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

Catherine Sackley, PhD; Derick T. Wade, MD; David Mant, FRCGP; Jo Copley Atkinson, MRes; Patricia Yudkin, DPhil; Karina Cardoso, MSc; Sonya Levin, MSc; Vanessa Blanchard Lee, DipCOT; Kevin Reel, MSc

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
The objectives of the study were to evaluate an evidence-based occupational therapy intervention delivered to the home, targeted to improving independence in personal activities 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.

### Methods

#### Study Population

_The Guide to Care Homes for Oxfordshire_ 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.

| Total residential care homes in Oxfordshire | 76 |
| Purposive sample on basis of size, type, location | 14 |
| 12 Entered study (in 3 groups of 4) |  |
| 416 Residents screened by home staff |  |
| 191 Patients eligible |  |

**Randomisation**

- 12 homes (118 patients consent)

**Standard care**

- 6 homes; 55 residents

**Three month assessment**

- (6 homes)
  - 46 Assessed
  - 9 Died

**Six month assessment**

- (six homes)
  - 35 Assessed
  - 11 Died (20 in total over 6 months)

**OT intervention**

- 6 homes; 63 residents

**Three month assessment**

- (6 homes)
  - 59 Assessed
  - 3 Died before seeing OT
  - 1 Died during/after treatment

**Six month assessment**

- (six homes)
  - 53 Assessed
  - 6 Died (10 in total over six months)

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 Barthe1 Activity of Daily Living Index (BI) (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). 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,” 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, 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.

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 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, 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, and the Rivermead Mobility Index (RMI), 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 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.

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<table>
<thead>
<tr>
<th>Care-home factors at baseline</th>
<th>Intervention</th>
<th>Standard Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>No.</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Classification:</td>
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<tr>
<td>Nursing or dual registered</td>
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</tr>
<tr>
<td>Residential</td>
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<td>2</td>
</tr>
<tr>
<td>Funding type:</td>
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<tr>
<td>Private</td>
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</tr>
<tr>
<td>Not-for-profit</td>
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<td>1</td>
</tr>
<tr>
<td>Local authority</td>
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<td>1</td>
</tr>
<tr>
<td>Beds per home</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>30.5 (8.5)</td>
<td>32.0 (11.5)</td>
</tr>
<tr>
<td>Residents with stroke per home</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>7–17</td>
<td>2–17</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>10.5 (3.5)</td>
<td>9.2 (5.2)</td>
</tr>
<tr>
<td>Participant factors at baseline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No.</td>
<td>63</td>
<td>55</td>
</tr>
<tr>
<td>Age (years)</td>
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<td></td>
</tr>
<tr>
<td>Range</td>
<td>62–102</td>
<td>44–99</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>88.6 (6.5)</td>
<td>86.3 (8.8)</td>
</tr>
<tr>
<td>No (% women)</td>
<td>52 (83%)</td>
<td>45 (82%)</td>
</tr>
<tr>
<td>Short orientation and memory concentration test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Impaired (&lt;22)</td>
<td>39 (62%)</td>
<td>32 (58%)</td>
</tr>
<tr>
<td>Not impaired (22–28)</td>
<td>17 (27%)</td>
<td>13 (24%)</td>
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<tr>
<td>Missing#</td>
<td>7 (11%)</td>
<td>10 (18%)</td>
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<tr>
<td>BI score</td>
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<tr>
<td>Range</td>
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<td>0–19</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>10.1 (5.7)</td>
<td>9.5 (5.2)</td>
</tr>
<tr>
<td># Some residents were unable to respond because of aphasia (14) or refused (3).</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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,
obviously, it would be appropriate to replicate the study with another group of patients. It is quite possible that no specific one intervention will be proven to be the key ingredient of effective rehabilitation in any situation. 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 difficult 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.

**Acknowledgments**

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**Disclosures**

None.

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


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