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A multicentre randomized controlled trial of leisure therapy and conventional occupational therapy after stroke

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Objective: To evaluate the effects of leisure therapy and conventional occupational therapy (OT) on the mood, leisure participation and independence in activities of daily living (ADL) of stroke patients 6 and 12 months after hospital discharge.
Design: Multicentre randomized controlled trial.
Setting and participants: Four hundred and sixty-six stroke patients from five UK centres.
Main outcome measures: The General Health Questionnaire (12 item), the Nottingham Extended ADL Scale and the Nottingham Leisure Questionnaire, assessed by post, with telephone clarification.
Results: Four hundred and forty (94%) and 426 (91%) subjects were alive at 6 and 12 months, respectively. Three hundred and seventy-four (85% of survivors) and 311 (78% of survivors) responded at 6 and 12 month follow-up respectively. At six months and compared to the control group, those allocated to leisure therapy had nonsignificantly better GHQ scores (–1.2: 95% CI –2.9, +0.5), leisure scores (+0.7, 95% CI –1.1, +2.5) and Extended ADL scores (+0.4: 95% CI –3.8, +4.5): the ADL group had nonsignificantly better GHQ scores (–0.1: 95% CI –1.8, +1.7) and Extended ADL scores (+1.4: 95% CI –2.9, +5.6) and nonsignificantly worse leisure scores (–0.3: 95% CI –2.1, +1.6). The results at 12 months were similar.
Conclusion: In contrast to the findings of previous smaller trials, neither of the additional OT treatments showed a clear beneficial effect on mood, leisure activity or independence in ADL measured at 6 or 12 months.

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Introduction

The effects of occupational therapy given to stroke patients have been examined in several small randomized trials.[1–5] In these trials the major focus of the intervention has been reducing physical dependence, and consequently the principal outcome measures have been based on performance in activities of daily living (ADL). This reflects the priority given to physical recovery in current clinical practice, but does not address the psychosocial problems that are common among stroke survivors and their carers.[6]

An alternative approach is to make the increased performance of leisure activities both the aim of the therapy and the basis of the intervention.[7] Leisure is a valid aim of therapy as it is known to be strongly related to overall life satisfaction.[8] Stroke patients are also known to have a markedly reduced level of leisure participation.[9] Interventions based on leisure fall naturally within the remit of occupational therapy, which aims to promote recovery through activity. The evidence from the small trials of leisure rehabilitation carried out to date has been inconclusive.[10–12] One of these, the Nottingham Leisure Study, which was a controlled trial, showed that leisure therapy improved both leisure participation and ADL ability whereas ADL-based therapy only improved ADL performance.[10,11] This was a small study, with only 20 patients in each group and so has limited generalizability.

We wished to test whether leisure-based intervention was better than ADL-based therapy at improving the mood, leisure participation and independence in ADL of stroke patients, and whether either was better than no additional input.

Methods

Participants

Recruitment to TOTAL (Trial of Occupational Therapy and Leisure) was conducted at five sites: Aintree Fazakerley Hospital, Bristol Southmead Hospital, Edinburgh Western General Hospital, Glasgow Royal Infirmary and Nottingham University Hospital. Sample size calculations indicated that 450 patients would give 80% power to detect a 2.5-point difference between groups on the General Health Questionnaire (12 item, 36 point),[13] and a 6-point difference on the Nottingham Extended ADL Scale (66 point),[14] with significance level 5%. At all sites except Glasgow, all inpatients with stroke (WHO definition[15]) during the study period were registered and assessed for inclusion. In Glasgow, all patients with stroke attending an outpatient stroke clinic during the study period were registered. Date of birth, sex, marital status, date of stroke and side of weakness were recorded for all registered patients. At discharge from inpatient care (or, in Glasgow, during the stroke clinic visit) the following exclusion criteria were applied:

1) Residence outside the catchment area of the local occupational therapy service
2) Discharge to residential or nursing home
3) Insufficient English understood in the patient's home for postal questionnaires to be completed
4) Documented history of dementia prior to stroke
5) Patient unable to tolerate interventions, for example because of other illness
6) (Glasgow only) Stroke more than six months before clinic visit.

Written consent was obtained and baseline information collected comprising date of discharge, current Barthel score (assessed by occupational therapist at each site),[16] pre-stroke Oxford Handicap Score[17] and main co-resident after discharge.

Random allocation and masking

The COSTAR (Collaborative Stroke Audit and Research) telephone randomization service was used to allocate patients to one of three groups: leisure, ADL and control. Randomization was stratified by centre and by a five-level composite measure of prognosis (level 1: pre-stroke Oxford Handicap score ≥3 or age ≥85; level 2: Barthel >16 and time since stroke onset <21 days; level 3: Barthel >16 and time since stroke onset ≥21 days; level 4: Barthel ≤16 and time since stroke onset <21 days; level 5: Barthel ≤16 and time since stroke onset ≥21 days).

Masking to individual allocation was maintained for the trial personnel until all outcome

information had been collected. Ethical approval was obtained at each participating centre.

Interventions

Participants allocated to the two treatment groups received occupational therapy interventions at home for up to six months after recruitment. The protocol specified a minimum of 10 sessions lasting not less than 30 minutes each. The treatment goals set in the ADL group were in terms of improving independence in self-care tasks and therefore treatment involved practising these tasks (such as preparing a meal or walking outdoors). For the leisure group, goals were set in terms of leisure activity and so interventions included practising the leisure tasks as well as any ADL tasks necessary to achieve the leisure objective. The treating therapist used a standard form to record brief details of date and duration of sessions. Participants allocated to the control group received no occupational therapy treatment within the trial. All participants were eligible for any existing rehabilitation services provided in their area, such as day hospital visits.

Outcome measures

The principal outcome point was at six months after randomization, but outcomes were also assessed at 12 months to examine the persistence of any effect if detected. Therefore, at these times the trial co-ordinating centre in Nottingham obtained information on death or change of address and sent surviving participants a postal follow-up questionnaire. The main outcome measures of the study were:

- For mood, the General Health Questionnaire (GHQ).[13] A widely used measure of emotional health. We chose the 12-item since brevity and lack of direct reference to suicidal thoughts were considered advantageous for postal assessment. With each item scored 0–3 the total range is 0–36: high scores denote greater emotional distress.
- For leisure activity, the Nottingham Leisure Questionnaire (NLQ).[18,19] A 30-item, 60-point scale, developed in stroke patients: higher scores denote a greater number of activities performed and/or greater frequency of activity.
- For independence in ADL, the Nottingham Extended ADL Scale (NEADL).[14] A widely used 22-item, 66-point measure of instrumental ADL, e.g. outdoor mobility, household tasks and leisure pursuits. Higher scores denote greater independence.

In addition to the main outcome scales, the questionnaires contained:

- The International Stroke Trial outcome questions[20]
- The Oxford Handicap Scale[17] – a 6-point composite rating of symptoms, disability and dependency: lower scores denote less dependency
- The Barthel ADL Index[16] – a 10-item, 20-point scale of self-care ADL ability: higher scores denote greater independence
- The London Handicap Scale (LHS)[21] – a six-section 0–100 scale of handicap: lower scores denote greater handicap.

A separate carer questionnaire included items on the level of care provided and the GHQ-12. Telephone and postal reminders were given if the outcome questionnaire was not returned, and recruiting centres were asked for help in achieving follow-up if necessary. Patients returning a questionnaire with any missing or unclear responses were contacted by telephone by a trial secretary masked to treatment allocation for clarification.

Statistical methods

For each outcome measure the analysis was by intention-to-treat, excluding nonresponders. The effect of treatment on outcome scores was assessed using multiple linear regression analysis.

Results

Recruitment took place between July 1996 and June 1998, with individual centres recruiting for at least 15 months of this period. In total 1750 patients were registered and 466 recruited as shown in the trial profile (Figure 1). The number of recruits at each centre was: Aintree 150, Bristol 60, Edinburgh 50, Glasgow 23, Nottingham 183. A summary of baseline characteristics for the three randomized groups is shown in Table 1: the groups were well-balanced on these factors.

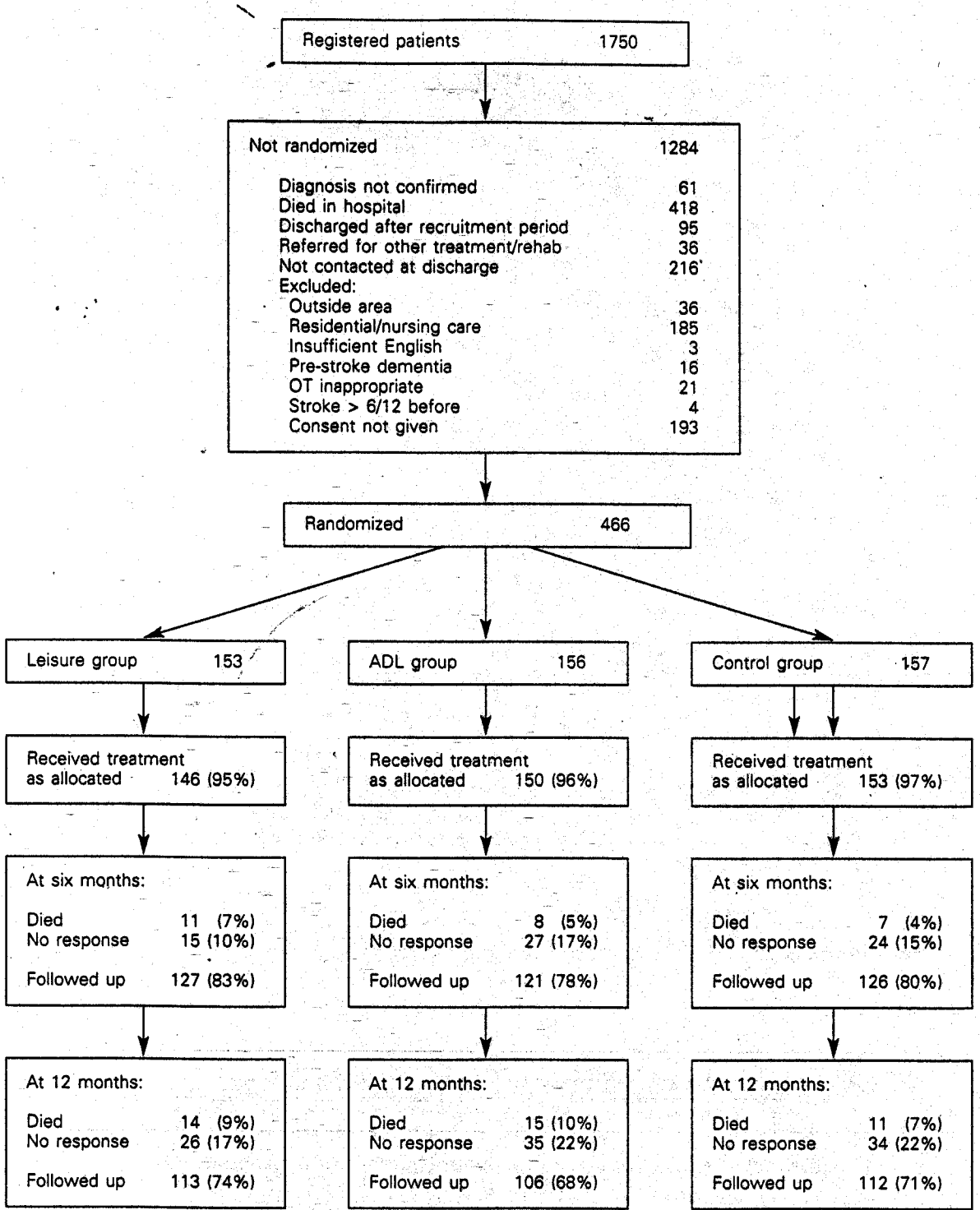

Figure 1 Flow of patients through study.

Table 1 Patient characteristics at baseline

	Leisure (n = 153)		ADL (n = 156)		Control (n = 157)	
	Median	(IQR)	Median	(IQR)	Median	(IQR)
Age	72	(65–79)	71	(66–78)	72	(65–78)
Barthel score	18	(15–19)	18	(16–20)	18	(16–19)
Length of stay, days[a]	23	(11–62)	26	(12–63)	30	(15–58)
	n	(%)	*n*	(%)	*n*	(%)
Sex						
Male	88	(58)	97	(62)	84	(54)
Female	65	(42)	59	(38)	73	(46)
Side of body affected						
Right	71	(46)	75	(48)	67	(43)
Left	69	(45)	65	(42)	74	(47)
Neither/bilateral	13	(8)	16	(10)	16	(10)
Pre-stroke Oxford Handicap Score						
0	79	(52)	85	(54)	77	(49)
1–2	61	(40)	62	(40)	64	(41)
3–4	13	(8)	9	(6)	14	(9)
Not known	0	(0)	0	(0)	2	(1)
Marital status						
Married	98	(64)	89	(57)	90	(57)
Widowed/sep	46	(30)	52	(33)	56	(36)
Single	9	(6)	15	(10)	11	(7)
Main co-resident						
Spouse	94	(61)	81	(52)	82	(52)
Living alone	44	(29)	55	(35)	49	(31)
Other	15	(10)	18	(12)	23	(15)
Not known	0	(0)	2	(1)	3	(2)

[a]Counted as zero for Glasgow patients.

The full treatment specified in the protocol (10 or more sessions) was given to 69% of patients in the leisure group and 62% in the ADL group. The mean (median) number of sessions was 8.5 (10) in each group, and the mean (median) duration of sessions was 59 (60) minutes for leisure and 52 (50) minutes for ADL. Seven leisure group patients (5%) and six ADL group patients (4%) received no treatment due to death, illness, unwillingness or error. Three control group patients received between one and four sessions of ADL treatment because in the clinical judgement of the occupational therapist there was an over-riding need; one control group patient received 11 sessions of leisure treatment in error.

Findings at six months

Overall, 440 patients (94%) were alive at six months, and 374 (85% of survivors) responded to the postal questionnaire. Figure 1 summarizes the response by treatment group. The proportion responding was similar in each group, and there were no significant differences in baseline characteristics between responders and nonresponders. The most common reasons for nonresponse at six months were overt or implicit refusal (29, 44% of nonresponders) and illness (10, 15%): no reason was ascertained for 19 (29%). The proportion of patients receiving help from a carer in completing the questionnaire was: leisure 40%, ADL 35%, control 33%. Carer questionnaires were completed for 274 participants (73% of responders).

Mean scores and standard deviations at six months for the measures of mood, leisure activity, independence in ADL, handicap, and mood

of carer are presented in Figure 2: the three groups had similar scores on all these measures. Multiple linear regression was used to estimate the effects of the additional treatments relative to control on each measure. All models were adjusted for the two stratification factors, centre and composite prognostic measure. The estimates and 95% confidence intervals are shown numerically and graphically in Figure 2. For leisure treatment, all the estimates were in the direction of improvement, as were the estimates for mood and ADL for ADL treatment, but none was significant at the 5% level. Examination of the residuals for each outcome measure showed no serious departures from the model assumptions. The models were refitted adjusting for baseline characteristics: in view of the high degree of initial balance between the groups the effect of adjustment on the estimates was very small, and these results are therefore not presented. Inclusion of interaction terms showed no evidence of differential treatment effects in subgroups defined by centre, baseline disability, age or side affected.

For mood, the groups were also compared on the proportion of patients classified as 'cases' of psychiatric disorder. Using the alternative scoring for the GHQ (responses scored 0,0,1,1: total score ranging from 0 to 12) and the recommended cut-off threshold of 2/3, the proportions of 'cases' were: leisure 62%, ADL 64%, control 67% (chi-square, (2 df) = 0.64, $p = 0.73$).

The Barthel score was not analysed by linear regression because of the extreme ceiling effect in this group of patients. Summary statistics for this and for the remaining outcome measures (Oxford Handicap Score and International Stroke Trial questions) are shown in Table 2:

Outcome	Range worst–best	Group	Mean (SD)	Estimate versus control (95% CI)
Mood (GHQ)	36-0	control	17.3 (6.9)	
		leisure	16.0 (6.9)	-1.2 (-2.9,+0.5)
		ADL	17.3 (7.1)	-0.1 (-1.8,+1.7)
Leisure (NLQ)	0-60	control	15.2 (7.7)	
		leisure	15.9 (6.9)	+0.7 (-1.1,+2.5)
		ADL	15.0 (8.0)	-0.3 (-2.1,+1.6)
ADL (NEADL)	0-66	Control	33.1 (18.9)	
		Leisure	33.3 (18.4)	+0.4 (-3.8, +4.5)
		ADL	34.7 (18.4)	+1.4 (-2.9, +5.6)
Handicap (LHS)	0-100	Control	63.5 (17.9)	
		Leisure	64.5 (14.7)	+0.9 (-3.3,+5.0)
		ADL	62.7 (17.7)	-1.1 (-5.3,+3.2)
Carer mood (GHQ)	36-0	Control	14.2 (5.8)	
		Leisure	13.4 (5.7)	-0.8 (-2.5,+0.9)
		ADL	14.2 (5.9)	0.0 (-1.7,+1.8)

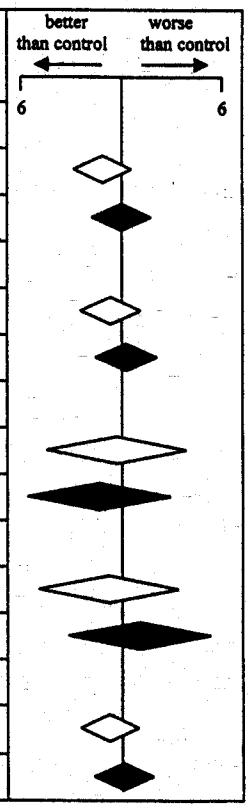

Figure 2 Effects of leisure and ADL treatments compared with control at six months. Open diamond, leisure versus control; shaded diamond, ACL versus control.

Table 2 Subsidiary outcomes at 6 and 12 months

Outcome measure	Leisure (n = 153)		ADL (n = 156)		Control (n = 157)	
	Median	(IQR)	Median	(IQR)	Median	(IQR)
Barthel score						
6 months	17	(14–19)	18	(15–20)	17	(15–20)
12 months	17	(14–18)	17	(14–19)	17	(14–20)
	n	(%)	n	(%)	n	(%)
Has the stroke left you with any problems?						
Yes – 6 months	104	(83)	102	(86)	103	(82)
Yes – 12 months	94	(85)	86	(82)	85	(80)
Do you need help from anybody with everyday activities?						
Yes – 6 months	83	(66)	79	(66)	85	(68)
Yes – 12 months	79	(72)	66	(62)	66	(62)
Oxford Handicap Score – 6 months						
0–1 (best)	34	(27)	27	(23)	28	(23)
2	25	(20)	28	(24)	24	(19)
3	44	(35)	40	(34)	39	(31)
4–5 (worst)	21	(17)	24	(20)	33	(27)
Oxford Handicap Score – 12 months						
0–1 (best)	27	(25)	30	(29)	31	(30)
2	20	(18)	22	(21)	19	(18)
3	37	(34)	31	(30)	31	(30)
4–5 (worst)	25	(23)	21	(20)	24	(23)

there were no significant differences between groups on any of these (Kruskal-Wallis, chi-square $p > 0.3$).

Findings at 12 months

Four hundred and twenty-six patients were alive at 12 months, of whom 331 (78%) responded at 12 months (Figure 1). No significant differences between the groups on any of the outcome measures were seen at 12 months. These results may be found in Table 2 and Figure 3.

Discussion

We have found no major short- or long-term beneficial effect of the additional leisure or ADL occupational therapy provided in this trial on the mood, ADL ability or leisure participation of stroke patients living in the community. These findings do not confirm those of the Nottingham Leisure study.[10] They also conflict with a study that showed occupational therapy to improve ADL ability in stroke patients not admitted to hospital.[3]

One explanation for this discrepancy could be the design of the trials used to assess effectiveness. A weakness of TOTAL was that outcome data were not obtained on all surviving patients. However there were no differences in known baseline factors between responders and nonresponders, and there is therefore no evidence of significant nonresponse bias. We used central telephone randomization and postal assessment

Clinical messages

- The findings of this trial do not support the routine use of either leisure or ADL-based occupational therapy for stroke patients in the community after discharge from hospital.
- Therapists providing such services should examine whether their interventions are achieving their stated goals.

Outcome	Range worst–best	Group	Mean (SD)	Estimate versus control (95% CI)
Mood (GHQ)	36-0	Control	16.2 (7.4)	
		Leisure	15.4 (7.3)	-0.5 (-2.4,+1.4)
		ADL	16.9 (7.3)	+0.8 (-1.1,+2.8)
Leisure (NLQ)	0-60	Control	15.1 (7.9)	
		Leisure	16.0 (7.5)	+0.9 (-1.1,+3.0)
		ADL	14.9 (8.1)	-0.3 (-2.3,+1.8)
ADL (NEADL)	0-66	Control	33.3 (19.5)	
		Leisure	32.7 (17.8)	-0.2 (-4.7, +4.4)
		ADL	34.1 (19.1)	+0.8 (-3.8, +5.5)
Handicap (LHS)	0-100	Control	64.4 (18.8)	
		Leisure	63.3 (16.3)	-1.5 (-6.2,+3.2)
		ADL	63.3 (18.2)	-1.1 (-6.0,+3.7)
Carer mood (GHQ)	36-0	Control	13.6 (5.2)	
		Leisure	12.4 (6.0)	-0.9 (-2.8,+1.0)
		ADL	14.2 (6.6)	+0.7 (-1.3,+2.7)

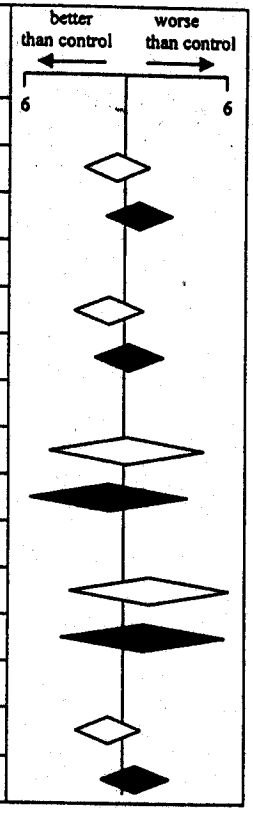

Figure 3 Effects of leisure and ADL treatments at 12 months. Open diamond, leisure versus control; shaded diamond, ACL versus control.

of outcome to avoid allocation and observer bias. Despite attempts to avoid it, observer bias may have influenced the two previously positive trials, both of which used colleagues who did not provide the intervention to assess outcomes.[3,10] For example, an independent assessor who visits the patient at home may be more likely to prompt activities done in therapy to be recorded as activities done independently, and hence the apparent benefit of treatment could be an artefact. We believe that the design of TOTAL makes it at least as reliable as other trials.

Another reason for the discrepancy between TOTAL and previously positive trials may be the nature of the treatment delivered. Not all occupational therapists will make the same interventions, and it is likely that those made in (largely) single-handed, single-centre trials were different in quality from those attempted in TOTAL, a multicentre trial. Interventions made in single-centre trials may not be representative of ordinary clinical practice. On the other hand, although the design of the TOTAL trial was essentially pragmatic, the protocol imposed some restrictions that would not have occurred in normal clinical practice. This might have limited the effectiveness of the interventions. Some TOTAL trial therapists felt they were hampered by the need to maintain a clear distinction between ADL- and leisure-based therapy. They were also required to attempt ten treatment sessions, whether they felt it was really indicated or not, and were thus restricted in the amount of time they could spend with those in whom they would have preferred to spend more time. Nevertheless, we believe that the treatment given in TOTAL was reasonably representative of what might be delivered in ordinary clinical practice. Further analysis of TOTAL and other trials will be needed to examine the relationship between spe-

cific interventions and specific areas of outcome.

Inadequate intensity of treatment in TOTAL could be suggested as another explanation for the lack of a significant effect being observed. Rehabilitation outcomes may improve slightly with increased treatment intensity.[22] The 10 hour-long sessions of leisure or ADL-based therapy used in TOTAL may not have been enough to achieve significant improvements, but this treatment intensity was not materially less than that given in other trials.[1–5] Trials of greater intensity of intervention are probably not warranted until the nature of the interventions and their relationships to outcome are more clearly defined.

Yet another possibility is that the outcome measures chosen were insensitive to real treatment effects. However, we are unlikely to have missed a clinically significant effect of treatment on functional recovery since the Extended ADL scale has been well validated and is widely used, including in other trials of occupational therapy in stroke reporting positive results.[3–5] The GHQ is also widely used but as yet relatively little is known about its responsiveness to this kind of intervention. No trials of occupational therapy in stroke have shown a benefit of therapy upon mood. We did not measure 'patient satisfaction'.

TOTAL was one of the largest trials to date in stroke rehabilitation and so its findings are more likely than smaller trials to be an accurate estimate of the effect of occupational therapy intervention. A systematic overview of all relevant trials in this area would be worthwhile. TOTAL was planned within the COSTAR (Collaborative Stroke Audit and Research) framework.[23] In this framework, several trials of different interventions (classified as either 'social', 'psychological' or 'physical') aimed at reducing post-stroke psychosocial distress have been planned using similar trial methodologies and, importantly, identical trial outcomes measured at similar points in time. This framework will be used to perform a preplanned meta-analysis ('epi-analysis') of the component trials as they are completed.

In addition to further analysis of the results of TOTAL together with those of other trials, detailed analysis of this and other trials is warranted to examine the relationship between specific interventions and specific aspects of outcome. This may lead to the identification of effective and ineffective practices.

Our results do not support the routine use of either leisure or ADL-based occupational therapy for stroke patients in the community after discharge from hospital. Until the exact value of community occupational therapy services for stroke is established, therapists should not assume that their interventions are always effective. Therapists should, at the least, strive to ensure that lasting changes in the patients' behaviour are achieved at the end of treatment.

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Contributors

All named authors contributed to the management, analysis and interpretation of the trial and to drafting or critically revising the paper in conjunction with the TOTAL Study Group. In addition, John Gladman, Avril Drummond, Michael Dewey, Nadina Lincoln and David Barer contributed to the study design, Chris Parker was the overall study co-ordinator and performed the

statistical analyses, and Philippa Logan and Kate Radford contributed to the occupational therapy interventions. John Gladman is guarantor.

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Appendix – TOTAL Study Group

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