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Individual Patient Data Meta-Analysis of Randomized Controlled Trials of Community Occupational Therapy for Stroke Patients

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Background and Purpose—Trials of occupational therapy for stroke patients living in the community have varied in their findings. It is unclear why these discrepancies have occurred.

Methods—Trials were identified from searches of the Cochrane Library and other sources. The primary outcome measure was the Nottingham Extended Activities of Daily Living (NEADL) score at the end of intervention. Secondary outcome measures included the Barthel Index or the Rivermead ADL (Personal ADL), General Health Questionnaire (GHQ), Nottingham Leisure Questionnaire (NLQ), and death. Data were analyzed using linear or logistic regression with a random effect for trial and adjustment for age, gender, baseline dependency, and method of follow-up. Subgroup analyses compared any occupational therapy intervention with control.

Results—We included 8 single-blind randomized controlled trials incorporating 1143 patients. Occupational therapy was associated with higher NEADL scores at the end of intervention (weighted mean difference [WMD], 1.30 points, 95% confidence intervals [CI], 0.47 to 2.13) and higher leisure scores at the end of intervention (WMD, 1.51 points; 95% CI, 0.24 to 2.79). Occupational therapy emphasizing activities of daily living (ADL) was associated with improved end of intervention NEADL (WMD, 1.61 points; 95% CI, 0.72 to 2.49) and personal activities of daily living (odds ratio [OR], 0.65; 95% CI, 0.46 to 0.91), but not NLQ. Leisure-based occupational therapy improved end of intervention NLQ (WMD, 1.96 points; 95% CI, 0.27 to 3.66) but not NEADL or PADL.

Conclusions—Community occupational therapy significantly improved personal and extended activities of daily living and leisure activity in patients with stroke. Better outcomes were found with targeted interventions. (*Stroke*. 2004;35:2226-2232.)

Key Words: community health services ■ occupational therapy ■ rehabilitation

Occupational therapy (OT) is an essential component in the rehabilitation of stroke patients and is primarily concerned with the re-ablement and re-settlement of patients into their chosen home environment. In recent years, there has been a greater emphasis in providing rehabilitation to patients in their own community setting. Consequently, several community OT studies have been conducted with the purpose of evaluating the effectiveness of such provision to stroke patients.

In general, 2 OT approaches have been tested. Firstly, several randomized controlled trials have investigated the provision of intervention based on activities of daily living (ADL).¹⁻⁵ Intervention in these trials encouraged patients to participate in personal activities of daily living (PADL) such

as washing, dressing, feeding, and bathing. Emphasis was also placed on extended activities of daily living (EADL), for example, outdoor mobility, kitchen tasks, and traveling on public transport. The findings from these trials have generally suggested that intervention given by an occupational therapist was beneficial in reducing activity limitation and may also reduce caretaker strain.

Other trials of OT^{6,7} have evaluated the effect of leisure therapy, which aimed to improve leisure participation, on a similar study population, but findings were conflicting. More recently, a large multicenter trial (TOTAL)⁸ documented that neither ADL nor leisure-based interventions were helpful in reducing levels of activity limitation or improving leisure participation or mood. The findings from TOTAL raised

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Conflict of interest: Lead investigators for all identified community occupational therapy trials have made significant contributions to the design, conduct, and interpretation of this study.

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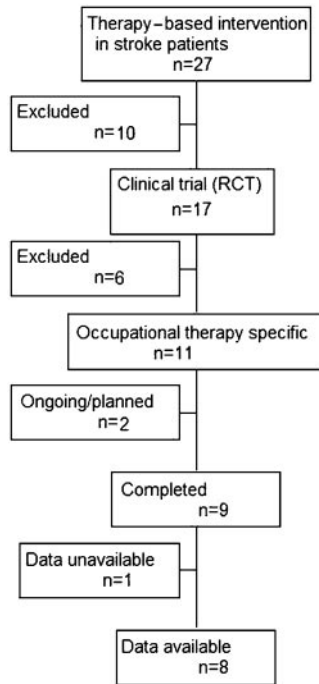


Figure 1. Flow diagram for search strategy.

considerable doubt over the efficacy of providing an OT service to stroke patients in the community. In these circumstances, a meta-analysis of combined data can be useful to estimate, more reliably, the overall effect of community OT interventions and to explore heterogeneity of results. Most clinical trials of rehabilitation after stroke are small and therefore relatively underpowered; meta-analysis allows statistical aggregation of all relevant trials, thereby improving the power of the analysis. A meta-analysis of OT using data from the literature has already been published.⁹ This large review, which aimed to determine whether OT interventions improve outcome for stroke patients, identified a small but significant effect size for the efficacy of comprehensive OT on self-care, extended ADL, and social participation. Our article has a more specific focus and aims to address the efficacy of community OT using individual patient data from randomized controlled trials. The benefits of conducting a meta-analysis based on individual patient data as opposed to

group data are that it can facilitate subgroup analyses and provide a more balanced interpretation and wider endorsement of the results.¹⁰

Materials and Methods

We adhered to the methodological principles of individual patient data meta-analysis as given by the Cochrane Collaboration Working Group on Individual Patient Data Meta-Analysis.¹⁰ We also adhered to the QUOROM statement (Appendix).

Trial Identification and Selection

A comprehensive literature search was conducted to ensure that all possible randomized controlled trials, whether published or unpublished, were identified for the analysis. Two of the authors (M.W., J.L.-B.) judged the eligibility for inclusion. We included all trials in which a home-based OT intervention was provided to patients with a clinical diagnosis of stroke. We included patients who lived in their own home or were residing in a nursing or residential home.

We used a search strategy developed by the Stroke Group of the Cochrane collaboration to identify all eligible trials.¹¹ We searched the Cochrane Stroke Group Trials Register (last searched November 2003) plus the following electronic databases: The Cochrane Library (Issue 4, 2003), MEDLINE (1966 to November 2003), EMBASE (1980 to November 2003), CINAHL (1982 to November 2003), PsycINFO (1967 to November 2003), AMED (1985 to November 2003), Wilson Social Sciences Abstracts (1984 to November 2003), and Science Citation Index and Social Sciences Citation Index (1981 to November 2003). Other strategies to ensure identification of all potentially relevant trials included scanning reference lists of relevant articles, original papers, and personal communication. No restriction on language was made. Abstracts from national and international OT conferences were hand-searched. The library at the College of Occupational Therapy was searched for relevant theses and dissertations. The methodological quality of each trial was assessed based on the procedure of randomization, concealment of allocation, and evidence of masked outcome assessments, using recognized criteria.¹²

Data Management

The contact trialist was identified and invited to collaborate in the project. Trialists provided data on computer disk, e-mail attachments, or in paper format.

An electronic database (SAS for Windows, Version 8.02; SAS Institute Inc) was compiled consisting of data from individual patients in all eligible trials. The data included demographic data (age and gender), dependency ADL score at baseline, receiving daily attention from a caretaker, living alone, information on type of intervention (ADL therapy, leisure therapy, routine care, intensity and duration), outcome measures (Nottingham Extended ADL [NEADL], Barthel Index [BI], Rivermead ADL, General Health

TABLE 1. Methodological Quality of Trial

Trial, Year of Publication	Type of Study	Concealment to Allocation	Method of Randomization	Blinded Outcome Assessment/Assessor
Turton, 1990	RCT	B	Quasi, block randomization	Unclear
Jongbloed, 1991	RCT	B	Unclear	Yes
Corr, 1995	RCT	A	Opaque, sealed envelopes	Yes
Drummond, 1995	RCT	A	Numbered opaque, sealed envelopes	Yes
Walker, 1996	Crossover	A	Numbered opaque, sealed envelopes	Yes
Logan, 1997	RCT	A	Numbered opaque, sealed envelopes	Yes
Walker, 1999	RCT	A	Numbered opaque, sealed envelopes	Yes
Gilbertson, 2000	RCT	A	Numbered opaque, sealed envelopes	Yes
Parker, 2001	RCT	A	Central randomization by telephone	Yes

A indicates low risk of bias; B, moderate risk of bias; C, high risk of bias.

TABLE 2. Patient Demographics and Characteristics at Baseline by Trial

Trial, Year of Publication	N of Patients	Gender, Male (%)	Dependent Patients* (%)	Age, Mean (SD)	Intervention	Intervention Length	Method of Follow-Up (at End of Intervention)	Intervention Assessment (mo)	End of Trial Assessment (mo)
Turton, 1990	22	12 (54.4)	—	58.5 (10.0)	ADL	min 8 wk	Assessor	2	12
Jongbloed, 1991	40	27 (71.1)	5 (13.5)	68.8 (10.6)	Leisure	5 sessions	Postal	1.25	4.5
Corr, 1995	110	41 (37.3)	51 (52.6)	75.5 (9.0)	ADL	up to 6 mo	—	—	12
Drummond, 1995	65	37 (56.9)	62 (95.4)	66.0 (11.2)	ADL or leisure	min 10 sessions	Assessor	3	6
Walker, 1996	30	16 (53.3)	22 (73.3)	68.1 (9.4)	ADL	12 wk	Assessor	3	6
Logan, 1997	111	56 (50.5)	—	72.4 (11.0)	ADL	6 wk	Postal	3	6
Walker, 1999	185	94 (50.8)	51 (27.6)	68.1 (9.4)	ADL	up to 5 mo	Assessor	6	12
Gilbertson, 2000	138	62 (44.9)	36 (26.1)	69.0 (12.0)	ADL	6 wk	Assessor	2	6
Parker, 2001	466	269 (57.7)	105 (22.6)	71.0 (10.3)	ADL or leisure	min 10 sessions	Postal	6	12

*Dependent patients are categorized either by Barthel Index <16 or by Rivermead ADL <10 at randomization.
— indicates data not recorded; min, minimum.

Questionnaire [GHQ], Nottingham Leisure Questionnaire [NLQ], timing, and method of follow-up [postal or independent assessor]). Data were checked for completeness and for consistency with published reports.

Data Analysis

Data for the NEADL scale, GHQ, and the NLQ were each transformed to a consistent scoring scale before analysis, using individual items. The primary outcome measure was the NEADL assessed at the end of the intervention phase. Secondary outcome measures included the NEADL at end of the trial, personal ADL (as measured by the BI or Rivermead ADL), GHQ, NLQ, and death, each at the end of intervention and end of trial.

Continuous outcome measures (NEADL and NLQ) and dichotomous outcome measures (death, dependency [BI <16, Rivermead ADL <10]), GHQ [12-point scale 2/3, 28-point scale 4/5]) were analyzed using linear and logistic regression techniques, respectively, with a random effect for trial. Data are presented either as weighted mean differences (WMD) for continuous outcomes or odds ratios (OR) for dichotomous outcomes, with 95% confidence intervals (CI). Heterogeneity was assessed and quantified using methodology and criteria as described by Higgins et al.¹³ Publication bias was assessed using Egger's Asymmetry test.¹⁴ In multivariate analyses, adjustments were made for the prognostic factors age, gender, baseline dependency, and method of follow-up.

A number of subgroup analyses were performed on NEADL and NLQ at the end of intervention: type of OT (ADL intervention, leisure intervention, control), method of follow-up (independent assessor, postal questionnaire), baseline dependency (dependent, independent), gender, age (65 years or younger, older than 65 years), and side of stroke.

Results

Trial Characteristics

Nine completed trials were identified (Figure 1) that fulfilled the inclusion criteria.^{1–8,15} Seven of the 9 trials were deemed to be of high methodological quality, with evidence of blinded randomization procedures, concealment of allocation, and masked outcome assessments (Table 1).

Of the 9 trials identified, data were obtained from 8. Table 2 summarizes the design features of the trials. Data from the ninth trial (n=22 subjects) were unavailable, having been discarded by the authors.¹⁵ Five of the 8 trials assessed the effect of training in activities of daily living, 1 assessed the effect of leisure therapy alone, and 2 assessed both interven-

tions in parallel groups of patients. The studies enrolled 1143 patients, mean age 71.4 (SD 10.5) years, male 52.7%. Of these, 655 received community OT (481 ADL therapy, 174 leisure therapy) and the remaining 488 received routine care. There were no important differences in baseline characteristics between patients allocated randomly to community OT or control. There was no evidence of missed trials because of publication bias when assessed using Egger's Asymmetry Test ($P=0.52$).¹⁴

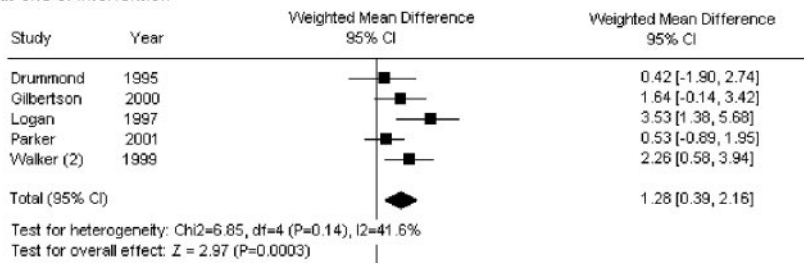
Outcomes

When all of the trials with outcome data were entered into an analysis unadjusted for baseline prognostic factors, patients receiving community OT had an NEADL score, which was higher by 1.28 points (on a 22-point scale) at end of intervention (5 trials; Figure 2), and 0.88 points higher at the end of trial (Table 3), as compared with those randomized to receive usual care. When NEADL was adjusted for baseline prognostic factors (age, $P=0.008$; baseline dependency, $P<0.001$), patients receiving community OT had a score 1.30 points higher at end of intervention and 1.17 points higher at the end of trial, as compared with those randomized to receive usual care (Table 3). Subjects receiving OT had a higher NLQ score, adjusted for age ($P=0.003$), baseline dependency ($P<0.001$), and method of follow-up ($P<0.001$) by 1.51 points (on a 37-item/74-point scale) at end of intervention and 1.80 points at end of trial as compared with usual care (Table 3). A significant 29% reduction in the odds of activity limitation (assessed using the BI or Rivermead ADL) was present at end of intervention (OR, 0.71; 95% CI, 0.52 to 0.98; Table 3). No effects were seen on minor psychiatric status (GHQ) in either patients or caretakers at end of intervention or on death at end of trial (Table 3). The duration and intensity of intervention did not appear to mediate the effect on the primary outcome (data not shown).

Heterogeneity

Moderate levels of heterogeneity were detected for NEADL at the end of intervention ($I^2=41.6\%$) and NLQ at the end of intervention ($I^2=50.0\%$) (Table 3). Sensitivity analyses were performed on the effect of prognostic factors and type of intervention on NEADL and NLQ at end of intervention.

Nottingham Extended Activities of Daily Living at end of intervention



Nottingham Leisure Questionnaire at end of intervention

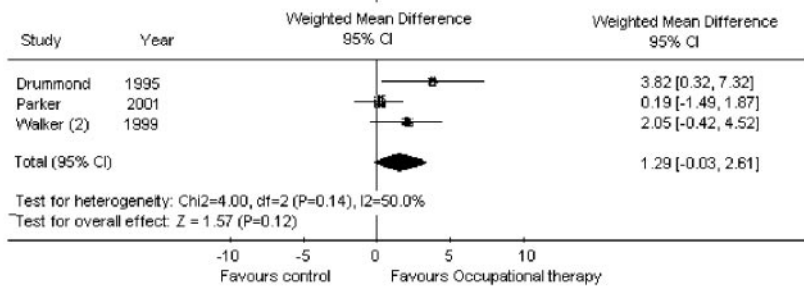


Figure 2. Nottingham Extended Activities of Daily Living and Nottingham Leisure Questionnaire, at the end of the intervention phase (unadjusted data).

Trial Level Characteristics

When assessed by type of intervention (ADL versus leisure therapy), ADL interventions were associated with significant increases in NEADL (WMD, 1.61 points; 95% CI, 0.72 to 2.49; Figure 3) but not in NLQ score at the end of intervention (Figure 4). Leisure therapy was significantly

associated with improved leisure scores (WMD, 1.96 points; 95% CI, 0.27 to 3.66; Figure 4) but not in NEADL scores at the end of intervention (Figure 3). An interaction between leisure score and mode of follow-up (face-to-face interview versus postal questionnaire) was present (P=0.01) (Figure 4).

TABLE 3. Summary of Efficacy Results for Community Occupational Therapy at End of Intervention and End of Trial Phases

Outcome	Data	N of Trials	Weighted Mean Difference (Points)	95% CI	Heterogeneity, I ²
End of Intervention Phase					
NEADL	Unadjusted	5	1.28	0.39, 2.16	41.6%
	Adjusted	4	1.30	0.47, 2.13	
Leisure Questionnaire	Unadjusted	3	1.29	-0.03, 2.61	50.0%
	Adjusted	3	1.51	0.24, 2.79	
End of Trial Phase					
NEADL	Unadjusted	6	0.88	-0.06, 1.81	0%
	Adjusted	5	1.17	0.30, 2.04	
Leisure Questionnaire	Unadjusted	3	1.53	0.10, 2.96	57.2%
	Adjusted	3	1.80	0.41, 3.21	
Outcome	Data	N of Trials	Odds Ratio (Poor Outcome)	95% CI	Heterogeneity, I ²
End of Intervention Phase					
Activities of Daily Living	Unadjusted	5	0.71	0.52, 0.98	22.5%
Patient GHQ	Unadjusted	3	0.76	0.54, 1.07	0%
Carer GHQ	Unadjusted	3	0.76	0.51, 1.15	32.6%
End of Trial Phase					
Activities of Daily Living	Unadjusted	5	0.75	0.55, 1.02	0%
Patient GHQ	Unadjusted	2	1.10	0.74, 1.63	0%
Carer GHQ	Unadjusted	2	1.10	0.69, 1.76	0%
Death	Unadjusted	8	1.02	0.68, 1.55	0%

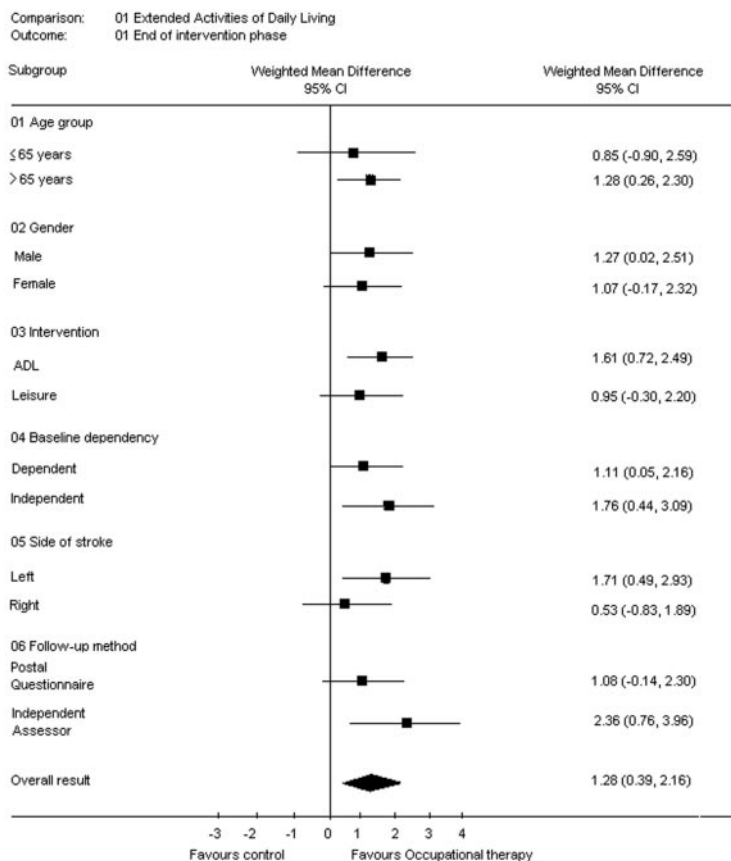


Figure 3. Nottingham Extended Activities of Daily Living at the end of the intervention phase.

Patient Level Characteristics

The effect of community OT on NEADL showed no apparent differences for gender, baseline dependency, or side of stroke (interaction terms all $P > 0.05$). The effect of ADL based intervention on NEADL varied by patient age; older patients appeared to benefit more than younger ones (interaction term between age and intervention, $P = 0.01$). No significant interactions existed between leisure score (NLQ) and any patient level variable; however, patients with lower levels of dependency appeared to benefit more (WMD, 2.86 points; 95% CI, 0.70 to 5.02; Figure 4).

Discussion

The principal finding from this study is that OT for stroke patients living in the community was associated with a higher NEADL score at the end of intervention and end of trial. This indicates that stroke patients were able to perform higher levels of activity as a result of receiving community OT. The magnitude of our intervention effect was 1.3 NEADL points, which would reflect the ability to achieve independence in 1 activity such as walking outdoors, household chores, or traveling on public transport. Independence in any one of these activities would enable the patient to participate in the more demanding activities of daily living, thereby adding to their quality of life. Although we did not have an a priori definition of the amount of change that would constitute a clinically meaningful improvement, we feel an increment of one point may be clinically important. This modest benefit is

in keeping with previously published studies and is not negated by the findings of TOTAL.⁸

The trial by Parker et al may have demonstrated little benefit from community OT for several reasons. The use of postal outcome may have made the findings of TOTAL less open to observer bias, and so it is possible that the smaller effect seen in TOTAL is more genuine than that found in other trials where independent assessments were implemented. However it must be noted that the Nottingham Leisure Questionnaire had not been previously developed or validated for postal use. Another reason why the TOTAL study may have not found a large clinical benefit is that the intervention in TOTAL was administered by clinicians and not research occupational therapists, who may have been less motivated as their daily work, was not contributing to a higher degree. Another possible reason is that the research protocol imposed some restrictions on the type of interventions making their effectiveness less than optimal.

Our findings also suggest that older patients would benefit more from community OT than younger patients. This finding may be simply because older people are likely to have greater activity limitation than younger ones (because of comorbidity such as visual impairment and musculoskeletal disorders) and therefore have more to gain from rehabilitation. Unfortunately, comorbidity could not be explored in the analyses because of insufficient data being recorded in the original trials.

Moderate levels of heterogeneity were found for many of the outcome measures at the end of intervention and sensi-

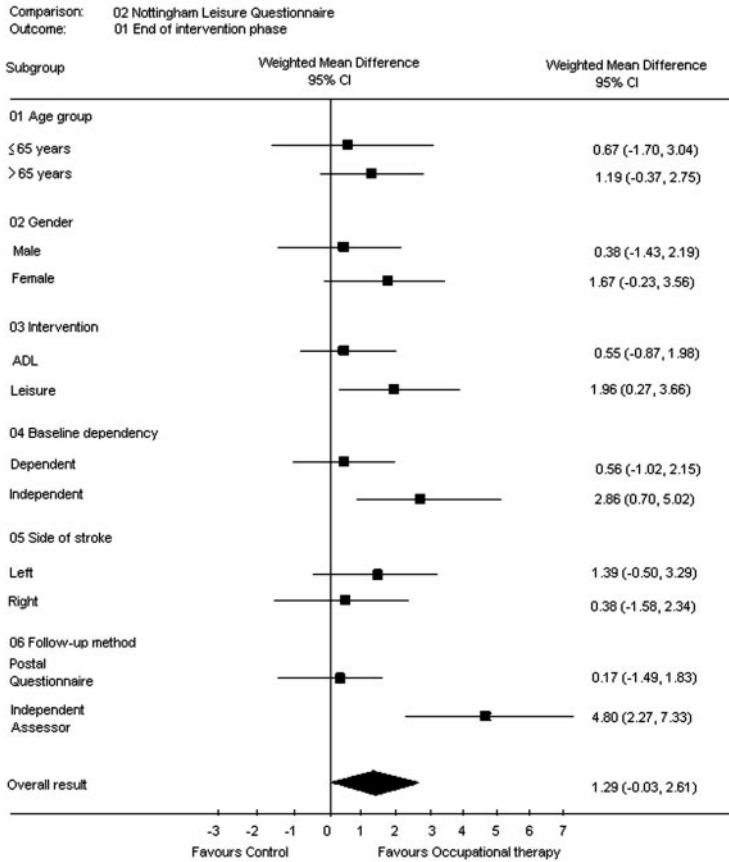


Figure 4. Nottingham Leisure Questionnaire at the end of the intervention phase.

tivity analyses indicated that the benefits of OT were greatest when targeted. OT aimed at influencing ADL appeared to improve personal and extended activities of daily living but not leisure activity. Conversely OT directed at influencing leisure pursuits improved leisure activities but not ADL scores. This observation that the provision of one specific intervention does not generalize to other areas is contrary to the current view held by many clinicians.¹⁶ However, our findings are consistent with other recent stroke rehabilitation trials.^{17,18} The duration and intensity of treatment sessions had little impact on the results, but the power of this analysis was reduced because limited data were available.

OT appeared to be effective in improving NLQ scores in patients who were independent at baseline; however, for the EADL scale, baseline dependency does not alter the benefits of OT.

The method of follow-up appeared to modulate the results when using the NLQ, in which a greater difference in the scores between the intervention and control group was seen in trials using an independent assessor. This may be explained by the fact that the NLQ was not specifically developed or validated for postal use; thereby in this format, it may be open to the introduction of bias. This finding has obvious implications for future studies using the NLQ as an outcome measure.

It is only in the past decade that a research culture has existed within the OT profession and existing evidence is sparse. This analysis of community OT trials included only relatively recent published work, and we identified no old unpublished studies. We used an extensive search strategy

and statistical testing for missing trials was nonsignificant. We therefore feel that we have probably identified all the available data. The unavailable data for 1 of the identified trials,¹⁵ accounted for only 2% of the total data. We therefore feel inclusion of these data would not have significantly altered our findings. We are currently aware of 2 ongoing trials that need to be included in future analyses.

Our findings endorse those found in the earlier published systematic review by Steuljens et al.⁹ However, our article provides more specific information about the relationship between specific interventions (ADL or leisure) and outcomes and shows the first results between patient characteristics and outcome. This information has important implications for service providers, who need to ensure that specific OT interventions are offered to those who would most benefit.

We believe that the findings from our meta-analysis provide a balanced interpretation of the available evidence. There may well be differences between services because of the differences in interventions and settings; in view of this, work now is needed to characterize the necessary conditions for effective and efficient services. However, the provision of OT remains justified on evidence-based grounds, and it would appear that the rehabilitation needs of a substantial number of stroke patients in the community can be met feasibly by OT with measurable and lasting benefits.

Acknowledgments

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Appendix

QUOROM Checklist

Heading	Descriptor	Reported Yes/No	Page Number
Title	Reported as a meta-analysis	yes	1
Abstract			
Structured format		yes	1–2
Objectives	State the clinical question	yes	1
Data sources	State databases	yes	1
Review methods	Selection criteria validity of assessment, data synthesis	yes	1
Results	Characteristics of RCTs, findings, and subgroup analysis	yes	1–2
Conclusion	Main results	yes	2
Introduction	Explicit clinical problem, rationale for review and intervention	yes	3–4
Methods			
Searching	Information sources and any restrictions	yes	5
Selection	Inclusion and exclusion criteria	yes	5
Validity assessment	Criteria and process used	yes	5
Data abstraction	Processes used	yes	5
Study characteristics	Type of study, patient characteristics, details of intervention, how clinical heterogeneity assessed	yes	Table 2
Data synthesis	Primary outcome, handling of data	yes	6–7
Results			
Trial Flow	Meta-analysis profile	yes	Figure 1
Study characteristics	Descriptive data for each trial	yes	Tables 2 and 3
Data synthesis		yes	Tables 2 and 3 Figures 2, 3, 4 Pages 7, 8, 9, 10
Discussion	Summarize key findings, interpret results, describe potential biases, suggest future research agenda	yes	10–13

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