Determining the feasibility and preliminary efficacy of a stroke instructional and educational DVD in a multinational context: a randomized controlled pilot study

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Objective: To assess the feasibility of conducting a randomised controlled trial of an instructional and educational stroke DVD and determine the feasibility and preliminary efficacy of this intervention in a multi-national context.

Design: Non-funded, pilot randomised controlled trial of intervention versus usual care.

Setting: International, multi-centre, community-based.

Participants: Community living adults up to 3-years post-stroke with moderate-to-severe disability and their nominated informal caregivers.

Interventions: Intervention patients viewed and practiced rehabilitation techniques demonstrated in the DVD over 6-weeks.

Main measures: Trial feasibility by number of active recruitment sites, recruitment efficiency, randomisation and follow-up. Intervention feasibility by patient and caregiver impressions. Preliminary efficacy by the quality of life - 5-level EQ-5D health status measure, General Health Questionnaire, and Centre for Epidemiological Studies–Depression at 2-months.

Results: Fourteen recruitment sites were established across 8 countries. Recruitment was achieved at nine (64%) sites. Over 16-months, 66 participants were recruited (mean (SD) age = 63.5 (12.47) years) and randomised to intervention (n = 34) and control (n = 32) groups. Fifty-four (82%) completed a follow-up assessment. Patient and/or caregiver comments about the benefits and barriers to accessing the intervention were

mixed. There were no significant between-group differences in outcomes at 2-months ($p > 0.05$).

Conclusions: Conducting a multi-national trial of a stroke DVD requires full funding. The intervention was acceptable to some patients and their caregivers, yet a generalised education approach did not fully meet their needs and/or expectations. A more individualised method may be required to meet peoples' changing needs during stroke recovery.

Introduction

Globally, there are more than 33 million survivors of stroke.[1] Despite stroke guidelines recommending the provision of long-term support,[2] most survivors do not receive regular on-going support following hospital discharge, especially those living outside of the main city centres.[3] Given the already limited resources for community rehabilitation, and continuing increases in the number of survivors due to population aging and advances in stroke care, current models of care and resources will not be able to accommodate the needs of survivors and their caregivers. Following hospital discharge, the majority of survivors of stroke require assistance at home by a family caregiver.[4] However, interventions aimed at improving this care provide evidence that educational needs are highly complex.[5, 6] Effective and feasible learning tools to teach patients and their family caregivers how to cope with common problems following stroke and to support active recovery as an international standard of care remain elusive. Although there has been extensive research in this area, most studies are focussed on the early discharge period within a single country and incorporate use of face-to-face delivery alone or combined face-to-face and telephone-based treatments.[5, 6] Less is known about the potential efficacy of other modes of delivery on a more global perspective.

Several methods of delivering stroke education have been examined, but the most optimal method remains unclear.[7] Written materials (flyers, booklets, books) are cost-effective and easily distributed, yet are only effective for literate patients free from

visual impairment. Uptake of written and verbal (discussions, counselling, etc.) education about stroke is often poor.[8] One possibility for delivering additional community-based support is through the use of DVD that can incorporate both visual and vocal methods to present materials. Support for survivors of stroke, delivered by DVD including video-based instruction at home, has been found to be safe, does not negatively impact caregivers,[9] and has achieved results similar to classroom-based instruction to support those affected by other health conditions.[10] We developed an instructional and educational home-based intervention specifically focused on common problems encountered by patients following stroke and their caregivers to be used in culturally and geographic diverse regions.

This multi-national randomised controlled trial was conducted to compare the intervention delivered by DVD and standard usual care to standard usual care alone. Given the home-based nature of the intervention, we aimed to determine the feasibility of conducting a randomised controlled trial of the DVD-based intervention in a multi-national context. We also sought to investigate the feasibility of the intervention and its preliminary efficacy to inform the potential value of conducting a full-scale trial in many centres in different countries.

Methods

Ethical approval was granted by the Health and Disability Ethics Committee (reference number: 13/NTB/1) and the Auckland University Ethics Committee (reference number: 13/59) for the co-ordinating centre in New Zealand. Relevant committee/s granted ethical approval at each additional study location. The trial was prospectively registered with the Australian New Zealand Clinical Trials Registry (reference number: ACTRN12612001287820). A detailed description of the procedure for the trial is available elsewhere.[11]

Potential study sites were identified through discussions with existing international professional networks including stroke clinicians and researchers. Those investigators who were interested in being involved in the pilot study as a recruitment site and/or study investigator were invited to contact the coordinating centre, become familiar with the study protocol, and invited to attend a researcher teleconference meeting to discuss the nature of their involvement in the trial. All interested collaborators were included in the trial. Researchers and/or stroke clinicians at each site identified potentially eligible patients from a range of in- and out-patient services. Twenty participants were deemed ideal to be recruited via each study site. Recruitment took place between May 2013 and October 2014.

We included patients who were aged 16 years or more, had a confirmed diagnosis of acute stroke in the previous 3 years, had mild to moderate disability (modified Rankin

Scale score of 2 - 4[12]), had access to a DVD player, and were discharged home. Patients were excluded if they were non-English speaking, participating in another trial, living outside the study area, and/or discharged home <24 hours of hospital admission due to no stroke related disability. Those with a self-reported history of disabling stroke (pre-stroke modified Rankin Scale score 3-5), alcohol/drug abuse, significant mental illness (including severe depression), and/or cognitive impairment were also excluded.

A member of the study team from each site screened potential patients for all study criteria. Screening and consent processes took place either in-person (at hospital or during a previously scheduled in-home visit) or by telephone with consent forms provided and received by return mail. Patients meeting the inclusion criteria were invited to nominate an informal caregiver to also participate in the study.

Following written informed consent, patients in both study groups completed a ~30-minute baseline assessment either in-person or by telephone. Conducted by a trained research assistant, baseline assessments included a selection of standardised outcome measures, described below, and gathered self-reported demographic information (i.e. age, gender, employment, marital status). Baseline information was further supplemented with details of the stroke (i.e. stroke type, stroke severity) obtained via medical records. Following collection of baseline data, a research assistant at each site randomised each patient to the intervention or control group. Randomisation was conducted using a free online computer generated block randomisation sequence[13]

balanced for age (<65; 65+), gender, and stroke severity (modified Rankin Scale[12]) score of 2 versus 3-4). Patients randomised to the intervention group were provided with a copy of the instructional and educational DVD in-person or by post. Based on observational learning principles,[14, 15] the professionally produced DVD was filmed in New Zealand by the University of Auckland Education and Media Centre. This intervention was designed to provide additional support to stroke patients and their informal caregivers to help them in their return to community living and promote on-going recovery. The content was based on the best available evidence, including educational materials and books endorsed by the New Zealand Stroke Foundation, National Stroke Foundation of Australia and the World Stroke Federation. Input into the design and content of the DVD was also obtained by survivors of stroke, caregivers, physiotherapists, neurologists, occupational therapists, rehabilitation specialists, New Zealand and Australian Stroke Foundation field workers and cultural groups. Particular attention was given to various aspects of caring for the patient at home, with the intention to provide easy-to-understand educational information and user-friendly dropdown menus.

The intervention (the instructional and educational DVD, see Appendix 1) consisted of six chapters and more than 40 different care and rehabilitation techniques delivered via DVD. The topics aligned with research priorities that have been identified by survivors of stroke, caregivers, and health professionals.[16] Educational components included

understanding stroke, and coping with stroke aftermath. Instructional topics comprised a range of rehabilitation exercises (i.e. hand massage, relaxation, breathing exercises) and early care and hygiene techniques (i.e. changing sheets, feeding, bathing, and dressing). Most of the information is presented by role models, including stroke survivors (across a range of age groups, European, Asian, and ethnic minority groups) and their informal caregivers. The average duration of each of the sessions was approximately 20 minutes (total DVD running time: 129 minutes).

Patients in the intervention group were asked to follow a set viewing schedule of topics (Table 1). This schedule involved watching one designated DVD segment each week. Where segments were focused on instructional rather than purely educational content, participants were also asked to practice the recommendations and rehabilitation procedures (ideally 5 days per week). Patients (and/or their caregivers) in the intervention group also received a brief (approximately 5-minute) weekly phone call from a 'non-blinded' study research assistant. A telephone log was used to record details of the number of days they had viewed the DVD in the past week, and any perceived benefits and barriers to accessing the intervention. Patients and/or their caregivers were also invited to make suggestions to inform the on-going development of the DVD, and these comments were also recorded on this log.

Patients in the control group were free to access locally available rehabilitation services but did not receive a copy of the intervention DVD nor a weekly phone call. These

patients were offered a copy of the instructional and educational DVD intervention following their completion in the trial.

After two months, all patients were telephoned by a trained research assistant, blinded to group allocation, and invited to complete the same standardised measures that were completed as part of the baseline assessment. Employment details of patients and caregivers were collected as were details of any recurrent strokes. Two-month follow-up assessments for both study groups were completed by January 2015.

Feasibility of the trial (primary endpoint) was assessed quantitatively in two areas. These included the feasibility of setting up and running study centres and the feasibility of patient processes (i.e. recruitment, acceptance and efficacy of randomisation, and proportion completing assessments).

Feasibility of the intervention (secondary endpoint) was measured qualitatively. Research assistants gathered impressions of the intervention from patients and their caregivers throughout their participation in the trial. Specifically, data were collected about their perceived benefits and barriers to accessing the intervention.

The following areas of well-being were assessed using standardised measures at baseline and two-months to examine the preliminary clinical efficacy (secondary endpoint) of the intervention: disability (modified Rankin Scale),[12] quality of life - 5-level EQ-5D health status measure (descriptive system),[17] general and psychiatric well-

being (General Health Questionnaire),[18] and depression (Centre for Epidemiologic Studies Depression).[19]

Caregiver burden was also assessed using the Centre for Epidemiologic Studies Depression and Caregiver Strain Index.[20] Only outcomes of patients are reported in the current analysis.

Data analysis

The feasibility of setting up and running study centres was assessed by calculating the number of active sites (including screening, randomisation, intervention delivery) as a proportion of the total number of participating sites.

The feasibility of patient processes was calculated by the proportion of patients who (i) consented to participate in the trial during the recruitment period, (ii) accepted their group allocation following randomisation, and (iii) completed an outcome assessment at 2-months. The efficacy of the randomisation process was also examined by running preliminary analyses to determine the commonality of the two study groups at baseline. Baseline characteristics were compared using t-tests for continuous variables and chi-square tests for categorical variables.

Feasibility of the intervention was assessed qualitatively by examining verbatim comments recorded in writing about patients' and caregivers' impressions of the intervention. All comments concerning the perceived benefits of the intervention were collated into a single document. The same process was then repeated for all comments

concerning any perceived barriers to accessing the intervention. Then, a single rater who was a member of the study team reviewed the raw data. Using inductive content analysis, similarities and differences as well as recurring themes were identified. Rigour was aided by regular discussion of the emergent analysis with the research team at the study co-ordination centre. All cases in the intervention group were included in this part of the analysis, with some data provided by patients and/or some by their nominated caregiver.

Preliminary clinical efficacy of the intervention was assessed quantitatively. All patients with baseline and 2-month data available were included in the analysis for the relevant study group (intervention or control). Patient scores were examined between baseline and 2-months and coded as reflecting 'no change', 'improvement', or 'worse' scores over time. Then, chi-square was used to compare patterns of change over time between the two study groups on each outcome measure. All quantitative data analyses were carried out using Statistical Package for the Social Sciences version 20.0.[21] Significance was set at two-sided $p = 0.05$. There was no correction for multiplicity given the exploratory nature of the analysis.

Results

Feasibility of setting up and running study centres

All interested sites were invited to take part in the trial, with a total of 14 recruitment sites established across 8 countries. Participant recruitment was established at nine (64%) of these sites in six out of a total of eight countries, with a total of 68 patients recruited (Table 2). A list of individual recruitment centres is available as supplementary data (Appendix 2). The reasons for non-recruitment varied, and included lack of funding to conduct the study, delays in ethics approval, and language barriers (Table 2)

[INSERT TABLE 2 ABOUT HERE]

Feasibility of patient processes

On average, a total of 4-5 participants across all sites were screened and recruited each month over a 16-month period. Two control participants were later excluded as checks revealed that they did not meet inclusion criteria due to a baseline modified Rankin Scale score of 1. All 66 (100%) patients accepted the outcomes of randomisation (Table 3). Randomisation processes were found to be efficient with no significant between-group differences in the baseline characteristics of the study sample (Table 4). Across both groups, a total of fifty-four (84%) patients completed a two-month follow-up assessment. Reasons for lost to follow-up included loss of contact or unavailability at the time of assessment.

[INSERT FIGURE 1 ABOUT HERE]

[INSERT TABLES 3 AND 4 ABOUT HERE]

Feasibility of the intervention

Patient and/or caregiver comments about the perceived benefits and barriers to accessing the intervention were mixed (Table 5). When asked about their impressions of the intervention, people talked about aspects of the intervention that they perceived as beneficial:

> "*All of it [DVD] was helpful, nothing in particular, all of it was helpful*". Female caregiver aged 66 years
>
> "*The information regarding different types of stroke provided the best explanation I have had since [family member] had his stroke*". Female caregiver aged 57 years
>
> "*The DVD explained very well what to expect when you had a stroke*". Male patient aged 68 years

People also spoke of the relevance of the intervention to their current needs:

> "*Very good for those with more severe stroke*". Male patient aged 73 years
>
> "*Not entirely relevant to [family member]*". Female caregiver aged 71 years
>
> "*Did not really apply to her [family member] – she is mobile*". Male aged 71 years

[INSERT TABLE 5 ABOUT HERE]

Preliminary clinical efficacy

More patients in the intervention group had improved quality of life regarding mobility, self-care, and usual activities as measured by the 5-level EQ-5D health status measure than controls at 2-months (Table 6). However, the extent of these changes did not differ significantly between the two groups – mobility, $\chi 2$ (1, 53) = 1.30, p = 0.52, self-care, $\chi 2$ (1, 53) = 3.53, p = 0.17, usual activities, $\chi 2$ (1, 53) = 1.63, p = 0.44. Changes in quality of life in terms of pain/discomfort ($\chi 2$ (1, 53) = 1.48, p = 0.47) and anxiety/depression ($\chi 2$ (1, 53) = 2.83, p = 0.24) appeared to be better in the control than intervention groups, but group differences in changes over time were not significant. Patterns of change between baseline and 2-months for disability (modified Rankin Scale, $\chi 2$ (2, 49) = 0.36, p = 0.83), general health status (General Health Questionnaire total score, $\chi 2$ (1, 49) = 0.009, p = 0.92) and depression scores (Centre for Epidemiologic Studies Depression total score, $\chi 2$ (2, 50) = 2.64, p = 0.26) were also similar across both groups.

[INSERT TABLE 6 ABOUT HERE]

Discussion

The main finding of this study is that conducting a multi-national trial of a stroke instructional and educational DVD covering common problems post-stroke is not feasible in the absence of full funding. Nearly half of all potential recruitment sites

encountered barriers that prevented the recruitment of any patients for the trial. However, this pilot study does provide preliminary evidence that an instructional and educational intervention delivered by DVD may be acceptable to survivors of stroke living in the community and their caregivers.

Despite international support for the trial and a willingness to be involved, several major obstacles hindered the recruitment of participants at some sites. Several barriers were beyond the investigators' control, including major delays in ethical approvals and a clash in the timing of the trial with changing stroke care guidelines. However, most barriers were due to a lack of funding to support the implementation of all study processes. For example, the low recruitment rate (as indicated by the small sample size) may be due at least in part to an absence of recruitment incentives, limited on-site study personnel to provide regular screening and recruitment, and a lack of public awareness of the trial. High financial costs are a well-documented challenge of multi-national collaborations that require careful coordination to overcome logistical challenges (i.e. obtaining ethical approvals from multiple committees) and to maintain scientific integrity.[22, 23] In the current study, for example, the recruitment of two participants who were later found to be ineligible may have arisen due a lack of staffing in the trial. Aspects of the trial design may have also have hindered the involvement of some study sites and the feasibility of patient recruitment. Only patients with moderate stroke within the last 3 years who were free from cognitive impairment were eligible to take

part in the trial. These criteria were introduced in order to reduce the variability in the study sample to ensure the inclusion of those for whom the intervention was expected to produce a positive effect. In retrospect, the removal of each of these criteria may have aided participant recruitment, and, consequently, provided greater opportunity to identify those most likely to benefit from the intervention in its current format.

Our findings also highlight the futility of running a trial with an English-speaking criterion in predominantly non-English-speaking locations. Future multi-national trials of instructional and educational interventions focused on stroke or other neurological events that are presented in English would likely benefit from limiting initial pilot studies to predominantly English-speaking locations. The availability of the intervention in a range of languages and/or with subtitles would enable greater opportunities for participation. However, such development would require careful cultural and linguistic adaptation of not only the intervention content but also wider study protocols, including culturally informed recruitment, consent and retention strategies.[24, 25] Therefore, findings from the current study must be interpreted cautiously given our findings reflect feasibility and potential efficacy among a small number of English-speaking patients at each site. It is important not to assume that benefits and barriers to accessing the intervention will be the same across ethnic minority and non-English speaking groups, for example.[26]

In the current study, all patients accepted the results of randomisation, with high completion rates at the 2-month follow-ups. Importantly, there was a differential loss of data with those in the intervention group being less likely to complete follow-up assessments. Loss to follow-up in the intervention group was 32% (n = 11) of patients, being higher than previous reports. Akl et al. (2012) examined loss to follow-up in 235 randomized controlled clinical trials published from 2005 to 2007 in five leading medical journals and found a median loss to follow-up of 6% of participants (interquartile range, 2–14%).[27] This result may have been due to an imbalance in the time commitment required across the two study groups, and/or a lack of relevance of some intervention content, as noted by some patients and/or caregivers.

In terms of feasibility of the intervention for stroke patients and their caregivers, encouragingly a range of benefits were reported. Most commonly, families found the overall intervention beneficial. Specific aspects of the intervention that participants found helpful were physical exercises and practical tips for survivors of stroke, and the reassurance offered by hearing about the experiences of other stroke patients and their caregivers. Descriptions of the intervention as 'reassuring' aligns with evidence that peer support is important to enhance well-being of stroke survivors through encouragement, motivation, and reduced isolation.[28] Our findings suggest that, in the absence of in-person peer support, reassurance may be effectively delivered via alternative medium (i.e. DVD).

The most common barrier to accessing the intervention was a misalignment between the needs of the survivors of stroke with the content of the intervention. Consistent with evidence from qualitative stroke studies,[29] findings clearly show that a 'one-size-fits-all' approach does not meet the needs and/or expectations of survivors of stroke and their families across the trajectory of recovery.

In terms of preliminary clinical efficacy, few promising effects of the intervention on the outcome measurements were found apart from a trend towards improvements in quality of life in relation to mobility, self-care, and usual activities in the intervention group. It is also concerning that more patients in the intervention than control group reported increased depression at 2-months. However, these collective findings should be interpreted with caution. Given the limited sample size and the short follow-up time, no significant group differences in functional outcomes at 2-months had been anticipated. Further, a variety of neurological deficits may present significant barriers to knowledge acquisition and educating those with stroke. Even with one-on-one education, the myriad of deficits post-stroke render it difficult to apply a common approach to education.[30] Authors of a recent systematic review found that up to 31% of stroke patients experience some degree of memory impairment at 12 months after stroke, and that this could lead to difficulties in everyday life.[31]

Limitations of this study include its small sample size and the absence of data concerning rates of patient eligibility, response rates to trial participation, and the

varying nature of usual care across sites. A further limitation is the absence of monitoring compliance (i.e. the amount of time actually spent viewing and practicing the intervention techniques) throughout the trial. Future trials should include monitoring compliance to content review and integration of strategies into daily activities to better understand sources of non-response bias, and to improve understanding of the potential value of an instructional and educational DVD post-stroke across varying countries, healthcare systems and cultures.

Further, based on our findings, future planned full-scale trials should also consider using some form of screening of individual patient and caregiver needs, potential barriers to knowledge acquisition, and learning preferences at the time of trial entry. Potential barriers that impede learning may include cognitive, language, cultural, and hearing deficits.[32] These patients may also require alternative methods of education.[33]The use of additional or alternative modes of delivery to support individualised instruction and education also requires consideration. A more flexible mode of delivery tailored to a brief assessment of current needs, with the capacity to meet changing needs of patients as they adjust to life post-stroke, may be more beneficial. Together, our feasibility findings indicate that an instructional and educational intervention delivered by DVD offers the potential to be acceptable and beneficial to some survivors of stroke. Exactly who, when, and how survivors of stroke and their caregivers may benefit requires further investigation.

Clinical messages

An instructional and educational intervention focusing on common problems post-stroke and delivered by DVD may be acceptable, with a range of benefits reported by stroke patients and/or their family caregivers.

Instructional and educational interventions must be individualised to ensure that they meet the needs, expectations and learning preferences of stroke patients and their family caregivers.

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Competing interests

None declared.

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Contributors

VF – study concept. KJ, VF – study supervision. KJ, SLW, SB, AM, AR, MM-L, JDP, DA, EOS, VL – supervision of trial implementation at local site/s. KJ, SB – data analysis and drafting of initial manuscript. All authors – study advisors, critical revision and subsequent development of the manuscript. KJ – guarantor of the accuracy and honesty of the manuscript.

Conflict of interest statement

The Authors declare that there is no conflict of interest.

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Table 1. Overview of timeline and content examples for the intervention arm.

Week #	Standard trial requirements and DVD viewing	Duration (minutes)
1	Baseline assessment (phone)	40
2	**Understanding stroke** What is a stroke? What is an ischaemic stroke? What is an intracerebral haemorrhage?	6
3	**Early care and hygiene** Recovery position Putting on a compressive stocking Dealing with incontinence	21
4	**Rehabilitation exercises** Bed exercises Mouth and voice exercises Balance exercises	55
5	**Moving around** Transfer from bed to chair Getting into the car Managing in the kitchen	16

Week #	Standard trial requirements and DVD viewing	Duration (minutes)
6	**Coping with stroke aftermath** Personal feelings after the stroke Returning home after stroke How to reduce your risk of another stroke?	21
7	**Experience of caregivers** Supporting a family member affected by stroke	11
8	Post-intervention postal questionnaire/phone interview	40

Table 2. Feasibility of setting up and running study centres.

Location	Total centres N = 14	Total participants N = 68	Recruiting sites N (%)	Non-recruiting sites N (%)	Reasons for non-recruitment
New Zealand	4	17	4 (100.00)	0 (0.00)	-
Australia	2	10	1 (50.00)	1 (50.00)	External delays in obtaining ethical approval
Nigeria	2	4	1 (50.00)	1 (50.00)	Predominantly non-English speaking patients
India	2	8	1 (50.00)	1 (50.00)	Inadequate financial resourcing
United Kingdom	1	0	0 (0.00)	1 (100.00)	Clash with changing treatment guidelines
Canada	1	18	1 (100.00)	0 (0.00)	-
United States	1	11	1 (100.00)	0 (0.00)	-
Egypt	1	0	0 (0.00)	1 (100.00)	Inadequate financial resourcing

Table 3. Feasibility of patient processes, by group.

Patient process, n (%)	Intervention (n = 34)	Control (n = 32)
Acceptance of randomisation	34 (100.00)	32 (100.00)
Request to withdrawal	0 (0.00)	0 (0.00)
Completed 2-month follow-up	23 (67.65)	31 (96.87)
Lost to follow-up	11 (32.35)	1 (3.13)

Table 4. Participant characteristics at baseline, by group.

	Intervention (n = 34)	Control (n = 32)
	Mean (SD)	Mean (SD)
Age (years)	61.82 (13.06)	64.34 (11.20)
	N (%)	N (%)
Gender (men)	27 (79.41)	20 (62.50)
NZ/European/Caucasian	21 (61.76)	19 (59.38)
Ischemic stroke	24 (70.59)	27 (84.38)
Intracerebral haemorrhage	6 (17.65)	3 (9.36)
First ever stroke	32 (94.12)	29 (90.63)
Education beyond formal schooling	19 (55.88)	15 (46.88)
Full-time employment	16 (47.06)	16 (50.00)
Married	24 (70.59)	21 (65.63)
Living alone	3 (8.82)	4 (12.50)
Nominated caregiver	25 (73.53)	16 (50.00)
Caregiver gender (men)	4 (16.00)	16 (100.00)

NZ: New Zealand. Note: Total n=66 due to 2 control participants not meeting the inclusion criteria.

Table 5. Feasibility of the intervention.

Theme	Responses N (%)
Benefits	
All helpful	8 (23.53)
Rehabilitation exercises	6 (17.65)
Practical tips (e.g. turning over in bed)	5 (14.71)
Stroke education	4 (11.76)
Reassurance	4 (11.76)
Caregiver advice	3 (8.82)
Sharing experiences	3 (8.82)
Recurrent stroke	2 (5.88)
At least one benefit	15 (44.12)
Barriers	
Content not relevant	7 (20.59)
Technical	3 (8.82)
Equipment (e.g. support rails not available)	2 (5.88)
Health (e.g. other illness)	2 (5.88)

Theme	Responses N (%)
Comprehension (e.g. language)	1 (2.94)
Time limitations	1 (2.94)
At least one barrier	11 (32.35)

Note: Multiple responses are possible per patient.

Table 6. Patterns of change in outcome measures from baseline to after the intervention (2-months), by group (%).

		Intervention[a] (n = 23)	Control[a] (n = 30)
Outcomes	Categories	N (%)	N (%)
Mobility (EQ-5D-5L)	No change	9 (39.13)	16 (53.33)
	Improvement	12 (52.17)	11 (36.67)
	Worse	2 (8.70)	3 (10.00)
Self-care (EQ-5D-5L)	No change	12 (52.17)	18 (60.00)
	Improvement	10 (43.48)	7 (23.33)
	Worse	1 (4.35)	5 (16.67)
Usual activities (EQ-5D-5L)	No change	9 (39.13)	13 (43.33)
	Improvement	13 (56.52)	13 (43.33)
	Worse	1 (4.35)	4 (13.33)
Pain/discomfort (EQ-5D-5L)	No change	10 (43.48)	14 (46.67)
	Improvement	7 (30.43)	12 (40.00)
	Worse	6 (26.09)	4 (13.33)
Anxiety/depression (EQ-5D-5L)	No change	18 (78.26)	19 (63.33)
	Improvement	1 (4.35)	6 (20.00)
	Worse	4 (17.39)	5 (16.67)
Disability (mRS)[b]	No change	8 (36.36)	8 (29.63)

		Intervention[a] (n = 23)	Control[a] (n = 30)
Outcomes	Categories	N (%)	N (%)
	Improvement	13 (59.09)	17 (62.96)
	Worse	1 (4.55)	2 (7.41)
General health (GHQ-28) †	No change	0 (0.00)	0 (0.00)
	Improvement	16 (76.19)	21 (75.00)
	Worse	5 (23.81)	7 (25.00)
Depression (CES-D)*	No change	6 (26.09)	10 (37.04)
	Improvement	5 (21.74)	9 (33.33)
	Worse	12 (52.17)	8 (29.63)

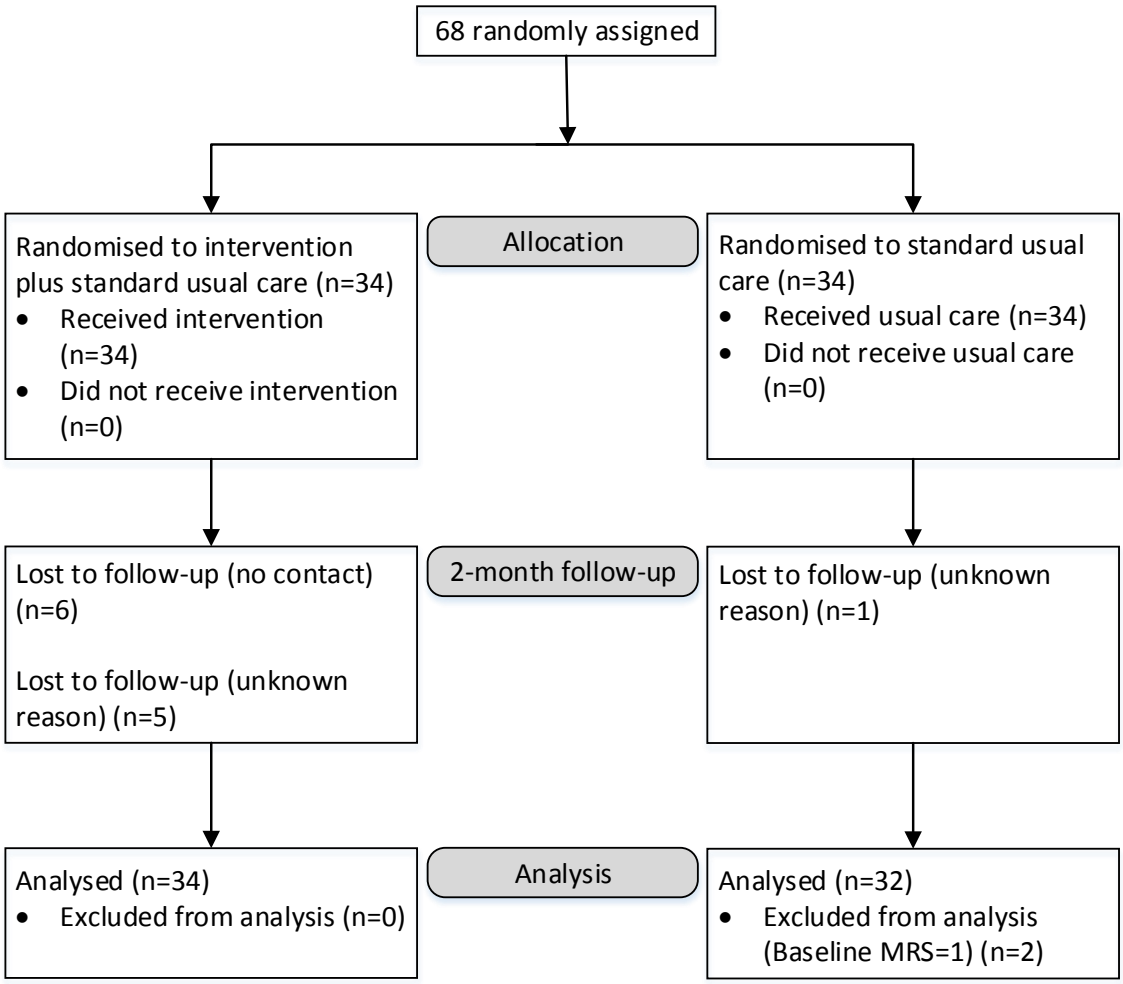
[a]N = 23 intervention and 30 controls due to loss to follow-up (11 intervention, 2 controls).

[b]N = 22 intervention and 27 controls as this item was missed at one site.

†N = 21 intervention and 28 controls due to losses to follow-up (11 intervention and 2 control cases) and missing data (2 intervention and 2 control cases) at 2-months.

* N = 23 intervention and N=27 controls due to losses to follow-up (11 intervention and 2 control cases) and missing data (3 control cases) at 2-months.

Figure 1. Flow diagram showing the procedure of allocation, 2-month follow-up and analysis.



Appendix 1. Additional information about the DVD provided to study participants.

The DVD video is an instructional and educational guide to stroke recovery. It provides easy-to-follow step-by-step educational and training materials for survivors of stroke and their families. The rehabilitation procedures can be used at home or any other facility by people who have no special medical background but who are caring for their loved ones. With this comprehensive stroke training solution DVD you will learn how to provide everyday care for a person with stroke and carry out rehabilitation exercises in a medically correct way.

The DVD contains over 40 different care and rehabilitation techniques to choose from (e.g. feeding, massage, physical exercises, bathing, walking, fatigue and memory management, etc). All training procedures are accompanied by easy-to-follow explanatory commentaries from health professionals. Survivors of stroke and their family caregivers also offer their experiences, and provide coping strategies.

The following chapters and topic examples are covered –

Chapter 1 – Understanding Stroke

What is a stroke?

What is an ischaemic stroke?

What is an intracerebral haemorrhage and subarachnoid haemorrhage?

Chapter 2 – Early Care and Hygiene

Recovery position

Preventing bedsores

Changing sheets

Mouth care

Eye care

Adjusting the bed

Putting on a compressive stocking

Chapter 3 – Rehabilitation Exercises

Bed exercises

Mouth and vice exercises

Breathing exercises

Arm and hand movements

Chapter 4 – Moving Around

Transfer from bed to chair

Walking

Using the toilet

Using stairs

Chapter 5 – Coping with Stroke Aftermath

Personal feelings after the stroke

Returning home after hospital

How to reduce your risk of another stroke

Chapter 6 – Experience of Caregivers

Caregivers share their experiences of caring for a family member affected by stroke

Appendix 2. Established trial recruitment sites

1	School of Physiotherapy, Dalhousie University, Canada
2	Conrod Injury Research Centre, Menzies Health Institute Queensland, Griffith University, Queensland, Australia
3	Waitakere Hospital, New Zealand
4	Waikato Hospital, New Zealand
5	Palmerston North Hospital, New Zealand
6	Northshore Hospital, New Zealand
7	Department of Medicine, University of Ilorin, Ilorin, Nigeria
8	Division of Physical Therapy, Department of Rehabilitation Medicine, School of Medicine, Emory University, United States of America
9	Stroke Unit, Department of Neurology, Christian Medical College, India

Note: Five sites unable to recruit any participants are not listed.

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