

# An Occupational Therapy intervention for residents with stroke-related disabilities in UK Care Homes (OTCH): cluster randomised controlled trial with economic evaluation

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## Scientific summary

### Occupational Therapy intervention in UK Care Homes

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# Scientific summary

## Background

Advances in acute care have reduced mortality rates following stroke significantly. As a result, the number of people living with stroke-related disabilities has increased. Approximately one-quarter of all stroke survivors are unable to return home following their stroke and require long-term institutional care. Care home residents living with stroke-related disabilities tend to have increased levels of dependence as a result of cognitive and physical impairments compared with stroke survivors living in the community.

Occupational therapy (OT) aims to improve quality of life by providing assistance and guidance in carrying out daily routines. OT is particularly relevant and applicable to a care home setting; however, access to OT services as a part of routine practice in UK care homes is restricted. Findings from a pilot study conducted by Sackley *et al.* (Sackley C, Wade D, Mant D, Atkinson J, Yudkin P, Cardoso K, *et al.* Cluster randomized pilot controlled trial of an occupational therapy intervention for residents with stroke in UK care homes. *Stroke* 2006;**37**:2336–41) confirmed the feasibility of a definitive trial evaluating the efficacy of OT for care home residents living with stroke sequelae. The pilot trial suggested that a modest duration of OT had both detectable and lasting effects on morbidity in care home residents with stroke-related disabilities. However, prior to the Phase III trial reported here, the evidence was inconclusive of whether or not OT is a service that is clinically effective and cost-effective in this population. This study represents the largest cluster randomised controlled trial of OT in care homes to date.

## Objectives

The predominant aim was to perform a definitive evaluation of OT for stroke and transient ischaemic attack (TIA) survivors in long-term institutional care. The primary objective was to test the hypothesis that a 3-month course of OT provided by a trained therapist (involving personalised task training, provision of adaptive equipment, minor environmental adaptations and staff education) would have a significant clinical impact on activity-based measures of daily living, compared with usual care. Secondary objectives aimed to explore the influence of the intervention on measures of mobility, depression and health-related quality of life (HRQoL). In order to assess the influence of the 3-month intervention over time, outcome measures were planned at 3-, 6- and 12-month follow-ups. In addition to the analysis of efficacy of OT in this population, the Occupational Therapy intervention for residents with stroke living in UK Care Homes (OTCH) study also contained a health economic evaluation that examined the mean incremental cost of the intervention per quality-adjusted life-year (QALY) gained.

## Methods

### Design

The OTCH study was a pragmatic Phase III, parallel-group, cluster randomised controlled trial with an economic evaluation.

### Setting

Eligible homes needed to provide care for older people (nursing or residential) and be registered with the local authority. All care home funding models were included (e.g. local authority, private and not for profit). Homes caring for residents with learning disabilities and drug addiction were excluded. A list of care homes local to 12 trial administrative centres (TACs) were sourced via the Care Quality Commission database. The TACs were based in the University of Birmingham; Bangor University; University of Central Lancashire; Dorset Primary Care Trust (PCT); University of Nottingham; Solent Healthcare PCT; Plymouth PCT; Wolverhampton PCT; Taunton PCT; Stoke-on-Trent PCT; Coventry & Warwickshire PCT; and Bournemouth & Poole PCT. Care homes from each area were selected at random and invited to participate. Care managers declaring interest were sent an information pack, and later visited by a member of the research team, who answered the managers' queries before they consented to participate. Any care homes providing OT as part of routine care were excluded.

### Participants

Residents were eligible for trial inclusion if they had had a confirmed or suspected stroke or TIA at any point prior to study commencement. Residents receiving end-of-life care were excluded. Once written consent from the care home manager had been received, staff at the home assisted the research team in identifying eligible participants by searching residents' notes to determine a diagnosis of stroke or TIA. If required, residents' general practitioners were contacted to confirm a diagnosis of stroke or TIA. Eligible participants (or family members, if appropriate) were approached by a member of the research team and given a full explanation of the study. A study information pack, which included details about the intervention and treatment allocation, was left with prospective participants or family members. A second visit to the care home was made by an assessor who collected written informed consent. As outlined in the Mental Capacity Act 2005 (Great Britain. *Mental Capacity Act 2005*. London: The Stationery Office; 2005) for residents lacking the capacity to give informed consent, family members could provide consent on a resident's behalf. Following receipt of informed consent, the assessor conducted screening and baseline measures.

Cognitive function and language impairment were assessed during screening; however, the results were not used as exclusion criteria. Residents with cognitive and language impairments were purposefully included as these characteristics are representative of the clinical population, thereby ensuring external validity of trial results. Once all participating residents had completed baseline and screening assessments, the care home was randomised. Care homes with a minimum of one consenting resident were eligible for randomisation.

### Screening measures

At baseline, the Sheffield Screening Test for Acquired Language Disorders was administered along with the Mini-Mental State Examination. The tests provided an indication of the participant's capacity to understand instructions and directly engage in therapy, which informed the research team of whether or not a consultee was required to assist the participant.

### Baseline assessments

The primary measure administered at baseline was the Barthel Index of Activities of Daily Living (BI). Secondary baseline measures included the Rivermead Mobility Index (RMI), Geriatric Depression Scale-15 items (GDS-15), and European Quality of Life-5 Dimensions, three levels (EQ-5D-3L) questionnaire. Proxy data were collected for participants who required consultee assistance. We collected demographic details including age, ethnicity, comorbidities and history of falls.

### Randomisation and masking

Randomisation occurred at the care-home level. To reduce the potential for bias, baseline assessments were recorded prior to randomisation. Once all consenting participants in a care home had been assessed at baseline, the home was randomised. Care homes were stratified according to the type of care provided (nursing or residential) and the location of the TAC. Homes were randomised 1 : 1 and allocated to either the active intervention group or the control group. The randomisation process was administered in Birmingham by the Primary Care Clinical Research and Trials Unit. The allocation sequence was generated by an independent statistician using nQuery Advisor version 7.0 (Statistical Solutions, Saugus, MA, USA). The sequence was generated using randomised blocks (size = 2) within strata and concealed from the research team. Once notification had been received that a care home was ready to be randomised, the strata data for the home were logged and the allocation was revealed to the study co-ordinator. Allocation information was then disclosed by the co-ordinator to the care home manager and the site therapist. Site allocation was concealed from the independent assessors, who were specifically trained in administering all primary and secondary outcome measures. Assessors were allocated to specific sites and conducted all the measures in their designated homes. It was not possible to mask allocation from treating therapists or residents.

### Intervention and control

In the active intervention, an OT package was delivered by qualified therapists and assistants to both the individual residents and the care home staff. The OT package for residents was targeted towards maintaining abilities in functional activity; in particular, personal activities of daily living (ADL) such as feeding, dressing, toileting, transferring and mobilising. This OT package followed a patient-centred goal-setting approach. Agreed goals of therapy (within the framework of the care home) were established between the resident and the therapist. The frequency and duration of therapy sessions were dependent on the agreed goals of therapy, and therapists had one-to-one contact with each participant for a period of up to 3 months.

Residents' allocated to the intervention received task-specific training, guidance and supervision to promote and support safe practice of personal ADL. The progress of the intervention was closely monitored by the therapist, and if necessary the goals of therapy were modified accordingly. To assess compliance, the dose and focus of the intervention for each resident was documented in a treatment log. When necessary, adaptive equipment was provided (e.g. adaptive cutlery), the resident's environment was altered slightly (e.g. installing bed levers) and minor alterations were made to the care home (e.g. providing raised toilet seats). In cases when a resident's environment was altered or adaptive equipment introduced, participants and care home staff were given relevant task-specific training. Any enabling features introduced to the residents' environment were not removed at the end of the intervention.

Staff in care homes allocated to the intervention received a group workshop, and personalised training for individual staff where necessary. Training focused on facilitating functional activity, mobility and the use of adaptive equipment relevant to residents with disabilities.

Residents in homes allocated to the control group received their usual care. Critically, this did not include an OT component. Staff in care homes allocated to the control arm received training once the study was completed.

### Outcome measures

The primary outcome measure was the BI score at 3 months after randomisation. The BI assesses dependency in 10 categories of self-care: feeding, grooming, transferring from bed to chair, toileting, washing, walking indoors, continence of urine, continence of faeces, dressing and use of stairs.

An increase of 2 points in the BI score was identified as the minimal clinically important difference. Secondary outcome measures included the RMI, the GDS-15 and the EQ-5D-3L. All measures were administered at 3-, 6- and 12-month time points.

### Sample size

This sample size calculation was based on data obtained in several pilot trials. In order to observe a clinically significant 2-point increase in the mean BI score at 3 months using a 1 : 1 randomisation allocation ratio, it was estimated that a sample size of 330 participants in each randomisation arm was required. This estimate was based on a standard deviation (SD) of 3.7 and an intracluster correlation coefficient (ICC) of 0.4 with 90% power at the 5% significance level. Assuming an attrition rate of 26%, with 10 eligible residents recruited per home, it was predicted that 45 care homes were required in each arm of the study ( $n = 900$  residents). The required sample size quoted in the original application was 840 residents from 84 care homes; however, this figure was amended at the start of the trial. The original figure of 840 was not sufficiently inflated for attrition.

### Economic evaluation

To assess economic viability of the OT package we conducted a within-trial cost–utility analysis. Costs were assessed from a NHS and Personal Social Services perspective, and outcomes were based on the EQ-5D-3L. In the base case, a complete case analysis was undertaken in order to estimate the mean incremental cost per QALY gain for the OTCH programme, in relation to a threshold of £20,000–30,000 per QALY. Sensitivity analysis assessed the robustness of conclusions to different assumptions in relation to the inclusion of high-cost participants, a more societal perspective and multiple imputations.

### Results

Participating care homes were randomised between 4 May 2010 and 28 February 2012. Recruitment exceeded the target. Additional care homes were recruited because the mean cluster size was lower than predicted but was comparable between treatment arms. A total of 1042 participants, from 228 care homes (114 homes in each condition), consented. No additional participants joined the trial following randomisation. According to the patient-centred goal-setting approach 23,683 out of 103,443 minutes (23%) of therapy time was spent on individual assessment, 50,188 out of 103,443 minutes (49%) on communication, 7295 out of 103,443 minutes (7%) on ADL training, 8415 out of 103,443 minutes (8%) on mobility training, 7681 out of 103,443 minutes (7%) on equipment and seating posture and 6181 out of 103,443 minutes (6%) on treating specific impairments.

Baseline BI data for the primary outcome were recorded from 99% of participants. Over 70% of all participants were graded as severe on the BI. BI severity was balanced between treatment arms. During the intervention 2538 therapy visits were made to 498 residents (mean 5.1 residents, SD 3.04 residents). Total therapy time was 1724 hours and median session duration was 30 minutes (interquartile range 15–60 minutes). Retention of care homes was high, with 204 out of 228 (89%) of homes providing data up to the final 12-month assessment. Of the 1042 participants, 313 (30%) died during the 12-month trial period. Prior to the primary outcome at 3 months, 64 out of 568 (11%) participants died in the intervention arm and 52 out of 474 (11%) died in the control arm. No adverse events attributable to the intervention were recorded.

Of the participants alive at 3 months, the BI was completed by 479 out of 504 (95%) in the intervention arm and 391 out of 422 (93%) in the control arm. No statistically or clinically significant differences were observed between groups for the BI at 3 months. The adjusted mean difference in BI score between groups was 0.19 points higher in the intervention arm [95% confidence interval (CI) –0.33 to 0.70;  $p = 0.48$ ; adjusted ICC 0.09]. Furthermore, no significant differences were observed in the analyses of the secondary outcome measures at 3 months that assessed mobility (mean difference in RMI of 0.02 units, 95% CI –0.28 to 0.31 units;  $p = 0.90$ ), mood (mean difference in GDS-15 of –0.21 units, 95% CI –0.76 to 0.33 units;  $p = 0.44$ ) and HRQoL (mean difference in EQ-5D-3L utility scores of 0.01, 95% CI –0.04 to 0.06;  $p = 0.65$ ). Similarly, at the 6- and 12-month end points, no significant differences were observed between groups across all outcome measures.

### Economic outcomes

In the base-case analysis, the mean incremental cost of the OTCH intervention was £438.78 (95% CI –£360.89 to £1238.46) and the incremental QALY gain was 0.009 (95% CI –0.030 to 0.048), giving an incremental cost of £49,825 per QALY. OT did not lead to any reduction in health-care expenditure in the active intervention participants, and the quality-of-life improvement over usual care was negligible. Sensitivity analyses supported these conclusions.

### Discussion

The results of this large cluster randomised trial report neutral findings. The personalised, 3-month course of OT intervention did not have a clinically significant impact on the abilities of older stroke survivors residing in care homes to engage in self-care activities more independently, according to the results of the BI. We also found no evidence of a significant influence of the intervention on any secondary outcome measures. The OT package was not estimated to constitute a cost-effective use of scarce NHS resources.

The majority of participants were graded as severe on the BI at baseline. This level of physical frailty may have limited residents' capacity to engage in therapy. However, the large sample population is representative of the UK care home population with regard to age, sex balance and levels of dependence as a result of stroke-related disabilities.

### Conclusion

We did not find evidence to suggest that a 3-month OT package designed for an older care home population with stroke-related disabilities is clinically beneficial, or that it provides a cost-effective use of resources.

### Future work

Further research into the effectiveness of environmental adaptations and equipment in promoting independence is required. Changing or adapting the environment rather than trying to retrain the individual resident may be a more effective approach.

### Trial registration

This trial was registered as ISRCTN00757750.

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