IJAHSP
The Internet Journal of Allied Health Sciences and Practice
http://ijahsp.nova.edu

A Peer Reviewed Publication of the College of Allied Health & Nursing at Nova Southeastern University
Dedicated to allied health professional practice and education
http://ijahsp.nova.edu Vol. 7 No. 1 ISSN 1540-580X

Practical Aspects of Repeated Measures Stroke Research: Recruitment, Resources, Time Frames and Survey Instruments

Leah Jeffries, B.Physio (Hons)[1]
Karen Grimmer-Somers, B.Phty; MMSc, PhD[2]
Julie Luker, MHlthSc[3]

1. Director, Centre for Allied Health Evidence, Adelaide, SA.
2. Senior Researcher, Centre for Allied Health Evidence, Adelaide, SA.
3. Senior Allied Health Clinician, ANCER Stroke Unit, Adelaide, SA.

Australia

CITATION: Jeffries, L., Grimmer-Somers, K., Luker, J. Practical aspects of repeated measures stroke research: recruitment, resources, time frames and survey instruments. *The Internet Journal of Allied Health Sciences and Practice*. Jan 2009, Volume 7 Number 1.

ABSTRACT

Background & Purpose: Systematic reviews of discharge planning interventions for stroke patients consistently fail to demonstrate strong evidence of effectiveness. This is commonly related to methodological inadequacies of the primary studies. This pilot study explored the feasibility and costs of conducting methodologically sound research using repeated data collection to determine acute stroke patients' wellbeing following hospital discharge. **Methods:** Researcher time was costed for the tasks of obtaining ethics permission, recruiting, obtaining consent, and retaining patients for two interviews. Recruitment occurred over 15 weeks from a tertiary hospital stroke unit. At both interviews, a semi-structured interview and four assessment instruments were administered (Nottingham Leisure Questionnaire (NLQ), Stroke-Adapted Sickness Impact Profile (SASIP), Geriatric Depression Screening Scale (GDSS), and the Orientation-Concentration-Memory Test (OCMT)). Changes in group scores assisted in sample size calculations. **Results:** It cost approximately $240 and took 1.7 weeks to recruit and consent each patient (with or without care taker). All assessment instruments were readily completed by telephone interview, although patients expressed frustration with some OCMT questions. NLQ and SASIP were the most sensitive for this sample, and based on change over time in these instruments, at least 60 patients are required in each arm for a well-powered intervention study. **Conclusion:** The real costs of planning research, recruiting patients, and collecting data should be recognized when budgeting for research into stroke outcomes post-discharge. Well-powered stroke follow-up studies require multi-site commitment and consistent researcher presence on the ward. It is recommended that a battery of questions are drawn from the four assessment instruments, and validated for telephone administration, to minimize respondent burden.

INTRODUCTION

Cardiovascular health is an international health priority area reflecting high health, social, emotional, and economic costs.[1] Strokes often leave survivors physically, emotionally, financially, and socially compromised, and impose large burdens on families.[2] International evidence-based clinical guidelines underpin good practices in acute stroke management internationally; however, there are less well-developed guidelines to underpin best-practice discharge planning, or supported transition from hospital back to the community.[3-6] Improvement in acute care for stroke patients has increased the survival time of many patients, as well as increasing longer term demand for rehabilitation and management services.[7-9] This has led to increased pressures on rehabilitation settings, community services, and unpaid care takers or family members, the extent of which is currently not well quantified.[10]

© The Internet Journal of Allied Health Sciences and Practice, 2009

In order to evaluate the effectiveness of discharge planning and post-discharge support services in optimizing patients' long-term well-being, it is important to conduct well-designed longitudinal research. Although there is a growing body of primary research addressing this topic, there is little evidence of the effectiveness of any intervention.[11-14] Reasons for this often lie in methodological inadequacies of the primary research, such as inadequate sample sizes, high loss-to-follow-up rates, limited follow up, and lack of standardization of outcome measures.[12,15]
Stroke follow-up studies currently use a wide variety of outcome measures, thus constraining comparisons, systematic reviews and the pooling of data.[12] Several stroke discharge planning studies use hospital length of stay and readmission rates as measures of discharge success.[13,16,17] However there is emerging opinion that a patient-centered approach is important during discharge planning, and a more valid measurement of its success should include patients' and care takers' reported experiences, patients' and care takers' satisfaction, as well as patients' changes in function and well-being.[18-20]

Stroke studies with inadequate sample sizes are frequently discouraging because of their inability to demonstrate significance.[11,13] Methodological flaws because of small sample size may be avoided through preliminary work to estimate the samples required for chosen assessment tools. However, the evidence of sample size calculation in patient-centered studies is rare, with constrained recruitment periods often dictating the final participant numbers.[11,12] The challenges of recruiting and keeping patients in longitudinal studies when they are dealing with significant life events has also been recognized by other researchers.[21,22] Stroke survivors commonly experience high degrees of frailty, with approximately one third of those discharged either readmitted to hospital or dead within a year of their stroke.[23,24] This uncertainty results in high rates of participant drop-out or loss to follow-up in many longitudinal stroke studies, again adding to methodological challenges for researchers.[11,13]

Research aimed at improving stroke services frequently has tight budgetary constraints, and there is a current lack of information to assist researchers to predict the costs of studies. Previous research into the costs of conducting clinical research has found that the costs vary according to the clinical target group, the methodologies, and the recruitment strategies employed.[22-24] These studies did not explore the practicalities of research involving acute stroke patients or the use of telephone assessments as a means of follow-up. Currently, researchers planning to investigate the effectiveness of discharge planning activities for stroke patients or their post–discharge experiences have little guidance regarding the costs or other practicalities associated with such work.

AIMS OF THE STUDY
This pilot study was conducted to explore the feasibility and costs of conducting methodologically sound research, using repeated data collection, to determine stroke patients' progress following discharge from acute hospital settings.
It aimed to determine:

- the barriers to obtaining timely approval from Human Research Ethics Committees
- a natural recruitment profile from a stroke-specific ward, including rates of patient eligibility, rates of patient consent, barriers to obtaining consent, time required for sample recruitment, and loss to repeat follow-up
- the practicalities of administering a battery of assessments to determine patients' and families' experiences during the transition period from hospital to community (see assessment tool details below)
- participants' attitudes towards multiple assessment instruments on repeated occasions of testing
- the clinical utility and respondent burden of the chosen instruments and sample size required for a larger study, and
- the costs of conducting a longitudinal study on patients with stroke.

The following four assessment instruments were used in the pilot study:

- The Stroke Adapted Sickness Impact Profile (SASIP30), which contains 30 items.[25] Higher scores indicated a greater impact of stroke on daily activities.
- The Geriatric Depression Screening Scale (GDSS), which contains 30 items requiring Yes/ No responses to simple statements.[26] Higher scores indicate fewer depressive symptoms.
- The Orientation-Memory-Concentration Test (OMCT) that contains seven items.[27] The higher the score the fewer challenges patients experienced.
- The Nottingham Leisure Questionnaire (NLQ), which is a valid indicator of leisure activities for this population e.g. Reading Books.[28,29] It provides 31 options of common leisure activities, to which patients responded Regularly, Occasionally or Never. Higher scores identified patients who regularly undertook a large number of activities.

© The Internet Journal of Allied Health Sciences and Practice, 2009

The rationale for the selection of these instruments included their common reporting in primary studies in recent systematic reviews, strong psychometric properties (evidence of validity, sensitivity to change, and reliability of administration) from their developmental literature, and the range of post-stroke social, physical, and emotional functioning that they covered.[1-8, 25-29] In total, the instruments contained 98 questions.

METHOD

Ethical approval was provided by the Human Research Ethics Committees of the researchers' university, and the recruitment site (a tertiary metropolitan hospital in South Australia, Australia). The principal researcher (LJ) was paid a Level B University research assistant rate ($31.50 per hour). The university provided infrastructure supports (telephone, computing, printing, and mailing) and the recruitment site provided support, senior clinician (JL) time and access to patients.

Patients were eligible for inclusion if they had been admitted to hospital with their first episode of stroke and were about to experience a planned discharge from hospital to a community dwelling or to a rehabilitation centre with the aim of subsequent discharge to a community dwelling. The patients were required to provide informed and written consent and have sufficient English language skills for interpreting and answering questions. The presence of a family member to provide assistance after discharge (defined as the principal unpaid care taker) did not influence patient eligibility for study inclusion. Patients suffering a subsequent stroke or other illness after consenting to participate remained eligible to participate. Patients were ineligible for inclusion if they were due to be discharged directly from hospital to a nursing home or if they were participating in other research projects.

The stroke unit of the participating hospital had admitted 374 acute stroke patients during the 2005/06 financial year (mean length of stay 13 days). Approximately 50% of these patients had been discharged directly home or had gone home via interim care during this period. On any one day during the 15 week recruitment period, there were between 8 and 28 patients on the ward (average 12 patients). All potentially eligible patients were identified and introduced to the researcher (LJ) by the senior clinician in the unit (JL). The researcher encouraged patients to read the information sheet, and then returned later to discuss the study. Patients were given the option of signing the consent form in the researcher's presence (with an additional witness) or discussing with family and returning it later to a box. Primary care takers were simultaneously recruited, if possible. If the patient nominated a primary care taker who was not present at the time, and an information sheet and consent form was sent to their home address. The care takers were invited to participate in semi-structured interviews (conducted independently of the patient), in which their experiences of discharge planning and the post-discharge period would be explored.

A package was subsequently sent to the home address of eligible consenting patients, containing a care taker information sheet and consent form, a reply-paid envelope (for care taker consent form) and the four assessment instruments on differently colored paper (Stroke Adapted Sickness Impact Profile (SASIP), Geriatric Depression Screening Scale (GDSS), Orientation-Memory-Concentration Test (OMCT), and Nottingham Leisure Questionnaire (NLQ)).[25-29] The package was sent to the participant's home address approximately three to four weeks after consent was obtained (allowing time for the participant to be discharged from hospital, either directly or via a rehabilitation/ step-down facility). If patients had mislaid the package prior to the second interview, a second package of the survey instruments was sent.

Allowing time for the arrival of the instrument package, the principal investigator telephoned consenting patients (and care takers) to arrange the initial interview. The project aimed to conduct two semi-structured telephone interviews (one as soon as possible after discharge, and one eight weeks later). The patient interviews involved completion of all four survey instruments. Patients and care takers were asked semi-structured questions during both interviews regarding their experiences of the discharge planning process (including involvement in family meetings, goal setting, and education prior to discharge), experiences of living at home after discharge, and estimated costs associated with discharge (home modifications, heating and cooling, equipment, payment for rehabilitation services, transport, medication etc.).

Patients and care takers were continually monitored throughout the interviews for fatigue. Between each questionnaire, patients were asked whether they were happy to continue, and if they seemed fatigued or wished to cease, they were offered other appointments to complete the interview.

Repeated data collection included telephone interviews rather than face-to-face interviews or written administration of survey instruments. This reflected our previous findings that this was the least costly option producing the least respondent burden for older patients.[10]

STATISTICAL ANALYSIS

© The Internet Journal of Allied Health Sciences and Practice, 2009

Effect size was calculated using the formula by Cohen, on assumptions that the mean of the initial administration of each instrument formed the baseline, and the initial Standard Deviation of this measure was an appropriate denominator for effect size calculation.[30] We estimated sample sizes for observational and intervention studies from these findings. Using WinEpi 2.0, and the change in each instrument, at 80% power, 5% alpha, we calculated the number of subjects required for independent samples, and for paired samples in an intervention study.[31] Costs were calculated retrospectively based on the time/resources allocated to the various stages of the study.

RESULTS

Barriers to approval from Human Research Ethics Committees

Two separate ethics applications were prepared, with each application requiring different information. Before approval was granted, both institutions' ethics committees required clarifications to the application. Subsequent amendments were different for each committee and changes for one committee then needed to be sent to the other. Consequently, obtaining approval took approximately six weeks longer than the anticipated one month turnaround time in each institution, with the total time for ethics applications to be approved being 11 weeks. This incurred additional researcher time-related costs, both in preparing the revisions to the ethics applications and in "downtime" when no research could be undertaken. The nature of the participant group did not appear to influence the extended ethics approval turnaround time; rather, it was related to differences in the ethics approvals processes and inter-dependence of institutions on each other ratifying changes.

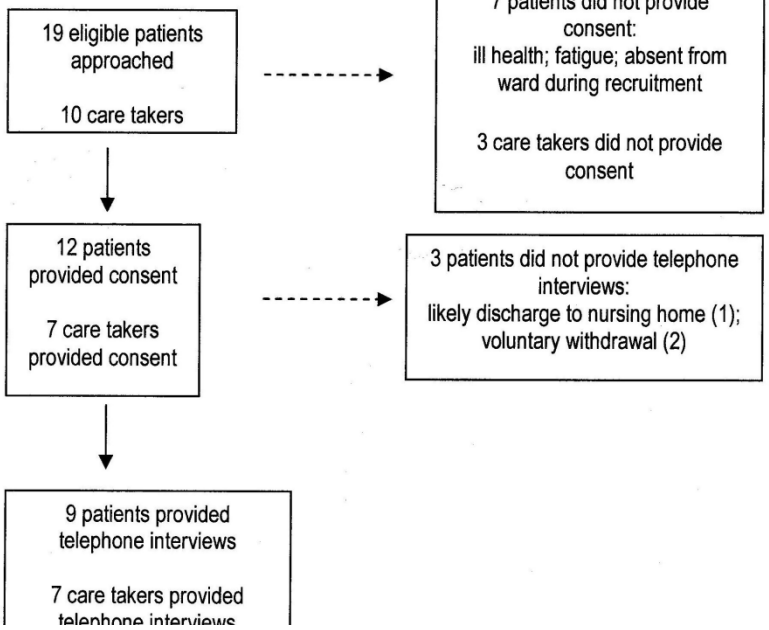
Recruitment Profile from a Stroke-Specific Ward

Patient recruitment took place on five occasions over 15 weeks (December 2005 to April 2006). The presence of potentially eligible patients was flagged by the senior clinician to the researcher. However, given the ineligibility of three in five patients, on average, and the 13 day average length of stay, it was rare that more than two potential patients were available for recruitment at any one time. In total, 19 patients and 10 care takers were approached to participate in the study; however, only 12 patients and seven care takers provided consent. The main barriers to eligible patients consenting to participate in the study were ill health, fatigue, or patients being absent from the ward at the time of recruitment.

Of the 12 stroke patients who agreed to participate in the study, only nine actually provided telephone interviews. Reasons for dropout included long term rehabilitation with likelihood of discharge to a nursing home (N=1) and voluntary withdrawal (N=2). One patient who withdrew had a care taker who wished to participate. Two participating patients did not have a primary care taker, and one care taker of the remaining stroke patients declined to participate. (See Figure 1.)

© The Internet Journal of Allied Health Sciences and Practice, 2009

Figure 1. Patient and care taker recruitment



Administration of the Assessment Battery and Interviews

Patients and care takers were comfortable with telephone interviews, and none reported difficulties hearing over the telephone or understanding the questions. Several patients expressed surprise (and some disappointment) that the interviews were not being conducted face-to-face. It seemed that there would have been little resistance from most participants if this had been the preferred method of data collection. Patients appreciated that the interviews were about them and their experiences, so they could "*tell their story."*

Patients commented that provision of the paper versions of the instruments assisted in the efficiency of the interview. Each instrument took on average five minutes to complete verbally, and none of the participants required a break between instruments.

- The Stroke Adapted Sickness Impact Profile (SASIP30) was the most difficult questionnaire to answer, given the number of negatively phrased questions (e.g. Q6: I show less interest in other people's problems, for example, don't listen when they tell me about their problems, don't offer to help'). Patient comments included "*double negatives are confusing"* and *"they would be worse for people that struggle more than I do."*
- The Geriatric Depression Screening Scale (GDSS) was answered efficiently, and with no requests for question clarification. Participants readily answered potentially invasive questions such as Q7: Are you in good spirits most of the time?
- The Orientation-Memory-Concentration Test (OMCT) was commonly viewed as pedantic, especially the sections requiring counting backwards (from 20 to 1, from December to January). The memory section requiring recall of a name and address proved most challenging. One patient commented, "*This is ridiculous, I finished kindergarten years ago!*" and was reluctant to answer further questions.
- The Nottingham Leisure Questionnaire (NLQ) might discriminate against patients who undertook few activities. Only two participants identified additional activities undertaken since leaving hospital ("*cryptic crosswords," "writing a book"*).

Patients and care takers, on the whole, responded willingly to semi-structured interview questions regarding their experiences in hospital and on returning home. All patients were able to recall their hospital experiences in considerable detail, as well as their participation (or not) in planning for discharge, and their early days at home. In all but one case, care takers were interviewed immediately following the interview with the stroke patient, during the same telephone call. Their comments were invaluable, not only as an indicator of the extent of the unpaid and unexpected burdens placed on them, but also to validate the responses of

© The Internet Journal of Allied Health Sciences and Practice, 2009

patients. Rarely did care takers give contradictory answers to the stroke patients, and they provided greater detail which put patient responses into perspective.

The use of semi-structured questions assisted in interview efficiency, and also in establishing themes without the need for complete interview transcription. This reduced the amount of time required for interpretation and analysis. The initial interviews were more sensitive in identifying new information than the second interviews, by which time the patients' health had improved considerably and the care takers were less concerned about their role in assisting the patient. No new information emerged during the second interviews about post-discharge experiences.

Estimation of Sample Size for Larger Studies

The group differences over time in responses to the four instruments were calculated to estimate the required sample size for larger studies (a cohort study, or a discharge planning effectiveness study). The average findings (SD) are reported in Table 1 for nine patients, two administrations, and four assessment instruments. These findings indicate that on average, patients suffered fewer depressive symptoms, less impact on health, more engagement in a range of leisure activities, and slightly poorer memory / concentration / orientation on the second assessment. Variability decreased in responses to all instruments at second interview, suggesting the patients' scores centralized after resuming community dwelling.

Table 1. Average (SD) total group scores for both administrations of all instruments

	GDSS 1	GDSS 2	NLQ1	NLQ2	OMCT1	OMCT2	SASIP30_1	SASIP30_2
Av	7.7	9.2	12.9	18.2	5.1	4.4	9.0	7.8
SD	5.7	4.7	9.8	8.3	5.1	2.5	6.8	3.3

Key:
GDSS [Geriatric Depression Screening Scale]
NLQ [Nottingham Leisure Questionnaire]
OMCT [Orientation-Memory-Concentration Test]
SASIP [Stroke-Adapted Sickness Impact Profile]

The average amount of time between interviews was 7.5 weeks. The average per week improvement was estimated for each instrument as the average difference in scores on administrations 1 and 2, divided by the average number of intervening weeks: GDSS (0.1), NLQ (-0.2), OMCT (0.1) and SDSIP30 (0.4). This indicates that despite the difficulty in interpreting the questions, the SDSIP30 was the most likely to be responsive over time, with GDSS and OMCT being least responsive.

The estimated effect sizes for repeat administrations of the instruments were 0.23 (GDSS), -0.55 (NLQ), 0.15 (OMCT)() and 0.53 (SDSIP30). This again highlighted the responsiveness of the NLQ and the SDSIP30.

The estimated sample sizes for observational and intervention studies are outlined in Table 2. This table also estimates observational study sample sizes calculated from Cohen effect size power tables for each instrument (alpha 5%).[32] The estimated power of each observational study sample is in brackets.

Table 2. Indicative Sample Sizes

	GDSS	**NLQ**	**OMCT**	**SASIP30**
Observational study	200 (64% power)	60 (86% power)	200 (64% power)	60 (86% power)
Intervention study				
○ *Independent samples*	272	284	646	55
○ *Paired sample*	138	144	325	30

Costs of conducting a longitudinal stroke study

Preparation of the ethics applications, and dealing with clarifications took approximately 11 hours ($346.50).

During the recruitment phase, the researcher spent approximately three hours at a time on the ward, and one hour each time in travel from the university to the hospital (four hours total each visit, 20 hours total recruitment time). The senior clinician spent approximately 15 minutes per week identifying eligible patients for the study, and approximately 30 minutes per recruitment visit

© The Internet Journal of Allied Health Sciences and Practice, 2009

introducing the researcher to potential patients (total 6.25 hours). Estimating a similar hourly rate to that of the researcher, this reflected a total of 26.25 salary hours for recruitment ($826.90)[1].

Table 3. Costs of the pilot study

Item	# of items	Unit cost per item	Total cost
Researcher (ethics approval)	11 hrs	$31.50	$346.50
Clinician (recruitment)	6.25 hrs	$31.50	$196.90
Researcher (recruitment)	20 hrs including travel	$31.50	$630.00
Researcher (assessments)	Approx 30 hrs	$31.50	$927.00
Researcher (mailing etc)	1 hr	$31.50	$31.50
Printing & postage	12 packages	$3.20	$38.40
Total cost			$**2170.30**

From a recruitment cost perspective, the patients who failed to provide consent represented a loss of approximately $304 initially in researcher and clinician time spent providing information to seven patients (and their care takers), which was not recouped by active patient enrolment. A further $130.60 was lost in recruitment time spent on patients who initially consented to participate and then became ineligible or withdrew. Thus, at one acute stroke facility which admits approximately 400 strokes annually, to recruit and obtain consent from one participating patient took 1.7 weeks on average and cost $91.90.

The costs of printing and postage included an hour of the researcher's time to compile and post the documentation to participants, while $38.40 was spent directly on printing and mailing information sheets, survey instruments, consent forms, and reply-paid envelopes (total $70).

The average length of time between actual recruitment and the first successful telephone interview was 6.5 weeks (range 3-11 weeks). While this sometimes reflected delays in patients returning home, it more frequently identified difficulties in contacting patients and arranging suitable interview times. The cost of arranging the initial interview time with patients and care takers was estimated at 5 minutes per call ($3) (assuming no cost for telephone calls or infrastructure), with some patients requiring more than one call. The interviews with patients lasted approximately 40 minutes each, whilst the interviews with care takers lasted approximately 20 minutes. The second interview with patients and care takers was less costly to arrange, as the time was generally agreed at the initial interview, and required only one reminder call. The length of time between initial and follow-up interviews ranged from 6 to 10 weeks. The total cost of the two telephone interviews with nine patients and seven care takers, and the time to arrange the interviews was $533. At the completion of each interview, note-taking for care takers took approximately 15 more minutes, and note-taking for patients, and survey data entry took approximately 30 more minutes ($394), reflecting a total cost for interviews (32 interviews from 16 subjects) of $927.

The total costs of recruiting, resourcing, and interviewing the patients and care takers in this study were $2170 ($135 per study participant). For this exercise, the total costs were spread across patients and care takers. However, given that the costs of recruiting and interviewing care takers were so much lower than for patients, this could be interpreted more usefully as approximately $240 per eligible, consenting, participating patient (with or without care taker).

DISCUSSION

This paper reports rare information on the resources required to establish and conduct a study into post-discharge experiences of patients with stroke. This should assist researchers who require background information in order to establish a viable study methodology. The authors acknowledge limitations in this study associated with the small sample size and recruitment from a single site, as research practicalities vary between participants and locations.[22,24]

[a] The hospital provided the clinician's time for recruitment, however it is costed here for completeness.

© The Internet Journal of Allied Health Sciences and Practice, 2009

Issues that need to be considered when writing ethics applications for stroke research include establishing formal links with staff in hospital settings, ensuring that patients understand their rights in agreeing to participate and are not pressured to do so, ensuring privacy, respect and confidentiality, and minimising respondent burden when collecting data longitudinally. Addressing these issues appropriately in the initial application should minimise time spent in making amendments to ethics applications.

The main barriers to recruitment of eligible patients in the acute stroke unit were patients' length of stay, variable weekly admission rates to the unit, potentially eligible patients' fatigue or illness at initial recruitment, and the researcher's constrained access to patients. Unless a researcher is based on a ward, or housed close to it, sample recruitment is usually on a "one-off" basis, where potentially eligible patients are only identified once. Therefore, planning for sample recruitment needs to take into account patient throughput, rates of potentially eligible patients, the most appropriate time during the length of stay for recruitment to occur, and assistance from a senior clinician on the ward.

The semi-structured nature of interviews, the use of readily identified (colored) copies of assessment instruments, the telephone administration of questions, the pre-arranged interview times, and the fact that the same researcher who recruited patients also surveyed them appeared to be important in retaining the participants. Patients indicated that they appreciated that the researcher was known to them and interested in their experiences. In order to engage patients in research, this would appear to be an important consideration. For some patients who had not enjoyed a trouble-free discharge, the interviews appeared to allow them to debrief about a difficult time to someone who was interested and asked relevant questions. One patient commented that *"if this helps someone else like me, then it will be a good thing."* Patients and their care takers had many stories to tell, and despite the semi-structured nature of the questions, rich individual information could be elicited. However, in a larger study involving more stroke patients and care takers, it could be useful to transcribe the audiotaped interviews in full, particularly if multiple researchers were involved in analyzing the data.[33] Transcription of high quality audiotapes by an experienced transcriber would add approximately 1 to 1.5 hours' cost to each hour of interview.[33]

No patient had difficulty answering any of the battery of 98 assessment questions on two occasions of testing, and the only complaints were about the pedantic nature of OMCT questions and some difficulty in understanding some SASIP30 questions. These four instruments provided different, congruent, and important information on patient outcomes. Given the frustration that patients reported with the OMCT and its consistently high mean scores on repeated administration, we suggest that its use may be more appropriate for cognitively impaired patients and not for repeated follow-up of community-dwelling patients. The NLQ provided the greatest change over time, the highest variability, and the largest effect size. Patients found it simple to answer and relatively complete, as it reflected the most common leisure activities for this group. These findings suggested that the NLQ would be a useful and efficient instrument for a larger study. The SASIP30 also demonstrated a large effect size and sensitivity to change; however, patients' concerns with wording and interpretation may constrain its usefulness in patients with cognitive impairment. The small GDSS effect, the high scores, and the lack of comment from patients to questions suggested that this group may not have suffered sufficient depressive symptoms to warrant use of this scale. Thus for a larger study of similar profile stroke patients, we suggest using the NLQ, rewording the SASIP30 into more positive contexts (while retaining psychometric properties), and considering the GDSS only if required. Moreover, in order to minimize potential respondent burden and administration costs, the 91 questions in these three instruments should be subjected to factor analysis to identify redundant questions, and to develop a battery of tests that is psychometrically sound, and appropriate for telephone administration for community-dwelling stroke patients.

The sample size estimates suggest that a well-powered observational study requires at least 60 patients using either the NLQ or SASIP30 as primary outcome measures, or a minimum of 120 patients for a two arm intervention study using the SASIP30 as a primary outcome measure. Given that 25% of initially eligible and consenting patients became ineligible or non-consenting before the first interview, approximately 75 patients should be recruited to ensure sufficient power in the final attenuated sample. From the recruitment rate found in this study, to recruit a sample of 60 patients from one site (admitting around 400 strokes per year) would require an average of 102 weeks. Clearly this is not feasible; thus, multi-site involvement appears essential. If four similarly sized hospitals were involved in concurrent sample recruitment, an appropriately sized sample could be recruited in a more viable 18-20 weeks.

Cost calculations in the current study focused on the activities of gaining ethics approval, recruiting, and gaining consent from acute stroke patients and repeated data collection via telephone interviews. These processes are all currently areas in which information is scarce. To establish an appropriate sample, researchers should budget approximately $90 to enroll each eligible and consenting patient, and an additional $73 to interview, enter data and transcribe information from two contacts with each subject. Thus, a minimum sample of 60 patients could cost $9800 simply in baseline recruitment and data collection. Emanuel's

© The Internet Journal of Allied Health Sciences and Practice, 2009

research group identified nine additional activities necessary to conduct clinical intervention research: study initiation, randomization, supply and management of the intervention, follow-up visits, management of adverse events, research quality audits and monitoring visits, communication with research sponsors, and post-study investigator meetings.[24] Their work provides valuable additional information on the significant costs associated with randomized intervention studies.

Acute stroke research would be impossible without the assistance of clinicians at the recruitment site. Ethically, hospital personnel were not permitted to directly recruit patients; however, they are an invaluable resource in identifying potential subjects and networking patients and researchers. An understanding of previous hospital stroke admission data, length of stay, and hospital staffing is essential when estimating the amount of time required for recruitment and the likely success of recruitment strategies.

SUMMARY AND RECOMMENDATIONS

This project provided rare information to assist researchers with efficient planning of study protocols for research into stroke outcomes including recruitment costs, recommended sample sizes, multi-site involvement, and involvement of clinicians. Due to patients' initial health status and their demanding schedules during acute stroke admissions, multiple contacts with patients may be required to finalise their recruitment whilst in the hospital. The time taken after discharge to establish contact with patients may also be longer than anticipated due to hospital stay and/or transfer to interim care. Telephone interviews were acceptable to patients and care takers, efficient to administer, and did not unduly burden respondents. Using the same person to recruit and interview patients is desirable in order to maintain patient trust. In order to capture information on the spectrum of issues appropriate to stroke recovery, a battery of relevant questions should be established, drawn from the most sensitive assessments instruments, and validated for telephone administration. The real costs of recruitment and data collection need to be considered when establishing a budget for research into stroke outcomes post-discharge.

REFERENCES

1. Murray CJL, Lopez AD. Alternative projections of mortality and disability by cause 1990\2020: Global Burden of Disease Study. *Lancet.* 1997;349:1498–1504.
2. Senes S. How We Manage Stroke In Australia. *Australian Institute of Health and Welfare*: Canberra; 2006.
3. Hack W, Kaste M, Bogousslavsky J, Brainin M, Chamorro A, Lees K, et al. European Stroke Initiative Recommendations for Stroke Management-update 2003. *Cerebrovascular Diseases.* 2003;16:311-337.
4. Langhorne P. Organisation of acute stroke care. *British Medical Bulletin*. 2000;56:436-443.
5. Royal College of Physicians Clinical Effectiveness and Evaluation Unit. National Clinical Guidelines for Stroke (No. 24). Edinburgh: SIGN; 2004.
6. National Stroke Foundation. National Guidelines for Acute Stroke Management. 2005. Available from http://www.strokefoundation.com.au.
7. Stroke Unit Trialists' Collaboration. Organized (stroke unit) care for stroke. *The Cochrane Database of Systematic Reviews.* 2004; Issue 3. Art.no: CD000197. DOI:10.1002/14651858.CD000197.
8. Langhorne P, Legg L. Evidence behind stroke rehabilitation. *Journal of Neurology, Neurosurgery and Psychiatry*. 2003;74(Suppl 4): iv18-iv21.
9. Jorgensen H, Kammersgaard L, Nakayama H, Raaschou H, Larsen K, Hubbe P, Olsen T. Treatment and rehabilitation on a stroke unit improves 5-year survival: a community-based study. *Stroke.*1999;30(5):930-933.
10. Grimmer K, Moss J, et al. Experiences of elderly patients regarding independent community living after discharge from hospital: a longitudinal study *International Journal for Quality in Health Care*. 2004;16(6):465-472.
11. Torp C, Vinkler S, Pedersen K, Hansen F, Jorgensen T, Olsen J. Model of Hospital-supported discharge after stroke. *Stroke*. 2006;37:1514-1520.
12. Shepperd S, Parkes J. McClaran J, Phillips C. Discharge planning from hospital to home (Review) *Cochrane database of Systematic Reviews.* 2004, Issue 1 Art.no.CD000313. DOI: 10.1002/14651858.CD000313.pub2.
13. Sulch D, Perez I, Melboun A, Kalra L. Randomized controlled trial of integrated (managed) care pathway for stroke rehabilitation. *Stroke*. 2000;31:1929-1934.
14. Mayo N, Wood-Dauphinee S, Cote R, Gayton D, Carlton J, Buttery J, Tamblyn R. There's no place like home: an evaluation of early supported discharge for stroke. *Stroke.* 2000;31:1016-1029.
15. Legg L, Langhorne P and Outpatient Service Trialists. Rehabilitation therapy services for stroke patients living at home: systematic review of randomized trials. *Lancet*. 2004;363(9406):352-356.
16. Patel M, Potter J, Perez J, Kalra L. The process of rehabilitation and discharge planning in stroke: a controlled comparison between stroke units. *Stroke.* 1998;29(12):2484-7.
17. Early Supported Discharge Trialists. Services for reducing duration of hospital care for acute stroke patients. *Cochrane Database of Systematic Reviews* 2005; Issue 2 Art. No:CD000443. DOI: 10.1002/14651858.CD000443.pub2.

© The Internet Journal of Allied Health Sciences and Practice, 2009

18. National Stroke Foundation. Walk in our shoes: stroke survivors and care takers report on support after stroke. 2007. Available from http://www.strokefoundation.com.au.
19. Cott C. Client-centred rehabilitation: client perspectives. *Disability & Rehabilitation.* 2004;26:24-29.
20. Pound P, Tilling K, Rudd A, Wolfe C. Does patient satisfaction reflect differences in care received after stroke? *Stroke*. 1999;30(1):49-55.
21. Williams A. recruitment challenges for end-of-life research. *Journal of Hospice and Palliative Nursing.* 2007: 9(2):79-85.
22. Patrick J, Pruchno R, Rose M. Recruiting research participants: a comparison of the costs and effectiveness of five recruitment strategies. *Gerontologist.* 1998;38(2):298-302.
23. Heller R, Fisher J, D'Este C, Lim L, Dobson A, Porter R. Death and readmission in the year after hospital admission with cardiovascular disease: the Hunter Area Heart and Stroke Register. *Medical Journal of Australia.* 2000;172(6):261-5.
24. Emanuel E, Schnipper L, Kamin D, Levinson J, Lichter A. The cost of conducting clinical research. *Journal of Clinical Oncology.* 2003;21:4145-50.
25. van Straten A, de Haan RJ, Limburg M, Schuling J, Bossuyt PM, van den Bos. A stroke-adapted 30-item version of the Sickness Impact Profile to assess quality of life (SA-SIP30). *Stroke*. 1997;28:2155-2161.
26. Yesavage J, Brink TL. Development and validation of a Geriatric Depression Screening Scale: a preliminary report. *Journal of Psychiatric Research*. 1983;17:37-49.
27. Katzman R, Brown T, Fuld P, Peck A, Schechter R, Schimmel H. Validation of a Short Orientation-Memory-Concentration Test of cognitive impairment. *American Journal of Psychiatry*. 1983;140:734-739.
28. Drummond AER, Walker MF. The Nottingham Leisure Questionnaire for stroke patients. *British Journal of Occupational Therapy*. 1994;57:414-418.
29. Drummond A, Parker C, Gladman J, Logan P. Development and validation of the Nottingham Leisure Questionnaire (NLQ). *Clinical Rehabilitation*. 2001;15:647-656.
30. Cohen J. Statistical power analysis for the behavioural sciences. Academic Press: New York; 1997.
31. Ortega C, de Blas I, Simón MC, Gironés O, García J, Alonso JL, Muzquiz JL, Ruiz I. A computer program for the temporal study of diseases in animal populations. *Rev. sci. tech. Off. int. Epiz.* 2000;19,735-743. Available from: http://www.oie.int/eng/publicat/rt/1903/A_R1935.htm.
32. Anthony D. Understanding advanced statistics: A guide for nurses and health care researchers. Churchill Livingstone: Sydney; 1999. p.206.
33. McLellan E, MacQueen KM, Neidig J. Beyond the Qualitative Interview: Data Preparation and Transcription. *Field Methods*. 2003;15(1):63-84

Funding
This study was supported by a seeding grant from the Directors of Allied Health Group (DAHG), representing leaders of allied health departments in hospitals funded by the South Australian Department of Health.

© The Internet Journal of Allied Health Sciences and Practice, 2009