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O'Connell, Beverly, Hawkins, Mary, Botti, Mari, Buchbinder, Rachelle and Baker, Linda 2009, Providing information to stroke survivors : lessons from a failed randomised controlled trial, *JARNA : the official journal of the Australasian Rehabilitation Nurses' Association*, vol. 12, no. 3, pp. 4-6.

## Available from Deakin Research Online:

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## **Providing information to stroke survivors: Lessons from a failed randomised controlled trial.**

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### **Acknowledgements**

We wish to thank the Medical Benefits Fund of Australia Limited for providing funding for this study under the MBF Research Awards. Rachelle Buchbinder is supported in part by an Australian National Health and Medical Research Council Practitioner Fellowship. The authors would also like to thank the service providers and their staff for their assistance with the project.

### **Abstract**

*We describe our experiences evaluating a printed individualised stroke patient-held record (PHR) that was developed to provide supportive information to stroke survivors on discharge from hospital. Ninety-three consenting stroke patients from rehabilitation and acute hospitals were randomised to receive a PHR or standard discharge information. The effectiveness of the PHR was assessed by telephone using the Stroke Impact Scale and an evaluation questionnaire, one month and four months post-discharge. The trial was terminated early (66 completions) because only 18 of the 28 intervention participants remembered receiving the PHR; 13 had read it and only one used it to manage their care. We concluded that as many stroke survivors did not remember information and instructions given in hospital, possibly due to impaired memory and stress, it is important for GPs or practice nurses to provide stroke survivors with educational information at frequent intervals along the continuum of care.*

**Key words:** Stroke, Patient Held Record, Patient Education, Discharge Information, Nursing, Research, Patient Care.

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ISSN: 1440-3994 (print)

## INTRODUCTION

Stroke remains one of the leading causes of morbidity and long term disability both internationally, (Schwamm et al., 2005, Bonita, 1992, Bergman et al., 1995) and in Australia (Australian Institute of Health and Welfare, 2006). Every year an estimated 40,000 to 48,000 stroke events occur in Australia (Australian Institute of Health and Welfare, 2006). Furthermore, between 200,000 and 250,000 people in Australia (Department of Human Services, 2006) are living with disabilities resulting from having a stroke. Most patients affected by stroke are discharged into the community (Exall and Johnston, 1999). A recent systematic review concluded that stroke discharge information improves outcomes for stroke survivors, increasing their knowledge about stroke, their satisfaction with the information provided, and reducing their depression levels following discharge from hospital (Smith et al., 2008). Strategies for providing stroke information that actively involve patients are likely to have a greater effect on mood, but to date in the literature there is no best way known to provide that information to stroke survivors (Smith et al.).

Studies have shown that the educational needs of stroke survivors following discharge from hospital are often not being met (Brereton and Nolan, 2000, O'Connell et al., 2003). Stroke survivors report low levels of satisfaction with information provided to them post discharge on how to manage their disability and the availability of support services (O'Connell et al., O'Mahoney et al., 1997). In addition, the communication between healthcare professionals is sub-optimal which often results in stroke survivors feeling isolated (O'Connell et al.).

Research provides inconclusive results about the value of generic stroke information for improving satisfaction and other health outcomes in patients following discharge (Mant et al., 1998). The use of a PHR, a booklet which contains stroke-related educational material, information and details of care management, has been proposed in the literature as assisting patients and their carers with discharge education and helping them manage their care in the community (O'Connell et al., 2000). Two studies have evaluated PHRs with stroke survivors; however, the findings

were equivocal. One possible explanation is that stroke survivors were not involved in development of the PHR and consequently it may not have been designed appropriately for their use (Ayana, 1998, Ayana et al., 2001). Other research found inadequacy in discharge education material given to stroke survivors because it was generic and failed to address the individual needs of each stroke patient (Brereton and Nolan, 2000). However, when individualised computer-generated education packages for stroke patients were evaluated they improved satisfaction with information received but there was no improvement in patients' stroke knowledge, self-efficacy, or perceived health status over non-individualised education packages (Hoffmann et al., 2007) leading to recommendations that written information be accompanied by verbal education. Further work is required to determine whether a specifically designed PHR assists the recovery and rehabilitation of stroke survivors post discharge from hospital.

## AIMS

The present study describes a Randomised Controlled Trial (RCT) aimed to develop and evaluate an individualised PHR. As the planned RCT was terminated, this paper will describe possible reasons for its failure.

## METHOD

### *Design and development of the individualised PHR:*

To ensure that all perspectives were addressed in the development of the PHR, we consulted with a panel of experts including a stroke Clinical Nurse Consultant, two medical consultants, two nursing academics, two stroke Nurse Unit Managers, a stroke medical specialist, a ward registrar, a GP, an occupational therapist, three individuals from the Stroke Association and three stroke survivors with two of their carers. The panel were informed by the literature in developing the content, format and delivery of the PHR (Eames et al., 2008). The PHR included the following sections:

- Information about the patient – demographic, health (allergies and impairments), medicines;
- Information and messages for the doctor and other health professionals – e.g., changes in

medicines and blood pressure; instructions to be followed; and plan of action;

- Information for the patient - health professional contact details; questions for their doctor and other health professionals, treatment goals and notes on their care; useful phone numbers e.g., personal and domestic care agencies, financial assistance, equipment hire, home alterations, personal alarms, information services, websites and transport; and, two brochures from the National Stroke Foundation. Participants were also given individualised fact sheets relating to specific problems associated with their stroke, based on the type of stroke, level of disability and symptoms, chosen from the following: Movement and Balance, Swallowing Difficulties, Bladder and Bowel Control (continence), Driving and Vision, Mood Changes, Pain, Sexuality, Speech and Communication.

#### *RCT of the PHR:*

The RCT protocol was approved by the hospitals' ethics committees and the University's Human Research Ethics Committee.

#### *Sample, setting and procedure:*

Potentially eligible stroke survivors were identified from their admission diagnosis at two rehabilitation hospitals and two acute hospitals situated in Melbourne, Australia. Inclusion criteria were: age 18 years and over, able to be discharged home, English proficiency, adequate communication level for interview, corrected vision and hearing, and no evidence of severe cognitive impairment. Participants, ranged in age from 32.1 to 91.3 years, were 33 men and 33 women with mean (SD) ages of 69.7 (2.2) and 75.5 (2.2) respectively. Patients who fulfilled inclusion criteria were invited to participate in the trial and provided written informed consent. Participants were randomly assigned, stratified by treatment site, to either active intervention or control group according to a computer-generated randomisation schedule in permuted blocks of four and six. To ensure blinding of treatment allocation, an external researcher held the randomisation codes and had no other role in the trial.

A sample size of 120 patients per group was

estimated as needed based upon the ability to show that the PHR had a small to moderate effect size on the impact of the stroke on patients as specified by (Cohen, 1977), with 80% power,  $p$  value = 0.05 (two-sided) and allowing for a 20% attrition rate.

Prior to discharge, all participants in both groups were given the usual discharge information which comprised a health summary sheet listing medications. Those in the intervention group also received an individualised PHR with verbal instructions on its contents and potential uses provided by a trained health care researcher who was a member of the research team.

Outcomes were assessed by a blinded outcome assessor with telephone interviews at four weeks (Time 1) and four months (Time 2) after discharge. The two outcome measures are described in detail below.

#### *PHR evaluation:*

The PHR Evaluation Questionnaire was developed by the research team to evaluate the usefulness of the PHR and it contained 17 questions with a yes/no response format relating to recall of use, knowledge of the PHR sections, helpfulness, ease of use, quality of information provided, utilisation and behaviour changes due to its use. There was also a section for the collection of qualitative data about stroke survivors' use of, and attitudes towards the PHR including questions about recall, use of information, contacts and changes made, improvements to their knowledge and suggestions for improvement.

#### *Stroke impact:*

Patients provided information about the impact of the stroke on their health and life by completing the Stroke Impact Scale Version 2.0 (SIS) (Duncan et al., 1999). The SIS contains 64 questions rated on a five-point scale. Items sought patients' views concerning stroke impact in the preceding week for the subscales Strength, Memory, Emotions and Communication; the preceding two weeks for the subscales Activities of Daily Living, Mobility and Ability to Use Hand; and the preceding four weeks for the subscale Handicap. The SIS utilizes the scoring algorithm of the SF-36 (Stuart and Ware, 1992) and thus yields lower

means on each of the domains when there is greater impact. In addition, stroke survivors rated their overall recovery on a scale of 0 to 100, with 100 representing full recovery. Examples of items are: "In the past week how would you rate the strength of your arm that was most affected by the stroke?" "In the past week, how difficult was it for you to remember things that happened the day before?"

#### *Sample size and data analysis:*

Based on admission data, discharge rates and our power calculation, the recruitment period was estimated at nine months. However, data were collected for more than two years and fell well short of our originally required number and therefore sample size was not achieved. A total of 184 patients were assessed for eligibility; 93 patients (46 intervention, 47 control) enrolled in the study and 66 patients (71%, 28 intervention and 38 control) completed the trial. A combination of recruitment and retention problems and non-use of the PHR resulted in the trial being terminated.

We performed analyses at four and eight weeks following the intervention. A qualitative analysis on the responses to the PHR evaluation was conducted by sorting responses into themes. Quantitative analyses for between group differences were compared by one-way between-groups MANOVAs (SPSS Version 14) and one-way repeated measures ANOVAs were performed on the total group to examine improvement on the SIS over time by comparing status on the SIS subscales at Time 1 and at Time 2 using a Bonferroni adjustment.

## RESULTS

#### *PHR evaluation:*

During the evaluation process it became evident that many stroke survivors did not recall having received the PHR. Although 28 stroke survivors in the intervention group were given a PHR only 18 recalled receiving it. Of these 18, only 13 had read any of the PHR following discharge and of these, few could name any of the sections that they had read. Only one stroke survivor had given the PHR to a health professional to read or use. Despite this, most of those who had read the PHR found it helpful and easy to use with nine reporting that they took action as a direct result of using it

including: discussing or sharing the PHR with family and friends ( $n = 6$ ); changing outlook on life, diet or exercise ( $n = 4$ ); contacting agencies or associations ( $n = 3$ ); and, seeking further information from the internet ( $n = 1$ ).

Qualitative data: Two major themes derived from the qualitative data were - *benefits of PHR* and *care issues* (see Table 1).

Stroke impact: At both Time 1 and Time 2, there were no statistically significant differences between groups for self-rated impairment and disability although those in the active group rated themselves as slightly *more* impaired and disabled than did those in the control group (means and SDs shown in Table 2).

Overall, there was a trend for stroke survivors to rate the impact of their stroke as reducing over time as they rated themselves as less impaired and disabled at Time 2 than at Time 1. However, the only statistically significant improvement was for levels of Handicap, [Wilk's Lambda = 0.79,  $F(1, 65) = 16.84$ ,  $p = .00$ ;  $\eta^2 = .21$ ].

## DISCUSSION

In this study we went to great lengths to address the knowledge needs of stroke survivors by involving them, their carers and many healthcare professionals in the development of the design, format and content of the individualised PHRs. Furthermore, a trained researcher provided the PHRs and education to the stroke survivors prior to discharge. All participants received a follow-up interview one month after discharge. Even so, at the four month period many had still not used their PHR.

The major factor that led to the decision to close the RCT was that a proportion of participants in the intervention group either failed to recall receiving the PHR or did not read the PHR. After four months, only two-thirds of the stroke survivors given a PHR recalled having received it, with less than half having read any of it. This prompted the termination of the RCT because given the poor uptake, even if an effect had been found, it could not be attributed to the intervention.

Of stroke survivors who read the PHR, there was little evidence that it was used to improve

**Table 1. Major themes and subcategories of qualitative data**

Major theme	Quote
Benefits of PHR	<p><i>I've cut down on fatty foods. I changed my eating habits.</i></p> <p><i>It prompted me to change diet, rest, reduce stress and gave me positive thinking.</i></p> <p><i>It helps ... to know who to contact and what to do.</i></p> <p><i>You can't have too much information. It's very hard to remember verbal information told to you in hospital.</i></p> <p><i>It was informative ... gave me knowledge I otherwise might not have.</i></p> <p><i>Apart from information my doctor [gave me] the PHR provided the only initial information I was given about my condition. I was grateful.</i></p>
Care issues	<p><i>We've had a lot of information and it's been a bit difficult drawing the information together in a meaningful way.</i></p> <p><i>The medical profession is very segmented ... there is a lack of continuity and follow through.</i></p>

**Table 2. Means (SD) for the Stroke Impact Scale (SIS) for Time 1 and Time 2**

SIS Subscale	Time 1			Time 2		
	Intervention <i>n</i> = 28 <i>M</i> ( <i>SD</i> )	Control <i>n</i> = 38 <i>M</i> ( <i>SD</i> )	Total <i>n</i> = 66 <i>M</i> ( <i>SD</i> )	Intervention <i>n</i> = 28 <i>M</i> ( <i>SD</i> )	Control <i>n</i> = 38 <i>M</i> ( <i>SD</i> )	Total <i>n</i> = 66 <i>M</i> ( <i>SD</i> )
Strength	71.61 (20.58)	76.15 (22.64)	74.22 (21.75)	68.97 (21.35)	77.14 (22.48)	76.67 (22.21)
Memory	77.17 (22.00)	88.15 (17.04)	83.50 (19.91)	81.12 (14.11)	88.44 (17.93)	85.34 (16.71)
Emotions	76.29 (16.66)	85.38 (15.40)	81.52 (16.46)	76.88 (17.42)	84.36 (14.39)	81.19 (16.06)
Communication	84.44 (17.66)	92.01 (12.69)	88.80 (15.34)	88.01 (13.48)	94.17 (9.07)	91.56 (11.48)
ADL	71.96 (16.49)	81.64 (19.03)	77.54 (18.50)	74.91 (18.25)	82.43 (17.71)	79.24 (18.20)
Mobility	82.82 (17.44)	78.87 (19.42)	76.30 (18.71)	72.02 (21.10)	81.29 (18.87)	77.36 (20.22)
Ability to Use Hand	53.06 (32.05)	65.66 (31.90)	60.32 (32.33)	54.42 (30.32)	68.92 (32.99)	62.77 (32.46)
Handicap	54.46 (21.57)	67.43 (22.88)	61.93*** (23.09)	66.96 (23.05)	77.22 (24.50)	72.87*** (24.26)
Recovery	70.14 (20.29)	74.03 (18.48)	72.38 (19.21)	70.29 (25.41)	76.58 (20.67)	73.91 (22.88)

\*\*\*  $p < .001$ . A score of 100 represents full recovery from stroke.

the communication of their care as only one gave it to health professionals to read so that they could note or alter the care management details. However, those who read the PHR found it helpful and easy to use, took action as a direct result of using it and appreciated the additional information. Although research has shown that such interventions can improve patients' knowledge about stroke (Smith et al., 2008), the results of this study suggest that providing stroke survivors with individualised PHRs as part of the discharge process from rehabilitation and acute hospitals did not reduce the impact of their strokes following discharge.

These findings pose questions about the timing and the methods of providing discharge information for this particular patient group. Although stroke survivors need education and information prior to discharge from hospital, stroke-related information needs to be repeated and reinforced following discharge (Smith et al., 2008) as information needs continue for at least six months thereafter (Hoffmann et al., 2004). This suggests that discharge strategies should include planned follow-up information provision for clarification and reinforcement if they are to successfully improve outcomes (Smith et al.). The lessons learnt from this research are outlined below.

#### *Selection criteria for stroke survivors:*

The selection criteria, set according to ethical considerations, resulted in the study participants having relatively low levels of impairment as supported by the SIS mean scores indicative of low to moderate levels of impairment consistent with minor strokes (Duncan et al., 1999). These stroke survivors may not have felt that they needed additional stroke information and this could explain why they did not use the PHR. Stroke survivors who were very unwell or mentally impaired post stroke may have been most in need of information and education, but they were excluded from this study. Exclusion from research is an issue as it denies access to possibly beneficial interventions (Stobbart et al., 2006). It is therefore incumbent on the research community to try to find ethical solutions to obtaining consent in vulnerable populations.

#### *Administering interventions to stroke survivors with impaired memory:*

Stroke survivors in this research were likely to have developed concentration, memory or cognitive deficits as a direct result of their strokes which inhibited the retention of information relating to the PHR. The literature shows that the lack of recall is not unique to our study (Hanger, 1998, Wellwood et al., 1995). Also, as the information was given at a time of stress it was more difficult to retain (Sauro et al., 2003). Posttraumatic stress disorder symptoms are relatively frequent in survivors of non-severe strokes, experienced by up to 31% of survivors and associated with anxiety and depressive symptoms (Bruggimann et al., 2006) that may also impair memory. Researchers need to be mindful of these factors when designing their studies.

#### *Recruitment issues and high, uneven drop-out rate:*

Although we rigorously determined the required sample size and duration for the RCT, we were unable to recruit the required numbers even with a considerable extension of the recruitment time. Additionally, high drop-out rates, particularly in the intervention group (18 of the initial 48 stroke survivors did not complete), caused unequal group sizes and also limited the extent to which the PHR could be said to have directly influenced outcomes. This had a major impact on our ability to complete the RCT. In some cases, loss to follow-up was due to stroke survivors experiencing illness or being placed in an aged care facility. Others were unwilling or unavailable to fully participate in the research. The high drop-out rate combined with the issues that few stroke survivors read or used the PHR prompted the research team to terminate the study. Conducting longitudinal studies on vulnerable populations presents many challenges. It may have been useful to have initially conducted a substantial pilot study in order to identify issues that would assist in the development and design of the larger study.

## **CONCLUSION**

This study described the development and attempted evaluation of individualised PHRs for stroke survivors. It also discussed the lessons learnt from the failure of the evaluation aspect of the study. We ensured that stroke survivors were included in the development of the PHR and that PHRs were individualised. However, we were unable to fully evaluate the



PHR because many stroke survivors did not recall receiving it. Likely reasons for this failure to recall include that many of those most in need of information were excluded from the research for ethical reasons, the stroke survivors included in the research had poor memories, were stressed at the time that the information was provided, or perceived that they didn't need the information, and finally there was an uneven drop-out rate across groups. It is recommended that in future, discharge information and PHRs be delivered to stroke survivors during their hospital admission with follow-up reinforcement at home after discharge in order to maximise recall and use. It may be useful for GP services to consider providing stroke support via their practice nurses. This will ensure that stroke survivors receive information at different points in the continuum of care.

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