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

Table 1. *Study outcomes*

Outcomes	Evaluation
Primary outcomes	
Stroke recurrence rate and death due to stroke	
Secondary outcomes	
Economic indicators	Unplanned consultation and days of hospitalization in conjunction with ischemic stroke and risk factors
Physiologic indicators	Framingham risk score-general cardiovascular disease 10-year risk, body weight, body mass index, blood pressure, total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides, serum creatinine, blood urea nitrogen, HbA1c, blood glucose, PT-INR (only as necessary)
Psychologic indicators	Self-efficacy scale of health behavior in patients with chronic disease, CES-D, SF-36
Evaluation of self-monitoring and lifestyle improvement actions	Evaluated subject frequency of checking blood pressure, taking medicine, following the prescribed diet, and exercising (0, never; 1, once a month; 2, once a week; 3, 2-3 times a week; 4, 4-5 times a week; 5, every day). The quantity and frequency of alcohol intake and smoking

Abbreviations: CES-D, Center for Epidemiologic Depression Scale; HbA1c, glycated hemoglobin; HDL, high-density lipoprotein; LDL, low-density lipoprotein; PT-INR, prothrombin time international ratio; SF-36, 36-item short form.

enrollment); and for excessive drinking, those who consumed 46 g of pure ethanol or more every day.

Regarding psychologic indicators, the self-efficacy scale on health behavior in patients with chronic disease,[16] the Center for Epidemiologic Depression Scale,[17] and the Medical Outcomes Study 36-item short form[18] were evaluated at enrollment and were either completed on-site or collected by mail.

Primary and Secondary Outcomes

The primary end points of this study are recurrence rate and mortality from stroke. The secondary end points include an improvement in the indicators listed in Table 1 (eg, economic, physiologic, and psychologic indicators and evaluation of self-monitoring and lifestyle improvement).

DMP for the Intervention Group

The intervention was performed based on the scheme shown in Figure 1. The program objectives were helping the subject to acquire skills for self-management and the control of ischemic stroke risk factors. The duration of the education program in this study was 6 months, which is the minimum duration required for behavior modification.[19]

The subjects were educated via interviews and phone calls (Fig 2). Interviews were conducted a total of 4 times: twice between registration and the first month of

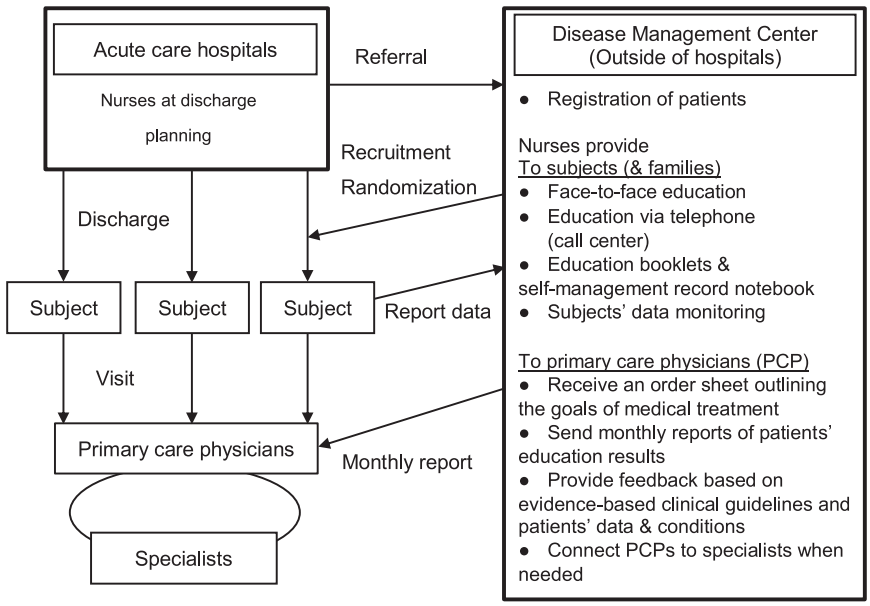

Figure 1. *Scheme illustrating the intervention.*

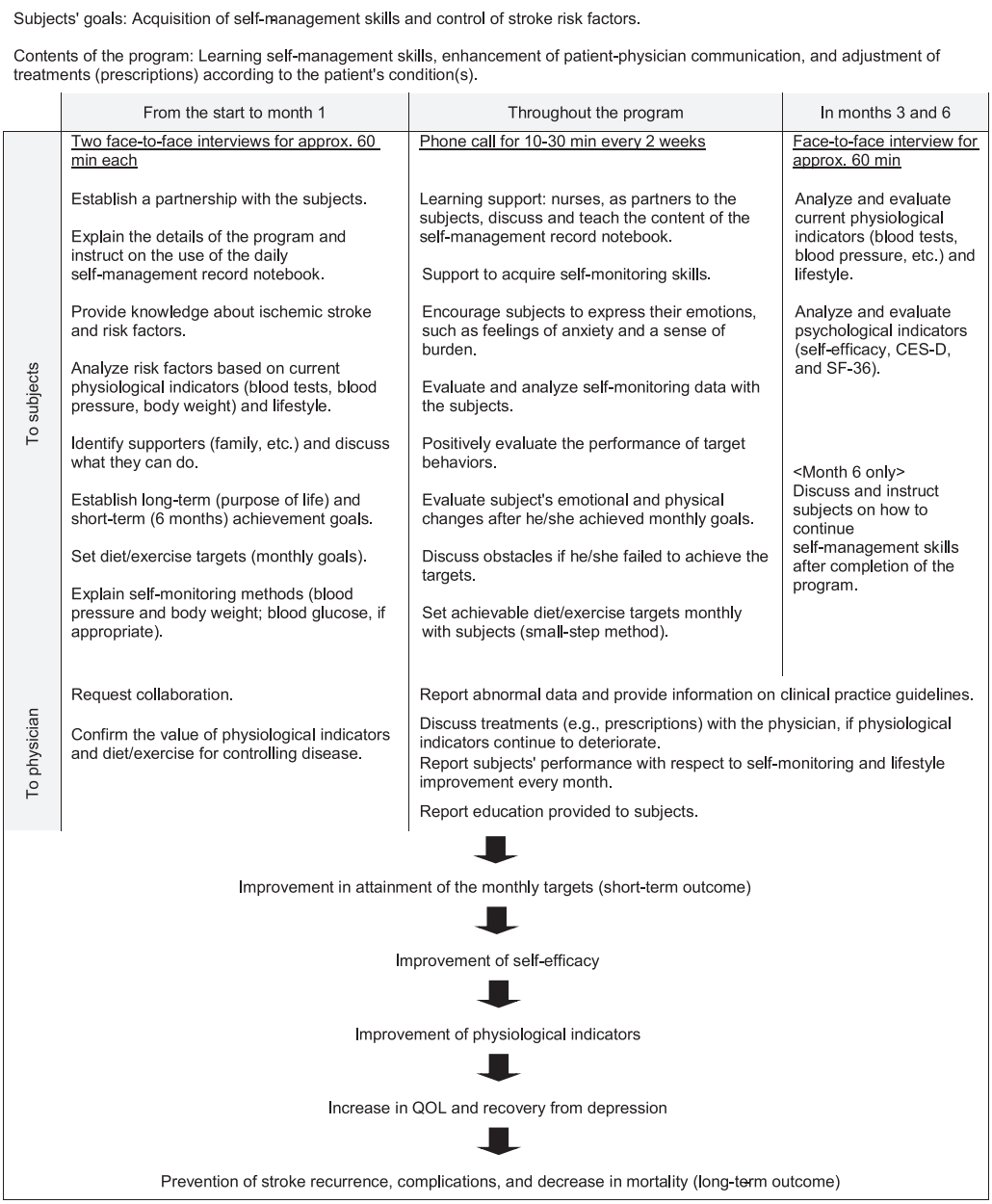

Figure 2. *Disease management program outline. Abbreviations: CES-D, Center for Epidemiologic Depression Scale; SF-36, 36-item short form.*

intervention, once at month 3, and once at month 6 in the subject's home or a collaborating medical facility. Phone calls were made a total of 10 times every 2 weeks.

The intervention supported for self-management and drug therapy to control subject's risk factors using 14 types of education booklets created by the researchers as well as a self-management record notebook in which the subject recorded daily blood pressure, body weight, and lifestyle improvement goals (in Appendix). The education booklets used were selected such that they were suitable for the individual subject.

Nurses worked collaboratively with patients and their physicians to achieve individualized clinical target values and self-management goals (Table 2). Abnormalities in self-monitored values or data or the development or exacerbation of subjective symptoms were reported immediately to the primary care physician. Appropriate treatment and therapeutic activities were assessed collaboratively by the nurses and primary care physicians and were based on the clinical practice guidelines.

The details of the intervention are Figure 2.

Education for the Usual Care Group

At the initial interview, the subjects were given instructions using a leaflet that consisted of material

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Table 2. *Goals of risk factor control and self-management*

Management goals	Target value	
Hypertension	Systolic blood pressure	Under 140 mm Hg
	Diastolic blood pressure	Under 90 mm Hg
Dyslipidemia	HDL cholesterol	Over 40 mg/dL
	LDL cholesterol	Under 140 mg/dL
	Triglycerides	Under 150 mg/dL
Diabetes mellitus	HbA1c	Under 6.5%

Management goals	Performance objectives
Blood pressure measurement	Measure twice daily (in the morning within 30 min of awakening and in the evening at bedtime)
Body weight measurement	Measure once daily
Medication	Comply as prescribed
Diet	Proper calories = Patient's ideal body weight (patient BMI 22 kg/m^2) × degree of activity (light, 20; heavy, 30)
	Upper limit of calories: 2000 kcal, salt intake: ≤6 g/d
	Proper amount of protein intake (in case of chronic kidney disease)
Exercise	Over 30 min a day, every day if possible, or 180 min a week
Smoking	Smoking cessation
Alcohol intake	Amount of alcohol per day is no more than 20 g of pure alcohol

Abbreviations: BMI, body mass index; HbA1c, glycated hemoglobin; HDL, high-density lipoprotein; LDL, low-density lipoprotein.
To convert values for LDL cholesterol to millimoles per liter, multiply by 0.02586; for HDL cholesterol, multiply by 0.02586; and for triglyceride, multiply by 0.01129. BMI is the weight in kilograms divided by the square of the height in meters.

extracted from the educational booklets. They also received a self-management record notebook, as described previously. Otherwise, the patients were given routine medical consultations as per standard practice.

Quality Assurance

Each of the 14 types of booklets (in Appendix) used in the present study covered the contents of the patient's education, according to the self-management and lifestyle recommendations of each of the clinical practice guidelines for stroke[4] and the risk factors.[8-12] The content was created based on discussions with neurologists, chronic disease nurse specialists, and registered dieticians.

To ensure quality, the intervention protocol was created such that 22 research nurses who possessed the knowledge and techniques needed for patient education could administer the intervention. Before the intervention, the research nurses were also given information on the various methods used to control ischemic stroke and the risk factors and received training on the different techniques used in disease management. During the intervention, they conducted twice-monthly conferences to strategies about subject's problems with nurses who specialized in chronic disease and stroke. Treatments were assessed based on the clinical practice guidelines.[4,8-12] The nurses also received advice from neurologists or diabetologists as necessary.

Data Collection Schedule

To investigate the effect of the program on outcomes, the subjects are followed for 2 years after properly adhering to the program (30 months from enrollment). Primary outcome and economic indicators are assessed every 3 months in both groups. Data on stroke recurrence or death caused by stroke are also confirmed. Furthermore, responses to the self-efficacy, quality of life, and depression scales as well as blood pressure, body weight, and blood test results are collected every 6 months.

Sample Size

Based on an annual 10% recurrence rate of stroke (including TIAs) in the usual care group,[15] a 60% risk reduction rate in the intervention group,[20] and 2.5 years of follow-up, the number of subjects required to detect differences between the intervention group and the usual care group was calculated to be 136 for each group (2-tailed 5% significance level, power level of 80%). Assuming that 10% of the subjects would be lost to follow-up, the sample size was set at 152 for each group and 304 for the 2 groups combined.

Statistical Analysis

The intent-to-treat analysis is used to compare the outcomes of the intervention and usual care group. To ensure the comparability of randomized samples, all

baseline indicators at the time of registration were analyzed. The data are expressed as the mean ± standard deviation or median (minimum-maximum) for the continuous variables and as frequencies and percentages for the discrete variables. The differences in continuous variables between the groups were examined using the *t* test or Mann–Whitney *U* test. The differences in categorical variables between the groups were examined using the χ^2 test.

For the primary end point, the cumulative incidence of events is estimated using the Kaplan–Meier method. The cumulative incidence curves for the 2 groups are compared using a log-rank test. The Cox proportional hazard model is also used to estimate the relative risk (hazard ratio) and the 95% confidence interval, adjusting for confounding factors, in which risk reduction is expressed as (1−hazard ratio) × 100%.

For the secondary end point analysis of compliance with the guidelines, the number of subjects with a systolic blood pressure 140 mm Hg or more,[8] low-density lipoprotein cholesterol of 140 mg/dL or more,[9] and glycated hemoglobin of 6.5% or more[10] are calculated every 6 months in each group and compared with a χ^2 test. Every 6 months data are analyzed with an analysis of covariance using baseline data as covariates for the physiologic indicators. The psychologic indicators and the extent to which self-monitoring and lifestyle improvement activities were implemented are analyzed with a Mann–Whitney *U* test.

Results

Of the 562 subjects who met the criteria, 321 consented to participate in the study (consent rate, 57.1%). The subjects were randomly assigned to the intervention group (n=156) or the usual care group (n = 165).

The demographic data and subject profile of each group are shown in Table 3. The mean age was 67.3 ± 8.5 years, and 16.8% of the subjects had a past history of stroke. The number of subjects who exhibited primary risk factors of ischemic stroke were as follows: 260 subjects (81.0%) had hypertension, 102 subjects (31.8%) had diabetes mellitus, 249 subjects (77.6%) had dyslipidemia, 47 subjects (14.6%) had atrial fibrillation, and 98 subjects

Table 3. *Baseline characteristics and subject profiles*

Characteristics	Intervention group, N = 156	Usual care group, N = 165	*P* value
Characteristics			
Females, n (%)	50 (32.1)	46 (27.9)	.465
Unemployed, n (%)	106 (67.9)	115 (69.7)	.810
Marital status: married, n (%)	128 (82.1)	131 (79.4)	.574
Living with another person, n (%)	134 (85.9)	137 (83.0)	.539
Average age, mean ± SD, y	67.1 ± 7.6	67.5 ± 9.3	.684
Subject profile			
Recurrent stroke history, n (%)	30 (19.2)	24 (14.5)	.297
Modified Rankin Scale score, median (min-max)	0 (0-3)	0 (0-3)	.952
Time to registration from onset, mean ± SD, d	109 ± 87	117 ± 84	.406
Hypertension, n (%)	131 (84.0)	129 (78.2)	.202
Diabetes mellitus, n (%)	51 (32.7)	51 (30.9)	.811
Dyslipidemia, n (%)	124 (79.5)	125 (75.8)	.503
Atrial fibrillation, n (%)	26 (16.7)	21 (12.7)	.346
Chronic kidney disease, n (%)	50 (32.1)	48 (29.1)	.628
Alcohol intake, n (%)	12 (7.7)	18 (5.6)	.146
Smoking, n (%)	24 (15.7)	36 (22.0)	.196
Subtype, n (%)			
Atherothrombotic	49 (31.4)	48 (29.1)	.809
Cardioembolic	23 (14.7)	19 (11.5)	
Lacunar	55 (35.3)	67 (40.6)	
Other	18 (11.5)	21 (12.7)	
Transient ischemic attack	11 (7.1)	10 (6.1)	
Treatment regimen, n (%)			
Antiplatelets	118 (75.6)	118 (71.5)	.402
Anticoagulants	31 (19.9)	34 (20.6)	.870
Antihypertensives	108 (69.2)	103 (62.4)	.199
Hypolipidemics	84 (53.8)	79 (47.9)	.285
Antidiabetics	34 (21.8)	33 (20.0)	.875

Abbreviation: SD, standard deviation.

(30.5%) had chronic kidney disease. The disease subtypes were as follows: atherothrombotic (n = 97, 30.2%), cardioembolic (n = 42, 13.1%), lacunar (n = 122, 38.0%), other ischemic stroke (n = 39, 12.1%), and TIA (n = 21, 6.5%). No statistically significant differences in the indicators were observed. There were no differences between the 2 groups with respect to subject disability as evaluated by modified Rankin Scale (Table 3).

The medications taken by the subjects were as follows: antiplatelets (n = 236, 73.5%), anticoagulants (n = 65, 20.2%), antihypertensives (n = 211, 65.7%), hypolipidemics (n = 163, 50.8%), and antidiabetics (n = 67, 20.9%). There were no significant differences in the use of any of these drugs between the 2 groups.

Discussion

The aim of this study is to evaluate the efficacy of DMPs in preventing recurrent stroke. Patient enrollment was closed at the end of November 2012, and follow-up studies are ongoing. This article describes the study rationale and design as well as the subjects' baseline features.

Depending on their recovery status and whether they are in the acute, recovery, or maintenance (living) phase of management, ischemic stroke patients often do not stay in the same medical institution where they undergo their initial consultation. For this reason, maintaining continuous support for patient education and long-term self-management is difficult. Patient education in medical clinics in Japan is primarily performed by physician, which places a large burden on physicians and may result in inadequate patient education. Therefore, this intervention scheme both supports physicians' practice and improves patient outcomes.

Because ischemic stroke has multiple divergent risk factors, we designed a comprehensive (as opposed to a single intervention) approach to control these factors. The aim of the program is for patients to gain knowledge and to learn techniques that they can use. DMPs strategy also incorporated behavior modification theories[19,21] such as methods to improve self-efficacy and depression. It may be possible to investigate the intervention process of recurrence prevention based on the behavior modification theory.

The limitations of the present study include the small sample size and the fact that the study could not be blinded. There was no way to blind the study because the group assignments had to be explained to patients when describing the study, and the educational intervention involved additional interaction with nurses that the usual care group did not receive. The sample size of this study was calculated based on a 60% risk reduction of ischemic stroke recurrence with DMPs. It was determined from a previous study evaluating a nurse-directed multidisciplinary intervention for congestive heart failure with a 56% decrease in readmission.[20] And, a stroke recurrence rate in the first year was approximately 5% in the Japanese stroke centers and 12.8% in the Japanese community-based observational study.[15,22] Therefore, we assumed that 60% reduction rate would be possible providing disease managements programs to the patients followed-up in the nonstroke center hospitals or clinics. In the present study, 52.3% of enrolled patients are under follow-up in the nonstroke center hospitals or clinics.

The low recruitment rate (57.1%) is another limitation of this study that may have led to selection bias. Some patients did not consent even when they were informed at recruitment of the presence of risk factors and of the fact that control of these risk factors influenced recurrence. This indicates that the number of patients who understand that recurrence prevention is important in ischemic stroke and that prevention is achieved through controlling risk factors are limited.

To reduce the number of patients with recurrent ischemic stroke, it is essential that patients understand the importance not only of rehabilitation but also of controlling risk factors. Our consent rate is similar to that reported in other studies of stroke.[23,24] We convinced that it is of great importance to thoroughly investigate the efficacy of DMPs for preventing stroke recurrence.

Conclusion

This article describes the rationale, design, and baseline features of a randomized controlled trial aimed at assessing the efficacy of DMPs in the prevention of recurrent ischemic stroke. Patient enrollment is closed, and follow-up studies are in progress. The results derived from this study could establish the potential usefulness of DMPs for the secondary prevention of ischemic stroke in a primary care setting.

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Supplementary Data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.jstrokecerebrovasdis.2014.10.007

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