

# Methodology of the Stroke Self-Management Rehabilitation Trial: An International, Multi-Site Pilot Trial

<sup>1</sup>Kelly Jones, <sup>1</sup>Rohit Bhattacharjee, <sup>1</sup>Rita Krishnamurthi, <sup>2</sup>Sarah Blanton, <sup>1</sup>Alice Theadom, <sup>3</sup>Suzanne Barker-Collo, <sup>4</sup>Amanda Thrift, <sup>1</sup>Priya Parmar, <sup>5</sup>Annick Maujean, <sup>6</sup>Annemarei Ranta, Emmanuel Sanya<sup>7</sup>, and <sup>1</sup>Valery L. Feigin, on behalf of the SMART Study Group\*

<sup>1</sup>National Institute for Stroke and Applied Neurosciences, School of Rehabilitation and Occupation Studies, Faculty of Health and Environmental Studies, Auckland University of Technology, Private Bag 92006, Auckland, New Zealand

<sup>2</sup>School of Medicine (SOM: Rehab), Emory University, 201 Dowman Drive, Atlanta, GA 30322, USA

<sup>3</sup>Department of Psychology, The University of Auckland, Private Bag 92006, Auckland, New Zealand

<sup>4</sup>Department of Medicine, School of Clinical Sciences, Monash University, Victoria 3800, Australia

<sup>5</sup>GO5 Health Sciences, Griffith Health Institute, Gold Coast Campus, Griffith University, Queensland 4222, Australia

<sup>6</sup>Department of Neurology, Palmerston North Hospital, and Department of Medicine, University of Otago –Wellington, Palmerston North Campus, 50 Ruahine Street, Palmerston North 4442, New Zealand

<sup>7</sup>Department of Medicine, University of Ilorin, Ilorin, Nigeria

\*SMART Study Group members are listed at the end of the paper

**Corresponding author:** Dr Kelly M Jones, PhD, National Institute for Stroke and Applied Neurosciences, School of Rehabilitation and Occupation Studies, Faculty of Health and Environmental Studies, Auckland University of Technology, AUT North Shore Campus, 90 Akoranga Dr, Northcote 0627, Private Bag 92006, Auckland 1142, New Zealand. Telephone: +64 9 921 9166; Fax: +64 9 921 9620; Email: kejjones@aut.ac.nz

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## **Abstract**

**Rationale:** Stroke is a major cause of long-term adult disability with many survivors living in the community relying on family members for on-going support. However, reports of inadequate understanding of rehabilitation techniques are common. A self-management DVD-based observational learning tool may help improve functional outcomes for survivors of stroke and reduce caregivers' burden.

**Aims:** This article describes the methodology of the stroke self-management rehabilitation trial. The overall aim of this pilot trial is to assess the feasibility and preliminary efficacy of a DVD-based intervention for improving functional outcomes of survivors of stroke 2 months post-randomization to inform the design of a full scale randomised clinical trial.

**Design:** Recruitment of a minimum of 20 survivors of stroke and their informal caregivers (where available) in each of the participating centres will occur across multiple international sites. Following baseline assessments, participants will be randomly assigned to an intervention or standard care group. The intervention comprises a structured DVD observation and practice schedule over 8-weeks. All participants will complete follow-up assessments.

**Study outcomes:** The outcome measures will include a global shift in the modified Rankin Scale scores as well as dichotomised scores, changes in quality of life, general health, depression and caregiver burden at 2 months post-randomization. A qualitative analysis of the effects of the intervention will also be undertaken.

**Discussion:** The results of the pilot study will provide knowledge of whether observational learning techniques delivered via DVD can effectively improve recovery following stroke and reduce caregiver burden.

## **Introduction**

Stroke is a leading cause of long-term disability, with recent projections forecasting a worldwide rise to 200 million disability adjusted life years lost per annum by 2030.<sup>(1)</sup> After acute hospitalisation, at least 45% of stroke survivors return home usually relying on family members for any further care and support.<sup>(2-4)</sup> Caregivers often report insufficient knowledge or skills to care for the stroke survivor,<sup>(5)</sup> but appropriate and effective educational tools are still lacking.<sup>(6)</sup>

Observational learning<sup>(7)</sup> is a well-established tool for professional teaching and adult learning<sup>(8, 9)</sup> and can effectively improve acquisition of motor skills<sup>(10)</sup>, psychological responses<sup>(10)</sup>, and behavioural changes.<sup>(11)</sup> However, there is limited evidence of its effectiveness post-stroke. This article describes the protocol used in a pilot trial of an intervention based on observational learning theory, presented through a DVD, as an adjunct to routine stroke education. We include information about study organisation and procedures that are not generally reported, to assist researchers who wish to conduct similar research.

## **Study Aims**

The three main aims of the Stroke Self MAnagement Rehabilitation Trial (SMART) are:

- 1) To provide preliminary efficacy estimates to inform the sample size estimates, inclusion criteria, and best primary outcome measures for a phase III randomized controlled trial;
- 2) To explore the feasibility of recruitment and likely level of support required to uptake the intervention; and
- 3) To determine levels of and identify barriers to adherence to trial protocol for informing a full-scale randomized controlled trial.

## **Methods**

### ***Design***

The SMART pilot trial is a randomized, multi-center, open-label clinical trial (See Figure 1 for further detail). The trial is registered with the Australian New Zealand Clinical Trials Registry: ACTRN12612001287820.

[INSERT FIGURE 1 ABOUT HERE]

### ***Patient Population***

Adults (>15 years) diagnosed with stroke<sup>(12)</sup> within the last 3 years with moderate to severe disability (defined as a Rankin Scale (RS) score of 2-4). After obtaining informed consent, all adults are screened for major depression using the Center for Epidemiological Studies – Depression Scale<sup>(13)</sup>. A score of 27 or above renders an individual ineligible to participate given the self-management nature of the trial. A complete list of inclusion and exclusion criteria is shown in Table 1.

[INSERT TABLE 1 ABOUT HERE]

### ***Randomization***

The use of a free online randomisation program, MinimPy<sup>(14)</sup> known as QMinim (see <http://qminim.saghaei.net/index.php>), ensures that each site can randomize participants in a consistent and timely fashion. Group distribution is stratified by age (<65; 65+), gender and stroke severity (mRS 2 or 3-4). A 1:1 ratio and a minimization method will ensure maximum balance between treatment arms and the elimination of selection bias.

### ***Intervention (DVD) group***

Following a baseline assessment in Week 1, over weeks 2-7 participants are instructed to watch a single, designated segment of the DVD each week (see Table 2) and to practice the recommendations and rehabilitation procedures. Viewing and practice ideally takes place 5

days per week. Participants receive a weekly phone call from a ‘non-blinded’ research assistant to monitor progress, and to record the most/least helpful aspects of each DVD segment. Any barriers to viewing and practising techniques demonstrated in the DVD are also documented (See Figure 2 for an overview). Week 8 involves a follow-up assessment. There are 3 levels of individual tailoring available to meet the recognised variation in needs of survivors of stroke and caregivers: 1) Face-to-face Clinician input: This level of input involves identifying those DVD components most relevant to recovery of the individual; 2) Study PI input: Where input from a clinician is not available, the Study PI at each recruiting centre in conjunction with the survivor of stroke may offer similar input based on evidence in current medical records (where available); and 3) Participant self-management: Participants are encouraged throughout the trial to view additional DVD segments that they feel are applicable to their rehabilitation process.

[INSERT TABLE 2 AND FIGURE 2 ABOUT HERE]

### ***Outcomes***

A ‘blinded’ research assistant collects baseline and outcome measures (Table 2) two months post-randomization. All assessments are administered by telephone for greater efficiency and to reduce study costs. On average assessments take 20-40 minutes to complete, with the option to complete assessments across two or more sessions if required. Where feasible, optional one and three month assessments are undertaken with participants in the intervention group. Survivors of stroke are also asked to nominate a caregiver (the main person who assists with their care in the home environment) to be invited to participate in the study. Caregivers complete short questionnaires presented in an interview format at baseline and two months (Table 3) to assess their well-being. Any outpatient rehabilitation services received by study participants during the trial are also recorded.

[INSERT TABLE 3 ABOUT HERE]

Providing the impact on participants is minimal, recruitment sites (Figure 3) can propose additional site-specific sub-studies to strengthen the value of the overall pilot trial. Current sub-studies include the recruitment of a contact control group to examine the possible effects of weekly phone calls on stroke recovery, and a semi-structured qualitative sub-study to capture participant experiences of the trial.

[INSERT FIGURE 3 ABOUT HERE]

### ***Sample Size***

The sample size of the SMART pilot study is based on a minimum number of 20 participants from each of the 7 currently active recruitment centres. This figure is based on evidence that the number of participants included in a pilot study should be approximately 0.03 times that planned to be included in the phase III study.<sup>(15)</sup>

### ***Statistical Analyses***

Data from each site will be analysed by the central research team. Differences between the two study groups will be explored using parametric and non-parametric techniques and summarised using means (95% confidence intervals [CI]), standard deviations, quartiles and range. Inferential analyses will be used to assess the efficacy of the intervention in improving functional outcomes: functional, health, quality of life, and mental well-being of stroke survivors and caregivers (Table 3). Continuous outcomes will be analysed using general linear models (GLM) and categorical outcomes with logistic regression. A priori identified confounding variables (age, sex, and ethnicity) will be adjusted for in all analyses. Other confounding variables will be assessed empirically, including demographic and stroke characteristics based on model fit criteria. Multivariable univariate models will be undertaken to assess associations between outcomes and predictor variables individually. False discovery

rate control<sup>(16)</sup> will be used to account for the multiplicity of tests of a given outcome.

Inferences will be based on a 5% significance level and two-sided alternatives. Given the variability of the study sample, time since stroke will be examined to identify those most likely to benefit from the learning tool.

### ***Data management***

All study participants are allocated a unique 6-digit registration number beginning with a 3 digit site-specific code. To monitor data quality, each site provides a copy of pilot data to the co-ordinating centre on two occasions: 1) following the addition of data for the first participant; and 2) mid-way through the trial. At the end of the study, each site will provide a final data set for merging into the main study database.

### ***Study Organization and Funding***

This pilot study includes tertiary university, secondary community, and rehabilitation hospital based recruitment sites, the Coordinating Centre, the Scientific Advisory Committee, and the Data and Safety Monitoring Committee (Figure 4). The Coordinating Centre is responsible for arranging quarterly teleconferences; periodic newsletter updates; monitoring of study processes; development of the final full data set; and undertaking key statistical analyses. Each site is responsible for overseeing all aspects of the day-to-day running of the trial including local ethical approvals and securing funding to support their involvement.

[INSERT FIGURE 4 ABOUT HERE]

### ***Summary***

The primary objective of this pilot trial is to assess the preliminary feasibility and efficacy of a DVD-based observational learning intervention for improving functional outcomes in survivors of stroke and their informal caregivers. The paucity of large scale, international, multi-site randomized clinical trials examining the effectiveness of stroke interventions may be partially due to the lack of methodological guidelines. The methods presented here could

serve as a ‘guide’ for future design of studies aimed at improving stroke recovery and reducing caregiver burden. At submission (July 2014), 7 sites were actively screening and recruiting participants with 50 survivors of stroke enrolled.

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### **Appendix**

SMART study group members (additional to manuscript co-authors)\*: Yogini

Ratnasabapathy, Denise Taylor, Elizabeth Kendall, Carolyn Ehrlich, Steven Wolf, Dominique Cadilhac, Marilyn MacKay-Lyons, Man Mohan Mehndiratta, Jeyaraj Durai Pandian, Deepti Arora, Peter Langhorn, Gustavo Saposnik, Narayanaswamy Venketasubramanian, Bo Norrving, Akshay Anand, Dheeraj Kurana, Michael Brainin, Natan Bornstein, Richard Lindley, Denise Taylor, Foad Abd-Allah, Reginald Obiako, Emmanuel Sanya, Maree O’Connor, Rene Stolwyk, and Peter New.

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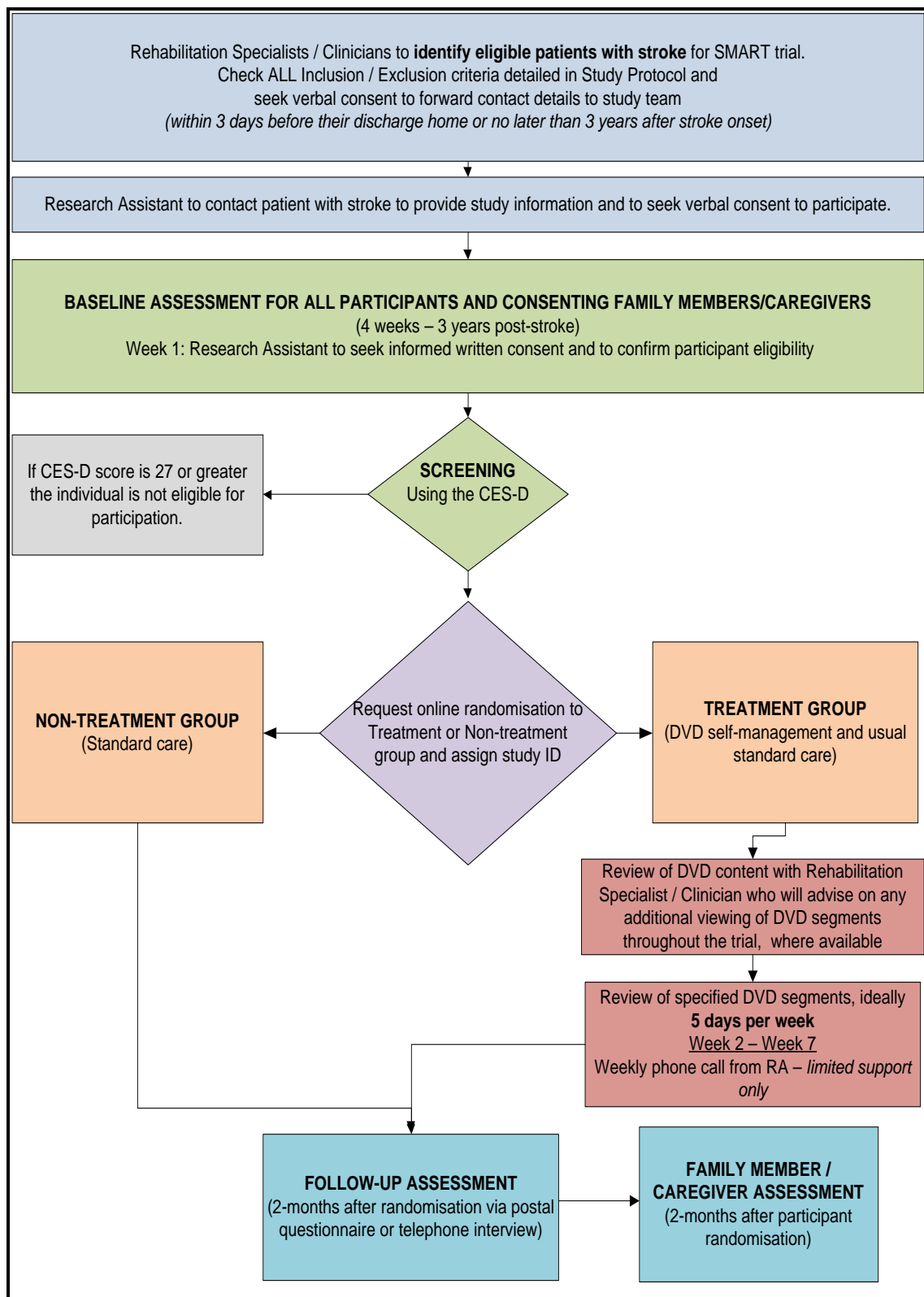


Figure 1. Standard Trial Design

CES-D = Centre for Epidemiological Studies - Depression<sup>(13)</sup>

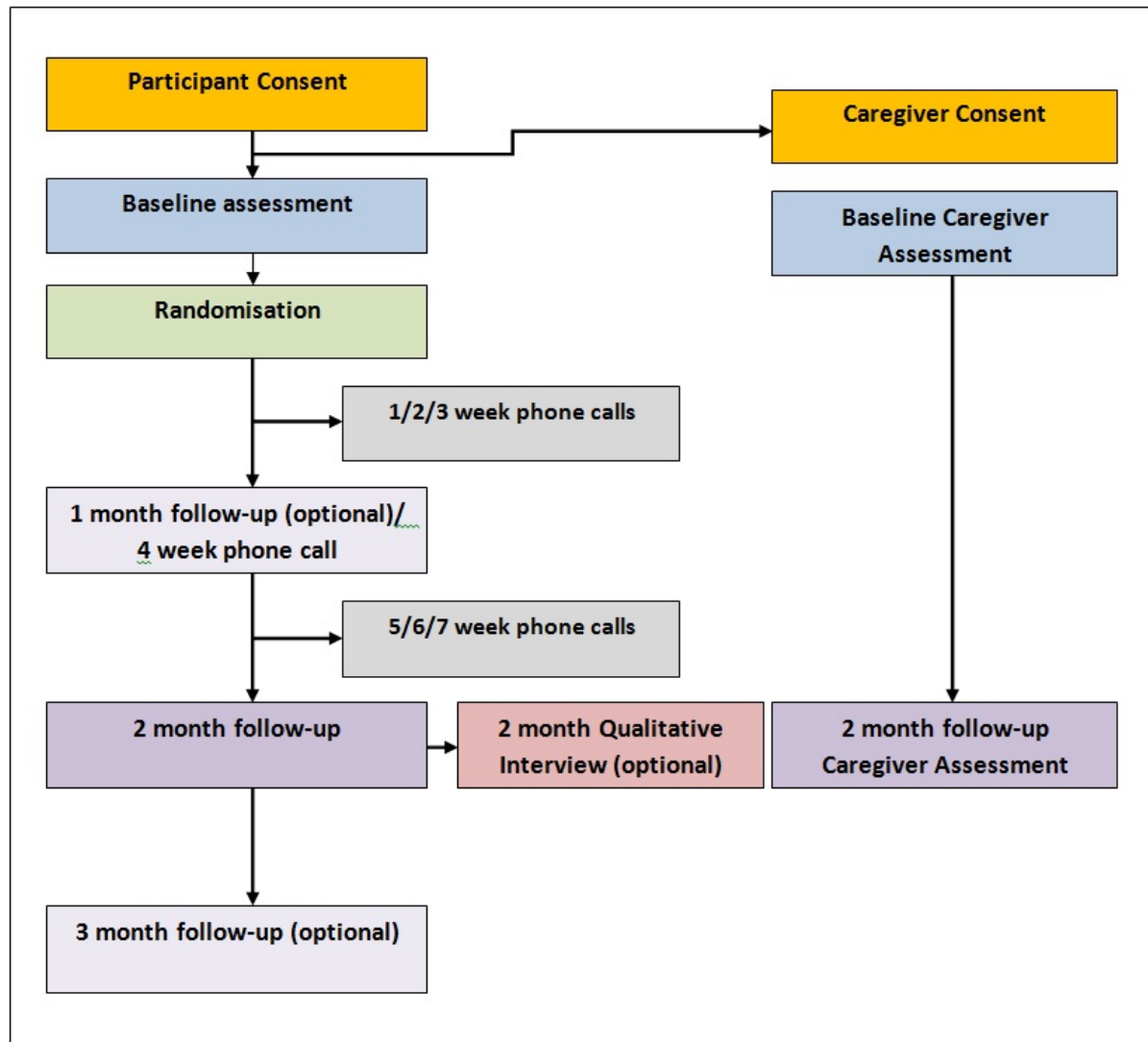


Figure 2. Study Overview for Intervention DVD group

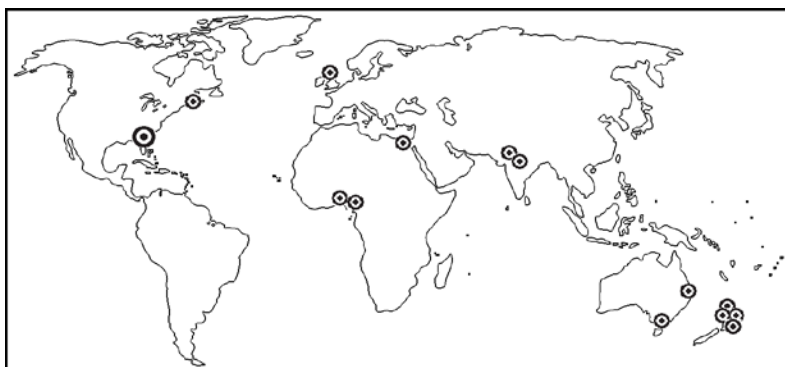


Figure 3. Geographical locations of SMART study sites

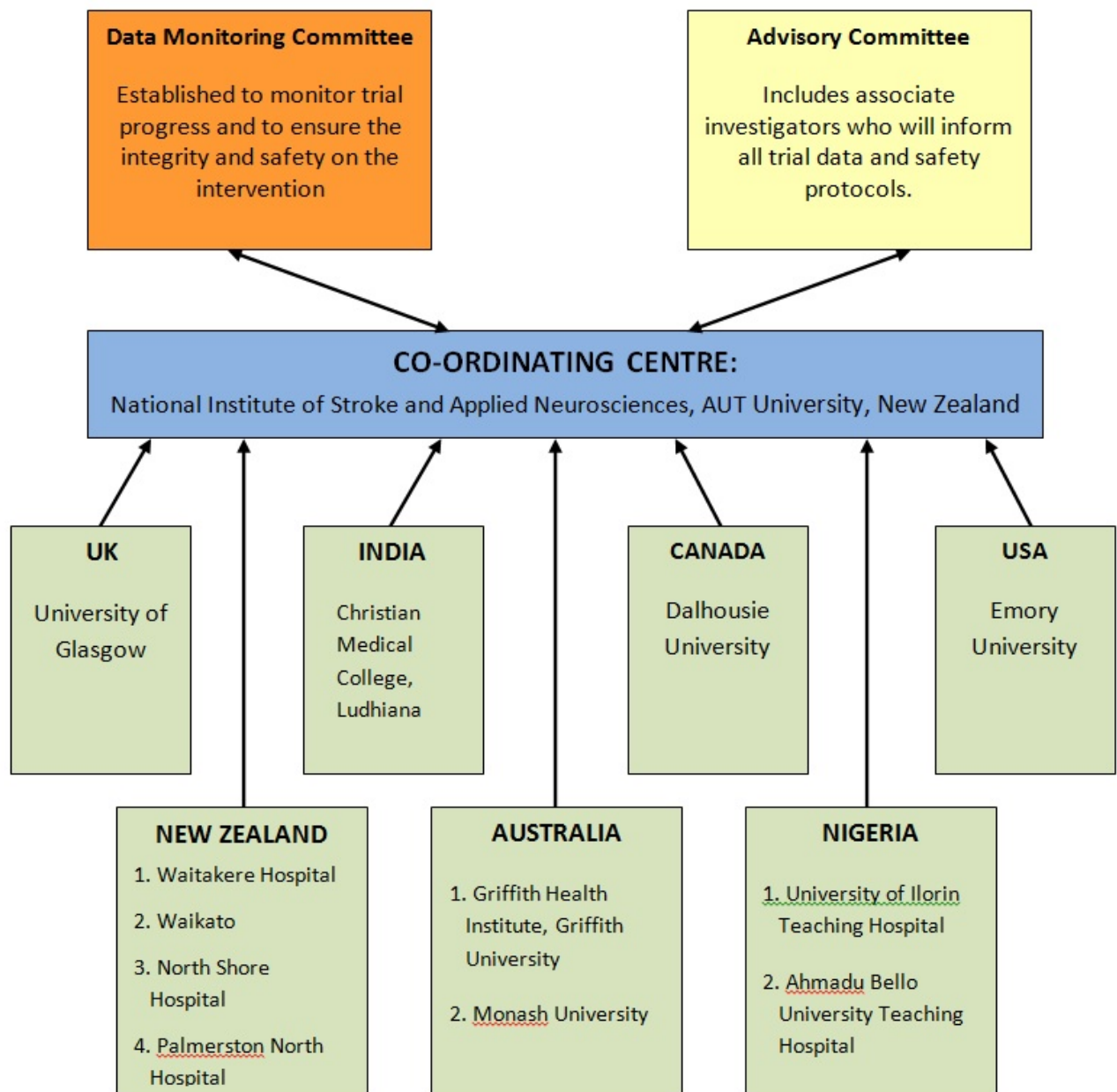


Figure 4. Study Organization

Table 1. Inclusion and Exclusion Criteria

<p><b>Inclusion Criteria</b></p> <ul style="list-style-type: none"> <li>•clinically diagnosed with stroke within the last 3 years with a moderate to severe level of disability (defined as a Rankin Scale score of 2-4)</li> <li>•discharged to own home</li> <li>•availability of a DVD player</li> </ul>
<p><b>Exclusion Criteria</b></p> <ul style="list-style-type: none"> <li>•inability to communicate with the researchers (including non-fluent English)</li> <li>•history of previous disabling stroke (pre-stroke MRS 3-5)</li> <li>•discharged home within 24 hours of hospital admission</li> <li>•living outside of the study area</li> <li>•admission to hospital from a residential care facility/rest home</li> <li>•unable to provide informed consent</li> <li>•participation in another clinical trial</li> <li>•history of alcohol or drug abuse</li> <li>•history of serious mental illness (including severe depression)</li> </ul>

Table 2. DVD Intervention topics by standard weekly viewing schedule

Learning Tool segment	Examples of contents (Running time - minutes)
Week 2. Understanding Stroke	What is a stroke? What is an ischemic stroke? (6 minutes)
Week 3. Early Care and Hygiene	Mouth and eye care; Feeding; Bathing and showering; Dressing (21 minutes)
Week 4. Rehabilitation Exercises	Breathing exercises; Muscle strengthening; Memory and Fatigue management; Balance; Relaxation (55 minutes)
Week 5. Moving Around	Walking; Using stairs; Getting into the car; Managing the kitchen (16 minutes)
Week 6. Coping with Stroke Aftermath	Personal feelings after stroke; How to reduce risk of another stroke?; Personal experience with the rehabilitation process; Effects on everyday activities (21 minutes)
Week 7. Experience of Caregivers	Personal feeling after stroke; Personal experiences of caring for a survivor of stroke (11 minutes)



Table 3. Standard Outcome Measures

<b>Domain-Measure</b>	<b>Baseline (mandatory)</b>	<b>1 month (optional†)</b>	<b>2 months (mandatory)</b>	<b>3 months (optional†)</b>
<u>Stroke Survivor Assessments</u>				
<b>Demographics</b> (questions established through prior stroke research)	✓	✓	✓	✓
<b>Stroke details</b> (including recurrent stroke details)	✓	✓	✓	✓
<u>Outcomes</u>				
<b>Disability</b> -Rankin Scale <sup>(17)</sup>	✓	✓	✓	✓
<b>Cost-effectiveness</b> -Euro Quality of Life <sup>(18)</sup>	✓	✓	✓	✓
<b>Self-Efficacy</b> -Daily-Living Self-Efficacy Scale <sup>(19)</sup>	✓	✓	✓	✓
<b>Mental Health</b> -Centre for Epidemiologic Studies – Depression scale <sup>(13)</sup>	✓	✓	✓	✓
<b>Mood</b> -General Health Questionnaire-28 <sup>(20)</sup>	✓	✓	✓	✓
<u>Optional Caregiver Assessments</u>				
<b>Caregiver Burden</b> -Carer Strain Index <sup>(21)</sup>	✓		✓	
<b>Mental Health</b> -Center for Epidemiological Studies – Depression Scale <sup>(13)</sup>	✓		✓	
<b>Life changes</b> -Bakas Caregiver Outcomes Scales <sup>(22)</sup>			✓	

† Optional assessments for stroke survivors in the treatment group only