

# Effects of the nurse-led program on disabilities improvement in patients with ischemic stroke

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## Abstract

To evaluate whether the nurse-led program can improve disabilities in patients with ischemic stroke for more than 6 months. This is a randomized, open-label study. Participants in the usual-care group received the usual care that included verbal stroke-related education and secondary prevention. Participants in the active group received the usual care plus the nurse-led program intervention. The disability was evaluated using National Institutes of Health Stroke Scale (NIHSS). The Mental Health Inventory-5 (MHI-5) was used to assess mental health status (MHS). The median duration since ischemic stroke was 8.4 and 8.6 months, respectively. At baseline, there was no difference in the median NIHSS value and the NIHSS category between these 2 groups. After 6 months' follow-up, the median NIHSS value was lower in the active group (4.1 vs 6.3). The proportion of patients with NIHSS of 1 to 4 was higher (50.0% vs 28.6%) while the proportion of patients with NIHSS of 5 to 12 (24.1% vs 51.8%) was lower in the active group. After multivariate regression analysis, the nurse-led program was negatively associated with increased NIHSS category (odds ratio of 0.70 and 95% confidence interval of 0.62–0.88). In the group with MHI-5 less than median, the nurse-led program was not associated with NIHSS category. While in the group with MHI-5 greater than median, the nurse-led program was associated decreased NIHSS category, with a significant interaction ( $P$  value = .03). In ischemic stroke patients for more than 6 months, the nurse-led program improves disabilities, which might be related to MHS improvement.

**Abbreviations:** MHI-5 = Mental Health Inventory-5, MHS = mental health status, NIHSS = National Institutes of Health Stroke Scale.

**Keywords:** disability, ischemic stroke, nurse-led program, rehabilitation

## 1. Introduction

Ischemic stroke is the leading cause of morbidity and mortality in China.<sup>[1,2]</sup> According to the epidemiological studies,<sup>[1,3]</sup> the burden of ischemic stroke is continuously increasing with populating aging and increased prevalence of hypertension in China.<sup>[4,5]</sup> Ischemic stroke has caused substantial health and economic loss in China.<sup>[2]</sup> Studies have demonstrated that rehabilitation after acute ischemic stroke is associated with improvement in disabilities and quality of life.<sup>[6,7]</sup> Nevertheless, a substantial proportion of patients could not receive immediate and systematic rehabilitation, which in turn lead to permanent disabilities.<sup>[8,9]</sup>

Professional nurses play important roles in the healthcare for patients with cardiovascular disease. For example, our prior study demonstrated that the nurse-led program helped improve quality of life and mental health status (MHS) in patients with chronic heart failure.<sup>[10–12]</sup> In addition, studies also have shown that the nurse-led rehabilitation programs

can provide substantial benefits for disabilities improvement in patients after acute ischemic stroke.<sup>[13–15]</sup> However, due to large number of patients with ischemic stroke and relatively limited health resources in China,<sup>[16]</sup> whether these programs can be successfully applied in China's patients with ischemic stroke is unknown. In addition, whether the nurse-led program was beneficial for disabilities improvement in those with ischemic stroke for more than 6 months was unknown. Furthermore, the mechanisms underlying the benefits of the nurse-led program on disabilities improvement have not fully understood yet. Considering the high incidence of poor MHS after ischemic stroke,<sup>[17,18]</sup> we thus hypothesized that the nurse-led program might be associated with MHS improvement, which in turn helps improve disabilities in patients with ischemic stroke.

Herein, we conducted a pilot study to evaluate whether the nurse-led program can help improve disabilities in patients with ischemic stroke for more than 6 months. In addition, we explored whether the benefits derived from the nurse-led program were associated with MHS improvement.

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The authors have no conflicts of interest to disclose.

The datasets generated during and/or analyzed during the current study are not publicly available, but are available from the corresponding author on reasonable request.

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## 2. Methods

### 2.1. Study design and participants recruitment

This is a randomized, open-label study. The current study was approved by the Clinical Research Ethic Committee of Hainan Western Central Hospital. Individuals, who were  $\geq 60$  years old, had documented ischemic stroke more than 6 months and with disabilities after ischemic stroke, were consecutively recruited after written informed consent was obtained. Since this was a pilot study, we planned to enroll 100 participants. Based on the random number produced from the random number generator, participants were assigned into the usual-care group and the active group. Clinical characteristics and medication use at baseline were recorded during personal interview. Renal and liver function, fasting plasma glucose, and lipid profile were measured after recruitment. Study flowchart was presented in the Figure 1.

### 2.2. The nurse-led program

Participants, who were assigned into the usual-care group, received the usual care that included verbal stroke-related education and secondary prevention. In addition, registered nurses would follow-up the adherence of secondary prevention at the 1st and 6th month after participating in the current study. Participants, who were assigned into the active group, received the usual care plus the nurse-led program intervention. These interventions included two main aspects: participants would receive telephone support from the intervention nurse every week. The nurse would encourage the participants, discuss concerns and problems arising from disabilities, motivate them to monitor their daily activities, and provide strategies and resources to help resolve their problems; personal interview at the outpatient clinic would be provided every 2 weeks. The intervention nurse would meet with participants and discuss about their concerns and problems, and they would help participants develop problem-solving skills, introduce resources, reinforce self-care knowledge and skills, and motivate them to self-monitor progress and outcomes toward care goals. The duration of the nurse-led program was 6 months and thereafter, all participants would come back to the outpatient clinic for the assessment of their disabilities. In the current study, the disability was evaluated using National Institutes of Health Stroke Scale (NIHSS), in which a higher score indicated worse disabilities.<sup>[19]</sup>

### 2.3. Assessment of MHS

At baseline and after 6 months' intervention, the Mental Health Inventory-5 (MHI-5) was used to assess the MHS in both

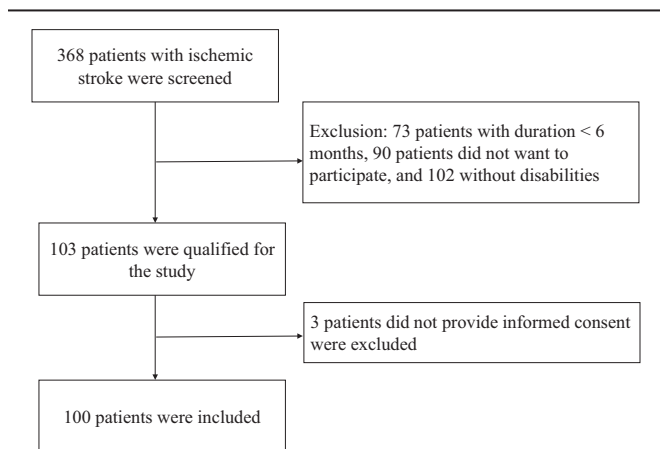


Figure 1. Study flowchart.

groups. The nurses who performed this assessment were blinded into the group assignment.

### 2.4. Statistical analysis

Continuous variables were presented as mean and standard deviation and categorical variables were presented as number and percentage. Comparisons of continuous variables were assessed by Student *t* test and comparisons of categorical variables were assessed by the  $\chi^2$ -test. Univariate and multivariate regression analysis was used to evaluate the association between the nurse-led program and disabilities improvement. In addition, we evaluated whether disabilities improvement was related to the improvement in MHS using logistic regression analysis. Odds ratio and 95% confidence interval was reported. All analyses were performed using SPSS 23.0 and a two-sided *P* value  $< .05$  was considered as statistical significance.

## 3. Results

### 3.1. Baseline characteristics

As shown in Table 1, there was no difference in baseline characteristics between these 2 groups. The mean age was 65.4 and 66.3 years, and male accounted for 53.6% and 53.7%, respectively. The prevalence of comorbidities and baseline blood pressure were comparable. All participants in both groups received antiplatelet and statins. The median duration since ischemic stroke was 8.4 and 8.6 months, respectively. During the follow-up study, participants in both groups were alive and the survival rate was 100%. The distribution of ischemic stroke hemisphere was also similar in both groups.

Table 1

Comparisons of baseline characteristics.

Variables	Usual-care group (n = 56)	Active group (n = 54)
Age (years)	65.4 $\pm$ 13.7	66.3 $\pm$ 14.1
Male, n (%)	30 (53.6)	29 (53.7)
Education $\geq$ high school, n (%)	28 (50.0)	28 (51.9)
Married status, n (%)	56 (100.0)	53 (98.1)
Smoking, n (%)	9 (16.1)	8 (14.8)
Hypertension, n (%)	48 (85.7)	47 (87.0)
Diabetes mellitus, n (%)	27 (48.2)	25 (46.3)
Dyslipidemia, n (%)	32 (57.1)	30 (55.6)
Systolic blood pressure, mm Hg	133 $\pm$ 16	132 $\pm$ 14
Diastolic blood pressure, mm Hg	77 $\pm$ 11	79 $\pm$ 10
Heart rate, beat per minute	79 $\pm$ 15	78 $\pm$ 16
Fasting blood glucose, (mmol/L)	6.0 $\pm$ 1.1	6.1 $\pm$ 1.0
Total cholesterol (mmol/L)	5.0 $\pm$ 0.9	5.1 $\pm$ 1.1
LDL-C (mmol/L)	3.0 $\pm$ 0.8	2.9 $\pm$ 1.0
Creatinine ( $\mu$ mol/L)	83.6 $\pm$ 14.5	83.0 $\pm$ 14.2
ALT (U/L)	21 $\pm$ 8	24 $\pm$ 12
eGFR (mL/min/1.73 m <sup>2</sup> )	70.3 $\pm$ 17.2	68.9 $\pm$ 16.5
Antihypertensive, n (%)	45 (80.4)	44 (81.5)
Antidiabetic, n (%)	27 (48.2)	24 (44.4)
Statins, n (%)	56 (100)	54 (100)
Antiplatelet, n (%)	56 (100)	54 (100)
Duration since stroke (months)	8.4 (6.3–10.9)	8.6 (6.4–11.0)
Ischemic stroke hemisphere		
Left, n (%)	25 (44.6)	25 (46.3)
Right, n (%)	31 (55.4)	29 (53.7)

ALT = alanine aminotransferase, eGFR = estimated glomerular filtration rate, LDL-C = low density lipoprotein-cholesterol.

\**P* < .05 versus the control group.

### 3.2. Assessment of NIHSS at baseline and follow-up

As presented in Table 2, at baseline, there was no difference in the median NIHSS value and the category of NIHSS between these 2 groups. However, after 6 months' follow-up, compared to the control group, the median NIHSS value was lower in the active group (4.1 vs 6.3). In addition, the proportion of patients with NIHSS of 1 to 4 was higher (50.0% vs 28.6%) while the proportion of patients with NIHSS of 5 to 12 (24.1% vs 51.8%) was lower in the active group.

### 3.3. Factors associated with increased NIHSS category at follow-up

Univariate and multivariate regression analysis was performed to evaluate factors associated with increased NIHSS category at follow-up. As shown in Table 3, after multivariate regression analysis, aging, hypertension, and increased duration since stroke were associated with increased NIHSS category, while antihypertensive therapy, the nurse-led program, and increase in MHI-5 were associated with decreased NIHSS category.

### 3.4. Association between the nurse-led program and NIHSS category at follow-up according to MHI-5

In order to evaluate whether improvement in MHS modified the association between the nurse-led program and NIHSS category, we separated participants into two subgroups based on the median MHI-5 at follow-up. As shown in Table 4, in the group with MHI-5 less than median, the nurse-led program was not associated with NIHSS category. While in the group with MHI-5 greater than median, the nurse-led program was associated decreased NIHSS category, with a significant interaction ( $P$  value = .03). In addition, when evaluating the medication knowledge after 6 months' follow-up, it is noted that participants in the nurse-led program were more likely to have improvement in medication knowledge compared to their counterparts in the usual-care group (85.7% vs 55.6%,  $P$  value = .01).

## 4. Discussion

To the best of our knowledge, the current study should be the first few studies to evaluate the effects of nurse-led program on disabilities improvement in ischemic stroke patients for more than 6 months in China. There are three potentially important findings of the current study. First, compared to the usual care, the nurse-led program can improve the disabilities after

6 months' intervention; second, the nurse-led program is also associated with MHS improvement; third, the mechanism underlying the improvement in disabilities with the nurse-led program might be partly due to the improvement in MHS. The current study provides novel insights into the management of disabilities in patients with ischemic stroke patients and further studies are needed to corroborate the current findings.

The prevalence and incidence of ischemic stroke is continuously increasing in China, especially in the area with limited health resources and healthcare workers.<sup>[3]</sup> Prior studies indicate that more than 50% of patients developed disabilities after ischemic stroke,<sup>[20–22]</sup> which significantly impairs their quality of life and MHS. In addition, disabilities after ischemic stroke are also associated with rehospitalization, economic loss, and substantial comorbidities and mortality. These data demonstrate the unmet need for the management of disabilities in patients with ischemic stroke.

Prior study has demonstrated in patients with anterior circulation ischemic stroke, reperfusion therapies with endovascular treatment were associated with improvement in cognitive function, and this benefit was further enhanced in individuals undergoing endovascular treatment plus intravenous thrombolysis.<sup>[23]</sup> Nevertheless, due to less accessibility to endovascular treatment, a large proportion of patients with acute ischemic stroke could not receive immediate reperfusion therapies. Therefore, rehabilitation may play important roles for this population group. Indeed, immediate and systemic rehabilitation has been recommended in the management of disabilities after acute ischemic stroke.<sup>[24,25]</sup> Results of prior studies have demonstrated that rehabilitation can substantially improve the disabilities.<sup>[26,27]</sup> Nevertheless, the benefits of rehabilitation on disabilities after ischemic stroke for more than 6 months are undetermined. The role of professional nurses in the management of patients with cardiovascular disease has been well demonstrated. For example, our prior studies show that, compared to the usual care, the nurse-led program significantly improved the MHS and quality of life for patients with chronic heart failure.<sup>[10–12]</sup> Therefore, leveraging on our prior experiences, we conducted a pilot study and examined whether the nurse-led program could improve the disabilities in patients with ischemic stroke. Results of the current pilot study demonstrate that compared to the usual care, the nurse-led program was associated with substantial improvement in disabilities as reflected by a lower NIHSS value and a lower proportion of patients with NIHSS of 5 to 12 in the active group. Furthermore, our results also confirm our prior findings that the nurse-led program was associated with improvement in MHS.<sup>[10–12]</sup> Notably, in patients with ischemic stroke, the prevalence of depression, anxiety, and other mental disorders are high.<sup>[28–30]</sup> Therefore, improvement in MHS could potentially help improve the disabilities. Indeed, our results indicate that when the MHI-5 was less than the median value, there was no association between the nurse-led program and disabilities improvement. While in those with MHI-5 greater than the median value, the nurse-led program confers benefit for the improvement in disabilities, supporting the importance of MHS in the management of patients with ischemic stroke and disabilities. Although the potential benefit of the nurse-led program on outcome improvement in patients with ischemic stroke has been reported previously,<sup>[13–15]</sup> there are some novelties of this study. First of all, this should be the first few studies of investigating the nurse-led program on the outcome improvement in the Chinese patients with ischemic stroke. Second, we have firstly evaluated the interaction of the intervention strategies (the nurse-led program vs usual care) and MHS on the outcome improvement. Last, the nurse-led program in this study was somewhat different from prior reports.<sup>[13–15]</sup> For example, in this study, culture-based support and encouragement was provided which could help improve their adherence to the program.

**Table 2**  
Assessment of NIHSS at baseline and follow-up.

	Control group (n = 56)	Active group (n = 54)	P value
NIHSS			
At baseline	6.8 (4.7–9.0)	6.9 (4.6–9.3)	.26
At 6 months	6.3 (4.4–9.0)	4.1 (2.9–7.8)	<.001
NIHSS = 0, n (%)			
At baseline	0	0	NA
At 6 months	2 (0.4)	5 (9.3)	.08
NIHSS = 1–4, n (%)			
At baseline	14 (25.0)	13 (24.1)	.73
At 6 months	16 (28.6)	27 (50.0)	<.001
NIHSS = 5–12, n (%)			
At baseline	32 (57.1)	30 (55.6)	.29
At 6 months	29 (51.8)	13 (24.1)	<.001
NIHSS ≥ 13, n (%)			
At baseline	10 (17.9)	11 (20.4)	.12
At 6 months	9 (16.1)	9 (16.7)	.30

NA = non-applicable, NIHSS = National Institutes of Health Stroke Scale.

**Table 3****Factors associated with increased NIHSS category at follow-up.**

Factors	Univariate regression		Multivariate regression	
	Odds ratio (95% CI)	P value	Odds ratio (95% CI)	P value
Age (per 10 years increase)	1.30 (1.14–1.96)	.005	1.14 (1.01–1.38)	.032
Male vs female	1.18 (1.05–1.40)	.038	1.06 (0.92–1.21)	.09
Smoking (yes vs no)	1.05 (0.95–1.14)	.27	NA	
Hypertension (yes vs no)	1.48 (1.30–2.17)	.003	1.29 (1.16–1.68)	.01
Diabetes mellitus (yes vs no)	1.37 (1.21–1.99)	.005	1.18 (0.99–1.56)	.06
Dyslipidemia (yes vs no)	1.12 (0.97–1.23)	.27	NA	
Antihypertensive (yes vs no)	0.72 (0.60–0.87)	.008	0.84 (0.78–0.92)	.01
Antidiabetic (yes vs no)	0.85 (0.77–0.91)	.03	0.92 (0.85–1.03)	.16
Statins (yes vs no)	0.92 (0.85–1.02)	.41	NA	
Duration since stroke (per 1 month increase)	1.54 (1.36–2.40)	<.001	1.40 (1.27–1.93)	.008
Nurse-led program (yes vs no)	0.60 (0.51–0.74)	<.001	0.70 (0.62–0.88)	.006
MHI-5 (every 5 scores increase)	0.71 (0.63–0.80)	<.001	0.85 (0.77–0.93)	.02
Ischemic stroke hemisphere (left vs right)	1.02 (0.89–1.13)	.45	NA	

CI = confidence interval, MHI-5 = Mental Health Inventory-5, NA = non-applicable, NIHSS = National Institute of Health Stroke Score.

**Table 4****Association between the nurse-led program and increased NIHSS category at follow-up according to MHI-5.**

	OR	(95% CI)	P value	P interaction
MHI-5 < median	0.87	0.72–1.04	.13	.03
MHI-5 ≥ median	0.63	0.54–0.89	.009	

Adjusted for age, gender, educational attainment, diabetes mellitus, systolic blood pressure, duration since stroke, and ischemic stroke hemisphere.

CI = confidence interval, MHI-5 = Mental Health Status Index-5, NIHSS = National Institute of Health Stroke Score, OR = odds ratio.

There are some clinical implications of the current findings. First, the current study shows that in patients with ischemic stroke for more than 6 months, the nurse-led program could improve the disabilities, which provides an important approach for the management of disabilities in these population group. Second, the current study indicates that MHS improvement is critically important for patients with ischemic stroke, and in daily clinical practice, it is essential to screen and treat poor MHS in patients with ischemic stroke. Third, combined with guideline recommended secondary prevention, the nurse-led program can provide additive benefit for disabilities improvement for patients with ischemic stroke for more than 6 months.

There are some limitations of the current study. First, this is a pilot study with a relatively small sample size. Multicenter and large sample size studies are needed to corroborate the preliminary findings. Second, this is an open-label study which might subject to the inherent biases. Third, since we only followed the patients for 6 months, whether these programs can improve the disabilities for a longer-term is unknown. Lastly, we did not collect data on the etiology of stroke and acute treatment (e.g., intravenous thrombolysis). In the future studies, it is needed to collect these data which could help further analyze the influences of the nurse-led program on outcome improvement in different etiologies of stroke and in patients receiving different therapeutic strategies.

## 5. Conclusion

In conclusion, in ischemic stroke patients for more than 6 months, the nurse-led program can provide benefits for the improvement in disabilities, which might be related to MHS improvement.

## Author contributions

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**Visualization:** Xiumei Fu.

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