the Australasian Rehabilitation Nurses' Association (JARNA)*, 13(1), 4-8.
- Smidt, N., de Vet, H. C. W., Bouter, L. M., Dekker, J., Arendzen, J. H., de Bie, R. A., . . . van der Windt, D. A. W. M. (2005). Effectiveness of exercise therapy: a best-evidence summary of systematic reviews. *The Australian Journal Of Physiotherapy*, 51(2 (Print)), 71-85.
- Smith, L. T. (1999). *Decolonizing methodologies: Research and Indigenous peoples*. Dunedin: University of Otago Press.
- Snyder, C. R., Harris, C., Anderson, J. R., Holleran, S. A., Irving, L. M., Sigmon, S. T., . . . Harney, P. (1991). The will and the ways: development and validation of an individual-differences measure of hope. *Journal Of Personality And Social Psychology*, 60(4), 570-585.
- Soundy, A., Smith, B., Butler, M., Minns Lowe, C., Helen, D., & Winward, C. H. (2010). A qualitative study in neurological physiotherapy and hope: beyond physical improvement. *Physiotherapy Theory And Practice*, 26(2), 79-88.
doi:10.3109/09593980802634466
- Statistics New Zealand. (2009). *Household Use of Information and Communication Technology: 2009*. Retrieved 8 February 2013, from www.stats.govt.nz
- Steel, K., Cox, D., & Garry, H. (2011). Therapeutic videoconferencing interventions for the treatment of long-term conditions. *Journal of Telemedicine and Telecare*, 17(3), 109-117. doi:10.1258/jtt.2010.100318
- Stegmayr, B., & Asplund, K. (1996). Exploring the declining case fatality in acute stroke. Population-based observations in the northern Sweden MONICA Project. *Journal Of Internal Medicine*, 240(3), 143-149.
- Stroke Foundation of New Zealand and New Zealand Guidelines Group. (2010). *Clinical Guidelines for Stroke Management* Wellington: Stroke Foundation of New Zealand.
- Stucki, G., Ewert, T., & Cieza, A. (2003). Value and application of the ICF in rehabilitation medicine. *Disability And Rehabilitation*, 25(11-12), 628-634.
- Sugavanam, T. G. C. M. W. F. (2013). The effects and experiences of goal setting in stroke rehabilitation - a systematic review [Article]. *Disability & Rehabilitation*, 35(3), 177-190. doi:10.3109/09638288.2012.690501
- Tasker, D., Loftus, S., & Higgs, J. (2012). Head, heart and hands: creating mindful dialogues in community-based physiotherapy. *New Zealand Journal of Physiotherapy*, 40(1), 5-12.
- Tieges, Z., Mead, G., Allerhand, M., Duncan, F., van Wijck, F., Fitzsimons, C., . . . Chastin, S. (2015). Sedentary behavior in the first year after stroke: a longitudinal cohort study with objective measures. *Archives of Physical Medicine and Rehabilitation*, 96(1), 15-23.
doi:10.1016/j.apmr.2014.08.015

- Tobias, M., Cheung, J., Carter, K., Anderson, C., & Feigin, V. L. (2007). Stroke surveillance: population-based estimates and projections for New Zealand. *Australian And New Zealand Journal Of Public Health*, 31(6), 520-525.
- Tong, A., Sainsbury, P., & Craig, J. (2007). Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal For Quality In Health Care: Journal Of The International Society For Quality In Health Care / Isqua*, 19(6), 349-357.
- Turner-Stokes, L., & Williams, H. (2010). Goal attainment scaling: a direct comparison of alternative rating methods. *Clinical Rehabilitation*, 24(1), 66-73. doi:10.1177/0269215509343846
- Turner, B. J., Fleming, J. M., Ownsworth, T. L., & Cornwell, P. L. (2008). The transition from hospital to home for individuals with acquired brain injury: a literature review and research recommendations. *Disability And Rehabilitation*, 30(16), 1153-1176.
- Tyson, S., Connell, L., Busse, M., & Lennon, S. (2009). What do acute stroke physiotherapists do to treat postural control and mobility? An exploration of the content of therapy in the UK. *Clinical Rehabilitation*, 23(11), 1051-1055. doi:10.1177/0269215509334837
- Tyson, S., & Turner, G. (2000). Discharge and follow-up for people with stroke: what happens and why. *Clinical Rehabilitation*, 14(4), 381.
- Tyson, S., Watson, A., Moss, S., Troop, H., Dean-Lofthouse, G., Jorritsma, S., & Shannon, M. (2008). Development of a framework for the evidence-based choice of outcome measures in neurological physiotherapy. *Disability And Rehabilitation*, 30(2), 142-149.
- U.S. Department of Health and Human Services. (2010). *Common Terminology Criteria for Adverse Events (CTCAE): version 4*: National Institutes of Health
- Vaismoradi, M., Turunen, H., & Bondas, T. (2013). Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study. *Nursing & Health Sciences*, 15(3), 398-405. doi:10.1111/nhs.12048
- Van De Port, I. G. L., Kwakkel, G., Van Wijk, I., & Lindeman, E. (2006). Susceptibility to deterioration of mobility long-term after stroke: A prospective cohort study. *Stroke*, 37(1), 167-171.
- van Delden, A. L. E. Q., Peper, C. L. E., Beek, P. J., & Kwakkel, G. (2013). Match and mismatch between objective and subjective improvements in upper limb function after stroke. *Disability And Rehabilitation*, 35(23), 1961-1967. doi:10.3109/09638288.2013.768303
- Wade, D. T. (1999). Goal planning in stroke rehabilitation: What? *Topics In Stroke Rehabilitation*, 6(2), 8-15.
- Wagner, L. M., Phillips, V. L., Hunsaker, A. E., & Forducey, P. G. (2009). Falls among community-residing stroke survivors following inpatient rehabilitation: a descriptive analysis of longitudinal data. *BMC Geriatrics*, 9, 46-46. doi:10.1186/1471-2318-9-46
- Welch, B. L. (1947). The generalization of "student's" problem when several different population variances are involved. *Biometrika*, 34, 28-35.
- Whittaker, R., Dorey, E., Bramley, D., Bullen, C., Denny, S., Elley, C. R., . . . Salmon, P. (2011). A theory-based video messaging mobile phone intervention for smoking cessation: randomized controlled trial. *Journal Of Medical Internet Research*, 13(1), e10-e10.
- Whittaker, R., Merry, S., Stasiak, K., McDowell, H., Doherty, I., Shepherd, M., . . . Rodgers, A. (2012). MEMO--a mobile phone depression prevention intervention for adolescents: development process and postprogram findings on acceptability from a randomized controlled trial. *Journal Of Medical Internet Research*, 14(1), e13-e13.
- Wikman, A., Wardle, J., & Steptoe, A. (2011). Quality of life and affective well-being in middle-aged and older people with chronic medical illnesses: a cross-sectional population based study. *PLoS ONE*, 6(4), e18952-e18952. doi:10.1371/journal.pone.0018952
- Wiles, R., Ashburn, A., Payne, S., & Murphy, C. (2002). Patients' expectations of recovery following stroke: A qualitative study. *Disability And Rehabilitation*, 24(16), 841-850.

- Wiles, R., Ashburn, A., Payne, S., & Murphy, C. (2004). Discharge from physiotherapy following stroke: The management of disappointment. *Social Science and Medicine*, 59(6), 1263-1273.
- Wiles, R., Cott, C., & Gibson, B. E. (2008). Hope, expectations and recovery from illness: a narrative synthesis of qualitative research. *Journal Of Advanced Nursing*, 64(6), 564-573.
- Winnard, D., Lee, M., & Macleod, G. (2015). *Demographic Profile:2013 Census, Population of Counties Manukau*. Auckland: Counties Manukau Health.
- Winter, J., Hunter, S., Sim, J., & Crome, P. (2011). Hands-on therapy interventions for upper limb motor dysfunction following stroke. *The Cochrane Database Of Systematic Reviews*(6), CD006609. doi:10.1002/14651858.CD006609.pub2
- Winters, J. M. (2002). Telerehabilitation research: Emerging opportunities. *Annual Review of Biomedical Engineering*, 4, 287-320. doi:4.112801.121923
- Wood, J. P., Connelly, D. M., & Maly, M. R. (2010). 'Getting back to real living': A qualitative study of the process of community reintegration after stroke. *Clinical Rehabilitation*, 24(11), 1045-1056. doi:10.1177/0269215510375901
- World Confereration for Physical therapy. (2011). *Policy statement: Description of physical therapy*. Retrieved from <http://www.wcpt.org/policy/ps-descriptionPT>
- World Health Organisation. (2011). *Global Health and Aging*: National Institute on Aging.
- Wottrich, A. W., Aström, K., & Löfgren, M. (2012). On parallel tracks: newly home from hospital--people with stroke describe their expectations. *Disability And Rehabilitation*, 34(14), 1218-1224. doi:10.3109/09638288.2011.640381
- Yap, T. L., & Davis, L. S. (2008). Physical activity: the science of health promotion through tailored messages. *Rehabilitation Nursing: The Official Journal Of The Association Of Rehabilitation Nurses*, 33(2), 55-62.
- Zhao, W., Waldman, B. D., Dillon, C., Pauls, K., Kim, J., Patterson, L., . . . Palesch, Y. (2010). A web-based medical safety reporting system for a large multicenter clinical trial: the ALIAS experience. *Contemporary Clinical Trials*, 31(6), 536-543.
- Zusman, M. (2013). Hands on, hands off? The swings in musculoskeletal physiotherapy practice. *Manual Therapy*, 18(3), e13-e13. doi:10.1016/j.math.2013.01.003

APPENDICES

Appendix A: An example of the search strategy for the systematic review (Scopus).

Appendix B: Multi-regional ethics approval.

Appendix C: Participant information sheet.

Appendix D: Consent form.

Appendix E: Invitation to participant

Appendix F: Newspaper advertisement

Appendix G: Telephone screening form

Appendix H: Letter to General Practitioner

Appendix I: Physiotherapy Initial assessment

Appendix J: Lower limb exercise menu

Appendix K: Upper limb exercise menu

Appendix L: Lower limb exercise example

Appendix M: Upper limb exercise example

Appendix N: Physiotherapy Follow-up assessment

Appendix O: Physiotherapy Telephone call

Appendix P: Participant workbook

Appendix Q: Adverse events recording form.

Appendix R: Recruiter procedure

Appendix S: Adverse events procedure

Appendix T: Training programme for blinded assessors

Appendix U: Blinded assessor procedure

Appendix V: Training programme for physiotherapists

Appendix W: Physiotherapist procedure

Appendix X: Training case scenarios for physiotherapists

Appendix Y: Letter to control group

Appendix Z: Participant interview confirmation letter

Appendix AA: Indicative questions for qualitative interview

APPENDIX A: SEARCH STRATEGY FOR THE SYSTEMATIC REVIEW

(SCOPUS)

1. Stroke – 229,457
2. CVA- 2,727
3. Hemipar*-14,810
4. Hemipleg*- 18,390
5. “cerebrovascular accident” OR “cerebrovascular disease” – 103,674
6. #1 OR #2 OR #3 OR #4 OR #5 -305,596
7. Telerehab*- 333
8. (rehab* w/5 distan*)- 229
9. (rehab* w/5 remote)- 258
- 10 (rehab* w/5 telecommunic*)-169
11. #7 OR #8 OR #9 OR #10 - 901
12. Telephon*- 111,324
13. phone OR phones OR phoning -45,604
14. “SMS” -8,369
15. “text message” -1,059
16. #12 OR #13 OR #14 OR #15 – 148,370
17. #6 AND #11- 160
18. #6 AND # 16- 1,180
- 19 #17 OR # 18 -**1,333**

APPENDIX B: MULTI-REGIONAL ETHICS APPROVAL



Multi-region Ethics Committee
c/- Ministry of Health
PO Box 5013
1 the Terrace
Wellington
Phone: (04) 816 2403
Fax: (04) 496 2343
Email: multiregion_ethicscommittee@moh.govt.nz

14 February 2012

Dr Denise Taylor
Health & Rehabilitation Research Centre
Auckland University of Technology
Private Bag 92006
Auckland 1142

Dear Dr Taylor

Ethics ref: **MEC/11/11/089** (please quote in all correspondence)
Study title: **Telerehabilitation To Improve Outcomes for People with Stroke: The ACTIV Trial**

Thank you for your letter dated the 3 February 2012 enclosing documentation relating to the above named study. This documentation has been reviewed and approved by the Chairperson of the Multi-region Ethics Committee under delegated authority.

Approved Documents

- Maori Consultation - Waitemata signed and dated 29 November 2011 by Giovanni Maihi Armaneo
- Maori Consultation - Counties Manukau signed and dated 8 December 2011 by Karla Rika Heke
- Maori Consultation - Otago signed and dated 9 March 2011 by Mark Brunton
- Maori Consultation - Canterbury signed and dated 21 December 2011 by Mark Tahu Potiki Stirling
- Locality Assessment - Waitemata DHB signed and dated 7 December 2011 by Peng Voon
- Locality Assessment - Counties Manukau DHB signed and dated 16 December 2011 by D Ralph Smith
- Locality Assessment - Southern DHB signed and dated 3 December 2011 by Vivian J Blake
- Locality Assessment - Canterbury DHB signed and dated 4 December 2011 by Greg Broyden
- Part 4 Declaration - Waitemata signed and dated 7 December 2012 by Duncan Reid
- Part 4 Declaration - Counties Manukau signed and dated 7 December 2012 by Duncan Reid
- Part 4 Declaration - Dunedin signed and dated 19 December 2012 by GD Baxter
- Part 4 Declaration - Princess Margaret Hosp. signed and dated 7 December 2012 by J Kinwan
- Participant Information Sheet (Waitemata) Version 4 dated 22 December 2012
- Participant Information Sheet (Counties Manukau) Version 4 dated 22 December 2012
- Participant Information Sheet (South Island Centres) Version 4 dated 22 December 2012

- Consent Form (Counties Manukau) Version 4 dated 22 December 2012
- Consent Form Version 4 dated 22 December 2012
- Amended Pages of NAF
 - Page 13
 - Page 16-17
 - Page 20
- Interview Guidelines Version 3 dated 12 October 2011
- Recruitment Protocol Version 2 dated 1 February 2012
- Economic Evaluation Questionnaire

Please do not hesitate to contact me should you have any queries.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Emma Phelan', with a stylized, cursive script.

Emma Phelan
Administrator
Multi-region Ethics Committee

APPENDIX C: PARTICIPANT INFORMATION SHEET



Participant Information Sheet Counties Manukau

Telerehabilitation to improve outcomes for people with stroke

Project Manager	Nicola Saywell	Phone: (09) 921 9999 x7084
Investigators	Denise Taylor Alain Vandal Suzie Mudge Leigh Hale Stephen Milosavljevic	Phone: (09) 921 9680 Phone: (09) 921 9999 x7726 Phone: (09) 921 9999 x7096 Phone: (03) 479 5425 Phone: (03) 479 7193

Invitation

Kia ora, talofa lava and hello, you are invited to take part in a study aiming to explore the effects of using technology like telephones and mobile phones to help with your rehabilitation. Please remember that:

- Your participation in this study is voluntary (your choice). You do not have to take part in this study
- If you do agree to take part, you are free to withdraw at any time, without having to give a reason. This will in no way affect your current or future health care
- Participation in this study will be stopped should any harmful effects appear or if your doctor feels it is not in your best interests to continue
- Due to the frequent telephone and text contacts required for this study, we are unable to include people who do not speak English.

This information sheet will explain the research study. Please feel free to ask about anything you do not understand.

What is the purpose of the study?

This study is looking at whether easily accessible technology can be used to encourage people to continue with exercises following stroke. The aim is to help improve independence when people move from hospital-based rehabilitation to living back at home. We want to deliver a programme called ACTIV: (Augmented Community Telerehabilitation Intervention)

We want to know if this programme can:

- a) Improve physical function for people following stroke
- b) Help people who have had a stroke to get back to activities that are important to them
- c) Reduce the number of hospital or rest home admission experienced by people following stroke.
- d) Deliver good results at a reasonable cost

How are people chosen to be asked to be part of the study?

People are being invited to participate in the research study if they meet all the following criteria:

- Are aged 20 years or older
- Have had a first-ever stroke causing a limitation in physical ability
- Have been discharged from rehabilitation
- Live at home

People may be excluded from taking part in the study if they are considered medically unsuitable to participate. Ninety-six people will participate in the study.

What happens in the study?

This programme will be offered to you once you have been discharged from inpatient and outpatient physiotherapy. If you choose to take part, you will:

- Be assessed before you take part in any exercise
- Have a 50:50 chance of doing the ACTIV programme.
- Be assessed straight after the programme.
- Be assessed after a further 6 months.

You may also be invited to an interview if you were part of the ACTIV group, to give us your feedback about doing the ACTIV programme.

At each stage of the ACTIV programme and the assessments, we encourage you to invite a support person from your whaanau or family to be present to offer encouragement and support.

The ACTIV Programme:

The ACTIV programme lasts for six months and consists of four visits from a physiotherapist. On the first visit the physiotherapist will work with you to decide on an activity you would like to be able to do again. You will be given

physiotherapist will visit at week 3, 12 and 26 and will phone at week 2, 4, 8, 16 and 20. The physiotherapist will also send text messages or e-mails if you are using a mobile phone or computer. All the visits will be at your own home, you can do the prescribed exercises at a time that fits in with your day. If you do not have a mobile phone, one will be given to you with a \$20 monthly credit. If you are in the control group, you will not be eligible to receive a mobile phone.

The Assessments:

At the beginning of the study, at 6 months and 12 months a physiotherapist will visit every participant at home. You will be asked to take part in a series of assessments and tests including:

- Questions asking you to rate your ability to do a range of activities you may undertake in your normal life
- A measurement of your hand grip strength
- A measurement of your balance
- Questions about your confidence in doing daily tasks
- We will ask you or a person you nominate, about any hospital or residential care admission you may have during the study
- We will collect data about costs relating to health care

There are 3 physical assessments in total, each one approximately 1½ hours long, carried out at the beginning of the study and 6 and 12 months later (4½ hours total).

If you are in the ACTIV group, there may also be interview at the conclusion of the programme to find out your experiences of participating. This interview will take between 45 and 75 minutes, will be conducted in your home and will be audio taped. After the interview, the audio tapes will be transcribed then deleted. You will be offered a transcript of the session if you would like to keep a record.

What are the benefits of participating?

People who take part in this study are acting as co-researchers. Your contribution will aid the development of a rehabilitation programme, to help people move from acute rehabilitation to independence at home and in the community following stroke.

What are the risks of participating?

The Study:

The exercises in this study are done independently by the participant, in their own home, although family/whānau or support people can assist. People with stroke may experience some fatigue and muscle soreness when they first start these exercises. Participants will have access to a physiotherapist to discuss any concerns about the programme or side effects experienced. Participants can also stop their involvement in this research at any time.

As people have a 50:50 chance of being allocated to the control group, some people may also be disappointed when they are admitted to the study but do not receive the ACTIV programme.

Compensation:

In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation, and Compensation Act 2001. ACC cover is not automatic, and your case will need to be assessed by ACC according to the provisions of the Injury Prevention, Rehabilitation, and Compensation Act 2001. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors, such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses, and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators. If you have any questions about ACC, contact your nearest ACC office or the investigator.

You are also advised to check whether participation in this study would affect any indemnity cover you have or are considering, such as medical insurance, life insurance and superannuation.

What are the costs of taking part in this study?

The cost to you is the time and effort you choose to contribute. If you are in the intervention group then we will provide a mobile phone (if you do not have one) and credit to the value of \$20 so that you can contact the physiotherapist or they can contact you. All visits from the physiotherapist will be at your own home and free of charge.

How will my privacy be protected?

Each participant will be assigned a specific code which is used to identify them on all documentation, rather than using their name. All data will be stored in a locked cabinet; forms containing any identifying information will be kept separate in a second locked cabinet. All data will be kept for a period of 10 years, after which time it will be destroyed. Only members of the research team directly involved will be able to see any of the collected information.

What will happen with the results?

The study findings will be submitted for publication in international rehabilitation journals. Presentations of the data will be made at national and international clinical and scientific meetings. Information about the findings from the study will be sent to the Stroke Foundation. If the findings are positive, we also intend to use free web-based packages, to train physiotherapists to deliver the programme in clinical practice.

Will I be able to have a copy of the results?

At the end of the study, all participants will receive a summary of the findings, along with an opportunity to discuss the findings with a researcher. All participants will also be offered an opportunity to attend a meeting/hui to discuss the findings.

If you have any concerns or questions?

If you have any questions please feel free to contact one of the researchers listed at the top of this information sheet.

If you have any queries or concerns regarding your rights as a participant in the study, you may wish to contact an independent health and disability advocate:

Free phone: 0800 555 050

Free fax: 0800 2 SUPPORT (0800 2787 7678)

Email: advocacy@hdc.org.nz

Seeking Cultural Support:

The researchers acknowledge the importance of spiritual health (Taha wairua), mental health (Taha hinengaro), family health (Taha whaanau), and physical health (Taha tinana) in a person's overall health and well-being. To ensure ongoing cultural safety we encourage those of you who identify as Maaori and who are participating in health research or clinical trials to seek cultural support and advice from your Kaumatua or Whaea. Alternatively, please alert your physiotherapist if you have any questions regarding any of these aspects of your health, they will have information and contact details about Maaori Health Services in your area.

Statement of Ethical Approval

This study has received ethical approval from the Multiregional Ethics Committee.

Ethics reference number MEC/11/11/089

APPENDIX D: CONSENT FORM



Consent Form

Telerehabilitation to improve outcomes for people with stroke



Project Manager	Nicola Saywell	Phone: (09) 921 9999 x7084
Investigators	Denise Taylor Alain Vandal Suzie Mudge Leigh Hale Stephen Milosavljevic	Phone: (09) 921 9680 Phone: (09) 921 9999 x7726 Phone: (09) 921 9999 x7096 Phone: (03) 479 5425 Phone: (03) 479 7193
For Information	Liz Binns	Freephone 0508 835373422 (TELEREHAB)

Only people who understand basic written and spoken English will be eligible to participate in this research.

Unfortunately, due to the frequent telephone and text contacts required for this study, we are unable to include people who do not speak English.

I have read and I understand the information sheet dated 19 October 2011 for volunteers taking part in the study investigating using telerehabilitation to improve outcomes after stroke. I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.	Yes	No
I understand that I have a 50:50 chance of being in the ACTIV programme.	Yes	No
I have had the opportunity to use whānau support or a friend to help me ask questions and understand the study.	Yes	No
I know who to contact if I have any questions about the study.	Yes	No
I understand that taking part in this study is voluntary (my choice), and that I may withdraw from the study at any time, and this will in no way affect my future or continuing health care	Yes	No
I understand that my participation in this study is confidential and that no material that could identify me will be used in any reports on this study.	Yes	No
I understand that the treatment, or investigation, will be stopped if it should appear harmful to me.	Yes	No
I understand the compensation provisions for this study.	Yes	No
I have had time to consider whether to take part in the study.	Yes	No
I know who to contact if I have any side effects from the study.	Yes	No
I consent to my interviews being audiotaped.	Yes	No
I would like the audiotape of my interview returned to me when the study is complete.	Yes	No

I agree to the information about any hospital admissions I may have during the study, being accessed by the researchers (for use in this study alone)	Yes	No
I agree to my GP or other current provider being informed of my participation in this study.	Yes	No
I am aware that I may be excluded from participation in the study if my medical practitioner feels I am not medically fit	Yes	No
I wish to receive a summary copy of the results	Yes	No

I _____ (full name) hereby consent to take part in this study.

Date:

Signature:

Project explained by:

Project role:

Signature:

Date:

APPENDIX E: INVITATION TO PARTICIPANTS



Date: _____

Dear _____,

The staff of the District Health Board, Stroke Services identified you as someone who may be interested in a research study currently being carried out by AUT University.

The study will investigate the use of technology such as telephones and mobile phones together with a limited number of face-to-face contacts, to support people as they move from hospital rehabilitation to living independently at home again. The researchers are recruiting people to take part in the study who; are 20 years or older and have had a first-ever stroke that has affected their physical function.

Enclosed is a detailed information sheet about the research study. A research assistant will phone you in the next week to 10 days, to see if you would be interested in participating in the study. You are under no obligation to join the study the phone call will simply establish if you are interested.

Please feel free to contact the Principal Investigator, Denise Taylor on (09)9219680 or Freephone 0508 835373422, if you would like to hear more about the study or have any questions about the research.

Kind regards,

Nicola L. Saywell

Nicola Saywell
Physiotherapist and Senior Research Officer
School of Physiotherapy
AUT University
nicola.saywell@aut.ac.nz
(021) 2086828
(09) 921 9999 x 7084

Telerehabilitation to improve outcomes for people with stroke

Version 3

Letter of invitation

10/05/12

APPENDIX F: NEWSPAPER ADVERTISEMENT



**Telerehabilitation to improve outcomes for people
with stroke**

**Are you interested in taking part in research investigating
home visits and phone messages to help you achieve
activities you enjoy doing?**

We are inviting anyone who had their first stroke less than 18 months ago and has
been discharged from hospital outpatient or community physiotherapy and has
some arm or leg weakness to participate.

What happens during the study?

The study involves being assessed using a variety of measures at the start, after 6
months and after 12 months.

If you would like to find out more information please contact Nicola Saywell on:
0508 835373422
OR
(09)9219502



APPENDIX G: TELEPHONE SCREENING FORM



Eligible: UL / LL
Ineligible: Cognitive
Physical
Not Interested



Telephone Screening Form

Recruiter: _____ DHB: _____ Date: _____

Participant Details: _____ NHI No: _____

Name: _____ DOB: _____ Age: _____

Address: _____ First Stroke: Yes / No
Ischaemic / Haemorrhagic

Phone: _____ Mobile: _____

General questions:

Did you receive our Letter? Yes / No

Can I answer any possible questions?

Are you currently in any other research study? Yes / No

If yes which one: _____

Are you interested and/or happy to continue? Yes / No

If not - reason: _____

Eligibility Screening: _____ TURN TO PAGE 2

Cognitive SIS Score: _____ / 6 Eligible if score ≥ 3

Lower Limb Screen:

Functional Ambulation
Category:

Eligible if category ≥ 4
NB: if category 6 = must answer 'NO' to at
least one of the walking parameters

Walking Parameters:
1. Yes / No
2. Yes / No

Upper Limb Screen:

Section A
No of questions answered 'YES'

_____ / 3

Eligible if answer 'YES' to at least 1 in |
section A AND answer 'NO' to at
least 1 in Section B

Section B
No of questions answered 'NO'

_____ / 3

Please Note: Must screen eligible for either upper limb or lower limb or both

Inclusion Criteria:

People will be eligible for inclusion if they: have had a first ever stroke of haemorrhagic or ischaemic origin, are aged 20 years or older, have been discharged from rehabilitation services to living in the community, have a limitation in physical function, have medical clearance to participate in a low to moderate activity programme from their GP and score at least 3 on a telephone cognitive screening questionnaire.

Limitation in physical function in walking and balance will be established if they have a functional ambulation category between 4 and 6 (and if category 6, also answer 'No' to at least one of the 2 walking parameter questions). Limitation in physical function in the arm will be established using the Upper limb function screening, if they answer 'Yes' to at least 1 question in section A and 'No' to at least 1 question in section B. People who have had brain stem and cerebellar strokes will be excluded from the study.

Cognitive Screening

Six-Item Screener:

I would like to ask you some questions that ask you to use your memory.

I am going to name three objects.

Please wait until I say all three words and then repeat them.

Remember what they are because I am going to ask you to name them again in a few minutes.

Please repeat these words for me: ① **APPLE** ② **TABLE** ③ **PENNY**

NB. Interviewer may repeat the names 3 times if necessary but repetition not scored.

Did participant correctly repeat all three words?

_____ / _____ / _____

☐

Yes

☐

No

1. What year is it? _____

Incorrect

Correct

☐

0

☐

1

2. What month is it? _____

☐

0

☐

1

3. What day of the week is it? _____

☐

0

☐

1

4. What were the three objects I asked you to remember?

a. Apple

☐

0

☐

1

b. Table

☐

0

☐

1

c. Penny

☐

0

☐

1

SCORE:

 / 6

NB: If score ≥ 3 proceed to Physical screens

Lower Limb Screening

1. Functional Ambulation Categories:

(Circle category)

1	Non-functional ambulation	Patient cannot ambulate, ambulates in parallel bars only, or requires physical assistance from more than one person to ambulate safely outside parallel bars
2	Ambulator-Dependent on maximal physical assistance	Patient requires manual contact of no more than one person during ambulation on level surfaces to prevent falling. Manual contacts are continuous and necessary to support body weight as well as maintain balance and /or assist with co-ordination.
3	Ambulator-Dependent on minimal physical assistance	Patient requires manual contact of no more than one person during ambulation on level surfaces to prevent falling. Manual contacts consist of continuous or intermittent light touch to assist balance or co-ordination.
4	Ambulator-Dependent on supervision	Patient can physically ambulate on level surfaces without manual contact of another person but for safety requires standby of no more than one person.
5	Ambulator-Independent level surfaces only	Patient can ambulate independently on level surfaces but requires supervision or physical assistance to negotiate any of the following: stairs, inclines, or non-level surfaces
6	Ambulator-Independent	Patient can ambulate independently on non-level and level surfaces, stairs, and inclines

2. Walking Parameters:

Can you get across the road in the time the green man is showing? Yes/No

Are you able to walk 400m? Yes/No
(i.e. ¼ mile, 1-2 blocks, 3 x rugby field)

Upper Limb Screening

3. With your affected arm are you able to:

- | | |
|---|--------|
| 1. Switch on a light? | Yes/No |
| 2. Bring a glass of water to your mouth? | Yes/No |
| 3. Move your fingers and thumb independently? | Yes/No |

4. Are you able to:

- | | |
|--|--------|
| 1. Use a keyboard equally with both hands? | Yes/No |
| 2. Holding a pencil with your affected hand make rapid dots on a piece of paper? | Yes/No |
| 3. Take a spoonful of liquid to your mouth without spilling it or bending your head? | Yes/No |

APPENDIX H: LETTER TO GENERAL PRACTITIONER

Date: _____



Dear Doctor _____

We are conducting a study investigating the effects of telerehabilitation to improve the outcomes for people with stroke. Your patient, _____, has kindly volunteered to participate in this study. As a participant in the research, your patient will be assessed using a range of questionnaires and physical outcome measures.

Depending on the group that _____ is randomized to; he/she may only receive the assessments or both the assessments and the intervention. This intervention will begin once they have been discharged from formal therapy, either inpatient or outpatient and aims to improve the transition between rehabilitation and independent living. It will be a 6-month programme, which will involve four face-to-face visits from a physiotherapist and encouragement to maintain the exercises via phone and text message. Participants who don't have a mobile will be given one with a \$20 monthly credit to enable participation. All the assessments and intervention will be carried out in the participants own home.

_____ has given us permission to notify you of their participation.

If you have any concerns about their safety to participate, please contact the research team within the next 10 days.

You can contact us at the following:

Tel: Nicola Saywell (09) 921 9999 ext. 7084 or 021 2086828 or email: nicola.saywell@aut.ac.nz

Tel: Denise Taylor (09) 921 9680 or email: denise.taylor@aut.ac.nz

If we do not hear from you, we will assume that you do not have any concerns about _____ participating in this research study. Thank you for your help in ensuring our participants' safety.

Yours sincerely

Nicola Saywell
Senior Research Officer
Health & Rehabilitation Research Institute
AUT University
Private Bag 92006
Auckland

Denise Taylor
Associate professor
Health & Rehabilitation Research Institute
AUT University
Private Bag 92006
Auckland


APPENDIX I: PHYSIOTHERAPY INITIAL ASSESSMENT





Date: / /	Participant ID:	Mobile phone: Y <input type="checkbox"/> N <input type="checkbox"/>
Physio Initials:	DOB: / / 19	Mobile No:
	Age:	Email address:
	Sex: M <input type="checkbox"/> / F <input type="checkbox"/>	

The ACTIV Programme – Initial Assessment Form	Medical History (Stroke)	Relevant Other Medical History:
		Hypertension <input type="checkbox"/> Diabetes <input type="checkbox"/> Cardiac condition <input type="checkbox"/> Respiratory condition <input type="checkbox"/> Osteoarthritis <input type="checkbox"/> Joint replacement <input type="checkbox"/> Other <input type="checkbox"/>
	Medication:	Relevant Social History:
	What do you want to do most? <i>(get participant to write in workbook)</i>	
	Participants perceived reason for difficulty:	
Simulation of chosen activity: <i>(observe and analyse participant while conducting chosen activity)</i>		
Functional Problem list:	Exercises chosen: <i>(3-4 maximum)</i>	

APPENDIX J: LOWER LIMB EXERCISE MENU


Lower Limb Exercise Chart																			
Participant ID No: _____		Physio Initials: _____																	
What they want to do most: _____																			

Activity	Visit No:		Date:			Ph Call No:		Date:			Ph Call No:		Date:						
	Time:	Reps:	Sets:	Speed:	BOS:	Time	Reps	Sets:	Speed:	BOS:	Time:	Reps:	Sets:	Speed:	BOS:				
A. 2 Leg Stand																			
B. Sit - Stand																			
C. Stepping Task																			
D. Step Up																			
E. Moving Objects																			
F. Walking																			
G. Turning																			
H. Heel Raises																			
I. Stair Climb																			
J. 1 Leg Stand																			
		Examples of altering complexity: • Eyes closed • Distance • Accuracy • Change surface • Holding an object										 Not a recommended parameter, however use if required.							

APPENDIX K: UPPER LIMB EXERCISE MENU

Upper Limb Exercise Chart															
Participant ID No: _____		Physio Initials: _____													
What you want to do most: _____		<div style="border: 1px solid black; padding: 5px; display: inline-block;"> ACT V </div>													

	Visit No: _____	Date: _____				Ph Call No: _____	Date: _____				Ph Call No: _____	Date: _____			
Activity	Time:	Reps:	Sets:	Speed:	Object:	Time:	Reps:	Sets:	Speed:	Object:	Time:	Reps:	Sets:	Speed:	Object:
A. Arm Lift															
B. Grasp (isolated)															
C. Reach to Touch															
D. Reach to Grasp															
E. Independent finger movement															
F. In-hand Manipulation															
G. Steriognosis															
H. Bi-manual Task															





Examples of altering complexity:

- Force grading
- Weight
- Secondary Task
- Symmetry
- Accuracy
- Speed


Not a recommended parameter, however use if required.

APPENDIX L: LOWER LIMB EXERCISE EXAMPLE

	Lower Limb Exercise Sheet		
	Exercise J	1 LEG STAND	Physio: _____ Phone No: _____
This exercise works on: _____ And helps you improve your: _____			
		Visit No:	Phone Call:
	How long:		
	How many:		
	How often:		
	How fast:		
	How much support:		
Comments: _____ _____ Try to work at a moderate level of exertion without getting short of breath or fatigued.			
<div style="border: 1px solid black; padding: 5px;"> IMPORTANT: - Ensure the area around you is clear of unwanted objects - Always have bare feet or shoes that fit firmly STOP if you are in pain! </div>			

ACT V

APPENDIX M: UPPER LIMB EXERCISE EXAMPLE

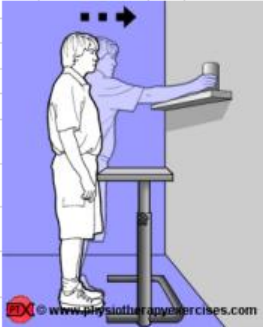


Upper Limb Exercise Sheet

Exercise D

REACH to GRASP


Physio: _____
Phone No: _____



This exercise works on: _____
And helps you improve your: _____

	Visit No:	Phone Call:	Phone Call:
How long:			
How many:			
How often:			
How fast:			
Object:			

Comments: _____



ACT V

IMPORTANT:

- Ensure the area around you is clear of unwanted objects
- Always have bare feet or shoes that fit firmly
STOP if you are in pain!

APPENDIX N: PHYSIOTHERAPY FOLLOW-UP ASSESSMENT



Follow Up Assessment Form

Date: _____

Assessment Number: _____

Participant ID:	Physio Initials:
-----------------	------------------

Are you able to do the activity we discussed?

--

Have you noticed any improvements/changes?

--

What do you want to do most? *(this may or may not have changed since last visit)*

--

Simulation of chosen activity: *(observe and analyse participant while attempting activity)*

--

Functional Problem list: Exercises chosen: *(3-4 maximum)*

The ACTIV Trial

APPENDIX O: PHYSIOTHERAPY TELEPHONE CALL



Date: _____

Participant ID No: _____ | Call #: _____ Physio Initials: _____

1. Since we last talked, have you managed to do any of your exercises? **None / Some / All**
(circle relevant answer)

Participant answer 'Yes' - Go to question 2

Participant answer 'No' - "Can you tell me what has stopped you?"

*If you are currently having a problem with your speech, vision,
or increased weakness you should call 111 or your GP*

2. If we look at the exercise plan we discussed which exercises have you been able to complete?

Participant answer 'something positive about exercise adherence' - "that is great, keep up the good work,"
"do you think you could do a little more, or could we make it a little harder?" (talk to participant about what they
find is very useful/difficult/easy, do you think you would manage to do x, y, z?)

Participant answer 'something negative or expressing difficulty' - "can you tell me what is preventing you from
doing your exercises" (time, are they confusing, are you feeling tired or weak, do you need some help with them?)

3. What would make it easier for you to complete the exercises?

May be a case of reducing the number of exercises? - Is there just one KEY exercise that is the most important?
May need to reduce intensity by reducing time, repetitions or difficulty.

4. Concluding statement

"remember that these exercises are really aimed at helping you to (relate to what they want to do)"

NOTES:

APPENDIX P: PARTICIPANT WORKBOOK



Augmented Community Telerehabilitation Intervention

© Participant Workbook

☉ Welcome to the programme

This study investigates if easily accessible technology (like a mobile phone) can be used as part of a low cost programme to encourage you to continue with exercises following a stroke. The aim of the ACTIV programme is to improve your independence as you move from hospital-based rehabilitation to living back at home.

☉ How has it come about?

- You probably made good progress in hospital and increased the number of things you could do
- Many people have told us that once they got home things seemed a lot harder than they did in hospital
- Increased difficulty with normal activity may have reduced your confidence
- You may have felt a sense of isolation after being discharged from hospital, especially if you have limited support or access to things you use to enjoy

☉ What does this mean?

You (with the help of your physio) will work out what activity you would like to work on and which exercises will help you achieve this. Over 6 months you will receive regular home visits, phone calls and text messages from your physio, to support and encourage you to achieve your target.

⊙ Visit and phone call schedule while on the **ACTIV** programme:

- Over the next 26 weeks (6 months) you will have the following visits and phone calls with your physio
- An assessment at 6 months and the final assessment 12 months after starting the programme

Your Physiotherapist is _____ and you can contact them on _____.

Contact:	Date:	Time:	With:
Visit 1 (week 1)			Physio
Phone call 1 (week 2)			Physio
Visit 2 (week 3)			Physio
Phone call 2 (week 5)			Physio
Phone call 3 (week 9)			Physio
Visit 3 (week 13)			Physio
Phone call 4 (week 16)			Physio
Phone call 5 (week 20)			Physio
Visit 4 – Final (week 26)			Physio
6 month Assessment (week 27)			Assessor
12 month Assessment (week 52)			Assessor



Programmes key goal: “Helping you get back to what you want to do”

So..... What do you want to do?

Write here:

◎ Steps to your target.....

It may be helpful to write down some steps you will take towards your target and the dates of your achievement:

Date Achieved:

- | | | | |
|-----------|-------|--------------------------|-------|
| ❖ Step 1: | <hr/> | <input type="checkbox"/> | <hr/> |
| ❖ Step 2: | <hr/> | <input type="checkbox"/> | <hr/> |
| ❖ Step 3: | <hr/> | <input type="checkbox"/> | <hr/> |
| ❖ Step 4: | <hr/> | <input type="checkbox"/> | <hr/> |

🕒 **Safety when exercising at home:**

- Ensure the area around you is clear of unwanted objects
- Always have bare feet or shoes that fit firmly
- When standing – exercise next to a stable surface for balance e.g. kitchen bench, kitchen table, wall, firm chair
- **STOP if you are in pain**

You and your physio have decided on some specific exercises to work toward your target

Remember...

- There may be days you find it harder than others to do your exercises
- Don't be discouraged as this is completely normal, the important thing is to keep active!
- Reflect on your progress and achievements so far (no matter how small they may seem)
- Acknowledge all possible emotions but try not to let them stop you achieving – eg frightened, unsettled, frustrated

“Good progress can still be made if you continue to work at it...”

⦿ Response to exercise:

- The following are some normal responses to exercise which you may experience:
 - Stiffness
 - Sore muscles / body
 - Increased tiredness / sense of fatigue after exercising

These should pass in 2-3 days and are a healthy sign you are challenging your body

- There is a very small possibility that you might experience more than just these responses so:
 - Once a month you will receive a brief phone call to see if you have experienced any problem that is more than the normal response to exercise. This may or may not be related to the programme.
 - If you experience any of the following, you should stop the programme immediately and seek medical advice:
 - Pain in the chest
 - Sharp, burning muscle pain which lasts longer than 2-3 days
 - An increase in any joint pain

Progress after stroke can be quite rapid especially in the first few weeks. Later on, improvements are usually subtle and progress may seem to slow down.

“It is your own efforts that will sustain your progress.....”

☉ Keeping Active:

‘Active’ doesn’t necessarily mean exercise. It also means simply doing **‘whatever you want to do’**. This includes every-day activities like making a cup of tea or polishing the furniture.

- By keeping active and trying to challenge yourself, your progress after stroke will improve
- People have found that the best way to keep active after stroke is to:
 - Set specific targets
 - Use regular exercise to work towards your target and
 - Reward yourself when you achieve

☉ Planning for your future.....

After stroke, having **‘hope for the future’** can be helpful in motivating you when progress seems slow. For most people, progress often is just getting on with the things they did before their stroke and returning to a normal life as soon as possible.



☉ Acknowledgements:

- This booklet contains some information and content which has been utilised from the 'Bridges Stroke Self-Management' workbook. Thank you to Dr Fiona Jones from St George's, University of London and Kingston University for willingly sharing both experience and resources.
- The pictures found on all exercise sheets in the ACTIV programme are generated from the PTX website (physiotherapyexercises.com). Thank you to Associate Professor Lisa Harvey from the Rehabilitation studies unit at the University of Sydney for allowing free use of the exercises.
- Some information in this participant workbook has been adapted from the Otago Exercise Programme. Thank you to the NZ falls prevention research group from the University of Otago.
- **Team members:**
Associate Professor Denise Taylor, Nicola Saywell, Associate Professor Alain Vandal, Associate Professor Leigh Hale, Dr Carl Hanger, Associate Professor Stephen Milosavljevic, Dr Suzie Mudge, Professor Paul Brown, Professor Valery Feigin

APPENDIX Q: ADVERSE EVENTS RECORDING FORM



Researcher: _____



Adverse Events Form

Date: _____

Participant No: _____

NHI No: _____

1. Have you experienced any adverse events such as falls, fatigue, muscle soreness or injury over the past 4 weeks?

Yes ☐ (fill out details below)

No ☐ (conclude phone call)

Detail: _____

2. Month event occurred: _____

3. Outcome of event (tick one only):

☐ Resolved without any lasting problems

☐ Resolved but with ongoing problems (fill out details below)

Ongoing problems: _____

☐ Other, specify _____

4. Have you had to seek any medical treatment as a result?

Yes ☐ (fill out details below)

No ☐

Detail: _____

5. Hospital admission:

Yes ☐ (fill out details below)

No ☐

Date of admission: _____

Hospital: _____

6. Have you had to alter your daily activities as a result?

Yes ☐ (fill out details below)

No ☐

Detail: _____

8. Fatal Event:

Yes ☐ (fill out details below)

No ☐

Date of death: _____

Cause of death: _____

APPENDIX R: RECRUITMENT PROCEDURE



Recruitment Procedure:



1. Liaise with nominated person within the stroke unit in your area twice weekly:
 - List names of all people admitted with first time stroke on recruitment register (dropbox)
2. Identify all who meet inclusion criteria
 - first ever stroke (haemorrhagic or ischaemic only)
 - aged 20 or older
 - have some physical limitation in upper or lower limb
 - planned discharge destination is their own home
 - have not had a brainstem or cerebellar stroke
3. If a patient does not meet the inclusion criteria only fill in boxes 1-4 on recruitment register
4. Visit all patients in hospital identified by the nominated person (see item 1) who meet the inclusion criteria, introduce yourself and let them know that AUT undertakes research – ask if they would be interested in receiving information about upcoming research once they have been discharged home
5. Identify actual discharge date and check if there is outpatient (O/P) or community therapy planned.
 - If O/P or community therapy is planned, note contact person for service on register and liaise to establish discharge date from that service. Once discharged from that service, action item 6
 - If no O/P or community therapy is planned, action item 6
6. Send the information sheet with an introduction and invitation letter
7. 7-10 days after sending info - phone person and check (on telephone screening form):
 - They have received the letter
 - Whether they have had a chance to read it
 - Whether they have any questions
 - If they are interested in joining the study
8. If they are interested and willing to answer screening questions continue to item 9, if not thank them for their time and conclude phone call.
9. Undertake cognitive screening questionnaire over the phone

10. If score is under 3, explain that they have not met the inclusion criteria and conclude phone call.
This needs to be done in a sensitive way as not meeting a cognitive threshold may be upsetting, so you may ask a couple of questions about their normal day-to-day activities to avoid a blunt dismissal.
11. If score is over 3 and the person is happy to participate, undertake physical screening questionnaire
12. If neither upper limb or lower limb fits criteria, explain they have not met the inclusion criteria and conclude the phone call
13. If inclusion criteria met, explain they are eligible for the study and will be contacted within a couple of days for an initial assessment to be scheduled (undertaken in their own home)
14. Send all eligible participants telephone screen to **Nada Signal** at AUT each week
15. E-mail assessor with
 - a) participant name
 - b) DOB
 - c) Address and phone number for initial assessment to be scheduled
 - d) Date of stroke and whether it is ischaemic or haemorrhagic.
16. Ensure you have put the initials of the assessor on the recruitment register (dropbox)
17. If you are in one of the Auckland centres alternate between your two assessors
18. **Transfer and/or update all information in recruitment register (dropbox) once processes completed, include reason for exclusion if not eligible.**

If you have any queries or concerns regarding the study or recruitment process, please contact:

Bobbie-Jo Wilson
Mobile: 021 323 081
E-mail: bjwilson@aut.ac.nz

APPENDIX S: ADVERSE EVENTS PROCEDURE



Adverse Events Procedure:

1. Open adverse events register (on dropbox) for a list of all participants and their information
2. Phone each participant monthly and complete an Adverse Events Form (do NOT leave any blanks)
3. Remind participants that they will receive an adverse events phone call every month (for a period of 6 months from start of study) regardless of the group they are in
4. On the final phone call, inform participant they will not receive any further adverse events calls
5. After completing each phone call – record and update details on the Adverse Events Register on Dropbox
6. File all completed adverse event forms numerically (by participant ID no.) under corresponding month in the adverse events folder at AUT
7. If you have any queries or concerns regarding the data collection or process for adverse events please contact:

Bobbie-Jo Wilson

Mobile: 021 323 081

E-mail: bjwilson@aut.ac.nz

Withdrawal from the study:

If at any stage the participant wishes to withdraw from the study, fill in a 'Withdrawal from the study' form and send to Bobbie-Jo Wilson by e-mail, record the date of withdrawal on the adverse events register.

Please note: If you are unable to contact a participant for a period of 1 week, please telephone emergency contact to find out if the participant is away or in hospital and how you can contact them.

APPENDIX T: TRAINING PROGRAMME FOR BLINDED ASSESSORS

Assessor Training Programme

Brief Study Outline:

- Description of study (helpful to answer possible questions from participants)
- Contact people (so able to refer queries to appropriate person)
- The broad aim of study
- Outcome measures (what you will be collecting)

Assessors Procedure

- Complete run through of the procedure to allow the process to be understood in detail

Research Aspect:

- Standardised – same steps and process for every individual
- Importance of filling in all boxes on every form (not leaving any room for assumptions and therefore errors)
- Importance of remaining Blinded (remind participants when making appointments not to discuss which group they are in)
- Acknowledging if become 'unblinded'
- Asking tricky questions

Assessment Procedure:

Informed consent

- o 1 x copy for AUT and 1 x copy for participant
- o Ethical dilemma of 50/50 dispersion
- Remind if they are NOT in the ACTIV group, will still have a 6mth & 12mth assessments

Checking of physical data

Quick check to confirm eligibility

Baseline assessment

Includes some economic data

SIS 3.0

Well validated and reliable in the stroke population

Physical assessments

- o Step test
- o dynamometer

The stroke self efficacy questionnaire

Developed by an advisor on our project as a specific tool to assess confidence in people with stroke

Economic Evaluation:

- Introduction to the use of the information that will be gathered
- Difficulty in some of the questions
- EQ5D

Dropbox Training:

- Installing Dropbox on computer
- Importance of having it installed properly so files update
- Individual folders to access
- Who to contact if you need help?

Equipment

- 1 standard step
- 1 stop watch
- 1 hand held dynamometer
- Assessor file
- Laminated procedure

APPENDIX U: BLINDED ASSESSOR PROCEDURE



Assessment Procedure:

1. Enter participants name, NHI no, DOB & contact details on the assessment register (dropbox) as you receive it from recruiter (by e-mail)
2. Enter date referral received on assessment register (dropbox)
3. Phone participant to make an appointment for the initial assessment within 4 working days of receiving the referral (update in dropbox)



NB: participant ID no. will be entered by Nada Signal once randomisation has occurred

Initial assessment:

4. Complete the informed consent process, if consent is gained continue with the assessment and leave a copy of informed consent with participant
5. Check that the participant fulfils the criteria for 'limitation in physical function' for lower limb, upper limb or both. The recruiter has already collected this data at telephone screening, but if they have given incorrect information on the phone, they will need to be excluded at this point.
6. If the participant identifies as Maori please advise them to seek advice and tautoko (positive behaviour support strategies) from their own whanau, Kaumatua or Kuia or local Maori health services as detailed on their information sheet
7. Perform assessment and record findings on assessment sheet
8. Inform participant that they will be contacted within a week to let them know whether they will be in the ACTIV or control group (outline the 50/50 chance of being in either group)
9. Remind participant they will receive a monthly phone call to check on any possible adverse events. Their emergency contact person will be called if participant not able to be contacted for one week.
10. Further assessments will be undertaken at 6 and 12 months, regardless of the group they are in (remind that you are not allowed to know which group they are in)
11. Fill out a Baseline confirmation assessment form, save it in your dropbox with participants initials and e-mail form to **Nada Signal**. This confirms the initial assessment has been completed and the participant can now be randomised.
Email address: nsignal@aut.ac.nz
12. Send the completed informed consent form and assessment sheet to **Liz Binns** at AUT
13. Send the letter to their GP informing them of their willingness to participate in the study and requesting confirmation that there are no concerns about their safety to participate
14. Update information on assessment register (dropbox) once completed

Follow-up assessment (6 & 12 month):

15. You will need to check the assessment register (dropbox) prior to ascertain participant ID no. prior to follow up assessment
16. Complete the follow-up assessment form (identifying either 6 or 12 month) and note any change in the participants details
17. Send the completed follow-up assessment form to Liz Binns at AUT
18. Update information on assessment register (dropbox) once completed

Please Note: You will be contacted closer to the participants 6 month and 12 month follow/up assessments (2-3 weeks prior) for convenient times to be scheduled

Withdrawal from the study:

If at any stage the participant wishes to withdraw from the study, fill in a 'Withdrawal from the study' form and send to Bobbie-Jo Wilson by e-mail, record the date of withdrawal on the assessment register.

If you have any queries or concerns regarding the study or assessment process please contact:

Bobbie-Jo Wilson
Mobile: 021 323 081
E-mail: bjwilson@aut.ac.nz

APPENDIX V: TRAINING PROGRAMME FOR PHYSIOTHERAPISTS



Physiotherapist Training Schedule

Day 1:

Tea/Coffee 10.30- 11am

Introduction and Rationale 11-12 noon

Introduction to the staff - Denise, Niki, BJ

Housekeeping, health and safety requirements.

Rationale:

Theoretical basis – reference to underpinning literature

Outline of study:

- Aims/questions of study and background
- Inclusion criteria (physical ability, range of participants)
- Recruitment areas & outcomes
- ACTIV programme(brief overview)
- Physio contact points (brief introduction to txt msg & WebSMS usage)

Lunch 12 noon

Undertaking the intervention 12.45pm – 2.30pm

Physio Protocol:

- Go through entire protocol
- Introducing different aspects i.e. Dropbox & ACTIV register, Web SMS for text messages
 - o All aspects to be gone over in depth later

- Consistency and following research ethos / protocols
- Privacy and confidentiality and professional responsibility

Initial Assessment:

- Working through Assessment form
 - Goal identification – focus on ‘what participant wants to do’
 - o Focusing on abilities and successes
 - o Achievable steps – using the exercises provided
 - Simulation of chosen activity
 - o The best you can do
-
- Problem list
 - o Prescribe exercises
 - o What is point of the exercises?
 - o Tailored to individual needs – “what they want to do most”

2.30pm – Tea/Coffee

Treatment Programme: exercise charts

- Intensity, repetitions and effectiveness vs. achievability and sense of purpose
 - o Negotiation of timetable for completing exercises
- Work through Exercise Charts – UL / LL
 - o Altering complexity of exercises

- Role playing/ Case scenarios
- Recap of day
- Outline for Day 2

Day 2:

9.30 -10am- Meet Suzie Mudge talk about support for the physios, where and when to contact her, reasons to contact her.

Follow Up Assessments (contact time line)**Home:**

- Work through F/U assessment form (following physio procedure)
- Discuss adverse events

10.30am – Tea/Coffee

11 – 1pm In computer lab**Messaging:**

Web SMS Training – look at system

- Text message protocol – content and idea behind/ examples
- E-mailing or telephone calls (participant preference)
- Reference physio contact points (timeline for contacts)

Participant Mobiles

- Training (look at phones) use and receive messages
- Practise use of phones and setting them up so they are easy to use for the participants
- Ordering if needing more

- Top Ups for participants
- Protocol if participants have own phones |

Dropbox Training:

- Installing Dropbox on computer
- Importance for having it installed properly so files update
- Individual folders to access
- Who to contact if needing help?

1pm - Lunch

1.45pm- Follow up contact

Telephone:

Work through telephone follow-up form

- Ideas behind telephone contact
- Get idea of participant success/ challenges
- Areas to focus on
- No new exercises to be given over phone

Focus on final visit

- How is it different?
- What should they know by now?
- What else can they expect?

2.45 Tea Coffee

Recap of training days

- Return to any area where more detail is needed
- Confusions or questions?

APPENDIX W: PHYSIOTHERAPIST PROCEDURE



Physiotherapist Procedure

- Enter participant details on the Physio register (dropbox) as you receive it from Nada Signal
- Phone participant to make an appointment for the start of the intervention (this is to be scheduled within one week of receiving information)
- E-mail Suzie Mudge with participant name, ID, DOB and planned date of first visit.
- Phone participant a week before all subsequent visits to arrange a suitable day and time and get participant to write it in on page 3 of their workbook



Initial Home Visit:

1. Complete the ACTIV programme - assessment form (**do not leave blanks**)
2. Write on appropriate exercise chart (UL/LL or both) what the participant "wants to do most"
3. Get participant to write what they want to do on page 4 in their participant workbook
4. Decide & prescribe the exercises (3-4 maximum) that best fit what they want to do most, & fill in all corresponding white boxes on the applicable exercise chart
5. Select individual exercise sheets from physio pack and fill in all boxes (engage participant in the process)
6. Fill in visit number above exercise boxes and explain to participant that they will fill in the phone call boxes over the phone with you
7. Observe participant doing all selected exercises and encourage their comment on success
8. Put the exercise sheets in the participant workbook to leave with them
9. Schedule a convenient day to ring the participant for the follow up telephone call and write in the participant workbook on page 3
10. Send the top copy of assessment form to Suzie Mudge at AUT (within 1 week of assessment)
11. Once initial home visit completed – enter all relevant information on Physio register (dropbox)

Subsequent Home Visits:

1. Check how participant is managing all exercises
2. Perform and complete ACTIV follow up assessment form with participant
3. Start a new exercise chart (UL/LL or both) for each face-to-face interaction with the participant and number accordingly (NB there are 2 phone calls between each visit except between the first and second visit when there is only 1)
4. Increase/change level of difficulty for existing exercises if appropriate
5. Select other exercises if these are now indicated (still no more than 4 in total)
6. Observe participant doing all selected exercises and encourage their comment on success

7. Remove all exercise sheets that are not being prescribed for this time period, so only current exercise sheets are in the participant's workbook
8. Send top copy of the ACTIV follow up assessment form to Suzie Mudge at AUT (within 1 week of follow up assessment)
9. Once subsequent home visits completed – enter accordingly on Physio register (dropbox)

Telephone Follow Up Interaction:

1. Go through / complete the telephone follow up form and gain participant feedback on exercises
2. No new exercises are to be prescribed by phone
3. Increase/change level of difficulty for existing exercises if appropriate and record on phone call portion of exercise chart
4. Get participant to record exercise changes on their individual exercise sheet in appropriate area
5. If you are unable to contact a participant for longer than 4 days, contact nominated alternative contact person
6. Send top copy of the telephone follow up form to Suzie Mudge at AUT with exercise charts (see no. 7)
7. Send top copy of all appropriate exercise charts being used (UL/LL or both) to Suzie Mudge at AUT once second telephone follow up has been completed. (NB there is 1 phone call after initial visit only)
8. Once any telephone follow up interaction completed – enter on Physio register (dropbox)

Text Messages:

1. Follow Message media – SMS procedure / tips for how to log into message software online
2. For weeks 1- 10 twice weekly messages need to be sent, with an emphasis on goal attainment and encouragement about their ability to achieve this goal
3. For weeks 11-26 weekly text messages need to be sent as above
4. Once any text or e-mail message completed - enter on Physio register (dropbox)
5. If you have any queries or problems regarding the message media software please contact:

BJ Wilson
Mobile: 021323081
E-mail: bjwilson@aut.ac.nz

Withdrawal from the study:

If at any stage the participant wishes to withdraw from the study, fill in a 'Withdrawal from the study' form and send to Suzie Mudge by e-mail, record the date of withdrawal on the physio register.

If you have any queries or concerns or need any professional support/advice regarding the ACTIV intervention please contact:

- Suzie Mudge
Mobile: 027 642 4007
E-mail: smudge@aut.ac.nz

APPENDIX X: TRAINING CASE SCENARIOS FOR PHYSIOTHERAPISTS

Case scenarios

1. 65-year-old woman previously fit and well and very independent.

She is frustrated that she is now unable to go shopping to her local shops and wants to go out with her grandchildren.

Most wants to go to the shops to get bread, milk and essentials AND wants to be able to care for her active 2-year-old granddaughter

2. 75-year-old man used to do many jobs round the home, lives with his very fit wife who is now extremely helpful and waits on him hand and foot. He is very clumsy with tools now and has poor sensation in his hand

Most wants to be able to use a hammer and a screwdriver

3. 80-year-old woman has returned to some previous activities after a mild stroke, but complains of being very slow and unsteady on stairs or rough ground. She walks very slowly now even on flat ground and has a daughter who thinks her Mum needs to go in a rest home

Most wants to walk a bit faster and more safely to prove to her daughter that she is fine at home.

4. 50-year-old Maori man with supportive family, wants to go on a Marae visit but will only go if he can get on the floor to sleep overnight there. He can only walk about 10m unaided

Most wants to be able to walk the 200m to get on the Marae and then get on and off the floor with minimal help

5. 74-year-old man who has come home for a trial, but is finding it very hard to get out of his chair and do anything for himself. He has good arm function but poor leg function. He has an elderly wife who uses a walking frame and is not able to help him physically

Most wants to be able to get out of his chair more easily and do more to help himself, for example get a drink, help with meal preparation or clear the mailbox.

6. 56-year-old woman, has been having occasional TIA's for several years and ignoring them, now has a moderately severe stroke and some neglect and difficulty walking.

Most wants to do the Tongariro crossing next year with her 15-year-old son.

APPENDIX Y: LETTER TO CONTROL GROUP



Date: _____

Dear _____,

Once again, thank you for volunteering for our study. By now, you have had your first assessment and a computer programme has randomly assigned you to a group. You have been assigned to the control group of the ACTIV trial, which means that you will not do the ACTIV programme.

We understand that you may feel disappointed at being assigned to the control group but it is important to remember that we don't know if the ACTIV programme will have a positive effect, which is why we need a control group and an ACTIV group to compare progress.

You will still receive an assessment in 6 months and in 12 months, which will give you information on your progress since your stroke. Many changes happen in the year following stroke and the results of all the measures taken during your assessments will show you how you have progressed. Please feel free to continue with any physical activities you would normally do, such as a walking group or an exercise class.

We can also send you a summary of the findings of the study. All participants will be invited to a meeting at the end of the study and will have an opportunity to discuss the findings with one of the researchers.

Despite not receiving the programme, your participation in this research project is making a significant contribution to research.

Please feel free to contact the Liz Binns on freephone 0508 835373422, if you would like to discuss this study or have any questions about the research.

Kind regards,

A handwritten signature in black ink that reads "Nicola I. Saywell".

Nicola Saywell
Physiotherapist and Senior Research Officer
School of Physiotherapy
AUT University

Telerehabilitation to improve outcomes for people with stroke

Letter to control group

Version 2

15/05/12

APPENDIX Z: PARTICIPANT INTERVIEW CONFIRMATION LETTER



Date

Dear:

Thank you for agreeing to participate in an interview now that you have completed the ACTIV intervention and assessments. We are very appreciative of your time and involvement in the research study.

You will have recently received a phone call regarding one of the Auckland-based researchers coming to xxx on xxxx to complete interviews in your region. This letter is to confirm that xxxx will be interviewing you at the time stated below regarding your experience of ACTIV. With your consent the interview will be recorded and transcribed for data analysis. We would like to reassure you that any information you provide will not be able to be linked directly back to you. All information will remain confidential. If at any stage prior to, during or following the interview you do not wish the information you provide to be used, we will immediately remove it from the study.

The following are the details regarding your interview:

Date: xxxx

Venue: Your residence (unless you would like to arrange to meet elsewhere)

Time: xxxx

Interviewer: xxxx

If you have any questions regarding the interview or the date and time are no longer suitable please do not hesitate to contact me:

Contact details:

Pip Charlesworth

pcharles@aut.ac.nz

(09) 921 9999 ext 8708.

APPENDIX AA: INDICATIVE QUESTIONS FOR QUALITATIVE INTERVIEW

Guidelines for semi structured interview at the end of the intervention

Programme-general impression

What are your general impressions of this programme?

(prompt to gain positives and negatives)

How would you describe this programme to a friend or family member who has had a stroke?

Can you think of anything that we might offer which might motivate other people with stroke to begin a programme like ACTIV? (Possibly prompt small financial incentive, food voucher or similar if participant not sure)

Can you tell me about anything that did not go well for you, whilst you were involved in this study? (this may include the assessments, so I have not limited it to the programme)

How could we improve the programme?

Did you feel that your whānau or family was encouraged to be involved in your programme?

If they were involved, what effect did that have on your participation in the programme?

(Did you find the programme culturally appropriate? Were there ways we could have improved it from a cultural perspective?)

Goal – “what do you want to do most”

Can you tell me what you chose as “what I want to do most” at the start of the programme and about your progress towards reaching it?

Do you feel you would be able to work towards a different physical goal now that you have practiced working towards one specific goal?

Can you tell me how you might go about working towards a different physical goal?

Exercises

Was it clear to you how the exercises were linked with the activity you wanted to do next?

Do you intend to continue with any of the exercises you have been doing? Can you tell me why or why not?

Were the exercises at about the right level for you? (Not too easy or too hard?)

(If they say too easy or hard ask if the therapist addressed this)

What are some of the things that might stop you from continuing with the exercises?

Telephone calls

What are your impressions of the telephone calls during the programme?

Is there anything else that you would have liked to discuss during the calls?

Text messaging

Is texting new for you or have you used it prior to being part of ACTIV?

What are your impressions of the text messaging during the programme?

Can you tell me about any impact they had on how you felt, or what you did (exercises or general activity)?

Have there been any occasions, when you found the reminders unhelpful/ intrusive/ upsetting?

Discuss any mentioned.

Is there anything else you would like to comment on, about your involvement in the programme?