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Cluster Randomized Pilot Controlled Trial of an Occupational Therapy Intervention for Residents With Stroke in UK Care Homes

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Background and Purpose—A pilot evaluation of an occupational therapy intervention to improve self-care independence for residents with stroke-related disability living in care homes was the basis of this study.

Methods—A cluster randomized controlled trial with care home as the unit of randomization was undertaken in Oxfordshire, UK. Twelve homes (118 residents) were randomly allocated to either intervention (6 homes, 63 residents) or control (6 homes, 55 residents). Occupational therapy was provided to individuals but included carer education. The control group received usual care. Assessments were made at baseline, postintervention (3 months) and at 6-months to estimate change using the Barthel Activity of Daily Living Index (BI) scores, "poor global outcome", (defined as deterioration in BI score, or death) and the Rivermead Mobility Index.

Results—At 3 months BI score in survivors had increased by 0.6 (SD 3.9) in the intervention group and decreased by 0.9 (2.2) in the control group; a difference of 1.5 (95% CI allowing for cluster design, −0.5 to 3.5). At 6 months the difference was 1.9 (−0.7 to 4.4). Global poor outcome was less common in the intervention group. At 3 months, 20/63 (32%) were worse/dead in the intervention group compared with 31/55 (56%) in the control group, difference −25% (−51% to 1%). At 6 months the difference was similar, −26% (−48% to −3%). Between-group changes in Rivermead Mobility Index scores were not significantly different.

Conclusion—Residents who received an occupational therapy intervention were less likely to deteriorate in their ability to perform activities of daily living. (*Stroke*. 2006;37:2336-2341.)

Key Words: nursing homes ■ occupational therapy ■ stroke

About 25% of people with stroke move from acute care directly to institutionalized care both in the UK and in the US,[1,2] and 20% to 40% of all care-home admissions have stroke as their admission diagnosis.[3,4] However, estimates of the prevalence of stroke for recipients of institutional care are imprecise, largely because of inaccuracies in diagnosis and record keeping[3,5] especially for residents who experience a stroke after admission. Stroke is the primary cause of severe disability in care-home populations.[6]

Residents frequently experience the adverse consequences of stroke, such as dependency in self-care ability, falls, pain, pressure ulcers and emotional distress[7,8] which leads to readmissions to hospital and increased general-practitioner workload.[9] Despite the potential for recovery in this group,[10] few residents have any access to rehabilitation.[11–13] Because rehabilitation, particularly the role of occupational therapy, is poorly understood, care-home staff do not know when or who to refer.[13] The "bread and butter" occupational therapy work of improving

independence in toileting, feeding and dressing, or changing environmental barriers such as seat, table and bed heights or improving mobility with the correct walking aid is not done.
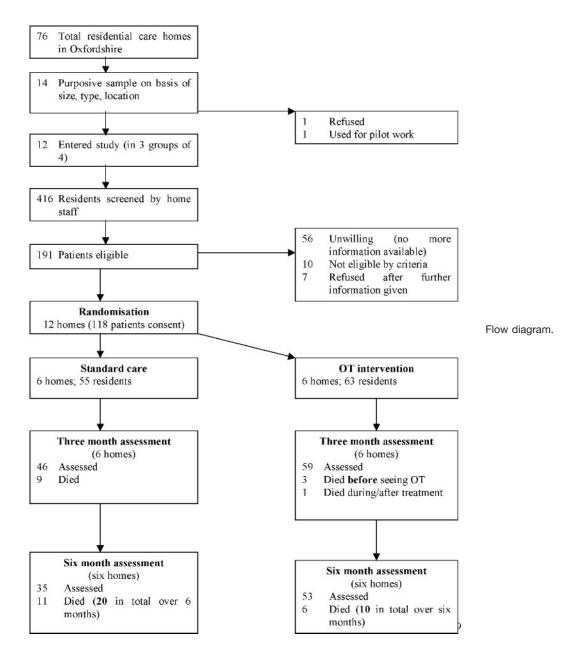
For stroke survivors living in their own homes, the benefits of occupational therapy to personal and extended activities of daily living have been demonstrated by meta-analysis.[14] These results are not immediately applicable to those living in institutional care because the physical and care environments are vastly different and the population is more frail. One small study examined the benefits of combined occupational therapy and physiotherapy to a frail population in a nursing home in North America that included stroke and found a positive influence on function and cost of care. The effects of an occupational therapy specifically targeted to activity of daily living for people with stroke living in nursing and residential homes have not been previously investigated.

Following the Medical Research Council (MRC) guidelines[15] concerning research into complex health interventions,

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76	Total residential care homes in Oxfordshire

14	Purposive sample on basis of size, type, location

1	Refused
1	Used for pilot work

12	Entered study (in 3 groups of 4)

416	Residents screened by home staff

191	Patients eligible

56	Unwilling (no more information available)
10	Not eligible by criteria
7	Refused after further information given

Randomisation
12 homes (118 patients consent)

Flow diagram.

Standard care 6 homes; 55 residents

OT intervention 6 homes; 63 residents

Three month assessment
(6 homes)
46 Assessed
9 Died

Three month assessment
(6 homes)
59 Assessed
3 Died **before** seeing OT
1 Died during/after treatment

Six month assessment
(six homes)
35 Assessed
11 Died (**20** in total over 6 months)

Six month assessment
(six homes)
53 Assessed
6 Died (**10** in total over six months)

the objectives of the study were to evaluate an evidence-based occupational therapy intervention[16] delivered to the home, targeted to improving independence in personal activity of daily living. A cluster-randomized design, with random allocation at the level of care home was chosen because the chance of contamination if residents were randomized individually was very high, outweighing the disadvantages of this design.[17]

Methods

Study Population
The Guide to Care Homes for Oxfordshire[18] was used to identify a purposive sample of nursing and residential homes that would include residents with stroke and reflected the variability of the population, such as location, size and source of funding. The managers or senior nurses of 14 homes were approached; 1 refused and 1 other home was used as a prepilot.

The remaining 12 homes were then entered into the study in 3 groups of 4, to control the occupational therapist's workload. At entry the staff of the homes were asked to screen all residents with the Barthel Activity of Daily Living Index (BI)[19] (score range 0 to 20) and provide information on stroke history and cognitive status (for consent purposes). All residents with moderate to severe stroke-related disability (BI score 4 to 15 inclusive) were included except those with acute illness and those admitted for end-of-life care. The BI screening scores were used to estimate the therapy workload.

Interventions
The intervention was developed by using existing evidence and the consensus of a group of expert occupational therapists (described in detail elsewhere[16]). The intervention was provided by an experienced qualified occupational therapist and was delivered at the level of the individual. It was targeted toward improving independence in personal activities of daily living, such as feeding, dressing, toileting, bathing, transferring and mobilizing. The frequency and duration was dependent on the resident and therapist's agreed goals, and it took place over the 3-month period that the therapist was attached to

the home. Occupational therapy followed a routine process using a "client centered approach,"[20] as far as possible and included a continuous process of assessment, treatment and reassessment.

Assessment

All residents in the intervention group were given an individual interview of ≈1 hour. The purpose of the initial assessment was to establish the resident's functional ability and to agree with the goals of the intervention. During the interview the residents were asked to identify their perceived problems and what they would like to achieve by participating in occupational therapy. In the event that a resident had difficulty communicating, a shared goal was agreed with a relative or care staff.

Occupational Therapy Intervention at the Level of the Resident

The content of the occupational therapy intervention was potentially multifaceted in that it could address (1) the resident's performance of a specific task (eg, eating, mobilizing) in given environment (eg, bedroom, bathroom), (2) the physical environment in which the task was being performed, and (3) specific impairments that may limit performance in activities of daily living (ADL) or cause discomfort (eg, tissue shortening in a hand).

Techniques used by the occupational therapist to improve performance in activities of daily living were likely to include (1) task-specific practice including dressing practice, transfer practice, mobility training, etc, (2) reducing the complexity or demands of the task by changing the tools required to perform the task or by altering the environment through the provision of aids and adaptations, or by simplifying the task, and (3) specific therapeutic interventions (eg, stretching to relieve tissue shortening in a hand and providing a splint). As part of the treatment, progress was reviewed and goals modified accordingly.

Occupational Therapy Intervention at the Level of the Nursing Home Staff and Carers

The content of the occupational therapy intervention would also include an element of education of nursing home staff and carers as to the purpose of the intervention and the promotion of independence using techniques, such as providing information on how to continue therapy/treatment in the absence of the therapist, how, why and when to use aids or adaptations. The therapist was also able to refer/discuss any problems with the study team, general practitioner or other agencies.

Residents in the control homes received usual care. As usual in the UK,[13] occupational therapy was not routinely used by any of the homes. None of the homes had an identified person with specific responsibility for ADL training or the provision of adaptive equipment.

Ethical Considerations

Home managers or home owners gave their consent on behalf of the home and care staff. The extent of data collection was outside normal practice and so consent was obtained from participating individuals. An "assent" consent procedure was used for residents with cognitive impairments, following the recommendations in the MRC guidelines for the mentally incapacitated.[21]

Randomization and Allocation Concealment

Randomization was carried out independently by a statistician. Homes were grouped into 4 strata, using combinations of type (residential, nursing, or both), funding source (private or local authority) and setting (urban or rural). Within each stratum, pairs of homes were allocated randomly, using computer-generated random numbers. Allocation was revealed only to the occupational therapist, not to the assessors.

Outcome Measures

Individual resident assessments were completed at baseline (the time of recruitment), 3 months (immediately after the intervention) and 6 months by 1 of 4 research staff masked to the trial allocation. Staff

TABLE 1. Baseline Characteristics of Homes and Residents by Trial Group

	Intervention	Standard Care
Care-home factors at baseline		
No.	6	6
Classification:		
Nursing or dual registered	4	4
Residential	2	2
Funding type:		
Private	4	4
Not-for-profit	1	1
Local authority	1	1
Beds per home		
Mean (SD)	30.5 (8.5)	32.0 (11.5)
Residents with stroke per home		
Range	7–17	2–17
Mean (SD)	10.5 (3.5)	9.2 (5.2)
Participant factors at baseline		
No.	63	55
Age (years)		
Range	62–102	44–99
Mean (SD)	88.6 (6.5)	86.3 (8.8)
No (%) women	52 (83%)	45 (82%)
Short orientation and memory concentration test		
Impaired (<22)	39 (62%)	32 (58%)
Not impaired (22–28)	17 (27%)	13 (24%)
Missing#	7 (11%)	10 (18%)
BI score		
Range	0–20	0–19
Mean (SD)	10.1 (5.7)	9.5 (5.2)

Some residents were unable to respond because of aphasia (14) or refused (3).

were trained in the use of the measures by instruction and observed practice and each assessor completed all the assessments at every time point in their allocated homes.

The primary outcome was the BI,[19] a commonly used measure of self-care independence containing 10 items and scored from 0 to 20 (with 20 being more independent). Secondary outcomes were "poor global outcome," defined as a deterioration in BI or death, as used previously in community trials of occupational therapy,[22] and the Rivermead Mobility Index (RMI),[23] a 15-item measure of functional mobility (scored from 0 to 15, with 15 being more mobile). In addition, the short Orientation-Memory-Concentration Test[24] was used at the first assessment to determine the level of a resident's cognitive impairment; it was not an exclusion criterion.

Sample Size

Because this was a pilot study, no formal power calculation was performed. With the resources available we estimated that we could include 12 care homes, with 10 residents in each. The expected sample of 120 residents would, in an individually randomized trial, have given 80% power to detect, at the 5% significance level, a mean difference between groups of 2 points in the Barthel score (assumed SD 3.8). Estimation of the relevant intracluster correlation coefficients, to determine the cluster design factor for a future trial, was one goal of the pilot study.

TABLE 2.   BI and Global Poor Outcome by Trial Group

BI Score	Intervention		Standard Care		Difference Between Groups* (95% CI)	Adjusted P Value†
	N	Mean (SD)	N	Mean (SD)		
Baseline	63	10.1 (5.7)	55	9.5 (5.2)		
All with 3-month follow-up:						
Baseline	59	10.2 (5.7)	46	9.2 (5.3)		
3 months	59	10.8 (5.5)	46	8.2 (5.2)		
Change: 3 months-baseline	59	0.6 (3.9)	46	−0.9 (2.2)	1.5 (−0.5 to 3.5)	0.07
All with 6-month follow-up						
Baseline	53	10.5 (5.7)	35	10.2 (4.9)		
3 months	53	11.3 (5.3)	35	9.3 (4.7)		
6 months	53	10.2 (5.9)	35	8.1 (4.5)		
Change: 6 months-baseline	53	−0.3 (4.2)	35	−2.1 (3.7)	1.9 (−0.7 to 4.4)	0.12
Global poor outcome‡	N	n (%)	N	n (%)	(%)	
3-months follow-up	63	20 (32)	55	31 (56)	−25 (−51 to 1)	0.05
6-month follow-up	63	32 (51)	55	42 (76)	−26 (−48 to −3)	0.03

*Adjusted for cluster design; †adjusted for cluster design and for baseline BI score; ‡died, or had worse BI score than at baseline.

Statistical Analysis

Analysis was done using SPSS v.10.0. Comparisons between means of individual values were made using the *t* test and between proportions using the χ^2 test. BI and RMI scores of participants may be affected by features of the care home, such as staff attitudes and training, and facilities in the home. Scores of participants within a home cannot therefore be regarded as independent. To allow for the 'clustering' of outcome measures within homes, the tests were based on appropriately adjusted standard errors, as advocated by Donner and Klar.[25]

Intracluster correlation coefficients were high: 0.26 for Barthel score at baseline, 0.18 for Barthel change to 3 months, 0.20 for Barthel change to 6 months, 0.14 for global poor outcome at 3 months, 0.09 for global poor outcome at 6 months. Adjustments for baseline scores were made using analysis of covariance. Analysis was by intention-to-treat, but this was modified in the case of BI and RMI scores because of the many deaths occurring before follow-up.

Results

Between April 2001 and September 2001, 118 people were recruited to the study (Figure). Baseline characteristics of homes and residents are shown in Table 1. Baseline BI scores, as measured by members of the research team at baseline, ranged from 0 to 20.

The mean BI scores of participants did not differ from those who did not take part. In the homes allocated to the intervention, of the 94 residents eligible the mean BI score of the 63 participants was 10.1 (SD 5.7) compared with 10.3 (3.5) for the nonparticipants. In the homes allocated to control, of the 97 residents eligible the mean BI score of the 55 participants was 9.5 (SD 5.2) compared with 10.4 (SD 3.4) for the nonparticipants.

Intervention

The median number of visits per resident per month was 2.7 (interquartile range 1 to 4.2, range 1 to 25), and the median time spent with the therapist per resident per month was 4.5 hours (interquartile range 2 to 6.9, range 1 to 10). Of the 525 total visits, 166 (32%) were spent on individual assessment,

goal setting and review and 79 (15%) on communication with residents, staff, relatives and referrals to general practitioners and other agencies. Individual mobility training sessions (n=111, 21%) included walking practice, bed-to-chair transfers, sit-to-stand practice and wheeling practice. Individual task-related training of basic activities of daily living (100, 19%) focused on toilet transfers, getting out of bed, dressing and eating practice.

The remaining (18, 3%) sessions were spent treating specific impairments (such as stretching a contracted hand) or leisure activities. Most therapy sessions lasted ≈30 minutes.

The BI scores and the proportion with poor global outcome are shown in Table 2. The proportion of residents with poor global outcome tended to be greater in the control than the intervention group, both at 3 months (difference −25%, 95% CI, −51% to 1%; P=0.05) and 6 months (difference −26%, −48% to −3%; P=0.03). Table 3 shows a similar set of data from the RMI; the trend is for residents receiving the intervention to benefit but it is not statistically significant.

The standard-care group demonstrated deterioration in the BI and the RMI over the 6 months of the study. The intervention group showed a tendency for improvement between the baseline and end of the intervention, but then deteriorated in a similar way to the standard-care group.

Discussion

This study suggests that residents of care homes experiencing activity limitation (disability) attributable to stroke, who receive a relatively brief intervention by an occupational therapist, are less likely to deteriorate in their ability to perform ADL. Occupational therapy (delivered both to individual residents and to the care staff) appears to counteract the underlying trend toward decline in self-care independence and mobility. The nearly 2-point difference would result in clinically significant outcomes for the resident. For example, those who received therapy would be more able to move

TABLE 3. RMI by Trial Group

RMI score	Intervention		Standard Care		Difference Between Groups* (95% CI)	Adjusted *P* Value†
	N	Mean (SD)	N	Mean (SD)		
Baseline	63	4.9 (3.6)	55	4.0 (3.4)		
All with 3-month follow-up:						
Baseline	59	4.8 (3.6)	46	3.9 (3.5)		
3 months	59	5.2 (3.7)	46	3.5 (3.1)		
Change: 3 months-baseline	59	0.4 (3.0)	46	−0.4 (1.9)	0.8 (−0.6 to 2.2)	0.12
All with 6-month follow-up						
Baseline	53	5.0 (3.7)	35	4.5 (3.3)		
3 months	53	5.5 (3.7)	35	4.0 (2.9)		
6 months	53	4.5 (3.5)	35	3.4 (2.7)		
Change: 6 months-baseline	53	−0.5 (3.5)	35	−1.1 (2.4)	0.6 (−1.2 to 2.4)	0.30

*Adjusted for cluster design; †adjusted for cluster design and for baseline RMI score.

themselves (transfer) from bed to chair, chair to toilet and move around the home.

Before further considering the implications of this study, some discussion of the limitations is appropriate.[7] Bias can arise from cluster designs and from the "third party" nature of obtaining access to residents and consent. For example, although the BI scores were supplied for all residents, the selection of people with stroke and the first approach were conducted by the staff who may have made decisions about suitability at that stage. Maintaining masking requires more attention with cluster designs because only 1 resident needs to reveal the group to unblind the assessor for the whole home. Moreover, various factors reduced the expected power of our study; for example, the wide variation in mean scores between care homes resulted in a very high intracluster correlation coefficient for these scores.

Despite these difficulties, the study is important for several reasons. First, it has demonstrated that even a relatively small level of occupational therapy intervention may have a significant, quite large effect on the residents of a care home. It has also shown that the research design and method is practical, and given the very large number of care homes in most western countries and the large number of people with stroke in those homes, it should be relatively easy to undertake a trial to confirm or refute our findings. This study should allow an informed calculation of the number of homes and residents needed.

The data in this study are consistent with 2 themes common to all rehabilitation research. First, a relatively small input by a specialist rehabilitation team or professional can have detectable and relatively long-lasting effects on morbidity and possibly mortality; the meta-analysis of stroke unit trials, and other trials of individual professions all suggest this. Second, it seems likely that the benefits arise from a problem-solving approach, not a specific intervention. It is quite possible that no specific one intervention will be proven to be the key ingredient of effective rehabilitation in any situation.

This research should lead to several courses of action. Most obviously, it would be appropriate to replicate the study with a larger sample. However, it might also be appropriate to study all residents in the nursing home, not simply those with stroke. There is no logical reason to expect only stroke survivors to be susceptible to benefit. It would also be appropriate to construct a meta-analysis investigating the effects of the process of rehabilitation in people with a wide variety of conditions, provided that the rehabilitation is undertaken by suitably specialized people.

Disclosures

None.

References

1. Rudd AG, Irwin P, Rutledge Z, Lowe D, Wade DT, Pearson M. Regional variations in stroke care in England, Wales and Northern Ireland: results from the National Sentinel Audit of Stroke. Royal College of Physicians Intercollegiate Stroke Working Party. *Clinical Rehabilitation*. 2001;15: 562–572.
2. Brown RD Jr, Ransom J, Hass S, Petty GW, O'Fallon WM, Whisnant JP, Leibson CL. Use of nursing home after stroke and dependence on stroke severity: a population-based analysis. *Stroke*. 1999;30:924–929.
3. Bowman C, Whistler J, Ellerby M. A national census of care home residents. *Age & Ageing*. 2004;33:561–566.
4. Yap LKP, Au SYL, Ang YH, Kwan KY, Ng SC, He CH. Who are the residents of a nursing home in Singapore? *Singapore Med J*. 2003;44: 65–73.
5. Fahey T, Montgomery AA, Barnes J, Protheroe J. Quality of care for elderly residents in nursing homes and elderly people living at home: Controlled observational study. *BMJ*. 2003;326:580–583.
6. Lee Y, Choi K. Functional disability of older persons in long-term care facilities in Korea. *Archives of Gerontology & Geriatrics*. 2002;34: 93–106.

7. Sackley CM, Dewey ME. The frequency of joint contractures, pressure sores, painful shoulder, other pain and falls after severely disabling stroke. *Clinical Rehabilitation*. 2002;16:114–115.

8. Langhorne P, Stott DJ, Robertson L, MacDonald J, Jones L, McAlpine C, Dick F, Taylor GS, Murray G. Medical complications after stroke: a multicenter study. *Stroke*. 2000;31:1223–1229.

9. Kavanagh S, Knapp M. The impact on general practitioners of the changing balance of care for elderly people living in institutions. *BMJ*. 1998;317:322–327.

10. Sackley CM, Dewey ME. Recovery from severely disabling stroke. *Clinical Rehabilitation*. 2001;15:455.

11. Duthie J, Chesson R. Physiotherapy in private nursing homes. *Physiotherapy*. 1996;82:566–572.

12. O'Dea G, Kerrison S, Pollock A. Access to healthcare in nursing homes:a survey in one English Health Authority. *Health and Social Care in the Community*. 2000;8:180–185.

13. Sackley CM, Gatt J, Walker MF. The use of rehabilitation services by private nursing homes in Nottingham. *Age & Ageing*. 2001;30:532–533.

14. Walker MF, Leonardi-Bee J, Bath P, Langhorne P, Dewey M, Corr S, Drummond A, Gilbertson L, Gladman JRF, Jongbloed L, Logan P, Parker C. Individual patient data meta-analysis of randomized controlled trials of community occupational therapy for stroke patients. *Stroke*. 2004;35: 2226–2232.

15. MRC. A framework for development and evaluation of RCTs for complex interventions to improve health. *Medical Research Council*. 2000;1–18.

16. Sackley CM, Atkinson JC, Walker MF. Occupational therapy in nursing and residential care settings: a description of a randomised controlled trial intervention. *British Journal of Occupational Therapy* 2004;67:104–110.

17. Medical Research Council. Cluster randomised trials: Methodological and ethical considerations. MRC clinical trials series. Medical Research Council November 2002. Available at: http://www.mrc.ac.uk/index/publications/pdf-cluster_randomised_trials-link. Accessed July 27, 2006.

18. Oxfordshire Care Association. Guide to Residential Homes, Nursing homes and Domiciliary Care. 2000.

19. Collin C, Wade DT, Davies S, Horne V. The Barthel ADL Index: a reliability study. *International Disability Studies*. 1988;10:61–63.

20. Paterson M, Higgs J, Wilcox S. The artistry of judgement: a model for occupational therapy practice. *British Journal of Occupational Therapy*. 2005;68:409–417.

21. MRC. The ethical conduct of research on the mentally incapacitated. 1991, London: MRC.

22. Gilbertson L, Langhorne P, Walker A, Allen A, Murray GD. Domiciliary occupational therapy for patients with stroke discharged from hospital: randomised controlled trial. *BMJ*. 2000;320:603–606.

23. Collen F, Wade D, Robb G, Bradshaw C. The Rivermead Mobility Index: a further development of the Rivermead Motor Assessment. *International Disability Studies*. 1991;13:50–54.

24. Katzman R, Brown T, Fuld P, Peck A, Schechter R, Schimmel H. Validation of a short Orientation-Memory-Concentration Test of cognitive impairment. *Am Journal of Psychiatry*. 1983;140:734–739.

25. Donner A, Klar N. In: *Design and Analysis of Cluster Randomization Trials in Health Research*. 2000, London: Arnold. pp. 96:114 ff.