

This is an electronic version of an article published in

Disability & Rehabilitation 2007;29(14):1117-27 and is available online at

<http://www.informaworld.com/smpp/title~content=g779970653~db=all>

Recovery from disability after stroke as a target for a behavioural
intervention: Results of a randomised controlled trial

Short Title: Intervention for Recovery in Stroke Patients

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Abstract

Purpose: Disability following stroke is highly prevalent and is predicted by psychological variables such as control cognitions and emotions, in addition to clinical variables. This study evaluated the effectiveness of a workbook-based intervention, designed to change cognitions about control, in improving outcomes for patients and their carers.

Method: At discharge, stroke patients were randomly allocated (with their carers) to a 5-week intervention (n = 103) or control (normal care: n = 100). The main outcome (at 6 months) was recovery from disability using a performance measure, with distress and satisfaction as additional outcomes.

Results: The intervention group showed significantly better disability recovery, allowing for initial levels of disability, than those in the control group, $F(1,201) = 5.61$, $p = 0.019$. Groups did not differ in distress or satisfaction with care for patients or carers. The only psychological process variable improved by the intervention was Confidence in Recovery but this did not mediate the effects on recovery.

Conclusions: A large proportion of intervention participants did not complete the workbook tasks. This was perhaps associated with the fairly low level of personal contact with workbook providers. The modest success of this intervention suggests that it may be possible to develop effective behavioural interventions to enhance recovery from disability in stroke patients.

Recovery from disability after stroke as a target for a behavioural medicine
intervention: results of a randomised controlled trial

Stroke is an important cause of acquired disability in western industrialized countries [1,2]. While stroke mortality has shown some decrease, the trends in risk factors suggest that the incidence of stroke will continue to be high [3]. This combined with some success in increasing survival rates has led to an expectation of continuing high rates of disability following stroke [4]. Recovery from disability is an important behavioural outcome [5] that occurs over variable time periods [6] and enhancing recovery is potentially achievable by behavioural and psychological intervention [7].

In the last twenty years there have been increasing numbers of controlled trials testing non-pharmacological interventions to reduce disability due to stroke. The majority of these manipulate the context or organisation of services i.e. where and how rehabilitation is delivered, without precise specification of the content of intervention. These interventions have shown some patient care environments to be successful in reducing disability when compared with an existing alternative [e.g. 8-12] although some have not found effects [e.g. 13-17]. The Cochrane review group concluded that stroke units as care environments increased the likelihood of the patient being independent one year after the stroke [18].

These findings give some support for the role of contextual factors envisaged in the updated World Health Organisation (WHO) model of impairment and disability, the International Classification of Function (ICF) model [19]. The dominant model of disability has been, either explicitly or implicitly, the earlier WHO model, the International Classification of Impairments, Disabilities and Handicaps (ICIDH) model, which defines disability as limitation in the performance of activities resulting from impairment [20]. The consequences of disease are conceptualised at three levels: impairment of structure or function, disability in the performance of usual activities and handicap in participating socially. Compatible with the ICIDH, many of the interventions to reduce post-stroke disability have concentrated on early pharmacological treatment to minimise brain impairment and indirectly disability [21]. By contrast, the ICF formulation clearly recognises the potential role of psychological, behavioural, social and contextual factors and indicates their relevance

to disabling conditions such as stroke. The ICF defines disability as behavioural [22]. To illustrate, disability such as walking limitations will be influenced by not only the extent of the injury (impairment) but also by the way the patient thinks about behaviours that define recovery from the impairment. For example, one patient may define recovery as 'walking without assistance' whereas another may define recovery in terms of speed of walking. Behavioural and cognitive interventions to promote recovery from disability would therefore seem appropriate.

On the other hand, the evidence that manipulating contextual factors can improve recovery outcomes [8-12] gives an optimistic clinical message. However such studies do not clarify the mechanisms (e.g. pharmacological, psychological) by which outcomes may be improved. Without clearer understanding of the mechanisms, the results of 'black box' trials will continue to be inconsistent and possibly non-replicable [23]. Further enhancement of recovery outcomes will depend on better understanding of the processes involved.

There is evidence that improving the intensity or delivery of physical interventions can improve a range of outcomes. A number of studies examining the effectiveness of additional physiotherapy or occupational therapy input have shown improved recovery [24-27]. In contrast, additional inputs not focused on physical therapy do not. For example, Forster [28] found no benefit of additional specialist nurse support, nor did Dennis et al. [29] observe gains from a family support worker. Trials of specialist physical re-training, usually physiotherapy or occupational therapy derived regimens, also show some success in reducing impairment [30-32]. Some of these trials show specific effects on particular impairments of, for example, upper versus lower limb function with greater intensity of the intervention [30], suggesting that rehearsal effects are important. Indeed, a systematic review by Van Peppen et al. [33] concluded that physical therapies show small to large effect sizes for task-oriented training, with effects mainly restricted to tasks directly trained in the exercise intervention. It has been proposed that these effects may be at least partially mediated by enhancing specific brain pathways and that similar effects might be obtained by mental rehearsal of motor imagery, but early findings show mixed evidence of benefits of such imagery [34,35].

Interventions based on psychological factors have been usually directed at cognitive (e.g. knowledge) rather than behavioural outcomes. The possibility that psychological or behavioural programmes might improve activity limitations for

stroke patients is largely unexplored. Nevertheless it is possible that successful stroke rehabilitation environments, such as physical therapy programmes, may operate psychologically, in addition to other routes of effectiveness, for example, through patients being motivated to meet clinicians' expectations. Indeed, one study showed that patients who were treated as if their formal caregivers expected them to make progress were more likely to achieve that progress [36].

A factor that is often assumed to influence patient outcomes is knowledge about the condition and its treatment. Trials where patients have been given additional information did not enhance physical capabilities [e.g. 37,38] and a recent systematic review of information provision interventions for stroke patients concluded that the effectiveness of such interventions has not been demonstrated [39]. However, as demonstrated in many other domains, information per se is a relatively weak method of changing behavioural outcomes [e.g. 40]. Successful interventions are likely to influence other psychological factors than simply knowledge or amount of information. They may promote different patterns of patient cognitions, emotions and behaviours, which in turn may influence recovery outcomes. An illustration of this is provided by Clark et al. [41], who reported modest benefits in activity limitations related to improved family functioning, following an intervention that included an information package but also visits from a social worker trained in family counselling.

Control cognitions (e.g. beliefs about whether the patient can influence outcomes) and mood have both been found to predict disability following stroke [42-48]. In a series of studies we have found that perceived personal control over recovery predicts recovery in stroke patients, after allowing for initial levels of disability and controlling for other demographic and clinical predictors. While mood (anxiety and depression) was also predictive, it was no longer significant when control cognitions were allowed for [42,48], suggesting that cognitions rather than mood mediated the effects. However, a recent RCT to train caregivers in caring tasks reported improvements in mood among both patients and their carers, yet no effects on patients' disability [49]. The relationships between patient emotions, cognitions, and recovery thus remain unclear.

The study reported here was designed to examine whether an intervention could be developed to enhance control cognitions, with resulting improvements in recovery outcomes. The intervention was introduced as a 'workbook' to promote the idea of the patients and their carers being in control, following the demonstration by

Lewin et al. [50] that a manual-based intervention was successful in enhancing emotional state in myocardial infarction patients. The current study examined a similar intervention for stroke patients, designed to increase perceived control by providing information, teaching coping skills and guiding self-management tasks. When piloted with 25 first stroke patients, the workbook intervention resulted in lower anxiety and depression (assessed using HADS), and higher satisfaction with care one month after discharge compared to 53 patients from an earlier predictive study [51]. However, this study was too limited to examine effects on recovery. While the intervention had been developed for patients at the time of discharge from hospital, an early feasibility trial was conducted with 39 individuals with chronic disabilities following stroke, because of the easier access to such people. No differences were found between the intervention and control group, although both groups showed reduced disability [52]. This suggests that, although some recovery occurs over time, there may be a ‘critical period’ following stroke during which patients’ cognitions are more amenable to change than at later stages in the recovery process.

In the trial to be described here, the primary outcome was recovery from disability, using a behavioural measure, a validated observed performance of activities [53], in order to minimise the social desirability biases that can occur in self-report assessments in single blind trials. This performance measure is not influenced by patient self-report measures – an important consideration in this study which deals with psychological process variables. Without this independence between measures, apparent relationships between process and outcome variables might simply be due to shared response bias [54]. As a secondary objective, we explored the effects of the intervention on patient and carer distress, as high levels of distress have been demonstrated [55,56] and a previous intervention with MI patients showed lasting emotional benefits for patients and carers [54]. In addition, we explored the psychological mechanisms mediating effects observed.

Research questions

1. Compared to normal care, does the workbook intervention result in: a) enhanced recovery in stroke patients 6 months after hospital discharge; b) improved emotional outcomes for patients and carers?
2. Are any intervention effects on recovery mediated by psychological variables?

Method

Design and procedure

This was a randomised controlled trial of a post-discharge workbook intervention for stroke patients and carers. A research nurse routinely administered clinical measures within 48 hours of hospital admission following stroke, which was medically diagnosed and confirmed by CT scan where appropriate. When the patient's condition was medically stable and while the patient was still in hospital or as soon as possible following discharge, patients and their carers were invited to participate.

The first interview (baseline) took place within 2 weeks of discharge from hospital, with the second interview at 8 weeks (after completion of the intervention) and the third interview at 6 months from baseline. If patients failed the cognitive screening test administered before each interview, they were not required to complete the measures and carers were invited to continue in the study. Patients and carers were interviewed separately. Duration of interviews was 45 – 120 minutes. Before the second interview, each patient's general practitioner was informed of the patient's involvement in the study.

Participants were randomised to the Intervention or Control group (see below) following the baseline interview. The Intervention group were contacted and visited by the workbook implementer within one week of baseline. A statistician (BP) prepared two separate randomisations for patients with carers who had also agreed to participate (carer-patient subgroup) and for carers partnered with a patient who could not participate because of cognitive and communication impairments (carer-only subgroup). Randomisation was done in batches to ensure equal numbers in groups. Research assistants who administered the interviews were kept blind to randomisation and participants were asked not to disclose if they had received the workbook intervention. Patients and carers were interviewed independently.

Administration of the workbook-based intervention

The intervention was administered by a workbook implementer (SJ) over a period of 5 weeks. The first intervention contact was a home visit. The implementer presented the workbook and instructed participants in its use. At the second contact (a home visit the following week), the implementer answered questions, provided encouragement, and offered more information about stroke risk factors. The third and

fourth contacts were by telephone at weekly intervals. During these contacts, the implementer monitored goals and achievements, and continued to provide encouragement. The last contact was a home visit during the fifth week of the intervention period, when the numbers of completed quizzes and tasks, diary days and set goals, were recorded.

The workbook text had an average reading level with a Flesch Reading Ease score of 70.6. This score is based on the average number of syllables per words and words per sentence. It is scaled from 0 to 100; the higher the score, the easier it is to comprehend. The workbook provided information about stroke and recovery; guidance on coping skills; and self-management instruction. It also drew on cognitive behavioural therapy techniques by including activities designed to allow the patient to attain the coping skills to encourage self-management: task materials (e.g. for goal setting), diary sheets and an audio relaxation cassette tape that described simple body relaxation and breathing exercises.

Measures

Disability/Activity limitations were assessed using Barthel Index [57], a self-report measure assessing 10 activities of daily living; and the Observer Assessed Disability (OAD; [53]), a performance measure in which patients perform 18 movements (e.g. arm raising) observed by the researcher, who rates each movement as performed or not performed. The measure shows a systematic pattern of improvement following stroke and is sensitive to variability in patient outcomes [43].

Recovery from disability was assessed using the OAD, allowing for baseline levels of disability assessed by the Barthel Index. The OAD was the primary outcome in the previous predictive study [43,48] as it allows for earlier disability and, in regression analyses, retains the same values when additional variables enter the equation. Recovery was defined as the deviation from the statistically expected disability at 6 months from baseline, with scores greater than 0 indicating better than average recovery (based on performance of the total group). In the regression equation used to create the recovery variable, the Barthel Index at baseline accounted for 44% of the variance in OAD at 6 months ($p < .001$). Residualised scores ranged from 3.20 to 3.36.

Emotional distress was assessed using the Hospital Anxiety and Depression Scale (HADS; [58]). It gives a total Distress score (range 0 – 42) as well as measures

of Anxiety and Depression (each scored from 0 to 21), which have been developed to avoid confounding with symptoms of physical disorders. It performs well psychometrically [59,60].

Satisfaction with treatment and advice were assessed using scales from 0 (totally unsatisfied) to 10 (totally satisfied). These measures predicted distress in the earlier study [55].

Perceived control over recovery was assessed using the Recovery Locus of Control Scale (RLOC; [43]). Items on a 5-point scale ('strongly agree' to 'strongly disagree') are combined such that higher scores indicate greater belief in personal control. This scale has predicted stroke outcomes in previous studies [42,43].

Confidence in recovery was assessed using patients' ratings of confidence in making a full recovery from 0 (not at all confident) to 10 (totally confident), based on a measure used by Lewin et al. with myocardial infarction patients [50]. This single item measure predicted distress in an earlier study [55,56].

Clinical assessments: Neurological impairment was assessed routinely by the research nurse within 48 hours of admission using the Orgogozo Index [61], a 9-item measure giving a total score out of 100 (maximum score for each item: consciousness 15; speech 10; eye and head movement 10; facial movement 5; arm lower 10; hand movement 15; leg power 15; foot dorsiflexion 10; upper limb tone 5; lower limb tone 5) and the National Institutes of Health Stroke Scale (NIH; [62]), a 13-item measure of level of consciousness, language, neglect, visual-field loss, extraocular movements, motor strength, ataxia, dysarthria, and sensory loss. Other clinical indices were side of deficit; number of previous strokes; comorbidity; and length of hospital stay.

Cognitive impairment was assessed using a combined Information and Orientation section of the Clifton Assessment Procedures for the Elderly (CAPE; [63]) with four additional items from the Mental Status Questionnaire (MSQ; [64]) making a total of 18 items (due to the tests sharing 8 items). Respondents were excluded from recruitment if they scored less than 8, a score indicating moderate impairment.

Additional carer measure: Carers' activity levels were assessed using the physical functioning scale of the Short Form 36 Health Survey Questionnaire (SF-36) [65]. Limitations in everyday activities were rated on a 3-point scale ('yes, limited a lot' to 'no, not limited at all').

Internal consistency statistics for the measures at each time of administration are provided in table 1. All were good to high, with the exception of RLOC which showed only moderate consistency.

[Insert table 1 about here]

Administration of measures

The actual timing of the three interviews was as follows: baseline, Mean = 24.02 days following discharge from hospital (SD = 16.61; Median = 19); second interview, Mean = 59.17 days after baseline (SD = 17.55; Median = 54); third interview, Mean = 197.34 days following discharge from hospital (SD = 22.10; Median = 190).

Participants

All patients who were fluent in English and discharged from Ninewells Hospital (Dundee, Scotland) following acute stroke were invited to participate (n=303), as were their carers. Carers were identified by the patient as the individual most involved in their care following discharge from hospital. 203 patients (67% of those invited; 124 males, 79 females) and 172 carers (45 males, 127 females) consented to participation. For 80% of patients this was their first stroke and 86% had comorbidity on admission to hospital. Further details of dropouts and numbers included are presented in figure 1 and descriptive statistics for the analysed sample are provided in table 2.

[insert figure 1 about here]

[Insert table 2 about here]

Of the 203 patients completing the baseline interview, 171 completed the second and 158 completed the third interviews. Patients who withdrew tended to have spent longer in hospital following their stroke (withdrew = 52.93 days in hospital (SD = 64.59); completed = 30.61 days in hospital (SD = 35.10); $t(201) = 2.23$; $p < .05$) and were more likely to have been in the Intervention group (withdrew/completed: Intervention 29/74; Control 16/84; $t(1,202) = 4.35$; $p < .05$). If carers were female, they were more likely to have dropped out (withdrew/completed:

Males = 6/39; Females = 36/91; $\chi^2 (1,172) = 4.06$; $p < .05$). There were no differences between those withdrawing and those completing on any other demographic or clinical variables, or on baseline disability and psychological variables.

Statistical methods

Missing values for items within measures were replaced with the series mean, providing 80% of the measure was completed. Data were examined for univariate outliers using z scores > 3.29 ($p = 0.001$). All variables were examined for approximation to a normal distribution using skewness and kurtosis statistics greater than ± 1 . Non-normal variables were transformed where appropriate. Group differences on baseline measures were investigated using chi-square, t-test and one-way analysis of variance (ANOVA). Regression analyses were performed to calculate recovery variables. To investigate differences between groups over the intervention and follow-up period, ANOVA for recovery outcomes and Repeated Measures ANOVA for other outcomes were performed. The Greenhouse-Geisser correction was calculated if the assumption of sphericity was violated.

Intervention effects were analysed on an intention-to-treat basis. For the main outcome, recovery from disability, if third interview OAD data were unavailable, they were replaced by second interview OAD scores; if no OAD score was available, they were given the average recovery score i.e. zero. These analyses were repeated including only patients for whom there was an OAD score at either the second or third interview. For distress, missing data at the second and third interviews were replaced by data for the same patient or carer at an earlier interview. For satisfaction, since there were no baseline data, data were analysed for patients who completed at least one assessment with missing data replaced by data from the interview where data were obtained. Where intervention effects were obtained, their mediation by psychological variables was examined using the methods of Baron and Kenny [66] and Sobell [67].

Results

Equivalence of groups at baseline (see table 2)

Table 2 indicates that there were no significant differences (at $p < .05$ level) in any background, psychological or outcome variable at baseline between patients in the control and intervention groups, nor in any background, psychological or outcome

variable at baseline between carers in the control and intervention groups or when the carer-patient and carer-only subgroups were analysed separately.

Effect of the workbook intervention on outcomes

Significance tests relating to the effects of the intervention are presented in table 3. Patients in the Intervention group had significantly better Recovery from Disability than the control group receiving normal care ($F(1,201) = 5.61, p = .019$; Control mean = $-0.17, s.d. = 0.95$; Intervention mean = $0.19, s.d. = 1.01$). When this analysis was repeated to include only those patients for whom an OAD score was available at either the second or third interview, this continued to be significant, $F(1,169) = 5.55, p = .02$. Additional analyses on Barthel Index over three interviews showed no group by time interaction, $F < 1$.

[Insert table 3 about here]

There were no significant effects of group by time interactions on the total HADS for patients ($F < 1$) or for carers ($F < 1$). There was a significant time effect, $F(1,198) = 23.15, p < .001$. Additional analyses on Anxiety and Depression separately showed no significant effects.

There were also no significant effects of group or group by time interactions for Satisfaction with Care among patients, $F_s < 1$.

Effect of the workbook intervention on psychological mediation variables

(see table 4)

- i) Perceived control: There was no significant group by time interaction between patients in the control and intervention groups for RLOC, $F_s < 1$.
- ii) Confidence in recovery: There was a significant group by time interaction effect for patients' Confidence in Recovery, $F(1,197) = 10.67, p = .001$, and no main effect of group. Confidence in Recovery declined over time for patients in the control group, but stayed relatively stable for patients in the Intervention group. However, the effect of the intervention on Confidence in Recovery did not mediate the intervention effect on Recovery. The size of the mediated effect (i.e. the difference between the unadjusted beta weights in the regression equation with OAD as the dependent variable and intervention group as the independent variable, with

and without Confidence in Recovery as an additional independent variable) was approximately 0.01, $z = .199$, n.s., using the Sobell analysis [67].

There were no significant effects of the intervention on carer outcomes (Distress; Satisfaction with care) or on psychological mediation variables (RLOC) when the carer-patient and carer-only subgroups were analysed separately.

[insert table 4 about here]

Discussion

Compared to normal care, the workbook intervention resulted in significant gains in the primary, pre-specified outcome by showing better recovery from disability for stroke patients at 6 months after discharge from hospital, taking account of initial disability levels. This is potentially an important finding given the prevalence of disability following stroke and the limited success of interventions to date. Participants were identified with as few exclusions as possible, enhancing the pragmatic value and generalisability of the study. The effect was obtained using a performance-based rather than self-report measure of recovery and is therefore less likely to be due to a simple social desirability effect. Nevertheless even a performance measure may be influenced by social factors; so this result may indicate that following the workbook patients were more able to perform in a social situation where they were motivated to perform. One might have expected to see effects on the Barthel Index, which is commonly used with stroke patients, but there is evidence that this measure lacks sensitivity to change [68]. The effect of the workbook intervention nevertheless compares well with other community-based interventions [e.g. 28, 29, 39] and provides support for the proposition that people with stroke and their carers can take some control of the recovery process.

However it is at best a modest intervention effect. Significant findings are found on only one outcome, with no effects on distress and satisfaction. It is important to consider whether the main recovery finding might be biased by excess of attrition from the Intervention group. Patients were lost from the study, and particularly from the Intervention group, mainly because they were too unwell to continue. This had not been a major problem in piloting [51,52], partly because those patients had passed the early stages of disability and partly because patient recruitment did not involve a sequential prospective cohort. The intervention was designed for patients at the stage

of discharge because that was considered to be the time when most benefit might be achieved and because psychological variables such as perceived control have been predictive of recovery outcomes in this early period.

Even in those patients who did participate in the intervention, additional analyses of workbook tasks show that a large proportion did not complete these tasks as planned. Our earlier work showed that many stroke patients were dissatisfied with the care they were receiving [55] and we had expected the workbook to meet a need that patients had expressed. Informally patients were positive, but this did not show in higher satisfaction ratings in the intervention group compared to the control group. However, satisfaction with care may have been reported in relation to hospital care alone, as patients may not have perceived the workbook intervention as part of the 'care package'. Satisfaction with the workbook was higher for the information and social support it provided, than for the behavioural activities included. The tasks may simply have been too difficult for patients and carers given the demands imposed by the patients' condition. Joice [69] found greater participation in a simpler intervention, although the latter was not effective in improving patient outcomes. Alternatively, the modest effects could perhaps be explained by the fairly low level of personal contact with workbook providers and the possible influence of this on compliance.

Other possible variables surrounding the workbook intervention that could account for the effects include the influence of consistent monitoring of goals and achievements, consistent encouragement, or perhaps factors associated with the individual skill level of the workbook implementer. The first two of these were integral to the intervention protocol and are replicable components of the intervention.

The intervention did not result in better outcomes for patients or their carers in terms of lower distress or higher satisfaction with care. Our previous studies suggest that these outcomes have different predictors and may therefore be affected by different mechanisms [43,55,56]. One might then expect that different interventions would impact differently on the behavioural (recovery from disability) assessment and on more emotional, evaluative measures.

The intervention did not affect the two proposed process variables, perceived control over recovery and distress. If the hypothesised mediators of effect are not improved, then one should not expect effects on the outcome. The failure to change perceived control was disappointing given earlier success in changing it in shorter

term interventions [43,70], suggesting that a more sustained intervention may be necessary for effects to last over months. However, internal consistency for the control measure was low (<0.6 at Interview 1) and this may have attenuated the observed relationships in the tests of mediation. One variable, 'confidence in recovery' was affected by the intervention, but did not mediate the recovery effects. This was the strongest effect observed and, if a reliable finding, could demonstrate long term value. At a stage when patients tend to have a declining belief in recovery (post hospital discharge), those with a sustained belief may continue to do the things that enhance their recovery or enable them to notice recovery. In our preliminary study, Frank et al. [52] found reduced disability in both intervention and control groups in patients at a much later stage in recovery and suggested that this might be due to the additional attention received by both groups during assessments.

Thus the evidence suggests on the one hand that a more intense intervention is required and on the other that patients and carers are unable to participate if the intervention is too taxing. This could prove a significant problem for self-management interventions for stroke patients that was not a problem for MI patients [50]. Stroke patients can however tolerate intensive programmes e.g. Page et al.'s [34] programme involved at least 20 hours of clinic tasks plus 2 sessions of homework each week over a period of 6 weeks. Thus, in order to have the effectiveness of physical therapy programmes, psychological interventions may need to achieve a similar intensity with support and structure, perhaps initially within a hospital setting.

In a field where very little work has been done to date, these results offer some encouragement to develop psychological interventions to enhance recovery in stroke patients. It will be important to persist in developing an intervention which is effective enough to warrant implementation, as stroke is a significant cause of disability, existing treatments have only limited effectiveness and predictive studies suggest that the best predictors of long term outcome, over and above the unmodifiable factors, relate to patients' beliefs and emotions.

Conclusion

This study provides evidence that a workbook-based behavioural intervention can result in a better health outcome for stroke patients compared with a control group receiving normal care only. Although the behavioural intervention has shown only a modest effect, it nevertheless shows promise in a field where there is a dearth of

effective interventions and in a condition which is a significant burden to patients, carers and health services. Additional work needs to be done to examine potential mediators of effects and factors associated with benefit from the workbook, including the extent of patient adherence to the programme. Further, it is important to continue to explore opportunities for interventions to improve recovery outcomes for stroke patients and their carers.

Acknowledgements

This research was supported by a grant from the Scottish Executive Chief Scientist Office (Grant No. K/CR1/1/7). We are grateful to all the patients, carers and clinicians who contributed to this research. We would like to thank Anjali Kapur for all the work she did in data collection as Research Assistant, Hazel Fraser for carrying out initial assessments and Helen Cameron-Smith, Martin Morthland, Alexandra Seidel, Erika Lorinz, Jo Hart, Rachael Powell, Stephen Ellis, Sylvia Briscoe, Sarah Fielding, David Craigie, James Hutchinson, Stephanie Lawrie, Kate Frost, Angela Martin, Lucy Falconbridge, Catriona Wootton, Anna Blackie, Isla Smith, Anna Everett and Leigh Drummond for assisting with interviews and data entry.

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TABLE 1. Alpha coefficients of internal consistency in study sample

Measure	Number of items	Cronbach alphas		
		Interview 1	Interview 2	Interview 3
Barthel Index	10	0.85	0.78	0.82
Observer Assessed Disability	18	-	0.92	0.79
HADS Anxiety (patients)		0.81	0.83	0.83
HADS Anxiety (carers)		0.80	0.83	0.85
HADS Depression (patients)		0.72	0.77	0.74
HADS Depression (carers)		0.79	0.80	0.80
Satisfaction (patients)	2	-	0.84	0.78
Satisfaction (carers)	2	-	0.84	0.76
Recovery Locus of Control (patients)	9	0.54	0.68	-
Recovery Locus of Control (carers)	9	0.57	0.61	-
Physical functioning scale of SF-36	10	0.82	0.80	

TABLE 2. Equivalence of groups on baseline variables: Descriptive statistics, t-tests and Chi-Square

PATIENTS	Control Group			Intervention Group			df	t
	N	Mean	SD	N	Mean	SD		
Background: Age	100	68.79	12.02	103	68.96	12.64	201	-0.10 ns
MSQ	92	7.88	3.59	89	7.00	4.07	179	1.54 ns
Stroke Number	100	0.16	0.37	103	0.26	0.44	201	-1.79 ns
Orgogozo	97	74.74	23.52	97	77.32	20.16	192	-0.82 ns
NIH	94	4.63	3.97	95	4.64	3.76	187	-0.00 ns
Disability: Barthel	99	18.36	2.74	103	18.02	3.14	200	-0.71 ns
Distress: Anxiety	99	5.50	4.17	102	6.02	5.32	199	-0.76 ns
Depression	99	6.03	3.81	102	6.89	4.46	199	-1.46 ns
Confidence in Recovery	97	8.07	2.21	103	7.71	2.30	198	1.14 ns
Perceived Control: RLOC	96	35.41	4.36	102	35.30	4.14	196	0.17 ns
		Control Group	Intervention Group	N	df	χ^2		
Gender (Male/Female)		61 / 39	63 / 40	203	1	0.00 ns		
Side of motor deficit (Left/Right)		43 / 53	45 / 47	188	1	0.32 ns		
Comorbidity (Yes/No)		83 / 17	92 / 11	203	1	1.70 ns		
Previous stroke (Yes/No)		16 / 84	27 / 76	203	1	3.17 ns		
With carer (Yes/No)		73 / 27	65 / 38	203	1	2.28 ns		
Further education (Yes/No)		9 / 29	8 / 21	67	1	0.13 ns		

CARERS ^P	Control Group			Intervention Group			df	t
	N	Mean	SD	N	Mean	SD		
Background: Age	89	60.99	13.17	80	62.51	14.63	167	-0.71 ns
Health - General	90	3.25	0.98	82	3.02	1.13	170	-1.44 ns
- Activity	90	25.76	5.04	82	24.18	6.03	170	1.86 ns
Distress: Anxiety	90	7.08	4.01	82	7.64	4.89	170	-0.84 ns
Depression	90	4.77	3.90	82	5.65	4.27	170	-1.41 ns
Perceived Control: RLOC	90	34.50	4.41	82	34.33	4.06	170	0.26 ns
		Control Group	Intervention Group	N	df	χ^2		
Gender (Male / Female)		28 / 57	27 / 48	172	1	0.78 ns		

ns: not significant at the $p < .05$ level; (p) these measures relate to the carers' perceptions regarding the patient's beliefs

TABLE 3. Intervention Effects on Outcomes: Patients

Outcomes		Control Group		Intervention Group		F, p for intervention effects
Measure/Interview		Mean	SD	Mean	SD	
OAD ^a	2 nd	0.05	0.98	-0.06	1.02	F(group)=5.61, p=.019
	3 rd	0.09	0.99	-0.09	1.00	
	Recovery	-0.17	0.95	0.19	1.01	
Barthel Index ^a	1 st :Baseline	1.50	0.63	1.57	0.73	F(group)=0.04, n.s.
	2 nd	1.43	0.59	1.44	0.65	
	3 rd	1.39	0.61	1.43	0.68	
	Recovery	-0.01	0.93	0.01	1.06	
Distress (HADS)	1 st :Baseline	11.54	6.93	12.99	8.90	F(group x time) =0.40, n.s.
	2 nd	10.42	7.25	12.09	8.31	
	3 rd	9.67	7.34	10.67	7.89	
Satisfaction with Care	2 nd	15.80	4.32	15.70	4.46	F(group)=0.00, n.s.
	3 rd	15.34	3.70	15.49	4.93	F(group x time)= 0.15, n.s.

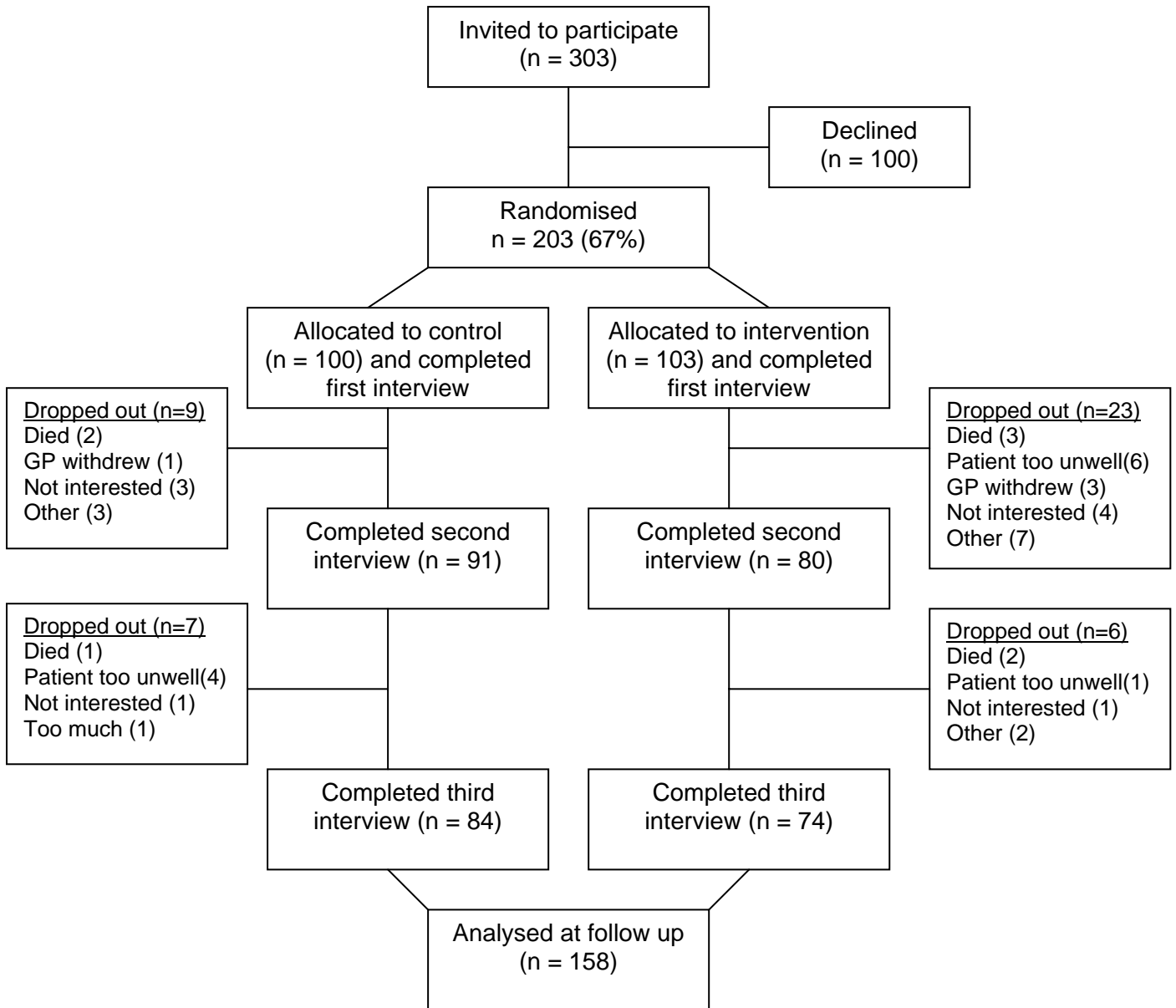
^a Transformed scores (higher scores = higher disability);. All Recovery variables are scored so that higher scores represent better recovery (compared to the performance of the whole group)

TABLE 4. Intervention Effects on Process

Measure/ Interview		Control Group		Intervention Group		F for Group and Group by Time Effects
		Mean	SD	Mean	SD	
Patients' RLOC	1 st :Baseline	35.40	4.38	35.30	4.14	0.05 n.s.
	2 nd	35.53	5.21	35.87	4.31	0.39 n.s.
Patients' Confidence in Recovery	1 st :Baseline	8.07	2.21	7.74	2.30	0.20 n.s.
	2 nd	7.18	2.47	7.77	2.18	10.67, p=0.001
Carers' RLOC	1 st :Baseline	34.50	4.40	34.33	4.06	0.04 n.s.
	2 nd	33.83	4.84	34.24	4.51	0.73 n.s.

*p<.05; **p<.01; ***p<.001; ns not significant at p<.05 level.

FIGURE 1. Dropouts and numbers included (patients)



END