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January 2006

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Recommended Citation

Lannin, Natasha and Cusick, Anne: Factors affecting patient recruitment in an acute rehabilitation randomized controlled trial 2006, 177-181.
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Factors affecting patient recruitment in an acute rehabilitation randomized controlled trial

Abstract

OBJECTIVE. To evaluate factors associated with randomized controlled trial patient recruitment by therapists. **METHOD.** Survey of 18 (of a possible 26) therapists who had agreed to recruit patients for a randomized controlled trial (78% response rate). **RESULTS.** Sixteen respondents had enrolled at least one patient. The site at which the therapist worked neither influenced the likelihood that a therapist would contact the researcher nor influenced the recruitment rate. Seventeen respondents reported that they contacted the researcher to discuss one or more of their patients for potential inclusion in the trial. Factors reported by therapists as reasons why they did not recommend the trial to eligible patients were not specific to study inclusion or exclusion criteria, rather were linked to personal judgments about patient suitability for the study. Regression analysis indicated that being enrolled or having completed master's level postgraduate studies, and choosing not to refer patients because of concern for their poor medical prognosis were the only factors that significantly influenced recruitment rate ($p < 0.001$). **CONCLUSION.** Recruitment practices vary amongst therapists. Selection of therapists with postgraduate qualifications as recruiters may be an effective way to enhance recruitment rate.

Keywords

rehabilitation, acute, randomized, affecting, controlled, recruitment, factors, patient, trial

Disciplines

Arts and Humanities | Life Sciences | Medicine and Health Sciences | Social and Behavioral Sciences

Publication Details

Lannin, N. & Cusick, A. 2006, 'Factors affecting patient recruitment in an acute rehabilitation randomized controlled trial', *American Journal of Occupational Therapy*, vol. 60, no. 2, pp. 177-181.

Factors Affecting Patient Recruitment in an Acute Rehabilitation Randomized Controlled Trial

Natasha Lannin,
Anne Cusick

OBJECTIVE. To evaluate factors associated with randomized controlled trial patient recruitment by therapists.

METHOD. Survey of 18 (of a possible 26) therapists who had agreed to recruit patients for a randomized controlled trial (78% response rate).

RESULTS. Sixteen respondents had enrolled at least one patient. The site at which the therapist worked neither influenced the likelihood that a therapist would contact the researcher nor influenced the recruitment rate. Seventeen respondents reported that they contacted the researcher to discuss one or more of their patients for potential inclusion in the trial. Factors reported by therapists as reasons why they did not recommend the trial to eligible patients were not specific to study inclusion or exclusion criteria, rather were linked to personal judgments about patient suitability for the study. Regression analysis indicated that being enrolled or having completed master's level postgraduate studies, and choosing not to refer patients because of concern for their poor medical prognosis were the only factors that significantly influenced recruitment rate ($p < 0.001$).

CONCLUSION. Recruitment practices vary amongst therapists. Selection of therapists with postgraduate qualifications as recruiters may be an effective way to enhance recruitment rate.

Lannin, N., & Cusick, A. (2006). Factors affecting patient recruitment in an acute rehabilitation randomized controlled trial. *American Journal of Occupational Therapy, 60*, 177-181.

Introduction

There is an urgent need to carry out randomized controlled trials to provide evidence of occupational therapy intervention effectiveness. The success of trials depends on the ability to recruit patients to become research subjects. Most existing surveys of recruitment issues and strategies provide guidance for drug or surgical trials (Visanji & Oldham, 2001). This study investigated factors associated with patient recruitment by occupational therapists for a randomized controlled trial conducted in multisite acute rehabilitation settings. To date there have been few randomized controlled trials in such settings and no studies investigating patient recruitment by occupational therapists. There are no studies dedicated to investigating recruitment rates or factors in other therapy fields (such as physical therapy). Most recruitment studies have instead been conducted in medicine, primarily cancer and primary care trials (Asch, Connor, Hamilton, & Fox, 2000; Benson et al., 1991; de Wit, Quarero, Zuithoff, & Numans, 2001; Peto, Coulter, & Bond, 1993; Taylor, Margolese, & Soskolne, 1984).

The trial linked to the present study investigated the effect of adding contracture management hand splinting to rehabilitation following stroke (Lannin, Cusick, Herbert, & McCluskey, in progress). It followed an earlier trial investigating hand splinting only (Lannin, Horsley, Herbert, McCluskey, & Cusick, 2003). Eligible patients were from six consenting acute rehabilitation hospitals. Evidence-based strategies were used to enhance referral by therapists at participating sites (Cavalieri, 2003; Visanji & Oldham, 2001). Information presentations, regular face-to-face, telephone and e-mail contacts, study and recruitment reminders, newsletters, and information about recruitment progress were used. In addition to these study-linked strategies, therapists were eligible to register their study participation for continuing

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professional development credits, and they had access to free continuing education sessions. It was intended that 63 patients would be recruited over 18 months (this target was based on previous randomized control trial recruitment patterns in a similar setting [Lannin et al., 2003]). Although 25 therapists across six sites had agreed to recruit patients, after 18 months only 50 had been enrolled.

Recruitment of patients for hospital-based research can be difficult (Benson et al., 1991). Barriers to trial recruitment that have been identified in physician studies include: attitudes such as accepting the uncertainty involved in many treatment decisions, which make professionals uncomfortable about referring patients to trials where usual treatments are not performed (Benson et al.; Taylor et al., 1984); concern about informed consent (Taylor et al.); possible effects of the trial on patient prognosis with physicians more likely to refer those patients with a poor prognosis for trial participation (Benson et al.); and forgetfulness by recruiting personnel (Bell-Sayer & Klaber Moffett, 2000; de Wit et al., 2001; Peto et al., 1993). There are also investigator-related barriers to recruitment, such as lack of time, heavy caseloads, or time spent in other research activities (Asch et al., 2000; Peto et al.). Design and resource issues such as the availability of dedicated and experienced recruiters have also been suggested to affect trial recruitment (Lovato, Hill, Hertert, Hunninghake, & Probstfield, 1997).

Aim

To identify factors associated with occupational therapist patient recruitment rates for a multisite randomized controlled trial conducted in an acute rehabilitation setting.

Method

Participants

Twenty-six occupational therapists who participated in the trial were targeted.

Instrument

An author-designed survey was used. Questions were initially developed on the basis of recruitment studies literature (Asch et al., 2000; Benson et al., 1991; de Wit et al., 2001; Peto et al., 1993; Taylor et al., 1984), refined following feedback by occupational therapy researchers involved in the conduct of randomized controlled trials. The 20-item questionnaire used a combination of multiple-choice and open-ended questions. There were four sections seeking (a) demographic information (e.g., for example their qualifica-

tions) (7 items); (b) information about their recruitment behavior (e.g., whether all, some, or none of eligible patients were entered) (5 items); (c) their views on the scientific design of the trial, including their own beliefs about the effectiveness of interventions under study (e.g., whether or not they believed splints were essential) (5 items); and finally (d) their views about obstacles to recruitment inherent in randomized controlled trials (Benson et al., 1991) (e.g., whether there were problems telling patients that they would be randomly assigned to groups, or problems explaining that as therapists they did not know which treatment was best) (2 items).

Procedure

The survey was mailed to the 26 occupational therapists. Because of the known low response rates of mailed surveys (Blumberg, Fuller, & Hare, 1974; Krysan, Schuman, Scott, & Beatty, 1994; Shostek & Fairweather, 1979) and the need for a good response rate (Asch, Jedrzejewski, & Christakis, 1997), a research assistant followed up written reminders with another copy of the instrument and telephone reminders in which participants could choose to respond to the questionnaire with data de-identified via telephone. These techniques have been shown elsewhere to improve response rates among health professionals (Asch et al.).

Data Analysis

Because of the sample size and descriptive intent of the survey, raw frequencies and percentages were used. Linear regression was used to examine hypotheses of independence between recruitment rate and factors that may have had an influence on it. Associations between recruitment in the trial and the responses to the questionnaire were examined. The results of the ordinary least-squares (OLS) regression analysis of recruitment rate are presented in Table 6 (decision factors where responses greater than $n = 2$ were entered into the model). Regression coefficients and their associated standard errors are reported. In addition, the relevant probabilities for testing the hypothesis that the regression coefficient is statistically significantly different from zero (no effect) are also reported. The levels of statistical significance used in analysis was $p < .05$.

Results

Participants

Eighteen surveys were completed giving a response rate of 78% (16 by post and 2 by telephone). Characteristics of respondents are shown in Table 1.

Table 1. Characteristics of Respondents

Characteristic	Percentage (No.) (N = 18)
Gender	
Male	5.5 (1)
Female	94.4 (17)
Qualification	
Bachelor's degree	88.8 (16)
Bachelor's degree (with dedicated research training known as "honors")	11.1 (2)
Master's degree	5.5 (1)
Enrolled in postgraduate study	16.6 (3)
Years of practice	
Less than 1	5.5 (1)
1- < 3	16.6 (3)
3- < 5	33.3 (6)
5- < 10	44.4 (8)
Primary Work Site	
Private (for profit) Hospital	16.6 (3)
Public Hospital-Rehabilitation Unit	22.2 (4)
Public Hospital-Stroke Unit	61.1 (11)
Primary Work Role	
Clinician	88.8 (16)
Manager	11.1 (2)
Previous Research Involvement	38.8 (7)

Recruitment Rate

Recruitment was initially categorized into "1 or more patients enrolled" and "no patients enrolled." Of the 18 occupational therapists who responded, 16 (89%) recruited 1 or more of their patients to the splinting trial, and 2 (11%) recruited no patients. Most respondents ($n = 9$) had referred between 2 and 5 patients, and only 1 therapist referred more than 10 patients (mean 3.8, mode 4). There was no evidence that site affected referral rate (chi-square = 21.47, $p = 0.60$).

Recruitment Plan Implementation

All respondents received the same recruitment strategies: information presentations, site visits, e-mail contact, newsletters, access to free continuing education, and use of study involvement for continuing professional development accreditation. Therapists were also invited to contact the researcher to discuss eligible patients at any time. There was variation in the extent to which the researcher was sought out by therapists to discuss eligible patients (Table 2). There was no evidence that site affected the likelihood that therapists would contact the researcher (chi-square = 9.14, $p = 0.52$), nor that contacting the researcher to discuss eligible patients was correlated to recruitment rate ($r = -.09$, $p > 0.05$).

Recruitment Behavior

No therapist reported actively discouraging patients from taking part in the trial (i.e., no therapist told eligible

Table 2. Implementation of Study Recruitment Strategy by Therapists

	Percentage (No.) (N = 18)
Researcher contacted about	
all eligible patients	72.2 (13)
most of the eligible patients	22.2 (4)
none of the eligible patients	5.5 (1)
Number of eligible patients recruited to the trial	
0	11.1 (2)
1	22.2 (4)
2-5	50.0 (9)
6-10	11.1 (2)
>10	5.5 (1)

patients not to participate or told them that the trial might have adverse outcomes). Six factors were reported as reasons why therapists chose not to present the trial to eligible patients (Table 3). None of these factors were specific to the inclusion or exclusion criteria, and must therefore be considered independent therapist judgments about study suitability. Four therapists identified that they did not recommend the trial to eligible patients.

Reasons for Recruitment Decisions

Over half the respondents declared a preferred treatment and one indicated a concern with the use of a randomized control trial design. Other design issues that were negatively viewed and underpinned decisions by therapists not to recruit included: random assignment, being unable to make an individualized decision about treatment, and patient discussions of treatment uncertainty. All three factors are integral parts of randomized controlled trials (Taylor, 1984). One respondent said, "The main reason I consider not entering patients on the trial is that I have my own thoughts on how I think a patient would best improve." Table 4 presents the perceived barriers to recruitment.

Table 3. Recruitment Behaviors

	Percentage (No.) (N = 18)
Number of therapists who reported that they had actively discouraged patients from taking part in the trial	0
Reasons trial not recommended to eligible patients*	
Concern that patient unlikely to understand what is likely to be involved	22.2 (4)
Patient's or family perceptions of study treatments	11.1 (2)
Patient's or family perceptions of use of a control group	11.1 (2)
Social/geographical problems with patient	11.1 (2)
Clinical work and practice (time constraints)	5.5 (1)
Therapist beliefs about the splinting treatments	5.5 (1)

Note. *Categories were not exclusive

Table 4. Randomized Controlled Trial Recruitment Barriers

	Percentage (No.) (N = 18)
Preference for one treatment	55 (10)
Anticipated compliance of eligible patients	33 (6)
Rigid eligibility criteria	33 (6)
Protocol controls cointerventions	22 (4)
Medical condition of eligible patients	22 (4)
Protocol does not allow individualized therapy	17 (3)
Acceptance of treatment uncertainty	5 (1)
Age of eligible patients	5 (1)
Concern about scientific design	5 (1)
Randomization	5 (1)

Suggestions for Enhanced Recruitment

A few suggestions for enhanced recruitment were made (Table 5). All suggestions were already employed within the trial, although citing them may indicate that more frequent reminders about the study may have improved recruitment rate. One respondent provides insight into this when in response to the question, *Do you have any suggestions about how recruitment to the trial or our management style could be improved?* She wrote, "No. Reminder e-mails, signs, regular contact from researchers was great, problem is with us clinicians."

Recruitment Rate and Association With Demographic and Decision-Making Factors

The OLS results indicate that having completed a master's level postgraduate degree (or being enrolled in a master's program) and choosing not to refer patients because of concern for their medical prognosis were the only independent variables in the model that exceed the conventional benchmarks for statistical significance. All other demographic factors and decision factors identified in the survey fall considerably short of that benchmark. The overall goodness of fit

Table 5. Subject Recommended Strategies To Improve Recruitment Rate

	Percentage (No.) (N = 18)
Use of eligibility checklist to screen all new admissions	11.1 (2)
Telephone reminders	11.1 (2)
E-mail reminders	5.5 (1)
Use of senior therapist to assist new therapists to assess potential patients	5.5 (1)

for the model is high ($R^2 = .822$); however, caution in interpreting the results is warranted because of the small sample size ($N = 18$).

Discussion

The key finding of this study is that therapists who have attained research qualifications (or are getting them) are more effective recruiting patients for a randomized controlled trial than other therapists. This factor is more important than other factors, and has not previously been identified as an attribute related to recruitment success in any field. Judgments about likely patient compliance and being able to satisfactorily obtain informed consent were identified as reasons for recruiting decisions, but they were not related to rates of recruitment. Choosing not to refer patients because of concern for their medical prognosis was the only patient-related factor that was significantly related to recruitment rate. Although the finding that therapists are concerned about informed consent is consistent with results of physician studies (Taylor et al., 1984), excluding eligible patients with poor medical prognosis is not. In fact, Benson and colleagues (1991) found that surgeons were more likely to recruit patients who were considered "a hopeless case."

Half the therapists expressed concern regarding the study protocol that controlled potential cointerventions.

Table 6. Regression Analysis of Recruitment (N = 18)

Variable	Regression Coefficient	Standard Error	Probability
<i>Demographic Factors</i>			
Years of practice	0.101	0.301	0.754
Master's degree (completed or enrolled)	0.606	0.232	0.040*
Honors' degree	-0.146	0.233	0.553
Previous involvement in research	0.221	0.276	0.454
<i>Decision Factors</i>			
Patient related—Poor medical prognosis	0.791	0.264	0.023*
Patient related—Capacity for informed consent	0.010	0.285	0.972
Patient related—Potential patient compliance	0.302	0.224	0.227
Patient related—Potential family issues	-0.011	0.235	0.962
Therapist related—Preference for one arm of study	0.227	0.311	0.493
RCT design—Need to control cointerventions	0.048	0.267	0.867
RCT design—Unable to make individualized decisions	-0.028	0.216	0.901

*significant at $p = 0.05$

$R^2 = .822$; adjusted $R^2 = .497$

Standard error of the estimate (SEE) = 2.109.

Because all controlled interventions lacked evidence of treatment effect, this finding may suggest difficulty on the part of therapists to accept the uncertainty within usually prescribed interventions and reluctance to admit the lack of evidence for them. This is consistent with previous literature (Benson et al., 1991; Taylor et al., 1984).

Many factors cited in the literature as investigator-related barriers to recruitment were investigated in the survey but were not found. Lack of time, for example, was not a barrier to recruitment (Asch et al., 2000; Peto et al., 1993); heavy caseloads or time spent in other research activities were also not identified as barriers (Asch et al., 2000). The latter may be a reflection of the pragmatic trial protocol used in the study that mimicked clinical practice and did not impose separate trial demands. The pragmatic trial protocol may also explain why three eligible patients were treated according to the protocol but not enrolled. The protocol may have been thoroughly integrated into practice.

Forgetfulness by recruiters, although a common factor in literature for poor recruitment (Bell-Sayer & Klaber Moffett, 2000; de Wit et al., 2001; Peto et al., 1993), was found in this study by only one person. It may be that the recruitment support strategies of the trial were successful; only 2 therapists identified the need for more reminders. The lack of dedicated recruiters for this study may have affected the speed of recruitment as this has been suggested as an important aspect of successful recruitment (Lovato et al., 1997). Even though no therapists reported heavy caseloads as a barrier and few admitted forgetfulness, day-to-day clinical practice may have preempted recruitment to the trial.

This study provides further suggestions for enhancing the conduct of randomized clinical trials by identifying the potential impact of therapist attributes on recruiting behavior. Reasons for recruitment decisions are also presented. Selection of therapists with research qualifications as recruiters may be an effective way to enhance recruitment rates. ▲

Acknowledgment

Project funding was provided by the School of Exercise and Health Sciences, University of Western Sydney, Sydney, Australia.

References

- Asch, D. A., Jedrzejewski, M. K., & Christakis, N. A. (1997). Response rates to mail surveys published in medical journals. *Journal of Clinical Epidemiology*, 50, 1129–1136.
- Asch, S., Connor, S. E., Hamilton, E. G., & Fox, S. A. (2000). Problems in recruiting community-based physicians for health services research. *Journal of General Internal Medicine*, 15, 591–599.
- Bell-Sayer, S. E. M., & Klaber Moffett, J. A. (2000). Recruiting patients to randomized trials in primary care: principles and case study. *Family Practitioner*, 17, 187–191.
- Benson, A. B., Pregler, J. P., Bean, J. A., Rademaker, A. W., Eshler, B., & Anderson, K. (1991). Oncologists' reluctance to accrue patients onto clinical trials: An Illinois cancer center study. *Journal of Clinical Oncology*, 9, 2067–2075.
- Blumberg, H. H., Fuller, C., & Hare, P. (1974). Response rates in postal surveys. *Public Opinion Quarterly*, 38, 113–123.
- Cavalieri, R. J. (2003). Recruiting strategies for clinical trials: Lessons learned from practice. *Applied Clinical Trials*, 12(1), 44–50, 58.
- de Wit, N. J., Quarero, A. O., Zuithoff, A. P. M., & Numans, M. E. (2001). Participation and successful patient recruitment in primary care. *Journal of Family Practice*, 50, 976.
- Krysan, M., Schuman, H., Scott, L. J., & Beatty, P. (1994). Response rates and response content in mail versus face-to-face surveys. *Public Opinion Quarterly*, 58, 381–399.
- Lannin, N. A., Cusick, A., Herbert, R., & McCluskey, A. (2006). *A randomized trial of effectiveness of two hand splint positions to apply stretch to the wrist of adults with hemiplegia following stroke*. Manuscript submitted for publication.
- Lannin, N. A., Horsley, S. A., Herbert, R., McCluskey, A., & Cusick, A. (2003). Splinting the hand in the functional position after brain impairment: A randomized, controlled trial. *Archives of Physical Medicine and Rehabilitation*, 84, 297–302.
- Lovato, L. C., Hill, K., Hertert, S., Hunninghake, D. B., & Probstfield, J. L. (1997). Recruitment for controlled clinical trials: Literature summary and annotated bibliography. *Controlled Clinical Trials*, 18, 328–357.
- Peto, V., Coulter, A., & Bond, A. (1993). Factors affecting general practitioners' recruitment of patients into a prospective study. *Family Practitioner*, 10, 207–211.
- Shostack, H., & Fairweather, W. R. (1979). Physician response rates to mail and personal interview surveys. *Public Opinion Quarterly*, 43, 206–217.
- Taylor, K. M., Margoese, R. G., & Soskolne, C. L. (1984). Physicians' reasons for not entering eligible patients in a randomized clinical trial of surgery for breast cancer. *New England Journal of Medicine*, 310, 1363–1367.
- Visanji, E. C., & Oldham, J. A. (2001). Patient recruitment in clinical trials: A review of the literature. *Physical Therapy Reviews*, 6, 141–150.