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Impact of a pre-discharge education session on stroke knowledge: a randomized trial

Charline Benoit MD (charline.benoit@aphp.fr, +33 146255973) ¹

Delphine Lopez NP (d.lopez@hopital-foch.org, +33 146255973) ¹

Murielle Loiseau NP (m.loiseau@hopital-foch.org, +33 146255973) ¹

Julien Labreuche PhD (julien.labreuche.chru@gmail.com, +33 320626969) ²

Maeva Kyheng MS (maeva33113@hotmail.com, +33 320626969) ²

Frédéric Bourdain MD (f.bourdain@hopital-foch.org, +33 146255973) ¹

Bertrand Lapergue PhD (b.lapergue@hopital-foch.org, +33 146255973) ¹

¹ Department of Stroke Center and Diagnostic and Interventional Neuroradiology, Foch Hospital,
University Versailles Saint-Quentin en Yvelines, Suresnes, France

² Univ.Lille, CHU Lille, EA 2694-Santé Publique:Épidémiologie et Qualité des Soins, F-59000
Lille, France. +

Correspondence:

Charline Benoit, MD

Department of Stroke Center and Diagnostic and Interventional Neuroradiology, Foch Hospital
40 rue Worth, 92150, Suresnes, France

E-mail: charline.benoit@aphp.fr

Tel: +33 146255973

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Impact of a pre-discharge education session on stroke knowledge: a randomized trial

Abstract:

Background and purposes: Stroke knowledge, awareness of risk factors and stroke warning symptoms is very poor among stroke survivors. We investigated whether a pre-discharge education intervention in the stroke unit could improve stroke knowledge in patients with TIA or minor stroke.

Methods: We performed a prospective single-center, randomized controlled trial (2013-2016) in patients with TIA or minor stroke. The intervention consisted in an interactive group session focused on stroke education, within the stroke unit before hospital discharge. Primary outcome was the 3-month change in stroke knowledge score (SKS) from randomization. Secondary outcomes were the 12-month change in SKS, the number of risk factors and warning signs named, control of risk factors and self-reported adherence.

Results: A total of 199 patients (mean [SD] age, 63.5 [12.4] years; 67 [33.7%] women) were randomized (99 in stroke education session). Intervention was associated with a greater improvement in SKS than in the control group (baseline-adjusted mean between-group difference, 1.6 point [95%CI, 1.4 to 1.9]; $p=0.001$). This difference was significantly maintained at 12 months. The number of risk factors and warning signs named were significantly increased in the intervention group at 3 months. Control of risk factors and self-reported adherence did not differ significantly between the two groups.

Conclusions: An interactive education session in the stroke unit significantly improved stroke knowledge at 3 months and 12 months in patients with TIA or minor stroke.

Introduction

Each year, recurrent strokes account for one in five strokes ^{1,2}. Stroke survivor's awareness of their risk factors may strengthen their commitment to secondary prevention medication and to lifestyle changes in order to prevent future strokes. Moreover, it has been shown that failing to recognize stroke symptoms is associated with a longer delay in seeking medical attention in cases of TIA or stroke ^{3, 4}. Despite these observations, numerous studies have shown, surprisingly, that the global level of stroke-related knowledge among this population at high risk of recurrent stroke is extremely poor ^{5,6,7}, pointing out the need to improve post-stroke education. In the case of minor strokes or TIA, our hypothesis is that the initial inpatient stay in a stroke unit could be the right time for a stroke education intervention, as the patients are available and concerned by their recent stroke.

This trial aims to assess the impact of a post-stroke education session within the stroke unit for patients after a TIA or a minor stroke, on patients' stroke knowledge at 3 months, compared to usual care.

Methods

We performed a single-center randomized, controlled, open-label trial to assess the effect of a single stroke education session within the stroke unit on patients' stroke knowledge. It was an investigator-initiated trial conducted between October 2013 and October 2016 at the Foch hospital stroke unit. This protocol was approved by the regional patient's protection committee (CPP Ile de France VI). It was registered with the United States clinical trials database (ClinicalTrials.gov: NCT02834273). Patients were enrolled within the first 48 hours after their admission and were included if aged 18 years or older with an initial diagnosis of minor ischemic stroke (NIHSS \leq 3) or TIA. Patients were excluded if they were unable to

give informed consent, if they had a consciousness disorder, aphasia, or cognitive impairment limiting comprehension.

Patients were randomized in a ratio 1:1 to usual care, or to an intervention consisting of a stroke education group session, carried out before hospital discharge, in addition to usual care. Group allocation was performed through scratch cards based on a computer-generated list provided by an independent statistician.

The stroke education session was conducted by a vascular neurologist or a nurse trained in stroke and therapeutic education, during two hours, using a PowerPoint presentation. The session was focused on stroke signification and mechanisms, risk factors, warning symptoms, and what to do in cases of stroke. It was conducted in a very interactive way, patients were encouraged to ask questions, and questions were also asked to them at the end in order to check if they had understood everything.

Data collection during the study was carried out using a structured case report form. At randomization and before the education session in the intervention group, main baseline characteristics including demographics, medical history, socio-economics, and established vascular risk factors were collected. The stroke knowledge survey was also verbally administered at this time-point, asking patients with open questions to name the stroke risk factors, warning symptoms and actions to be taken in cases of stroke. Participants were followed-up at 3 and 12 months. At each follow-up visit, the stroke knowledge survey was re-administered, and self-reported adherence to treatment, HbA1c, LDL-cholesterol, blood pressure values, and occurrence of new stroke or TIA events were recorded.

The primary outcome was the 3-months change in stroke knowledge score (SKS) from randomization. The SKS was calculated according to patients' answers to the stroke knowledge survey as follows: 1 point per correct risk factor given, 2 points per correct warning symptom named and 3 points per correct actions, and scored from 0 to 29. Secondary

outcomes included the 12-month change in SKS, the positive response rates for individual items of stroke knowledge, the number of named stroke risk factors, and of warning symptoms at 3 and 12-months. We also analysed the evolution of Hba1c, LDL-cholesterol, blood pressure levels and self-reported adherence at 3- and 12 months.

Statistical analysis

The study was designed to have a statistical power of 80% with a two-sided alpha level of 0.05 to show a difference in 2.4 points in SKS between the two groups assuming a standard deviation of 5.2 points and an attrition rate of 25%. This assumption was based on unpublished single-arm observational studies conducted at our centre where SKS was recorded in 67 patients.

All analyses were performed on all randomized patients in their original group of randomization (according to intention to treat (ITT) principle). Categorical variables were expressed as frequencies and percentages. Quantitative variables were expressed as means (standard deviation), or medians (interquartile range) for non-normal distribution. Normality of distributions was assessed graphically and by using the Shapiro-Wilk test. Comparison in change in SKS at 3-months and 12-months after randomisation between the two treatment groups was made using a constrained longitudinal data analysis (cLDA) model ⁸. In this model, both the baseline and post-baseline values are modeled as dependent variables using a linear mixed model, and the true baseline means are constrained to be the same for the two treatment groups to adjust for observed baseline difference. The between-group differences in changes from randomization to the time of interest were estimated by the time-by-treatment group interaction. Normality of model residuals were satisfied. Missing data for SKS were treated by multiple imputation, using regression switching approach (chained equation with m=10 imputations obtained using the R statistical software version 3.03). Imputation procedure was performed under the missing at random assumption using the allocated arm,

and all patients' characteristics at randomization as covariates (see table 1) with a predictive mean matching method for continuous variables, logistic regression models (binary, ordinal or polynomial) for qualitative variables⁹. We combined the estimates from each imputed dataset using the Rubin's rules¹⁰. Complete-case analysis was performed as a sensitivity analysis.

Regarding other outcomes, we used Mann-Whitney U tests to compare the number of recognized stroke risk factors and of warning symptoms at 3 and 12-months and we used the Chi-square test to compare the rate of patients who were unable to name any risk factor and the rate of treatment adherences. We used a linear mixed model for repeated measures (an unstructured covariance pattern model to account for the correlation between repeated measures within the same patients) to compare the post-randomisation values of HbA1c, LDL-cholesterol and blood pressure values; in this model, intervention group, time*intervention group and baseline values were introduced as fixed effects and post-hoc comparisons at each follow-up time were performed using linear contrast. Normality and homoscedasticity of the residuals were checked graphically.

All statistical tests were 2-sided and $p < 0.05$ was considered statistically significant. No adjustment for multiple comparisons was applied for secondary outcomes and thus all secondary objectives are considered exploratory. Data were analyzed using the SAS software package, release 9.4 (SAS Institute, Cary, NC).

Results

During the study period, a total of 199 patients (mean [SD] age, 63.5 [12.4] years; 67 [33.7%] women) were randomized (99 in the stroke education group) and included in the intention-to-treat (ITT) analysis (Figure 1, supplemental materials). One hundred and eighty patients (90.4%) completed the 3-month follow-up and 166 (83.4%) the 12-month follow-up. As

shown in Table 1, baseline characteristics were well balanced across the study groups. 174 patients (87.4%) were enrolled with a minor stroke, with an overall median NIHSS score at enrolment of 1 (IQR, 0 to 2).

Stroke knowledge at baseline

The mean (SD) SKS value at baseline was 10.8 (3.2) in the intervention group and 10.9 (3.2) in the control group. Regarding the baseline positive response rate among both groups, only 37% of them could mention high blood pressure and 22.6 % of them, diabetes mellitus as stroke risk factors. 15.1% of them could not name any stroke risk factor. Only 54% could mention difficulty in speaking and only 30.2 % of them vision loss as stroke symptoms.

Stroke knowledge outcomes

In ITT analysis after handling missing SKS values by multiple imputation, the education session presented a greater improvement in SKS than the control group (mean baseline-adjusted between-group difference, 1.6 point (95%CI, 1.4 to 1.9; $p=0.001$). A similar result was found in a complete-case analysis (Table 2). The difference in improvement in SKS in favour of the intervention group remained significant at 12 months, with a mean baseline-adjusted between-group difference of 1.1 point (95%CI, 0.9 to 1.2; $p=0.006$).

As shown in Figure 1, the positive response rates at 3-and 12-months for most of SKS items were greater in the intervention than the control group. The proportion of patients who were unable to name any risk factor was significantly lower after intervention than in controls at 3 months (13.2 vs. 3.4%, $p=0.017$) but not at 12-months (2.4 vs. 3.6%, $p=1.00$). Similarly, the number of correctly named risk factors found at 3 months was higher after intervention than in controls at 3 months but not at 12 months. The mean number of symptoms named by patients was also greater in the intervention group than in controls at 3 but also at 12-months (Table 3).

Control of Main Risk factors

Levels of the main risk factors (Hba1c, LDL-cholesterol, blood pressure) at 3- and 12-months did not differ significantly according to the study groups (all $p > 0.37$). Self-reported adherence was high in both groups at 3 months (95.6% in intervention vs. 93.3% in control, $p=0.53$) as well as at 12 months (93.8% vs. 96.4%, $p=0.49$). During the 12-month follow-up, 11 patients had an occurrence of a new stroke or TIA event; 7 in the intervention group and 4 in the control group.

Discussion

In this randomized trial, stroke knowledge was improved at 3 months in the intervention group compared to the group on usual care. Moreover, this is the first study assessing the long term efficiency at one year on stroke knowledge of a brief pre-discharge educational intervention.

Some authors differentiate passive educational interventions with no subsequent systematic follow-up or reinforcement procedure, and active educational interventions in which there is an active participation with a subsequent agreed plan for reinforcement¹¹. Active educational interventions such as nurse tailored educational intervention at home^{15,16}, repeated group educational session in hospital after discharge¹⁷ may lead to more convincing effects on stroke knowledge than passive educational intervention such as individualized multimedia computer programs¹², information booklet¹³, video information¹⁴. However these long and tailored active post-discharge programs are time consuming, expensive and not so convenient to apply. Our educational intervention stands on the border between these two kinds of information provision process: the session is interactive, long enough to reinforce patient stroke knowledge and to let him ask questions, but occurs only once and does not have to be repeated. Moreover, hospitalization in the stroke unit appeared to be a “teachable moment”¹⁸, the patient being concerned by the recent stroke event, available and motivated. In addition, providing a pre-discharge education session is an appropriate way to avoid losing patients to follow-up before starting the education program.

Strikingly, baseline stroke knowledge was very poor, confirming previous observations^{5,6,19}. A significant number of patients could not mention any stroke risk factor, and within this population of hypertensive patients, less than half of them could mention hypertension as a stroke risk factor. Despite the public campaigns focused on stroke preparedness held these

recent years²⁰, only half of the patients were aware that speech trouble was a symptom of stroke, suggesting a need for more effective approaches.

Knowledge of both stroke risk factors and warning signs was significantly improved at 3 months. Regarding only the number of risk factors named, the difference between groups was not found at 12 months, because this parameter had also improved at one year in the control group. We may hypothesize that the 3-month follow-up appointment acted as a post-discharge education reinforcement in the control group.

A limit of our trial is that patients with minor stroke or TIA represented only a limited sample of the patients that were admitted in our stroke unit. However, educating this subset of patients is a crucial issue: because their stay in the stroke unit is very short, they are the more at risk to return home without understanding their risk factors, and to be lost to follow-up. In addition, our educational intervention cannot be applied to patients with aphasia or with cognitive impairment. For these patients, an education program more focused on their carers should be developed.

Finally, we found no difference in risk factor control between the two groups, but our study was not powered for this issue.

Conclusion

A pre-discharge interactive education session within the stroke unit improves stroke knowledge at 3 months and at one year in patients with TIA or minor strokes. This educational intervention is simple, realistic and convenient to apply, and could be easily generalized in stroke units.

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Tables Legends

Table 1. Baseline characteristics of the patients

Values expressed as no./total no. (%) unless otherwise as indicated. ^a 1 missing value in control group, ^b 5 missing values in control group, ^c 11 missing values (7 in control group).

Abbreviations: BP=blood pressure; IQR=interquartile range; LDL-C=low density lipoprotein cholesterol; NIHSS=National Institutes of Health Stroke Scale; SD=standard deviation; TIA=transient ischemic attack

Table 2. Three-and Twelve month Changes in Stroke Knowledge Score

^a after mean of 10 imputations to treat the missing values. ^b baseline-adjusted mean (95% confidence interval) are reported.

Abbreviations: CI=confidence interval; SD=standard deviation

Table 3. Number of corrected risk factors and symptoms of stroke at 3- and 12-months

^a mean or absolute rate differences between the two groups (intervention vs. controls).

Figures legends

Figure 1. Individual Items of Stroke Knowledge Questionnaire

A) 3-months after randomization

B) 12-months after randomization

Figure 1. Individual Items of Stroke Knowledge Questionnaire

A) 3-months after randomization

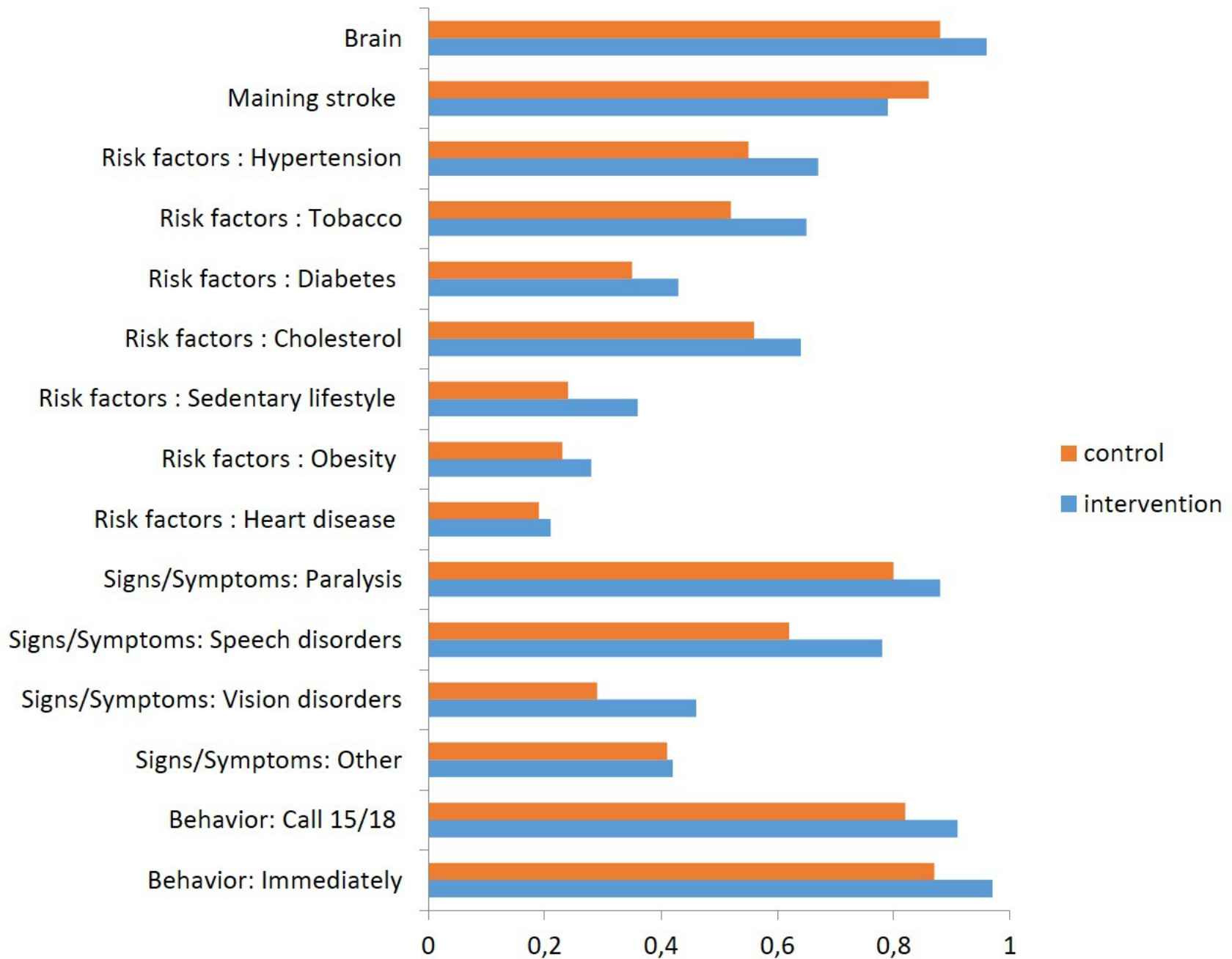


Table 1. Baseline characteristics of the patients

Characteristics	Control (n=100)	Intervention (n=99)
Age (year), mean (SD)^a	62.2 (12.8)	64.8 (12.0)
Women	37/100 (37.0)	30/99 (30.3)
Qualifying event		
Ischemic stroke	90/100 (90.0)	84/99 (84.8)
TIA	10/100 (10.0)	15/99 (15.2)
Medical history		
Hypertension	58/100 (58.0)	56/99 (57.1)
Hypercholesterol	37/100 (37.0)	40/99 (40.4)
Diabetes	15 /100(15.0)	14/99 (14.1)
Current smoker	25/100 (25.0)	23/98 (23.5)
Atrial fibrillation	9/100 (9.0)	13/98 (13.3)
Previous stroke or TIA	12/96 (12.5)	11/98 (11.2)
Antithrombotic medications	30/84 (35.7)	28/82 (34.1)
Antiplatelet	26/99 (26.3)	22/98 (22.4)
Anticoagulation	5/99 (5.1)	6/99 (6.1)
Socio-economics characteristics		
Married	75/100 (75.0)	64/99 (64.6)
Pensioner	41/99 (41.4)	54/98 (55.1)
Profession (of worker)		
Farmer	6/58 (10.3)	3/44 (6.8)
Artisan, merchant	25/58 (43.1)	14/44 (31.8)
Senior manager	11/58 (19.0)	10/44 (22.7)
Worker	15/58 (25.9)	16/44 (36.4)
Unemployed	1/58 (1.7)	1/44 (2.3)
Education level		
2/3rd cycle	39/100 (39.0)	35/99 (35.4)
High School /1st cycle	33/100 (33.0)	28/99 (28.3)
Primary/college.CE	28/100 (28.0)	36/99 (36.4)
Examination findings		
NIHSS, median (IQR)	1.0 (0 to 2)	1.0 (0 to 2)
Systolic BP, mmHg, mean (SD)	160 (28)	159 (27)
Diastolic BP, mmHg, mean (SD)	84 (15)	85 (15)
LDL-C, mg/dl, mean (SD)^b	117 (39)	103 (39)
Hba1c, %, median (IQR)^c	5.6 (5.4 to 6.0)	5.6 (5.3 to 5.8)

Table 2. Three-and Twelve months Changes in Stroke Knowledge Score

	Control		Intervention		Differences in Changes From Baseline (month 0) Score adjusted on baseline score, Mean (95% CI)	P Value
	N	Mean (SD)	N	Mean (SD)		
Complete case-analysis						
0	99	10.9 (2.6)	98	10.8 (3.2)		
3	90	11.1 (3.7)	86	13.1 (3.6)		
12	81	12.8 (2.9)	83	14.1 (2.8)		
3-0		0.3 (-0.4 to 1.0) ^b		2.3 (1.5 to 3.0) ^b	1.9 (1.0 to 2.9)	<0.001
12-0		1.9 (1.3 to 2.5) ^b		3.2 (2.6 to 3.8) ^b	1.3 (0.5 to 2.1)	0.001
Intention to treat analysis ^a						
0	100	10.9 (2.6)	99	10.8 (3.1)		
3	100	11.4 (3.7)	99	13.0 (3.7)		
12	100	12.8 (3.0)	99	13.9 (2.9)		
3-0		0.5 (0.4 to 0.6) ^b		2.1 (2.0 to 2.3) ^b	1.6 (1.4 to 1.9)	0.001
12-0		1.9 (1.8 to 2.1) ^b		3.0 (2.9 to 3.2) ^b	1.1 (0.9 to 1.2)	0.006

^a after mean of 10 imputations to treat the missing values. ^b baseline-adjusted mean (95% confidence interval) are reported.

Abbreviations: CI=confidence interval; SD=standard deviation.

Table 3. Number of corrected risk factors and symptoms of stroke at 3- and 12-months

	Control		Intervention		Effect size ^a	
	N	Value	N	Value	(95%CI)	P Value
3-month						
Risk factors						
No risk factors known, % <i>(n)</i>	91	13.2 (12)	89	3.4 (3)	-9.8 (-17.7 to 1.9)	0.017
Number per patient, mean (SD)	90	2.7 (1.6)	86	3.3 (1.7)	0.61 (0.12 to 1.10)	0.015
Sign/symptoms						
Number per patient, mean (SD)	91	1.7 (0.9)	89	2.1 (0.9)	0.41 (0.15 to 0.67)	0.002
12-month						
Risk factors						
No risk factors known, % <i>(n)</i>	82	2.4 (2)	84	3.6 (3)	1.1 (-4.0 to 6.3)	1.00
Number per patients, mean (SD)	81	3.2 (1.4)	83	3.6 (1.5)	0.37 (-0.09 to 0.82)	0.11
Sign/symptoms						
Number per patient, mean (SD)	81	1.9 (0.9)	84	2.3 (0.8)	0.37 (0.11 to 0.63)	0.005

^a mean or absolute rate differences between the two groups (intervention vs. controls).

Abbreviations: CI=confidence interval; SD=standard deviation.