Baseline Feature of a Randomized Trial Assessing the Effects of Disease Management Programs for the Prevention of Recurrent Ischemic Stroke

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Background: Comprehensive and long-term patient education programs designed to improve self-management can help patients better manage their medical condition. Using disease management programs (DMPs) that were created for each of the risk factor according to clinical practice guidelines, we evaluate their influence on the prevention of stroke recurrence. *Methods:* This is a randomized study conducted with ischemic stroke patients within 1 year from their onset. Subjects in the intervention group received a 6-month DMPs that included self-management education provided by a nurse along with support in collaboration with the primary care physician. Those in the usual care group received ordinary outpatient care. The primary end points are stroke recurrence and stroke death. Patients were enrolled for 2 years with plans for a 2-year follow-up after the 6-month education period (total of 30 months). *Results:* A total of 321 eligible subjects (average age, 67.3 years; females, 96 [29.9%]), including 21 subjects (6.5%) with transient ischemic attack, were enrolled in this study. Regarding risk factors for stroke, 260 subjects (81.0%) had hypertension, 249 subjects (77.6%) had dyslipidemia, 102 subjects (31.8%) had diabetes mellitus, 47 subjects (14.6%) had atrial fibrillation, and 98 subjects (30.5%) had chronic kidney disease. There were no significant differences between the 2 groups with respect to subject characteristics. *Conclusions:* This article describes the rationale, design, and baseline features of a randomized controlled trial that aimed to assess the effects of DMPs for the secondary prevention of stroke. Subject follow-up is in progress and will end in 2015. **Key Words:** Stroke—disease management programs—self-management—prevention of recurrence—primary care setting—risk factor control.

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Various types of clinical practice guidelines have been created that offer high quality treatments. There is a high probability that patients will reduce or discontinue medications on their own, leading to a high risk of stroke recurrence.[1] The prevention of ischemic stroke recurrence improves with meticulous control of the associated risk factors. In addition, many of the risk factors are associated with lifestyle activities such improper diet, lack of exercise, smoking, and overconsumption of alcohol. Adequate control of risk factors is difficult without lifestyle adjustments. In patients with coronary artery disease, it has been shown that positive changes in lifestyle in combination with medical therapy decrease the mortality rate.[2] Patients and their families often do not have enough information regarding risk factors for ischemic stroke and the available methods of self-management.[3] Comprehensive and long-term patient education programs designed to improve self-management can help patients better manage their medical condition in a manner consistent with the guidelines while addressing their individual risk factors.[4]

We used disease management programs (DMPs) aimed at preventing the recurrence of ischemic stroke as a tool for providing such education. DMPs lead to treatment optimization, prevention of treatment-related complications, and reduced aggravation of physiologic and psychologic conditions.[5] DMPs have been shown to be effective in preventing the deterioration of diseases and in reducing increases in medical expenses.[6,7] In this DMP Stroke Trial, we used DMPs that were created for each risk factor according to clinical practice guidelines [4,8-12] to evaluate the efficacy of the program in preventing stroke recurrence.

This article describes the rationale, design, and baseline features of a randomized controlled trial aimed at assessing the efficacy of DMPs facilitated by nurses in the prevention of stroke recurrence.

Methods

Trial Design

This is a multicenter, randomized (1:1), open-label, parallel group study conducted in outpatients with a prior history of stroke. The study protocol and informed consent form were approved by the institutional review board of each center. Written informed consent for participation was obtained from each patient. In addition, this study is being conducted under the health insurance system of Japan, in accordance with the Declaration of Helsinki and the Ethical Guidelines on Clinical Studies of the Ministry of Health, Labour and Welfare of Japan. This study is registered under the following IDs: UMIN000007808 and NCT02121327.

Study Population

Between September 2010 and November 2012, we enrolled patients between 40 and 80 years within 1 year from the onset of ischemic stroke (including transient ischemic attack [TIA]). The diagnosis of the stroke subtype was made by the physician as either atherothrombotic or cardioembolic or lacunar or other based on the National Institute of Neurological Disorders and Stroke criteria.[13]

Patients were excluded if they had severe complications or physical symptoms that would hinder their ability to carry out the program content. These were patients with modified Rankin Scale scores of 4 or more at discharge or with dementia (scores of ≤20 of 30 on the revised Hasegawa's Dementia Scale[14]). However, if a caregiving family member living with the patient could support management, the patient was included even if he/she had dementia. Patients were excluded if they received medical care in a medical/nursing care facility. Additionally, pregnant women and individuals under terminal care were excluded.

Study Setting and Randomization

This study is a randomized controlled trial comparing the intervention group, members of which underwent DMPs conducted by nurses, and the usual care group, members of which received conventional treatment without DMPs. Because the recurrence rate differs depending on the subtype of ischemic stroke,[15] the subjects were randomized to either the intervention or the usual care group after being stratified by ischemic stroke subtype.

Subsequently, with the objective to prevent recurrence in ischemic stroke patients, the intervention group received the 6-month DMPs. After completion of the educational programs, the subjects are followed for 24 months for stroke recurrence monitoring over a total of 30 months.

At the time of registration, information regarding the subjects' baseline characteristics and whether any person was living with the subject was collected. The diagnostic criteria for risk factors were as follows: for hypertension, those who were taking antihypertensives or had a blood pressure of 140/90 mm Hg or more[8]; for diabetes mellitus, those who were taking antidiabetic medications and/or insulin or had a glycated hemoglobin level of 6.5% or more[10]; for dyslipidemia, those who were taking hypolipidemics, had high-density lipoprotein cholesterol less than 40 mg/dL, low-density lipoprotein cholesterol 140 mg/dL or more, or triglyceride 150 mg/dL or more[9]; for chronic kidney disease, those with an estimated glomerular filtration rate less than 60 mL/minute/1.73 m^2 (calculated from gender, age, and serum creatinine)[11]; for smoking, those with a current smoking habit (ie, those who smoked within 1 month of