Family-led rehabilitation after stroke in India (ATTEND): a randomised controlled trial

*The ATTEND Collaborative Group**

Summary

Background Most people with stroke in India have no access to organised rehabilitation services. The effectiveness of training family members to provide stroke rehabilitation is uncertain. Our primary objective was to determine whether family-led stroke rehabilitation, initiated in hospital and continued at home, would be superior to usual care in a low-resource setting.

Methods The Family-led Rehabilitation after Stroke in India (ATTEND) trial was a prospectively randomised open trial with blinded endpoint done across 14 hospitals in India. Patients aged 18 years or older who had had a stroke within the past month, had residual disability and reasonable expectation of survival, and who had an informal family-nominated caregiver were randomly assigned to intervention or usual care by site coordinators using a secure web-based system with minimisation by site and stroke severity. The family members of participants in the intervention group received additional structured rehabilitation training—including information provision, joint goal setting, carer training, and task-specific training—that was started in hospital and continued at home for up to 2 months. The primary outcome was death or dependency at 6 months, defined by scores 3–6 on the modified Rankin scale (range, 0 [no symptoms] to 6 [death]) as assessed by masked observers. Analyses were by intention to treat. This trial is registered with Clinical Trials Registry-India (CTRI/2013/04/003557), Australian New Zealand Clinical Trials Registry (ACTRN12613000078752), and Universal Trial Number (U1111-1138-6707).

Findings Between Jan 13, 2014, and Feb 12, 2016, 1250 patients were randomly assigned to intervention (n=623) or control (n=627) groups. 32 patients were lost to follow-up (14 intervention, 19 control) and five patients withdrew (two intervention, three control). At 6 months, 285 (47%) of 607 patients in the intervention group and 287 (47%) of 605 controls were dead or dependent (odds ratio 0·98, 95% CI 0·78–1·23, p=0·87). 72 (12%) patients in the intervention group and 86 (14%) in the control group died (p=0·27), and we observed no difference in rehospitalisation (89 [14%] patients in the intervention group *vs* 82 [13%] in the control group; p=0·56). We also found no difference in total non-fatal events (112 events in 82 [13%] intervention patients *vs* 110 events in 79 [13%] control patients; p=0·80).

Interpretation Although task shifting is an attractive solution for health-care sustainability, our results do not support investment in new stroke rehabilitation services that shift tasks to family caregivers, unless new evidence emerges. A future avenue of research should be to investigate the effects of task shifting to health-care assistants or team-based community care.

Funding The National Health and Medical Research Council of Australia.

Published **Online**
June 27, 2017
http://dx.doi.org/10.1016/S0140-6736(17)31447-2

See **Online/Comment**
http://dx.doi.org/10.1016/S0140-6736(17)31489-7

*Members listed at end of paper

Correspondence to:
Prof Richard I Lindley,
The George Institute for Global Health and University of Sydney,
PO Box M201, Camperdown,
NSW 2050, Australia
rlindley@georgeinstitute.org.au

Introduction

Stroke rates are rising in low-income and middle-income countries (LMICs) but services are scarce.[1] Task shifting rehabilitation activities to unpaid caregivers might offer a sustainable alternative to conventional rehabilitation, and provide an affordable strategy to meet the health demands both in high-income countries and LMICs.[2–5] India, with a sixth of the world's population, has only around 35 stroke units, located mainly in urban centres.[6,7] Consequently, most people have no access to specialised stroke care and little access to conventional rehabilitation programmes. Given that LMICs have only about 3% equivalent purchasing power to spend on health care compared with high-income countries, any new model of stroke rehabilitation should be both sustainable and effective.[8,9] Our hypothesis was that family caregiver-delivered rehabilitation would increase independence and survival after stroke unit admission. We report the results of the Family-led Rehabilitation after Stroke in India (ATTEND) trial, which assessed a rehabilitation training programme to deliver family-led rehabilitation after stroke.

Methods

Study design and participants

ATTEND was a prospectively randomised open trial with blinded endpoint (PROBE) done across 14 hospitals in India. Approvals were obtained from the ethics committees of the University of Sydney, Australia, and at each participating hospital. Permission was also obtained from the Health Ministry Screening Committee, New Delhi, India. The trial methods were piloted in Ludhiana (Punjab, India)[10] and the protocol was published before unblinding.[11]

Patients were eligible if they had a family-nominated caregiver (ie, an informal family caregiver or family-hired help or nurse) who was willing to deliver rehabilitation, were aged 18 years or older, had had a stroke within the

Research in context

Evidence before this study

In low-income and middle-income countries, community rehabilitation is seen as a high priority for health-care delivery to reduce disability. Systematic reviews of early supported discharge (ESD) stroke services have shown this model of care reduces death or dependency without adverse effects on family caregivers. We updated the search strategy (to Jan 6, 2017) for the Cochrane review of ESD services for people with acute stroke that categorises interventions into those with or without coordinated multidisciplinary team input. We identified two randomised controlled trials (n=289 in total) in the latter category that had tested a similar intervention: the ATTEND pilot study and an unpublished Chinese trial of nurse-delivered rehabilitation after stroke.

Added value of this study

This randomised controlled trial is the first large trial to our knowledge to test task shifting of stroke rehabilitation to family members. This approach did not improve outcome (compared with usual care) after stroke unit admission. The results were consistent with previous smaller trials of ESD services without multidisciplinary team coordination.

Implications of all the available evidence

Family-led rehabilitation did not improve outcomes, but did not increase harms such as increased burden of care for the family. These results do not support investment in new stroke rehabilitation services that shift tasks to family caregivers, unless new evidence emerges. Future models of low-cost stroke rehabilitation should investigate task shifting to non-family workers or team-based community care.

past month, were able to be randomised within 7 days of admission to hospital, had residual disability (defined by needing help from another person for everyday activities), had a reasonable expectation of survival (ie, not for palliative care, with no evidence of widespread cancer or similar terminal condition), would be available for follow-up for 6 months, and they and their caregiver provided consent. Site coordinators screened all admitted stroke patients and obtained written informed consent from patients and caregivers.

Overall management of the study was coordinated from The George Institute for Global Health (Sydney, Australia). Weekly teleconferences were undertaken between study personnel in Sydney and India during the preparation, conduct, and close-out of the trial. The national clinical coordination centre was based in Ludhiana and project management was based at The George Institute India (Hyderabad, Telangana, India). The Indian Institute of Public Health (Hyderabad, Telangana) provided independent trial monitoring. Additional logic checks and central monitoring of data were done.

Randomisation and masking

The trial funded full-time coordinators (physiotherapists) and masked assessors at each site. The coordinator assessed patients for eligibility, obtained consent from them, and gathered key baseline and demographic data before randomisation. Coordinators were also responsible for training the patients and caregivers. Patients were randomly assigned (1:1) to intervention or a usual care control group via a secure web-based central randomisation system with minimisation by site and stroke severity (National Institutes of Health Stroke Scale [NIHSS] scores <8 *vs* ≥8). To address potential unblinding, coordinators were not permitted to treat other non-trial stroke patients or share an office with the masked assessor. Additionally, they were instructed to undertake patient training sessions in a private room or behind curtains. Assessors were kept unaware of the details of the trial intervention, including having separate training sessions at annual collaborator meetings. Any inadvertent unblinding at an assessment was recorded.

Procedures

The family rehabilitation training intervention was delivered in addition to routine rehabilitation at each site. An international steering group developed the culturally specific intervention, piloted an early version,[10] and incorporated features to ensure it could be affordable when scaled up. The intervention was designed to be delivered by a rehabilitation professional (coordinator), started in hospital, and continued at home. It involved training family members to provide a simplified version of evidence-based rehabilitation,[12–14] and included comprehensive impairment and disability assessment by the coordinators; information provision; joint goal setting with the patient and caregiver for basic activities of daily living (ADL), extended ADL (EADL), and communication; caregiver training for limb positioning; encouragement of the practice of task-specific activities; and reminders to prepare the patient and carer for hospital discharge. The training was designed to take place for about 1 h a day in hospital for about 3 days, with the intention of expediting early supported discharge.[11] After hospital discharge, the coordinator made up to six home visits to assess progress, continue caregiver training activities, and reset goals, and was available for further support by telephone for up to 2 months after randomisation. No trial assessments were done by the coordinators during these home visits, which were purely for guidance and training. A written intervention guide was available for the coordinators and an intervention manual for the patient and caregiver. To

reduce potential contamination, the manual was given to participants on the first home visit to prevent access by control participants in hospital.[10] The coordinator ceased contact 1 month before the first follow-up (ie, at 2 months after randomisation) to reduce the risk of unblinding. Only the coordinators and members of the steering and management committees were aware of the details of the family rehabilitation training intervention (including the written guide). In our trial sites, usual care consisted of some therapy, in the form of assessment and treatment by a physiotherapist, during hospital stay, with post-discharge care varying from no therapy to some outpatient therapy sessions.

To ensure intervention fidelity across sites, coordinators were collectively trained at study initiation and annual collaborator meetings, supplemented by on-site training as required. Intervention training was led by physiotherapists from India and Australia. Day-to-day support was provided by a clinical coordination team that included a neurologist and physiotherapist. A log of trial interventions was kept by the coordinator for each participant for hospital and home visit activities. Intervention patients (with their caregivers) were encouraged by the coordinator to keep a daily log of rehabilitation activities for 30 days after discharge.

Baseline characteristics and events during the initial hospital stay were obtained by the unmasked coordinators: all other trial assessments were done at 3 months and 6 months after randomisation by trained masked assessors who assessed the patient and caregiver at home, or at the hospital, or by phone if a face-to-face visit was not possible. Patients were assessed with the modified Rankin scale (mRS), which is a global seven-level measure of functioning with scores of 0–2 representing good outcome and functional independence, 3–5 representing increasing levels of disability, and 6 death;[15] the simple validated recovery and dependency questions;[16] the Barthel Index of ADL (on a scale of 0–100 with lower scores representing fewer activities);[17] the Nottingham EADL scale (on a scale of 0–66 with lower scores representing fewer activities);[18] the WHO Quality of Life (WHOQOL-BREF, with domains scored from 0 to 100 with lower scores representing lower quality of life);[19] the EuroQol Group 5-Dimension Self-Report Questionnaire, which includes an overall health state (on a scale of 0–100, with lower scores representing lower quality of life);[20] and the Hospital Anxiety and Depression Scale subscales (HADS, with lower scores indicating fewer symptoms).[21] Caregivers were assessed with the Caregiver Burden Scale (on a scale from 21 to 84, with lower scores representing less burden) and the HADS subscales.[22]

Outcomes

The primary outcome was the proportion of patients who were dead or dependent at 6 months as defined by scores of 3–6 on the mRS, with an ordinal shift analysis of the full range of categories of the mRS as a secondary outcome. Other secondary outcomes were the simple validated recovery and dependency questions, length of hospital stay, place of residence (whether the same as before stroke [yes/no]), the Barthel Index, the Nottingham EADL scale, quality of life (WHOQOL-BREF and the EuroQol Group 5-Dimension Self-Report

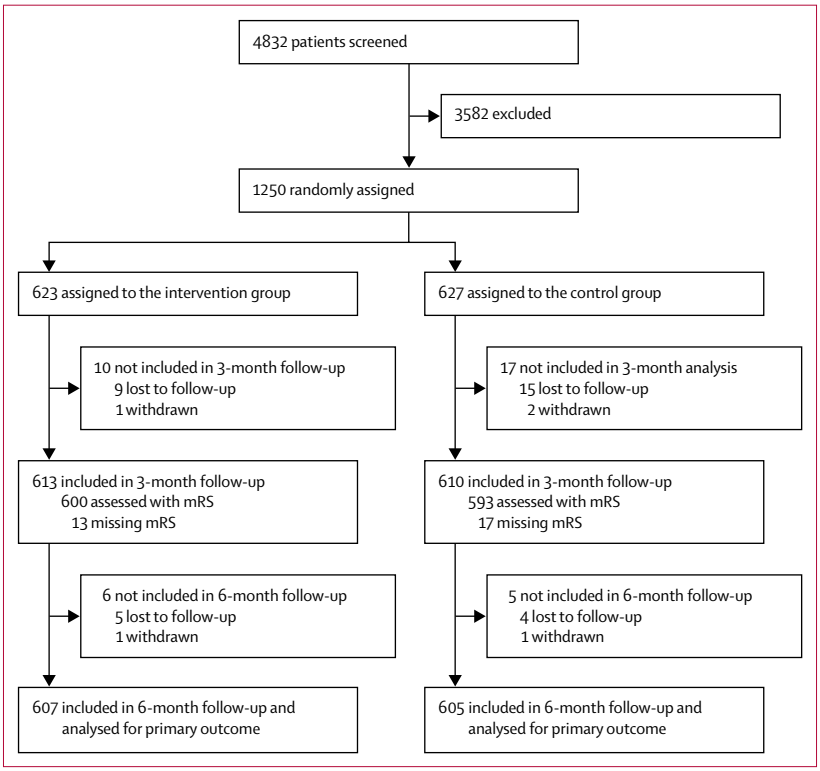

Figure 1: **Trial profile**

	Intervention (n=623)*	Control (n=627)	Total (N=1250)
Sex			
Male	421 (68%)	416 (66%)	837 (67%)
Female	202 (32%)	211 (34%)	413 (33%)
Age (years)			
n, mean (SD)	623, 57·5 (12·92)	627, 58·0 (14·21)	1250, 57·7 (13·58)
Median (IQR)	58 (50–66)	59 (49–67)	59 (50–66)
Range	18–95	19–95	18–95
18 to <40	58 (9%)	63 (10%)	121 (10%)
40 to <50	89 (14%)	97 (15%)	186 (15%)
50 to <60	189 (30%)	159 (25%)	348 (28%)
60 to <70	175 (28%)	176 (28%)	351 (28%)
70 to <80	89 (14%)	89 (14%)	178 (14%)
≥80	23 (4%)	43 (7%)	66 (5%)
Marital status			
Married	563 (91%)	557 (89%)	1120 (90%)
Unmarried	16 (3%)	18 (3%)	34 (3%)
Separated	2 (<1%)	1 (<%)	3 (<1%)
Widowed	41 (7%)	51 (8%)	92 (7%)

(Table 1 continues on next page)

	Intervention (n=623)*	Control (n=627)	Total (N=1250)
(Continued from previous page)			
Main caregiver			
Spouse	257 (41%)	261 (42%)	518 (41%)
Mother	14 (2%)	11 (2%)	25 (2%)
Father	3 (<1%)	6 (1%)	9 (1%)
Grandparents and others	2 (<1%)	2 (<1%)	4 (<1%)
Daughter or daughter-in-law	151 (24%)	125 (20%)	276 (22%)
Son or son-in-law	171 (27%)	192 (31%)	363 (29%)
Sister	3 (<1%)	8 (1%)	11 (1%)
Brother	17 (3%)	19 (3%)	36 (3%)
Hired help or nurse	4 (1%)	3 (<1%)	7 (1%)
Highest level of education completed (patient)			
No schooling	88 (14%)	96 (15%)	184 (15%)
Less than primary school	58 (9%)	65 (10%)	123 (10%)
Primary school	113 (18%)	106 (17%)	219 (18%)
Secondary school	68 (11%)	57 (9%)	125 (10%)
High school	123 (20%)	142 (23%)	265 (21%)
College/university	142 (23%)	140 (22%)	282 (23%)
Postgraduate degree	29 (5%)	21 (3%)	50 (4%)
Unknown	1 (<1%)	0	1 (<1%)
Field of work (patient)			
Management	4 (1%)	7 (1%)	11 (1%)
Professional and related	22 (4%)	19 (3%)	41 (3%)
Service	85 (14%)	75 (12%)	160 (13%)
Sales/commercial	64 (10%)	57 (9%)	121 (10%)
Construction	27 (4%)	29 (5%)	56 (4%)
Armed forces	7 (1%)	9 (1%)	16 (1%)
Farming/forestry/fishing and related	60 (10%)	65 (10%)	125 (10%)
Clerical/administrative support	21 (3%)	14 (2%)	35 (3%)
Installation and related	8 (1%)	4 (1%)	12 (1%)
Manufacture/production	16 (3%)	21 (3%)	37 (3%)
Transportation/driver	25 (4%)	27 (4%)	52 (4%)
Housewife	181 (29%)	186 (30%)	367 (29%)
Not applicable	102 (16%)	114 (18%)	216 (17%)
Work situation (patient)			
Full-time paid work	224 (36%)	186 (30%)	410 (33%)
Part-time paid work	46 (7%)	50 (8%)	96 (8%)
Retired	96 (15%)	111 (18%)	207 (17%)
Unemployed	47 (8%)	31 (5%)	78 (6%)
Home duties	171 (27%)	203 (32%)	374 (30%)
Student	3 (<1%)	3 (<1%)	6 (<1%)
Other	35 (6%)	43 (7%)	78 (6%)
Accommodation details			
Own house	501 (81%)	498 (79%)	999 (80%)
Own apartment/flat	19 (3%)	26 (4%)	45 (4%)
Rented flat	37 (6%)	36 (6%)	73 (6%)
Rented accommodation in a house	42 (7%)	47 (7%)	89 (7%)
Government/company-provided house	22 (4%)	17 (3%)	39 (3%)
Jhuggi (slum)	0	1 (<1%)	1 (<1%)
Other	1 (<1%)	2 (<1%)	3 (<1%)

(Table 1 continues on next page)

Questionnaire), patient and caregiver anxiety and depression according to the HADS subscales, and the Caregiver Burden Scale. We also assessed the following health economic outcomes, which will be reported elsewhere: health-care resource use (visits to health professionals, hospitalisation, and medication use), indirect costs to the family (eg, a family member giving up employment to act as a caregiver), direct medical costs (eg, private treatment, admission charges, drug treatments), and non-medical direct costs (eg, travelling costs). Adverse events, including a prespecified list of those most frequent after stroke, were sought. The prespecified list was comprised of deaths due to the initial stroke, myocardial infarction, pneumonia or other vascular or non-vascular causes, and hospitalisation due to recurrent stroke, myocardial infarction, bony fracture, infection, or other causes. Patients and caregivers were given a health diary to record details of any re-hospitalisation, with details obtained at each assessment.

Statistical analysis

On the basis of the Early Supported Discharge Stroke trials,[13] in which death or dependency was 50% in controls, we estimated that a sample size of 1200 patients (600 per group) was needed to provide 90% power (α=0·05) to detect a 21% relative risk reduction (10·5% absolute reduction) in death or dependency in the intervention group with a 20% loss to follow-up.

All analyses were by intention to treat, and all tests were two-sided with a nominal level of significance of 5%. The primary analysis compared the proportion of patients who were dead or dependent (mRS 3–6) at 6 months between the intervention and usual care groups in an unadjusted logistic regression model. Sensitivity analyses were adjustment for study site, stroke severity (NIHSS score <8 or ≥8), age (as a continuous variable), sex, household income (<5000 INR, 5000 to <15 000 INR, 15 000 to <30 000 INR, 30 000 INR and more, no answer or missing data), and patient level of education (completed college [diploma or certificate], university [degree], or postgraduate studies; completed high school [up to grade 12]; completed primary school or secondary school [up to grade –10]; did not complete primary school; no schooling or data missing); and a so-called leave one out analysis whereby the effect on the primary outcome was be calculated with all the participants from a single site removed one at a time.[23] We did nine prespecified subgroup analyses (age, sex, stroke severity, stroke pathology, stroke Oxfordshire Community Stroke Project Classification, carer type, education level, household income, and type of accommodation) by adding the subgroup variable as well as its interaction term, with the intervention as fixed effects to the logistic regression model used for the primary analysis. Sex had been inadvertently omitted (due to author error) in the published statistical analysis plan but was prespecified in our internal analysis and is included for

completeness.[23] Other analyses included all seven categories of the mRS with ordinal logistic regression and a permutation test proposed by Howard and colleagues.[24,25] Analyses of secondary outcomes at 3 and 6 months used *t* tests to compare means (eg, mean scores) and χ^2 tests to compare proportions (eg, place of residence). We analysed length of hospital stay using a log-rank test and serious adverse events using Fisher's exact test. Further details are available in the Statistical Analysis Plan,[23] which was finalised and submitted for publication before unblinding. All analyses were done with SAS Enterprise Guide version 7.1 (SAS/Stat version 9.4). An independent Data and Safety Management Committee monitored the unblinded accumulating results and adverse events according to a written charter.

The trial was registered at the Clinical Trials Registry-India (CTRI/2013/04/003557) and the Australian New Zealand Clinical Trials Registry (ACTRN12613000078752), and has a Universal Trial Number (U1111-1138-6707).

Role of the funding source

The National Health and Medical Research Council had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Between Jan 13, 2014, and Feb 12, 2016, 4832 patients were screened, of which 1250 were randomly assigned to the intervention group (n=623) or the control group (n=627; figure 1). Baseline characteristics are shown in table 1. At hospital discharge, we found no between-group differences in mRS scores (562 [90%] of 622 patients in the intervention group *vs* 567 [90%] of 627 controls, p=0·96) nor in the Barthel Index scores (mean 43·0 [SD 23·17] in the intervention group *vs* 43·2 [23·39] in controls, p=0·88; appendix).

The training programme was delivered as planned with a mean time of 3·0 h (SD 1·6; median 2·9 [IQR 2·0–3·3]) in hospital. An additional 3·1 h (SD 1·7; median 2·8 [1·9–4·2]) of training were delivered during home visits. Intervention patients and caregivers reported 17·8 h (SD 21·6) of rehabilitation given in the first 30 days after hospital discharge (data available from 574 participants). Details of the rehabilitation provided to both groups as part of routine care and the intervention are shown in the appendix. We found no evidence of a difference in total routine hospital rehabilitation time (2·0 h for intervention patients *vs* 2·1 h for controls, p=0·23), although intervention participants practised fewer mobility activities than did controls (521 [84%] of patients in the intervention group practised at least one activity *vs* 553 [88%] in the controls, p=0·023). We showed no statistical differences between groups in other non-trial routine rehabilitation activities (appendix).

At 6 months, roughly the same number of participants were dead or dependent in the intervention group and in the control group (table 2). The neutral results were

See Online for appendix

	Intervention (n=623)*	Control (n=627)	Total (N=1250)
(Continued from previous page)			
Living situation pre-stroke			
Independent at home	616 (99%)	610 (97%)	1226 (98%)
Dependent at home	6 (1%)	12 (2%)	18 (1%)
Other	0	5 (1%)	5 (<1%)
Financial situation			
Patient or his close family owns the house	507 (82%)	508 (81%)	1015 (81%)
Patient or his close family owns the flat	18 (3%)	20 (3%)	38 (3%)
Rented from landlord	77 (12%)	83 (13%)	160 (13%)
Government-owned or allocated housing	20 (3%)	16 (3%)	36 (3%)
Monthly household income (INR)†			
<5000	93 (15%)	101 (16%)	194 (16%)
5000–14 999	178 (29%)	196 (31%)	374 (30%)
15 000–29 999	166 (27%)	151 (24%)	317 (25%)
30 000–59 999	99 (16%)	74 (12%)	173 (14%)
60 000–100 000	18 (3%)	20 (3%)	38 (3%)
>100 000	8 (1%)	12 (2%)	20 (2%)
Decline to answer	39 (6%)	43 (7%)	82 (7%)
Do not know	21 (3%)	30 (5%)	51 (4%)
Days from stroke onset to randomisation			
n, mean (SD)	623, 4·9 (3·8)	627, 5·1 (4·1)	1250, 5·0 (4·1)
Median (IQR)	4 (3–6)	4 (2–6)	4 (3–6)
Range	0–28	0–29	0–29
Stroke type			
Ischaemic	478 (77%)	478 (76%)	956 (76%)
Large artery atherosclerosis	214/478 (45%)	213/478 (45%)	427/956 (45%)
Cardioembolism	75/478 (16%)	54/478 (11%)	129/956 (13%)
Small artery occlusion	113/478 (24%)	131/478 (27%)	244/956 (26%)
Determined, other aetiology	16/478 (3%)	21/478 (4%)	37/956 (4%)
Undetermined	60/478 (13%)	58/478 (12%)	118/956 (12%)
Intracerebral haemorrhage	143 (23%)	148 (24%)	291 (23%)
Unspecified	1 (<1%)	1 (<1%)	2 (<1%)
OCSP classification‡			
Total anterior circulation syndrome	67/478 (14%)	51/478 (11%)	118/956 (12%)
Partial anterior circulation syndrome	263/478 (55%)	269/478 (56%)	532/956 (56%)
Posterior circulation syndrome	72/478 (15%)	76/478 (16%)	148/956 (15%)
Lacunar syndromes	76/478 (16%)	81/478 (17%)	157/956 (16%)
NIHSS score			
n, mean (SD)	622, 10·1 (4·9)	627, 9·6 (4·8)	1249, 9·9 (4·9)
Median (IQR)	9 (6–13)	9 (6–12)	9 (6–13)
Range	1–29	1–28	1–29
0 to <5	72 (11·6)	103 (16·4)	175 (14·0)
5 to <10	247 (39·7)	241 (38·4)	488 (39·1)
10 to <15	188 (30·2)	182 (29·0)	370 (29·6)
≥15	115 (18·5)	101 (16·1)	216 (17·3)

(Table 1 continues on next page)

	Intervention (n=623)*	Control (n=627)	Total (N=1250)
(Continued from previous page)			
Medical history			
Hypertension	455/618 (74%)	460/620 (74%)	915/1238 (74%)
Diabetes mellitus	273/611 (45%)	265/614 (43%)	538/1225 (44%)
Dyslipidaemia	120/540 (22%)	132/536 (25%)	252/1076 (23%)
Atrial fibrillation	46/579 (8%)	44/589 (7%)	90/1168 (8%)
Coronary artery disease	93/595 (16%)	98/605(16%)	191/1200 (16%)
Obesity	95/621 (15%)	97/620 (16%)	192/1241 (15%)
Smoking	158/618 (26%)	143/622 (23%)	301/1240 (24%)
Alcohol use	164/619 (26%)	169/622 (27%)	333/1241 (27%)
Drug addiction	4/620 (1%)	1/621 (<1%)	5/1241 (<1%)
Carotid stenosis	112/562 (20%)	105/568 (18%)	217/1130 (19%)
Previous stroke/TIA	110/615 (18%)	112/617 (18%)	222/1232 (18%)
Rheumatic heart disease	21/611 (3%)	22/617 (4%)	43/1228 (4%)
Neoplastic disease	3/615 (<1%)	4/617 (1%)	7/1232 (1%)
Pregnancy	0/618	2/621 (<1%)	2/1239 (<1%)

Data are n (%) unless indicated otherwise. INR=Indian rupees. OCSP=Oxfordshire Community Stroke Project. NIHSS=National Institutes of Health Stroke Scale. TIA=transient ischaemic attack. *Data complete for sex and age. One patient withdrew from the intervention group after randomisation and the denominator is 622 for other baseline variables.†US$1=68 INR. ‡Classification for patients with ischaemic stroke.

Table 1: **Baseline characteristics**

similar in adjusted analyses, leave-one-out sensitivity analyses, and across all secondary outcomes (tables 2, 3, figure 2, appendix). The mean number of days from randomisation to hospital discharge was 6·0 (SD 6·8) in the intervention group and 6·3 (7·5) in the controls (p=0·65). The intervention did not reduce total length of stay (mean stay of 9·3 [SD 7·4] days in the intervention group *vs* 9·5 [7·9] days in the controls, p=0·58; appendix). We found no significant differences in non-fatal or fatal adverse events: 72 (12%) deaths occurred in the intervention group compared with 86 (14%) in the control group (p=0·27); 112 non-fatal events occurred in 82 (13%) patients in the intervention group compared with 110 events in 79 (13%) patients in the control group (p=0·80); and 89 (14%) patients in the intervention group were rehospitalised after discharge compared with 82 (13%) patients in the control group (p=0·56; appendix). In the intervention group, deaths due to the initial stroke occurred in nine (1%) patients and 18 (3%) controls (p=0·12). We showed no between-group difference in caregiver strain, nor in anxiety or depression on the HADS. We documented unblinding in 33 (5%) intervention patients and 21 (3%) control patients (p=0·09).

	Intervention (n=623)	Usual care (n=627)	Total (n=1250)	Odds ratio (95% CI)	p value*
Death or dependency (mRS score 3–6)					
Month 3 (unadjusted)	336/600 (56%)	337/593 (57%)	673/1193 (56%)	0·97 (0·77–1·22)	0·77
Month 3 (adjusted)†	335/599 (56%)	337/593 (57%)	672/1192 (56%)	1·00 (0·77–1·29)	0·99
Month 6 (unadjusted; primary outcome)	285/607 (47%)	287/605 (47%)	572/1212 (47%)	0·98 (0·78–1·23)	0·87
Month 6 (adjusted)†	284/606 (47%)	287/605 (47%)	571/1211 (47%)	1·02 (0·80–1·31)	0·87
Ordinal analysis of mRS scores‡					
Month 3 (unadjusted)					
0	23/600 (4%)	27/593 (5%)	50/1193 (4%)	0·92 (0·75–1·12)	0·42
1	147/600 (25%)	130/593 (22%)	277/1193 (23%)	..	..
2	94/600 (16%)	99/593 (17%)	193/1193 (16%)	..	..
3	141/600 (24%)	133/593 (22%)	274/1193 (23%)	..	..
4	116/600 (19%)	107/593 (18%)	223/1193 (19%)	..	..
5	22/600 (4%)	30/593 (5%)	52/1193 (4%)	..	..
6	57/600 (10%)	67/593 (11%)	124/1193 (10%)	..	..
Month 3 (adjusted)				0·94 (0·76–1·15)	0·52
Month 6 (unadjusted)					
0	56/607 (9%)	55/605 (9%)	111/1212 (9%)	1·00 (0·82–1·22)	1·00
1	170/607 (28%)	183/605 (30%)	353/1212 (29%)	..	..
2	96/607 (16%)	80/605 (13%)	176/1212 (15%)	..	..
3	120/607 (20%)	123/605 (20%)	243/1212 (20%)	..	..
4	82/607 (14%)	65/605 (11%)	147/1212 (12%)	..	..
5	11/607 (2%)	13/605 (2%)	24/1212 (2%)	..	..
6	72/607 (12%)	86/605 (14%)	158/1212 (13%)	..	..
Month 6 (adjusted)	..	..	..	1·03 (0·84–1·27)	0·75

Data are n/N (%). mRS=modified Rankin scale. *p value calculated from the likelihood ratio of the logistic regression. †Adjusted analysis includes the following covariates: study site, stroke severity, age, sex, income, and education. ‡Ordinal analysis using proportional odds logistic regression.

Table 2: **Analysis of mRS**

We found one significant interaction on the pre-specified subgroup analysis, by sex, in which men had reduced odds of death or dependency at 6 months compared with women (figure 3).

Discussion

Our study showed that the addition of family-led rehabilitation training to usual stroke unit care did not decrease death or dependency at 6 months, nor was there any benefit noted at the 3-month assessment. Additionally, the training did not influence any of the other physical, emotional, or quality-of-life outcomes. The intervention was safe, with an observed non-significant reduction in deaths, and no increase in caregiver burden. The training was delivered as planned with a mean of 3·0 h (median 2·9) of hospital training and a mean of 3·1 h (median 2·8) of community-based training, with components consistent with the trial intervention guide. In the context of these Indian stroke units, in which patients received a total of only 2 h of therapy, the intervention more than doubled the amount of hospital rehabilitation and provided additional community caregiver and patient training. In the intervention group, 30 min of daily rehabilitation activities were reported by the patient and caregivers in the month after discharge (17 h over 30 days).

The ATTEND intervention failed to reduce length of hospital stay. When our results are viewed in the context of the systematic review of early supported discharge after stroke,[13] it can be seen that interventions without coordination from a dedicated multidisciplinary team currently do not have evidence of benefit. We also note that the smaller RECOVER trial of nurse-delivered rehabilitation after stroke in China was negative (R Lindley, personal communication).

Our results are also consistent with the absence of benefit seen in a systematic review[26] of trials of caregiver-mediated exercises to improve activities of daily living. In this overview, the authors noted that the data were insufficient (only 333 patients were included in the six trials analysed) and that the quality of evidence was low to moderate. Although the ATTEND intervention emphasised caregiver-mediated exercises, these were not the only component of the intervention.

The absence of benefit of the family-rehabilitation intervention has important implications for stroke recovery research, behavioural change, and task shifting in general. Our training programme might not have

	Month 3			Month 6		
	Intervention	Control	p value	Intervention	Control	p value
Recovery, dependency, and place of residence						
Complete recovery from stroke*	72/546 (13%)	78/530 (15%)	0·55	133/534 (25%)	142/514 (28%)	0·28
Need help for everyday activities*	332/543 (61%)	320/528 (61%)	0·60	266/533 (50%)	245/514 (48%)	0·17
Place of residence†			0·81			0·92
Same as before stroke	516/543 (95%)	500/528 (95%)		502/533 (94%)	483/512 (94%)	
Other	27/543 (5%)	28/528 (5%)		31/533 (6%)	29/512 (6%)	
In another hospital since admission for stroke	1/27 (4%)	1/28 (4%)		1/31 (3%)	0	
In family or friends' home	17/27 (63%)	14/28 (50%)		16/31 (52%)	11/29 (38%)	
In same hospital since admission for stroke	0	0		0	1/29 (3%)	
Other dwelling place	9/27 (33%)	13/28 (46%)		14/31 (45%)	17/29 (59%)	
Barthel Index						
Total score‡			0·41			0·74
n, mean (SD)	543, 76·1 (25·24)	525, 74·8 (26·05)		533, 82·1 (23·09)	512, 82·6 (23·19)	
Median (IQR)	85 (60–100)	85 (60–100)		95 (70–100)	95 (70–100)	
Range	0–100	0–100		0–100	0–100	
Caregiver burden						
Total score‡			0·21			0·52
n, mean (SD)	543, 30·9 (10·70)	524, 31·7 (11·38)		532, 28·9 (10·01)	511, 29·3 (10·85)	
Median (IQR)	27 (22–35)	29 (22–37)		25 (21–33)	25 (21–33)	
Range	21–73	21–80		21–77	21–81	
Nottingham Extended ADL Scale						
Total score†			0·43			0·86
n, mean (SD)	537, 27·1 (17·21)	523, 26·3 (17·31)		527, 31·0 (17·67)	509, 31·2 (17·52)	
Median (IQR)	27 (12–40)	25 (11–40)		31 (16–45)	32 (17–44)	
Range	0–66	0–66		0–66	0–66	

(Table 3 continues on next page)

	Month 3			Month 6		
	Intervention	Control	p value	Intervention	Control	p value
(Continued from previous page)						
WHO Quality of Life						
Physical health‡			0·96			0·63
n, mean (SD)	534, 51·2 (12·65)	521, 51·3 (12·28)		525, 54·3 (12·06)	509, 54·7 (12·11)	
Median (IQR)	56 (44–63)	56 (44–63)		56 (44–63)	56 (44–63)	
Range	13–81	6–81		13–94	19–100	
Psychological‡			0·99			0·17
n, mean (SD)	534, 49·2 (15·16)	521, 49·3 (14·99)		525, 52·1 (15·09)	509, 53·4 (14·63)	
Median (IQR)	50 (38–56)	50 (38–63)		56 (44–63)	56 (44–63)	
Range	6–100	6–94		0–94	6–88	
Social relationship‡			0·42			0·45
n, mean (SD)	529, 60·8 (17·21)	519, 60·0 (16·89)		523, 63·0 (17·41)	509, 62·2 (18·43)	
Median (IQR)	69 (50–75)	56 (50–69)		69 (50–75)	69 (50–75)	
Range	0–100	0–100		0–100	0–100	
Environment‡			0·61			0·76
n, mean (SD)	534, 65·3 (14·70)	521, 64·8 (15·78)		525, 67·8 (15·69)	509, 68·1 (15·95)	
Median (IQR)	69 (56–75)	63 (56–75)		69 (56–75)	69 (56–81)	
Range	19–100	13–100		19–100	19–100	
Quality of life*			0·41			0·52
Very poor	21/535 (4%)	34/521 (7%)		17/526 (3%)	17/509 (3%)	
Poor	97/535 (18%)	86/521 (17%)		77/526 (15%)	72/509 (14%)	
Neither poor nor good	176/535 (33%)	167/521 (32%)		115/526 (22%)	105/509 (21%)	
Good	225/535 (42%)	217/521 (42%)		284/526 (54%)	268/509 (53%)	
Very good	16/535 (3%)	17/521 (3%)		33/526 (6%)	47/509 (9%)	
Satisfaction with health*			0·31			0·65
Very dissatisfied	24/535 (4%)	17/521 (3%)		18/526 (3%)	16/509 (3%)	
Dissatisfied	142/535 (27%)	123/521 (24%)		111/526 (21%)	92/509 (18%)	
Neither satisfied nor dissatisfied	152/535 (28%)	156/521 (30%)		105/526 (20%)	104/509 (20%)	
Satisfied	204/535 (38%)	203/521 (39%)		257/526 (49%)	254/509 (50%)	
Very satisfied	13/535 (2%)	22/521 (4%)		35/526 (7%)	43/509 (8%)	
EuroQol Group 5-Dimension Self-Report Questionnaire						
Mobility*			0·37			0·32
I have no problems in walking	256/539 (47%)	226/523 (43%)		292/529 (55%)	282/510 (55%)	
I have some problems in walking	235/539 (44%)	247/523 (47%)		201/529 (38%)	204/510 (40%)	
I am confined to bed	48/539 (9%)	50/523 (10%)		36/529 (7%)	24/510 (5%)	
Self-care*			0·52			0·75
I have no problems with self-care	235/539 (44%)	212/523 (41%)		278/529 (53%)	280/510 (55%)	
I have some problems bathing or dressing myself	199/539 (37%)	197/523 (38%)		176/529 (33%)	162/510 (32%)	
I am unable to bathe or dress myself	105/539 (19%)	114/523 (22%)		75/529 (14%)	68/510 (13%)	
Usual activities*			0·95			0·59
I have no problems in performing my usual activities	185/538 (34%)	175/523 (33%)		227/529 (43%)	232/510 (45%)	
I have some problems in performing my usual activities	210/538 (39%)	206/523 (39%)		211/529 (40%)	188/510 (37%)	
I am unable to perform my usual activities	143/538 (27%)	142/523 (27%)		91/529 (17%)	90/510 (18%)	
Pain/discomfort*			0·70			0·64
I have no pain or discomfort	228/538 (42%)	210/523 (40%)		270/529 (51%)	273/510 (54%)	
I have moderate pain or discomfort	270/538 (50%)	269/523 (51%)		231/529 (44%)	208/510 (41%)	
I have extreme pain or discomfort	40/538 (7%)	44/523 (8%)		28/529 (5%)	29/510 (6%)	

(Table 3 continues on next page)

	Month 3			Month 6		
	Intervention	Control	p value	Intervention	Control	p value
(Continued from previous page)						
Anxiety/depression*			0·70			0·44
I am not anxious or depressed	229/538 (43%)	212/523 (41%)		265/529 (50%)	257/510 (50%)	
I am moderately anxious or depressed	266/538 (49%)	272/523 (52%)		238/529 (45%)	219/510 (43%)	
I am extremely anxious or depressed	43/538 (8%)	39/523 (7%)		26/529 (5%)	34/510 (7%)	
Overall health state‡			0·68			0·18
n, mean (SD)	539, 63·2 (21·21)	523, 63·8 (20·82)		529, 70·1 (20·36)	510, 71·8 (20·40)	
Median (IQR)	65 (50–80)	65 (50–80)		70 (55–90)	75 (60–90)	
Range	3–100	0–100		0–100	0–100	
Hospital Anxiety and Depression Scale						
Patient						
Total score‡			0·67			0·90
n, mean (SD)	536, 11·3 (8·35)	520, 11·5 (8·72)		527, 9·0 (7·81)	509, 9·1 (8·64)	
Median (IQR)	10 (5–17)	10 (4–18)		7 (3–14)	7 (2–13)	
Range	0–39	0–39		0–38	0–42	
Anxiety score‡			0·57			0·91
n, mean (SD)	536, 4·8 (4·01)	520, 4·9 (4·36)		527, 3·7 (3·74)	509, 3·7 (4·19)	
Median (IQR)	4 (1–7)	4 (1–8)		3 (0–6)	2 (0–6)	
Range	0–18	0–18		0–18	0–21	
Score ≥8*	122/536 (23%)	138/520 (27%)	0·15	84/527 (16%)	83/509 (16%)	0·87
Depression score‡			0·79			0·91
n, mean (SD)	536, 6·5 (4·94)	520, 6·6 (4·99)		527, 5·3 (4·64)	509, 5·3 (4·96)	
Median (IQR)	6 (2–10)	6 (2–10)		4 (2–8)	4 (1–8)	
Range	0–21	0–21		0–21	0–21	
Score ≥8*	197/536 (37%)	198/520 (38%)	0·66	145/527 (28%)	141/509 (28%)	0·95
Caregiver						
Total score‡			0·62			0·86
n, mean (SD)	546, 7·5 (7·52)	527, 7·7 (7·88)		532, 5·5 (6·68)	511, 5·5 (6·80)	
Median (IQR)	5 (2–12)	5 (1–12)		3 (0–9)	3 (0–8)	
Range	0–42	0–39		0–36	0–42	
Anxiety score‡			0·67			0·91
n, mean (SD)	546, 3·7 (3·86)	527, 3·8 (4·17)		532, 2·7 (3·40)	511, 2·6 (3·51)	
Median (IQR)	2 (0–6)	2 (0–6)		1 (0–4)	1 (0–4)	
Range	0–21	0–20		0–16	0–21	
Score ≥8*	83/546 (15%)	96/527 (18%)	0·19	55/532 (10%)	50/511 (10%)	0·77
Depression score‡			0·61			0·82
n, mean (SD)	546, 3·8 (4·17)	527, 3·9 (4·16)		532, 2·9 (3·69)	511, 2·8 (3·60)	
Median (IQR)	3 (0–6)	3 (0–6)		1 (0–5)	2 (0–5)	
Range	0–21	0–21		0–21	0–21	
Score ≥8*	100/546 (18%)	100/527 (19%)	0·78	68/532 (13%)	56/511 (11%)	0·36

ADL=activities of daily living. *p value by χ^2 test. †p value by χ^2 test only performed on "same as before stroke" versus "other". ‡p value by *t* test.

Table 3: **Analysis of secondary outcomes at months 3 and 6**

been sufficient (in time and content) to deliver effective family rehabilitation, as we observed only about 30 min of daily activities in the intervention group. Conventional western rehabilitation is usually associated with greater daily therapy time (1–2 h).[27] Training of family members was designed to be sustainable, and if family members required more training to meet the needs of their family patient, then the aspiration of routinely providing rehabilitation through task shifting to family caregivers might not be feasible. Family dynamics might also limit the effectiveness of this strategy, and task shifting to a non-family generic health worker, such as the established Indian Accredited Social Health Activist (ASHA), might have been a more effective strategy, although probably more expensive. Technology-assisted rehabilitation might also be another option of task shifting that is the subject of current trials.[28]

The absence of benefit might also have been due to individual training components being ineffective in changing behaviour. This possibility was raised by another trial, undertaken in the UK, in which caregiver training (part of our intervention) was ineffective in the acute setting.[29] Because we were aware of these results before beginning our study, we also placed emphasis on the importance of continuation of caregiver training after hospital discharge. The comprehensive nature of our intervention might have diluted the effect of individual components, and this less specified approach—eg, too much time spent on information provision—might have been at the expense of training task-specific mobility exercises.

Although our primary outcome was not significant, the sample size might still have been insufficient to detect a more modest treatment effect. However, the consistency of results across all health dimensions provides support for the overall neutral effect. The main qualitative differences between conventional rehabilitation in high-income countries, compared with our family rehabilitation intervention, are in the professional multidisciplinary

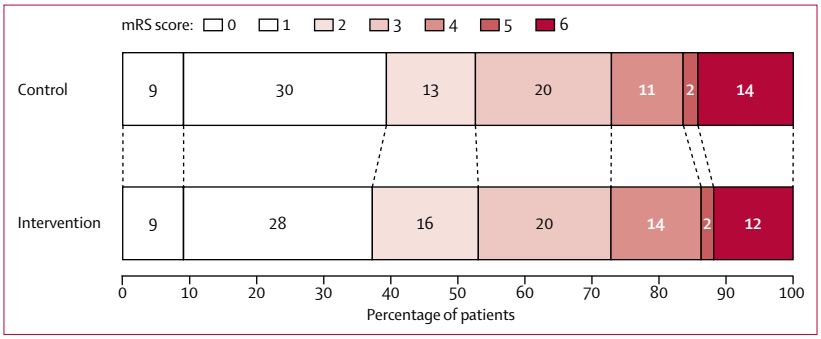

Figure 2: **Patients achieving each mRS score at 6 months**
mRS=modified Rankin Scale.

	Events/patients		Odds ratio (95% CI)	p value for interaction
	Intervention	Control		
Age (years)				
0 to <40	11/56 (20%)	18/56 (32%)	0·52 (0·22–1·23)	0·2265
40 to <50	34/87 (39%)	36/96 (38%)	1·07 (0·59–1·94)	
50 to <60	72/186 (39%)	69/154 (45%)	0·78 (0·50–1·20)	
60 to <70	95/168 (57%)	86/171 (5%)	1·29 (0·84–1·97)	
≥70	73/110 (66%)	78/128 (61%)	1·26 (0·74–2·15)	
Sex				
Female	115/198 (58%)	102/204 (50%)	1·39 (0·93–2·05)	0·0374
Male	170/409 (42%)	185/401 (46%)	0·83 (0·63–1·10)	
Stroke severity (NIHSS)				
0 to <5	18/71 (25%)	15/98 (15%)	1·88 (0·87–4·05)	0·1353
5 to <10	84/242 (35%)	85/237 (36%)	0·95 (0·65–1·38)	
10 to <15	101/185 (55%)	106/173 (61%)	0·76 (0·50–1·16)	
≥15	82/109 (75%)	81/97 (84%)	0·60 (0·30–1·20)	
Stroke type				
Intracerebral haemorrhage	69/139 (50%)	78/142 (55%)	0·81 (0·51–1·29)	0·3544
Ischaemic	216/467 (46%)	209/462 (45%)	1·04 (0·80–1·35)	
OCSP subtype				
Lacunar syndromes	22/76 (29%)	19/79 (24%)	1·29 (0·63–2·63)	0·5097
Partial anterior circulation syndrome	126/253 (50%)	124/260 (48%)	1·09 (0·77–1·54)	
Posterior circulation syndrome	29/71 (41%)	37/72 (51%)	0·65 (0·34–1·27)	
Total anterior circulation syndrome	39/67 (58%)	28/50 (56%)	1·09 (0·52–2·29)	
Caregiver type				
Daughter or daughter-in-law	89/148 (60%)	65/123 (53%)	1·35 (0·83–2·18)	0·4292
Son or son-in-law	84/166 (51%)	102/184 (55%)	0·82 (0·54–1·25)	
Spouse	97/252 (38%)	105/253 (42%)	0·88 (0·62–1·26)	
Other	15/41 (37%)	15/45 (33%)	1·15 (0·47–2·80)	
Patient's education level				
College, university, or postgraduate	66/165 (40%)	58/154 (38%)	1·10 (0·70–1·73)	0·1660
High school completed	50/123 (41%)	73/137 (53%)	0·60 (0·37–0·98)	
Secondary, primary, or less than primary school	114/231 (49%)	104/223 (47%)	1·11 (0·77–1·61)	
No schooling	54/87 (62%)	52/91 (57%)	1·23 (0·67–2·24)	
Household income				
<5000	57/93 (61%)	53/97 (55%)	1·31 (0·74–2·34)	0·4821
5000–14 999	72/173 (42%)	94/190 (49%)	0·73 (0·48–1·10)	
15 000–29 999	69/163 (42%)	59/146 (40%)	1·08 (0·69–1·70)	
≥30 000	55/121 (45%)	44/103 (43%)	1·12 (0·66–1·90)	
No answer or missing	32/57 (56%)	37/69 (54%)	1·11 (0·55–2·24)	
Type of accommodation				
Own house	234/489 (48%)	233/482 (48%)	0·98 (0·76–1·26)	0·9774
Other	51/118 (43%)	54/123 (44%)	0·97 (0·58–1·62)	

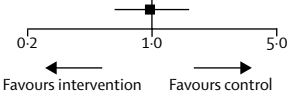

Figure 3: **Main subgroup analyses on the primary outcome (dead or dependent)**
NIHSS=US National Institutes of Health Stroke Scale. OCSP=Oxfordshire, UK, Community Stroke Project Stroke Classification. *Household income in Indian rupees (INR) per month (US$1=68 INR).

structure and frequent review meetings. Our results suggest that the lower dose of family rehabilitation training, delivered by one professional, although based on evidence-based components across multiple disciplines, is an ineffective model of care. Since our trial was done at stroke units around India, our findings have not ruled out the possibility that the intervention could offer benefits in non-specialised hospitals, especially in rural and remote settings.

The unexpected interaction with sex, with the observed improved outcome in men compared with women, might be due to the play of chance and requires further analysis. However, in Indian society, important sex differences might exist in the receipt and provision of a complex intervention such as ours. Our process evaluation aims to explore this, and other, aspects of the trial, in more detail.[30]

Strengths of our study include the piloting and development of a structured intervention supported by written materials and use of robust trial methods to address priorities set out in the WHO and World Bank World Report on Disability.[9] Our funding provided sufficient resources to address the research question comprehensively and has contributed to building stroke research capacity across India. Our trial data are consistent with epidemiological evidence that stroke is affecting people in India about 15 years younger than those in high-income countries, highlighting the public health importance of improving global rehabilitation services, especially since many of our participants were still in paid work.[31] However, generalisability of our results to other areas of the country without rehabilitation might be limited, given that our participants were generally from urban centres with higher-than-average education and income.

Task shifting is an attractive solution for health-care sustainability.[4,32,33] However, none of 22 recommendations of the WHO Task Shifting Guidelines referenced evidence generation on effectiveness, despite acknowledgment that implementation of these recommendations and guidelines should be accompanied by rigorous evaluation.[4] Our assessment of training the patient and family caregiver showed that this particular model of rehabilitation was ineffective. Our results illustrate that task shifting away from conventional rehabilitation, without rigorous evaluation, could waste limited resources. Our neutral results will be further interrogated through a process assessment that will examine the social and economic influences on the behaviour of carers and patients. ATTEND was developed from the evidence base current at the time and focused on pragmatic solutions. Future research in this area could incorporate more behavioural change theory and evidence when developing a new intervention.

Writing committee
Richard I Lindley* (The George Institute for Global Health and Sydney Medical School—Westmead Hospital, Discipline of Medicine, University of Sydney, Sydney, NSW, Australia), Craig S Anderson (The George Institute for Global Health, Royal Prince Alfred Hospital and Faculty of Medicine, University of New South Wales, Sydney, NSW, Australia), Laurent Billot (The George Institute for Global Health, Faculty of Medicine, University of New South Wales, Sydney, NSW, Australia), Anne Forster (Leeds Institute of Health Sciences, University of Leeds, Leeds, West Yorkshire, UK), Maree L Hackett (The George Institute for Global Health, Faculty of Medicine, University of New South Wales, Sydney, NSW, Australia; and University of Central Lancashire, Preston, UK), Lisa A Harvey (University of Sydney, Sydney, NSW, Australia), Stephen Jan (The George Institute for Global Health, Faculty of Medicine, University of New South Wales, Sydney, NSW, Australia), Qiang Li (The George Institute for Global Health, Camperdown, Sydney, NSW, Australia), Hueiming Liu (The George Institute for Global Health, Camperdown, Sydney, NSW, Australia), Peter Langhorne (Institute of Cardiovascular and Medical Sciences, University of Glasgow, Glasgow, UK), Pallab K Maulik (The George Institute for Global Health India, Delhi, India and George Institute for Global Health, University of Oxford, Oxford, UK), Gudlavalleti Venkata Satyanarayana Murthy (Indian Institute of Public Health, Hyderabad, India), Marion F Walker (University of Nottingham, Nottingham, Nottinghamshire, UK), Jeyaraj D Pandian* (Christian Medical College and Hospital Ludhiana, Ludhiana, Punjab, India).
*Co-Principal Investigators.

Management committee
M Alim (The George Institute for Global Health India), C Felix (The George Institute for Global Health India), D B C Gandhi (Christian Medical College and Hospital Ludhiana), RIL, JDP, A Syrigapu (Indian Institute of Public Health), D K Tugnawat (Indian Institute of Public Health), S J Verma (Christian Medical College and Hospital Ludhiana).

Steering committee
CSA, LB, AF, MLH, LAH, SJ, RIL (co-chair), PL, PKM, GVSM (co-chair), B R Shamanna (University of Hyderabad, Gachibowli, Hyderabad, India), MFW, JDP.

Data and safety monitoring committee
G Hankey (University of Western Australia, WA, Australia), A Thrift (Monash University, Melbourne, VIC, Australia), J Bernhardt (University of Melbourne, VIC, Australia), M M Mehndiratta (Janakpuri Super Speciality Hospital, New Delhi, India), L Jeyaseelan (Christian Medical College, Vellore, India).

Data management
The George Institute for Global Health, Sydney, NSW, Australia: P Donnelly, D Byrne, S Steley; *The George Institute for Global Health, Bangalore, India:* V Santhosh.

Statistical analysis
LB, S Chilappagari (The George Institute for Global Health India), QL, J Mysore (The George Institute for Global Health, Sydney, NSW, Australia).

Principal Investigators
India: Christian Medical College, Ludhiana, Punjab: JDP. *Apollo Gleneagles Hospitals, Kolkata, West Bengal*: J Roy. *All India Institute of Medical Sciences, New Delhi, Delhi*: M V Padma. *Baptist Christian Hospital, Tezpur, Assam*: L John. *Christian Medical College and Hospital, Vellore, Tamil Nadu*: S Aaron. *GNRC Hospitals, Dispur, Assam*: N C Borah. *Lalitha Super Specialty Hospital, Guntur, Andhra Pradesh*: P Vijaya. *Nizam Institute for Medical Sciences, Hyderabad, Andhra Pradesh*: S Kaul. *Postgraduate Institute for Medical Sciences and Research, Chandigarh*: D Khurana. *Sree Chitra Tirunal Institute for Medical Sciences and Technology, Kerala*: P N Sylaja. *Global Hospitals, Chennai:* D S Halprashanth. *BGS Global Hospitals, Bangalore, Karnataka*: B K Madhusudhan. *Amrita Institute of Medical Sciences, Kochi, Kerala*: V Nambiar. *St Stephen's Hospital, New Delhi, Delhi*: S Sureshbabu.

Stroke coordinators, blinded assessors, and site staff
India: Christian Medical College, Ludhiana: M C Khanna, G S Narang. *Apollo Gleneagles Hospitals*: D Chakraborty, S S Chakraborty, B Biswas. *All India Institute of Medical Sciences*: S Kaura, H Koundal. *Baptist Christian Hospital*: P Singh, A Andrias. *Christian Medical College and Hospital, Vellore*: D S Thambu, I Ramya, J George, A T Prabhakar,

P Kirubakaran, P Anbalagan. *GNRC Hospitals*: M Ghose, K Bordoloi, P Gohain. *Lalitha Super Specialty Hospital*: N M Reddy, K V Reddy, T N M Rao. *Nizam Institute for Medical Sciences*: S Alladi, V R R Jalapu, K Manchireddy, A Rajan. *Postgraduate Institute for Medical Sciences and Research*: S Mehta, C Katoch, B Das, A Jangir, T Kaur. *Sree Chitra Tirunal Institute for Medical Sciences and Technology*: S Sreedharan, S Sivasambath, S Dinesh, B S Shibi. *Global Hospitals, Chennai*: A Thangaraj, A Karunanithi, S M S Sulaiman. *BGS Global Hospitals, Bangalore*: K Dehingia, K Das, C Nandini, N J Thomas. *Amrita Institute of Medical Sciences*: T S Dhanya, N Thomas, R Krishna, V Aneesh, R Krishna. *St Stephen's Hospital*: S Khullar, S Thouman, I Sebastian.

Contributors

JDP originally suggested the study. JDP, RIL, CSA, LB, AF, MLH, LAH, SJ, PL, PKM, GVSM, and MFW designed the study and obtained funding. QL and LB did the statistical analysis. HL led the process evaluation. RIL wrote the first draft of the manuscript, and all writing committee members contributed, edited, and approved the final version.

Declaration of interests

MLH reports grants from National Health and Medical Research Council (NHMRC) of Australia and from National Heart Foundation (NHF), Australia, during the conduct of the study, and reports other support from Boehringer Ingelheim, outside the submitted work. LB, RIL, CSA, PKM, PL, GVSM, and JDP report grants from NHMRC, during the conduct of the study. CSA reports personal fees from Boehringer Ingelheim, Takeda, AstraZeneca, and Medtronic, outside the submitted work. AF reports grants from The George Institute for Global Health, Sydney, during the conduct of the study, and was lead investigator of similar work undertaken in the UK (*Lancet* 2013; **382:** 2069–76). RIL reports personal fees from Covidien and Pfizer, outside the submitted work. QL, LAH, MFW, HL, and SJ have nothing to declare.

Acknowledgments

The trial was funded by Project Grant APP1045391 from the National Health and Medical Research Council of Australia. PKM is a recipient of an Intermediate Career Fellowship of Wellcome Trust—Department of Biotechnology India Alliance. MLH is a recipient of a National Heart Foundation Future Leader Fellowship, Level 2 (100034, 2014–2017). SJ is the recipient of an NHMRC Senior Research Fellowship. CSA holds an NHMRC Senior Principal Research Fellowship. HL is the recipient of an NHMRC APP1114897 scholarship to undertake her doctorate.
The steering committee designed the study, gathered the data (in collaboration with the hospital sites), made the decision to submit the manuscript for publication, and vouched for the fidelity of the study to the protocol. The George Institute for Global Health was responsible for analysis of the data.

References

1 Feigin VL, Forouzanfar MH, Krishnamurthi R, et al. Global and regional burden of stroke during 1990–2010: findings from the Global Burden of Disease Study 2010. *Lancet* 2014; **383:** 245–55.
2 Joshi R, Alim M, Kengne AP, et al. Task shifting for non-communicable disease management in low and middle income countries—a systematic review. *PLoS One* 2014; **9:** e103754.
3 Govindarajan V, Ramamurti R. Delivering world-class health care, affordably. *Harvard Bus Rev* 2013; **91:** 117–22.
4 WHO. Task shifting: rational redistribution of tasks among health workforce teams: global recommendations and guidelines. Geneva: World Health Organization Press, 2008.
5 Langhorne P, de Villiers L, Pandian JD. Applicability of stroke-unit care to low-income and middle-income countries. *Lancet Neurol* 2012; **11:** 341–48.
6 Kalkonde YV, Deshmukh MD, Sahane V, et al. Stroke is the leading cause of death in rural Gadchiroli, India: a prospective community-based study. *Stroke* 2015; **46:** 1764–68.
7 Pandian JD, Sudhan P. Stroke epidemiology and stroke care services in India. *J Stroke* 2013; **15:** 128–34.
8 Dieleman JL, Templin T, Sadat N, et al. National spending on health by source for 184 countries between 2013 and 2040. *Lancet* 2016; **387:** 2521–35.
9 WHO. World report on disability. Geneva: World Health Organization, 2011.
10 Pandian JD, Felix C, Kaur P, et al. Family-led rehabilitation after stroke in India: the ATTEND pilot study. *Int J Stroke* 2015; **10:** 609–14.
11 Alim M, Lindley R, Felix C, et al. Family-led rehabilitation after stroke in India: the ATTEND trial, study protocol for a randomized controlled trial. *Trials* 2016; **17:** 1–8.
12 Stroke Unit Trialists Collaboration. Organised inpatient (stroke unit) care for stroke. *Cochrane Database Syst Rev* 2007; **4:** CD000197.
13 Early Supported Discharge Trialists. Services for reducing duration of hospital care for acute stroke patients. *Cochrane Database Syst Rev* 2012; **9:** CD000443.
14 French B, Thomas LH, Leathley MJ, et al. Repetitive task training for improving functional ability after stroke. *Cochrane Database Syst Rev* 2007; **4:** CD006073.
15 van Swieten JC, Koudstaal PJ, Visser MC, Schouten HJA. Interobserver agreement for the assessment of handicap in stroke patients. *Stroke* 1988; **19:** 604–07.
16 Lindley RI, Waddell F, Livingstone M, et al. Can simple questions assess outcome after stroke? *Cerebrovas Dis* 1994; **4:** 314–24.
17 Mahoney FI, Barthel DW. Functional evaluation: the Barthel Index. A simple index of independence useful in scoring improvement in the rehabilitation of the chronically ill. *Maryland State Med J* 1965; **14:** 61–65.
18 Nouri FM, Lincoln NB. An extended activities of daily living scale for stroke patients. *Clin Rehabil* 1987; **1:** 301–05.
19 The WHOQOL Group. Development of the World Health Organization WHOQOL-BREF quality of life assessment. *Psychol Med* 1998; **28:** 551–58.
20 EuroQol G. EuroQol—a new facility for the measurement of health-related quality of life. *Health Policy* 1990; **16:** 199–208.
21 Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983; **67:** 361–70.
22 Elmstahl S MB, Annerstedt L. Caregiver's burden of patients 3 years after stroke assessed by a novel caregiver burden scale. *Arch Phys Med Rehabil* 1996; **77:** 177–82.
23 Billot L, Lindley RI, Harvey LA, et al. Statistical analysis plan for the family-led rehabilitation after stroke in India (ATTEND) trial: a multicenter randomized controlled trial of a new model of stroke rehabilitation compared to usual care. *Int J Stroke* 2017; **12:** 208–10.
24 Howard G, Waller JL, Voeks JH, et al. A simple, assumption-free, and clinically interpretable approach for analysis of modified Rankin outcomes. *Stroke* 2012; **43:** 664–69.
25 McCullagh P. Regression models for ordinal data. *J Roy Stat Soc B Met* 1980; **42:** 109–42.
26 Vloothuis JDM, Mulder M, Veerbeek JM, et al. Caregiver-mediated exercises for improving outcomes after stroke. *Cochrane Database Syst Rev* 2016; 12: CD011058.
27 Intercollegiate Stroke Working Party. National clinical guideline for stroke, 4th edn. London: Royal College of Physicians, 2012.
28 Hassett L, van den Berg M, Lindley RI, et al. Effect of affordable technology on physical activity levels and mobility outcomes in rehabilitation: a protocol for the Activity and Mobility using Technology (AMOUNT) rehabilitation trial. *BMJ Open* 2016; **6:** e012074.
29 Forster A, Dickerson J, Young J, et al. A structured training programme for caregivers of inpatients after stroke (TRACS): a cluster randomised controlled trial and cost-effectiveness analysis. *Lancet* 2013; **382:** 2069–76.
30 Liu H, Lindley R, Alim M, et al. Protocol for process evaluation of a randomised controlled trial of family-led rehabilitation post stroke (ATTEND) in India. *BMJ Open* 2016; **6:** e012027.
31 Pandian JD, Singh G, Kaur P, et al. Incidence, short-term outcome, and spatial distribution of stroke patients in Ludhiana, India. *Neurology* 2016; **86:** 425–33.
32 Eaton J, McCay L, Semrau M, et al. Scale up of services for mental health in low-income and middle-income countries. *Lancet* 2011; **378:** 1592–603.
33 Lancet. Scale up services for mental disorders: a call for action. *Lancet* 2007; **370:** 1241–52.