Caregiver-Delivered Stroke Rehabilitation in Rural China

The RECOVER Randomized Controlled Trial

Bo Zhou, PhD*; Jing Zhang, MSc*; Yi Zhao, PhD; Xian Li, PhD; Craig S. Anderson, PhD; Bin Xie, MD; Ninghua Wang, MD; Yuhong Zhang, PhD; Xiaojun Tang, MSc; Janet Prvu Bettger, PhD; Shu Chen, MSc; Wanbing Gu, MSc; Rong Luo, MSc; Qiongrui Zhao, MSc; Xiaoxia Li, MSc; Zhenxing Sun, MSc; Richard I. Lindley, MD; Sarah E. Lamb, PhD; Yangfeng Wu, PhD; Jingpu Shi, PhD; Lijing L. Yan, PhD

Background and Purpose—Stroke disability is a major health burden in rural China where rehabilitation services are inadequate. We aimed to determine the effectiveness of a novel nurse-led, caregiver-delivered model of stroke rehabilitation in rural China.

Methods—A multicenter prospective, randomized open, blinded outcome assessed, controlled trial was conducted in 3 rural county hospitals in China: Zhangwu, Liaoning Province (Northeast); Qingtongxia, Ningxia Hui Autonomous Region (Northwest); and Dianjiang, Chongqing Municipality (Southwest). Adult patients (age 18–79 years) with residual disability (Barthel Index score $\leq$80/100) after a recent acute stroke were randomized to a new service model or usual care. The new intervention was multifaceted and was based on a task-shifting / training-the-trainers model, supported by a custom-designed smartphone application, where patients and caregivers received evidence-based in-hospital education and stroke rehabilitation training (focus on mobility, self-care, and toileting), delivered by trained nurses before hospital discharge, and 3 postdischarge support telephone calls. Outcome assessments were undertaken before hospital discharge and at 3 and 6 months. Primary outcome was physical functioning (Barthel Index scores) at 6 months, assessed by research staff blind to treatment allocation, adjusted for baseline covariates in an intention-to-treat analysis. Secondary outcomes included measures of mobility, health-related quality of life, mood, and caregiver burden. The study included a process evaluation that assessed intervention fidelity.

Results—From November 2014 to December 2016, 246 stroke patients were randomized to intervention (n=118) or control (n=128) groups. There was no statistically significant difference in adjusted 6-month Barthel Index scores between groups (70.1 versus 74.1, mean difference, $-4.0$ [95% CI, $-10.0$ to 2.9]), nor any differences across the other outcome measures. Process evaluation interviews revealed that the intervention was desirable and positively accepted by nurses, caregivers, and patients but was considered too complex despite efforts to simplify materials for the rural context. Key strategies identified for future studies included the use of community health workers, smartphone application enhancement, and simpler and more frequent training for nurses, caregivers, and patients.

Conclusions—A novel nurse-led, digital supported, caregiver-delivered stroke rehabilitation program did not improve patient physical functioning after stroke in rural China. Further stroke rehabilitation research suitable for resource-poor settings is required, with several components being suggested through stakeholder interviews in our study.

Clinical Trial Registration—URL: https://www.clinicaltrials.gov. Unique identifier: NCT02247921. (Stroke. 2019;50:1825-1830. DOI: 10.1161/STROKEAHA.118.021558.)

Key Words: caregivers ◼ China ◼ nurses ◼ rehabilitation ◼ stroke

© 2019 The Authors. Stroke is published on behalf of the American Heart Association, Inc., by Wolters Kluwer Health, Inc. This is an open access article under the terms of the Creative Commons Attribution Non-Commercial License, which permits use, distribution, and reproduction in any medium, provided that the original work is properly cited and is not used for commercial purposes.

DOI: 10.1161/STROKEAHA.118.021558
Stroke is a major health burden in China, particularly in rural regions where there are high rates and poor access to services and optimal care. The economic burden of stroke is also high, with the average cost of hospital care being estimated at ¥10,489 (US $1,311), which is about 92% of annual median household income for rural families in the absence of insurance. Despite recognition of high levels of disability among survivors, rehabilitation services are limited in many parts of China, especially in rural regions, where there are few health professionals specifically trained in recognition and management of stroke-related complications. As family members have prime responsibility for the care of disabled patients at home in rural China, it seems logical to focus the provision of rehabilitative care to them.

Previous studies on family-based stroke intervention in countries outside of China have had inconsistent results. We designed an innovative rehabilitation based on Western approaches to service delivery involving task-shifting and training-the-trainer model, where positive results have been shown for various conditions. The task-shifting model, in particular, seems most suitable in low-resource contexts where there are few health professionals; whereas the training-the-trainer model is based on a knowledge, skills, and agency loop: moving from specialist to nurse, nurse to caregiver, and caregiver to patient. We aimed to determine the effectiveness of the program to improve the basic self-care (activities of daily living [ADL]) physical function of patients disabled after a recent stroke in a multicenter randomized controlled trial, the RECOVER (Rehabilitation Through Caregiver-Delivered Nurse-Organized Service Programs for Disabled Stroke Patients in Rural China).

Methods

Data from this study are available from the corresponding author on reasonable request.

Design

Full details of the study protocol for the RECOVER trial have been published. In brief, the study was conducted at 3 county hospitals in rural China: Zhangwen, Liaoning Province (Northeastern China); Qtongxia, Ningxia Hui People Autonomous Region (Northwestern China); and Dianjiang, Chongqing municipality (Southwestern China). Hospitalized patients with a clinical diagnosis of acute stroke (ischemic, hemorrhagic, or undifferentiated) considered suitable for rehabilitation by their attending physician were eligible for the study if they were aged 18 to 79 years, required assistance with ADL (score ≤40 versus 40–80) after a recent stroke in a multicenter randomized controlled trial, the RECOVER (Rehabilitation Through Caregiver-Delivered Nurse-Organized Service Programs for Disabled Stroke Patients in Rural China).

Intervention

Up to 3 nurses from each hospital received training from accredited rehabilitation physicians and therapists at Peking University First Hospital over 2 days, with a menu-style checklist used to guide their training and techniques, and case-based methods and teach-back approaches used to assess their skills. They also received a further day of training on returning to their respective hospitals. The nurses screened for eligible patients and family caregivers, and those randomized to the intervention group were provided with skills and guidance, using a culturally appropriate, picture-rich, easy-to-understand manual and several 15- to 30-minute training sessions. They were also given a videodisk of their training and a “daily reminder” guide to help motivate patients to complete a routine of daily support exercises at home (further details of the TIDieR template [Template for Intervention Description and Replication] are provided in Table I in the online-only Data Supplement). The nurses also offered patients and caregivers follow-up checks on their status and problem-solving recommendations through 3 telephone calls scheduled at 2, 4, and 8 weeks after discharge. Patients in the control group received conventional care without any additional recommendations or activities.

The rehabilitation intervention was based on the Motor Relearning Theory, which emphasized task and environmental specific patient and caregiver training that focused on 3 recovery goals: (1) mobility (transfer, mobility, and stairs) tailored towards a patient’s level of function, covering in-bed movements, sitting and standing balance, and walking; (2) self-care (grooming, feeding, dressing, and bathing); and (3) continence/toileting (bowel, bladder, and toilet use). The training also included information on the usual patterns of poststroke recovery, importance of cardiovascular risk factor control, awareness and implications of low mood, importance of task practice, and in the use of a tailored discharge plan, established jointly with patients and caregivers, that covered their recovery goals.

Outcomes

The primary outcome was ADL defined by scores on the BI at 6 months postrandomization, assessed in-person by trained research nurses who were blind to the treatment assignment. Secondary outcomes included BI scores at predischarge and 3-month postrandomization; modified Rankin Scale scores at 3 and 6 months; scores on the Functional Ambulation Category; Patient Health Questionnaire 9, and EuroQol-5-dimension at 6 months; and a measure of Caregiver Burden Index at 6 months. Other information collected included hospital length of stay and medical costs obtained from questionnaires completed by participants and all adverse events including rehospitalization and death, with details recorded by nurses reported to the study coordinating center.

Process Evaluation

A process evaluation assessing fidelity to the intervention, involved standardized, semistructured interviews (20–40 minutes) with nurses who delivered the rehabilitation model of care and 2 patient/caregiver pairs at each site, was undertaken during site monitoring visits at 3 and 9 months. Participatory observation of the intervention and focus groups with nurses, which lasted >60 minutes, were also conducted. All interviews were voice-recorded with consent, and the transcripts analyzed by independent researchers using a thematic framework for coding and descriptions of opinions.

Statistical Analysis

Based on studies indicating considerable variability in BI scores among stroke survivors, with SD ranging 10 to 302,25 and scores for improvement of 10 to 35 points,26 we estimated that a sample size of 86 patients per group would provide 90% power (2-sided α of 0.05) to detect a 10-point difference in BI scores between groups. Assuming a SD of 20, this between-group difference corresponds to a standardized effect size of 0.50. However, taking account of 10% missing primary outcome, the target sample was 200 patients (100 per group).
The primary analysis was based on a modified intention-to-treat population that included all randomized patients who completed at least one BI assessment; a complete data analysis was used in those with a primary outcome at 6 months. Multiple linear regression was used to adjust for baseline imbalances, and mixed models were used to account for repeated measures and missing values. Predefined subgroups included age, sex, stroke type and sequence (first versus recurrent), severity of 6-month BI score, and by site. All analysis was conducted using SAS 9.4 software (SAS Institute, Inc, Cary, NC).

**Results**

Between November 2014 and December 2016, 447 acute stroke patients were screened for inclusion, but 168 were excluded for clinical reasons and 4 for other reasons, and 29 refused participation (Figure 1). Overall, 246 patients were randomized into intervention (118) and control (128) groups, but 2 patients died before receiving the intervention (Figure 1).

Table 1 outlines the baseline characteristics of participating patients and their caregivers. Most patients (mean age 65.5 years; 45.1% male) had suffered their first (81.2%) primarily ischemic (77.2%) stroke. Caregivers (mean age 52.1 years) had either primary school (30.3%) or middle school (31.5%) education.

Table 2 shows that at 6 months, there was no significant between-group difference in BI scores (70.1±25.5 and 74.1±23.0, mean difference, −4.0 [95% CI, −10.0 to 2.9]; crude P=0.23 and adjusted P=0.27). A mixed model indicates that BI scores similarly increased in both groups during follow-up (baseline, before discharge, and at 3 and 6 months), but did not significantly differ between the intervention and control groups (Figure 2). Secondary outcomes were also similar between groups, except for Functional Ambulation Category scores being higher in the usual care group (P=0.04) after adjustment confounders. The neutral treatment effect on the primary outcome was consistent across subgroups (Figure 3).

Table 3 provides details surrounding the training associated with the intervention. Training was completed by most patient/caregivers (92%) over 2 or 3 sessions, for a duration of >1 hour (91%), and most (99%) received 3 postdischarge follow-up telephone calls.

Table II in the online-only Data Supplement provides a summary of the key themes identified from the in-depth individual interviews with 7 nurses and 6 patient/caregiver pairs from participating hospitals, indicating not only high acceptability of the intervention but also certain challenges, such as extra workload and complexity of the training.

**Discussion**

Our novel nurse-led, caregiver-delivered, rehabilitation model of care did not improve physical recovery, according to basic ADL measured by the BI, over usual care for patients recently...
disabled from acute stroke in rural China. Although there is evidence of effectiveness of task-shifting and training-the-trainers in other contexts, the use of this approach to stroke rehabilitation in low-resource settings cannot be recommended, despite being coveted and enthusiastically accepted by hospital executives, nurses, family caregivers, patients, and other stakeholders.

Our results are consistent with other recently completed trials, including one that used a similar task-shifting family-delivered stroke rehabilitation intervention in India,6 and another cluster clinical trial of training caregivers in the United Kingdom.7 Moreover, a meta-analysis8 of several trials involving 333 patients showed that caregiver-mediated rehabilitation did not improve ADL function after stroke. Our trial differed from these studies in several aspects but most notably in regards to the approach to training and support which was free of direct input from rehabilitation physicians and therapists; rather, nurses were trained to deliver rehabilitation to patients/caregivers in hospital and at home.

Our imbedded process evaluation showed that the stroke rehabilitation program was well implemented by the nurses (dose delivered), and nearly all caregivers and patients received training in hospital and at home (dose received). Even so, the qualitative interviews disclosed several negative responses, highlighting challenges in delivering this model of care which affected fidelity of the intervention. Despite our efforts to ensure that the training could be integrated into routine care, the trainer nurses expressed concern over an increase in workload and that their other duties assumed priority over those associated with the intervention. Although increased in-hospital rehabilitation may assist patients, it may not be feasible in a task-shifting model without freeing up nursing time from other tasks. Another concern of nurses was inconsistency in the delivery of care by caregivers, whereas patients expressed reluctance to exercise without appropriate supervision, which led to the level of participation of patients in exercises fell off upon their discharge home. Thus, future task-shifting models of care need to ensure there are sufficient human resources (ie, nurses and caregivers), with the potential to integrate a trained community health worker, to facilitate the development of skills by patients at home.

Another potential limitation of our study was that the nurses were insufficiently skilled to deliver an appropriate standard of intensity of training to caregivers and patients to affect a significant change. The multidisciplinary intervention design team aimed to develop contextually appropriate training materials and innovative easy-to-use tools for training. Nevertheless, many nurses and caregivers/patients expressed difficulties in acquiring certain rehabilitation skills, raising the issue as to whether the nurses would have benefited from a longer period of training and for caregivers/patients to have had greater frequency of engagement. Conversely, the rehabilitation tools and training materials might have been too complex. Greater thought is required to develop task-shifting or training-the-trainer interventions that balance simplicity with effectiveness.

The RECOVER trial indicates that rigorous evaluations of rehabilitation services are possible in low-resource...
settings, in particular for task-shifting and training-the-trainers approaches being successfully adapted to rural China. The study team’s evidence-based rehabilitation training with picture-rich manuals for both nurses and patients/family caregivers was acceptable to all parties and achieved clear, practical benefits across the intervention program. In this context, several important future research directions were defined: training time and intensity reconfigurations, training manual development, community healthcare worker uptake, and smartphone application enhancement.

In summary, our evaluation of task-shifting stroke rehabilitation by nurses who trained family caregivers to provide care, though desired and well-accepted by stakeholders, did not produce significant improvements over usual care in the recovery of ADL among participants in rural China. In this foundational study, future directions for research have been highlighted that include the utilization of community healthcare workers, enhancement of smartphone applications for communication, education and data collection, and review of the appropriate format and duration of training. More efforts and different models are required to develop effective approaches to improve recovery from stroke in low-resource setting of China and other countries.

**Acknowledgments**
R. Luo and J. Zhang searched the literature; Drs Xie, Wang, Y. Zhang, Prvu Bettger, Lindley, Anderson, Lamb, Wu, Shi, and Yan were responsible for study design; Dr Xie and Wang developed the intervention protocol; Q. Zhao, X. Li, and Z. Sun collected data; XL, J. Zhang, and Dr Yan analyzed and interpreted the data; Drs Zhou, Y. Zhang, Shi, YZ, and X. Tang were responsible for project implementation; J. Zhang, Drs Zhou, YZ, Chen, and W. Gu undertook project management; Q. Zhao, X. Li, Z. Sun, J. Zhang, Drs Zhou, YZ, X. Tang, and Yan were responsible for quality control; and J. Zhang and Dr Zhou wrote the first draft of the article. All authors made critical revisions of the article. We thank all directors, nurses, patients, and caregivers of participating hospitals for their cooperation in the study and Yu Liu of Beihang University for developing the smartphone application.

**Sources of Funding**
This study had principle funding from the China Medical Board (United States) and Amsterdam Health and Technology Institute,
the Netherlands and additional funding from The George Institute China and Duke Kunshan University. None of these organizations had any role in writing of the article or the decision to submit it for publication. The corresponding authors had full access to all the data in the study and final responsibility for the decision to submit for publication.

Disclosures

There is no support from any organizations for the submitted work. No financial relationships with any organizations that might have an interest in the submitted work in the previous 3 years. Dr Anderson reports receiving Advisory Board fees from Amscan and Boehringer Ingelheim and grants and speaker fees and travel reimbursement from Takeda. No other relationships or activities that could appear to have influenced the submitted work. The other authors report no conflicts.

References

1. Yang L, Wu M, Cui B, Xu J. Economic burden of cardiovascular diseases in China. Expert Rev Pharmacoecon Outcomes Res. 2008;8:349–356. doi: 10.1586/14737167.8.4.349
2. Yang Y, Shi YZ, Zhang N, Wang S, Ungvari GS, Ng CH, et al. The disability rate of 5-year post-stroke and its correlation factors: a national survey in China. PLoS One. 2016;11:e0165341. doi: 10.1371/journal.pone.0165341
3. Jianjun Y, Yongshan H, Wu Y, Wenhua C, Yulian Z, Xiao C, et al. The effects of community-based rehabilitation on stroke patients in china: a single-blind, randomized controlled multicentre trial. Clin Rehabil. 2009;23:408–417
4. Xianghong Meng WW, Hong Dai. Investigation on current status of rehabilitation of stroke at Chongwen district in Beijing. Chin J Rehabil Med. 2009;24:4.
5. Sit JW, Wong TK, Clinton M, Li LS, Fong YM. Stroke care in the home: the impact of social support on the general health of family caregivers. J Clin Nurs. 2004;13:816–824. doi: 10.1111/j.1365-2702.2004.09943.x
6. ATTEND Collaborative Group. Family-led rehabilitation after stroke in India (ATTEND): a randomised controlled trial. Lancet. 2017;390:588–599. doi: 10.1016/S0140-6736(17)31447-2
7. Forster A, Dickerson J, Young J, Patel A, Kalra L, Nixon J, et al. TRACS Trial Collaboration. A cluster randomised controlled trial and economic evaluation of a structured training programme for caregivers of inpatients after stroke: the TRACS trial. Health Technol Assess. 2013;17:1–216. doi: 10.3310/hta17460
8. Vloothuis JD, Mulder M, Veerbeek JM, Konijnendeld M, Visser-Meily JM, Ket JC, et al. Caregiver-mediated exercises for improving outcomes after stroke. Cochrane Database Syst Rev. 2016;12:CD011058. doi: 10.1002/14651858.CD011058.pub2
9. Gustavsen M, Jansen R, Kjendahl A, Lorentzen A. Motor Relearning Program approach improves short-term motor outcomes and reduces hospital stay after stroke. Aust J Physiother. 2002;48:59.
10. Ogedegbe G, Gyanfi J, Plange-Rhule J, Surkis A, Rosenthal DM, Arihenhuwua C, et al. Task shifting interventions for cardiovascular risk reduction in low-income and middle-income countries: a systematic review of randomised controlled trials. BMJ Open. 2014;4:e005983. doi: 10.1136/bmjopen-2014-005983
11. Yan LL, Chen S, Zhou B, Zhang J, Xie B, Luo R, et al. A randomized controlled trial on rehabilitation through caregiver-delivered nurse-organized service programs for disabled stroke patients in rural china (the RECOVER trial): design and rationale. Int J Stroke. 2016;11:823–830. doi: 10.11171/1747493016654290
12. Mahoney FI, Barthel DW. Functional evaluation: the barthel index. Md State Med J. 1965;14:61–65.
13. Hoffmann TC, Glassiou PP, Bourtou L, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ. 2014;348:g1687. doi: 10.1136/bmj.g1687
14. Sulter G, Steen C, De Keyser J. Use of the Barthel index and modified Rankin scale in acute stroke trials. Stroke. 1999;30:1538–1541.
15. Kwon S, Hartzema AG, Duncan PW, Min-Lai S. Disability measures in stroke: relationship among the Barthel Index, the Functional Independence Measure, and the modified Rankin Scale. Stroke. 2004;35:918–923. doi: 10.1161/01.STR.0000119385.56094.32
16. Nunn A, Bath PM, Gray LJ. Analysis of the modified Rankin Scale in randomised controlled trials of acute ischaemic stroke: a systematic review. Stroke Res Treat. 2016;2016:9482876. doi: 10.1155/2016/9482876
17. Mehrholz J, Wagner K, Rütte K, Meissner D, Pohl M. Predictive validity and responsiveness of the functional ambulation category in hemiparetic patients after stroke. Arch Phys Med Rehabil. 2007;88:1314–1319. doi: 10.1016/j.apmr.2007.06.764
18. Zhang YL, Liang W, Chen ZM, Zhang HM, Zhang JH, Weng XQ, et al. Validity and reliability of patient health questionnaire-9 and patient health questionnaire-2 to screen for depression among college students in China. Asia Pac Psychiatry. 2010;3:5:268–275. doi: 10.1111/j.1469-8991.2010.01203.x
19. Gusi N, Olivares PR, Rajendram R. The eq-5d health-related quality of life questionnaire. In: Preedy VR, Watson RR, eds. Handbook of Disease Burdens and Quality of Life Measures. New York, NY: Springer; 2010.
20. Liu PC, Gau BS, Hung CC. Development and psychometric testing of a chinese version of the caregiver burden index for parents of children with allergies. J Pediatr Nurs. 2015;30:208–218. doi: 10.1016/j.pedin.2014.04.006
21. Pope C, Ziebland S, Mays N. Qualitative research in health care. Analysing qualitative data. BMJ. 2000;320:114–116. doi: 10.1136/bmj.320.7227.114
22. Reding MJ, Potes E. Rehabilitation outcome following initial unilateral hemispheric stroke. Life table analysis approach. Stroke. 1988;19:1354–1358.
23. Lu J, Yu Y, Fan JT, Xu Y, Hao FC. Impact of different treatment and evaluation methods on stroke rehabilitation effect. Tianjin Med J. 2010;11:2.
24. Shah S, Vanclay F, Cooper B. Efficiency, effectiveness, and duration of stroke rehabilitation. Stroke. 1990;21:241–246.