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# Effect of simulator training on driving after stroke

## A randomized controlled trial

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**Abstract—Background:** Neurologically impaired persons seem to benefit from driving-training programs, but there is no convincing evidence to support this notion. The authors therefore investigated the effect of simulator-based training on driving after stroke. **Methods:** Eighty-three first-ever subacute stroke patients entered a 5-week 15-hour training program in which they were randomly allocated to either an experimental (simulator-based training) or control (driving-related cognitive tasks) group. Performance in off-road evaluations and an on-road test were used to assess the driving ability of subjects pre- and post-training. Outcome of an official predriving assessment administered 6 to 9 months poststroke was also considered. **Results:** Both groups significantly improved in a visual and many neuropsychological evaluations and in the on-road test after training. There were no significant differences between both groups in improvements from pre- to post-training except in the “road sign recognition test” in which the experimental subjects improved more. Significant improvements in the three-class decision (“fit to drive,” “temporarily unfit to drive,” and “unfit to drive”) were found in favor of the experimental group post-training. Academic qualification and overall disability together determined subjects that benefited most from the simulator-based driving training. Significantly more experimental subjects (73%) than control subjects (42%) passed the follow-up official predriving assessment and were legally allowed to resume driving. **Conclusions:** Simulator-based driving training improved driving ability, especially for well educated and less disabled stroke patients. However, the findings of the study may have been modified as a result of the large number of dropouts and the possibility of some neurologic recovery unrelated to training.

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Driving performance is impaired by motor, visual, cognitive, and perceptual deficits that are commonly experienced after stroke.<sup>1,2</sup> Some studies evaluated the effect of driving training after brain injury. In a recent randomized controlled trial,<sup>3</sup> 47 experimental and 50 control stroke patients received 20 sessions of specific computer-based visual processing and attention-training programs aimed at improving their driving abilities. Results revealed no significant differences between groups in perceptual evaluations and on-road test after training except in a visual test, which was in favor of subjects in the experimental group that were trained using the visual test itself. The study lacked follow-up assessments. Use of paper-and-pencil-based perceptual training,<sup>4</sup> computerized video method,<sup>5</sup> and simulator-based<sup>6,7</sup> and on-road<sup>8</sup> training methods

have been reported as well. Major methodologic limitations in most of these studies include the use of few and highly heterogeneous subject populations, absence of control groups, and no follow-up assessments. Still, the results from the studies reported on the simulator-based<sup>6,7</sup> and on-road<sup>8</sup> training methods seemed promising.

On-road training of driving after brain injury is potentially dangerous in spite of the adaptations installed in the training cars to ensure safety.<sup>9,10</sup> In contrast, simulators are safe devices in which subjects show less anxiety.<sup>6,7,10</sup> Without convincing evidence and need to better establish the effect of driving training after stroke, this study investigated the immediate and long-term effect of a simulator-based program on the on-road performance and overall driving fitness in stroke patients.

**Methods.** Subjects were recruited from the Rehabilitation Unit of the University Hospital Pellenberg, Belgium, and were eligible for inclusion in the study if they had a history of first stroke and were fewer than 3 months poststroke. Subjects had to possess a

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valid driver license and actively drove before the stroke. Patients older than 75 years were excluded to limit the influence of other old age-related problems. Those with history of epilepsy in the previous 6 months were not included in accordance with the Belgian law.<sup>11</sup> Severe motor or sensory aphasia was another exclusion criterion because of the need to effectively communicate with subjects during training. All patients that fulfilled the criteria listed above and freely consented to participate by completing an informed consent document were included in the study.

The study was designed as a randomized controlled trial. Based on computerized number generation, an independent person who was blind to the neurologic status of the subjects randomly allocated each subject to either the experimental or the control group. The number of subjects needed for the study was determined a priori to ensure sufficient statistical power. The effect size required to determine the number of subjects was estimated on the basis of results from a previous study.<sup>12</sup> This revealed that a sample of 72 subjects was needed to achieve an 80% chance with an  $\alpha$  level of 0.05 of detecting an effect size of 0.5 between groups in the on-road test (a main outcome measure). In anticipation of inevitable dropouts, the number of subjects included in the study was increased to 83.

**Intervention.** In addition to regular hospital rehabilitation programs, each subject, irrespective of group membership, received a total of 15 hours of driving-related training spread over 5 weeks at 1 hour a day, three times a week.

Subjects in the experimental group received simulator-based driving training in a stationary full-sized Ford Fiesta 1.8 car with automatic gear transmission system and all its original mechanical parts. Adaptive aids such as left-sided accelerator pedal, right-sided indicator stick, and steering spinner were coupled to the simulator when required. All experimental subjects that needed adaptations were taught the use of the steering spinner and the left accelerator pedals. The simulator was powered on a STISIM Drive System (version 1.03; Systems Technology Inc.). The high-fidelity system contained a "Scenario Definition Language" with which an on-line interactive 13.5-km driving scenario that took about 25 minutes to complete was developed. Life-size computer-generated images were projected on to a screen (approximately 2.30 m by 1.70 m) with a visual angle of 45°. The driving scenario started on a two-lane road with urban-like traffic and progressed to a four-lane highway with 120-km/h speed restriction and possibilities to overtake other cars before terminating on a two-lane road in a rural setting.

Subjects took 2 to 3 hours (within 1 week) to get acquainted with the simulator by driving a 3-km scenario designed to enable gradual familiarization with major parts of the car and simulated driving situations. This was followed by a pretraining assessment in the simulator during which subjects drove the interactive 13.5-km scenario. Number of collisions, pedestrians hit, excessive speed, traffic light faults, total faults, and run-time were documented. Each subject received a feedback from the pretraining assessment. Training then progressed by exposing subjects to a variety of different 5-km training scenarios containing common traffic demands. Subjects received training on lane tracking, speed control, overtaking, and road sign recognition as well as responding to unexpected multitasking traffic-related situations with different complexities. Post-training assessment administered in the fifth week of training in the simulator was conducted by exposing subjects to the interactive 13.5-km scenario presented during the pretraining assessment. The tasks of the 13.5-km scenario were presented using a "time frame program" that made the scenario sequence presented during consecutive trials different. As a result, the retention of the task sequence from a previous attempt was impossible. Controls received standardized training by performing driving-related cognitive tasks such as route finding on a paper or road map, memory training with numbers, and forming different patterns using tiles. Recognition of road and traffic signs was also trained using 40 cards with pictures of different traffic situations.

**Evaluation.** Physicians from the rehabilitation hospital evaluated the neurologic status of all subjects at intake and documented details such as age, sex, academic qualification, side of lesion, and type of stroke (based on CT scans and MRI). Time interval between stroke onset and participation in the study, driving experience, and average distance driven annually were also documented. Clinical examinations of visual field, visual inatten-

tion, speech, and tactile inattention were performed. Physical therapists evaluated the overall disability of subjects using the Barthel Index,<sup>13</sup> and neuropsychologists evaluated mental status using the Mini-Mental State Examination.<sup>14</sup>

Before and after training, all subjects performed an assessment that consisted of visual and neuropsychological evaluations and an on-road test of driving ability. The pretraining assessments performed between 6 and 9 weeks poststroke and post-training assessments performed between 11 and 14 weeks poststroke took place in the rehabilitation hospital. The assessments were administered by neuropsychologists and driving assessment experts from the CARA Department of the Belgian Road Safety Institute, Brussels. The experts were aware that subjects were participating in a randomized study but were blind to subjects' group allocation. Tests were included in the predriving assessments based on their reported accuracy in predicting driving performance in stroke patients.<sup>12,15,16</sup> The visual tests comprised monocular and binocular acuity and the kinetic vision test, which evaluated the ability to recognize objects in motion.<sup>17</sup> The neuropsychological evaluation consisted of the useful field of view (UFOV) and component tests of the Stroke Driver Screening Assessment (SDSA). The UFOV evaluated the degree of reduction in the UFOV<sup>18</sup> and component test of the SDSA; that is, dot cancellation test, square matrix test (direction and compass), and road sign recognition test jointly evaluated attention and executive reasoning abilities.<sup>15,16</sup> A reliable<sup>19,20</sup> and valid<sup>20</sup> on-road test was performed in an adapted car around the hospital premises. Based on performance in the on-road test, a three-class decision of 1) "fit to drive," 2) "temporarily unfit to drive," or 3) "unfit to drive" was unilaterally made by the driving assessment experts from CARA. Performance in the on-road test and the three-class decision of driving fitness were the primary outcome measures at post-training.

Subjects included in the study were encouraged and scheduled to perform a 6-month official predriving assessment. In Belgium, stroke patients with neurologic impairment(s) are legally not allowed to drive for the first 6 months after stroke.<sup>11</sup> To resume driving, patients must perform a predriving assessment that contains medical, visual, and neuropsychological evaluations and an on-road test administered at the CARA Department of Belgian Road Safety Institute in Brussels. Based on the outcome of the predriving assessment, a group consisting of a physician, psychologist, and occupational therapist from CARA decides the driving fitness of patients using the same three-class decision ("fit to drive," "temporarily unfit to drive," or "unfit to drive"). According to Belgian law,<sup>11</sup> only candidates that are judged "fit to drive" based on performance in the predriving assessment performed at CARA may be relicensed to resume driving. A candidate could be "fit to drive" in a manual or automatic car with or without adaptations. Some restrictions such as maximum speed capacity, driving only in specified areas, or driving with licenses that are valid for a specified period of time may be applied. However, candidates judged "temporarily unfit to drive" or "unfit to drive" are not permitted to resume driving. Temporarily unfit to drive candidates have the opportunity to be reassessed either after a 10-hour driving lesson, allowing more time for better recovery after stroke, or after further medical evaluation. Those judged "unfit to drive" are not to be reassessed again. The decision is usually due to very poor performance in the predriving assessment or severe visual problems that make driving completely unsafe. As a result, "fit to drive" decisions were converted to pass and "temporarily unfit to drive" or "unfit to drive" decisions to fail classifications. Performance in the on-road test, the three-class decision, and the pass/fail classifications based on the outcome of the official driving assessments in the Belgian Road Safety Institute were considered as the primary outcome measures at follow-up.

All procedures were in accordance with ethical standards of human experimentation and approved by the Medical Ethics Committee of the University Hospitals Leuven, Belgium.

**Data analysis.** General and clinical characteristics were compared between the experimental and control groups using  $\chi^2$  for nominal data, Wilcoxon rank sum test for ordinal data or not normally distributed ratio variables, and unpaired *t* tests for normally distributed ratio variables. The differences between the groups at pre- and post-training assessments as well as improvements from pre- to post-training were tested using unpaired *t* tests and Wilcoxon rank sum tests. Within-group improvements in

each group were determined by comparing outcome of post- with pretraining driving assessments using paired t tests and Wilcoxon signed rank tests. The decisions of driving fitness (in three classes) based on the on-road test were compared between groups pre- and post-training and for improvements from pre- to post-training using  $\chi^2$  tests.

Differences between the experimental and control groups at follow-up were determined using Wilcoxon rank sum test for the on-road test, Fisher exact for the three-class decision, and  $\chi^2$  test for the derived pass/fail classification. The high dropout rate at follow-up was investigated by performing logistic regression analyses including neurologic evaluations, pre- and post-training assessment variables, as independent variables. Differences in improvement in performance in the on-road test from pre- to post-training between the dropouts in the experimental and control groups during the follow-up period were also examined. Additionally, intent-to-treat analyses were done for the on-road test, the three-class decision of fitness to drive, and the pass/fail classification at follow-up using the post-training scores of dropouts.

Improvements in the tasks evaluated in the simulator immediately after 15 hours of training were investigated using Wilcoxon signed rank tests. Multiple regression analyses were performed to evaluate if improvement in simulator tasks predicted improvement in the on-road test after training and at follow-up. Only significant variables from the univariate regression analyses were included in the multivariate analyses.

To identify subgroups of subjects in the experimental and control groups and in the total population that benefited more from the training programs, logistic regression analyses were performed. Neurologic evaluation and pretraining assessment tests were used as independent variables and improvements in the three-class decision from pre- to post-training as the dependent variable. Only significant variables from univariate analyses were included in stepwise multivariate logistic regression analyses. Interactions between the variables included in the subset from the multivariate analyses were also explored.

For significance testing, Bonferroni correction was applied to all comparisons that involved visual and neuropsychological tests. Consequently,  $p \leq 0.025$  was considered significant in the visual evaluations and  $p \leq 0.007$  for neuropsychological evaluations. In all other instances,  $p \leq 0.05$  were considered significant. All statistical procedures were performed with the SAS System.<sup>21</sup>

**Results. Subjects.** The progress of subjects through the trial is presented in the figure. One hundred twenty-six stroke patients were admitted into the rehabilitation hospital in 20 months. From the 101 patients that met the inclusion criteria, 83 (65.9%) willingly consented to take part in the study. Forty-two subjects were randomly allocated to the experimental group and 41 to the control group. During training, five subjects from both groups dropped out for reasons not directly related to training programs. Thirty-seven subjects in the experimental and 36 in the control groups completed the training program.

Fifty-two subjects performed the follow-up assessment in Brussels. Twenty-one subjects (11 experimental and 10 control subjects) were lost to follow-up. Three experimental and five control subjects officially postponed their follow-up assessments further than 9 months poststroke and were classified as “out of time frame.” Other reasons for dropouts are reported in the figure.

Data from the pretraining neurologic evaluations of all 73 subjects that completed the training programs are displayed in table 1. There were no significant differences between the experimental and control groups for all variables. Only level of education (qualification) was significantly different between both groups when the data of the 52 subjects that performed the follow-up assessments were compared (see table E-1 on the *Neurology* Web site; go to [www.neurology.org](http://www.neurology.org)).

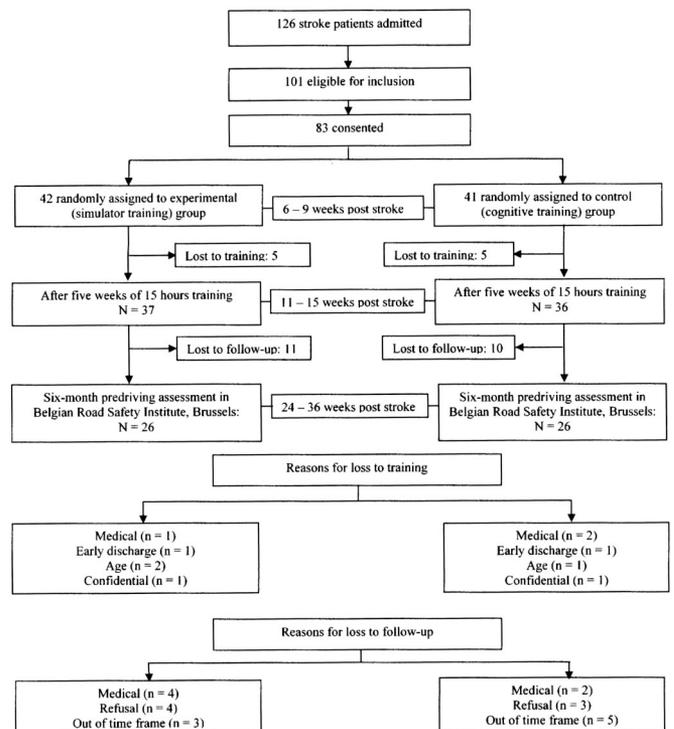


Figure. Trial profile.

*From pre- to post-training.* Comparisons of visual and neuropsychological tests between groups (table 2) showed no significant differences for all variables at pre- and post-training assessments. A similar outcome was observed for comparisons of improvements (pre- post-training difference) between groups with the exception of the road sign recognition test ( $p = 0.007$ ). In each of the groups, however, significant within-group improvements in performance were found in one variable of the visual tests (kinetic vision) and many variables of the neuropsychological tests.

There was no significant difference between the experimental and control groups at pretraining for performance in the on-road test. Both groups significantly improved from pre- to post-training. The median improvement in the experimental group (34) was 23 points higher than in the control group (11). The interquartile range observed in both groups indicated a large variability in the subject population. Though the experimental group showed better improvement than the controls in the on-road test (see figure E-1 on the *Neurology* Web site), the difference between groups was not significant.

Between-group differences in the three-class decision on fitness to drive based only on performance in the “on-road test” at pre- and post-training are reported in table 3. There was no difference between groups at pretraining ( $p = 1.00$ ), whereas the difference tended toward significance at post-training. After training, most subjects that improved from “unfit to drive” to “fit to drive” decisions (two-level improvement) were from the experimental group. Almost an equal number of subjects in both groups improved from either “unfit to drive” to “temporarily unfit to drive” or from “temporarily unfit to drive” to “fit to drive” decisions (one-level improvement). Whereas the earlier decision category of more control subjects remained unchanged (zero-level improvement), no subject in either

**Table 1** Comparisons of neurologic evaluation of experimental and control groups in 73 subjects that completed training

Variable	Experimental, n = 37	Control, n = 36	Statistic	Significance
Age, y, mean (SD)	54 (12)	54 (11)	t = -0.18	NS
Sex, n				
Male	28	31	$\chi^2 = 1.29$	NS
Female	9	5		
Qualification, n				
Primary	3	3	$\chi^2 = 0.79$	NS
Secondary	16	12		
Tertiary	18	21		
Side of lesion, n				
Left	16	16	$\chi^2 = 0.32$	NS
Right	19	19		
Bilateral	2	1		
Type of stroke, n				
Ischemic	27	29	$\chi^2 = 0.58$	NS
Hemorrhagic	10	7		
Onset-participation interval, mean (SD)	53 (6)	54 (6)	t = 0.40	NS
Driving experience, mean (SD)	34 (12)	32 (11)	t = -0.52	NS
Distance driven annually, mean (SD)	24 (16)	23 (14)	t = -0.13	NS
Visual field loss, n				
Yes	6	8	$\chi^2 = 0.43$	NS
No	31	28		
Visual inattention, n				
Yes	10	9	$\chi^2 = 0.04$	NS
No	27	27		
Aphasia, n				
Yes	17	15	$\chi^2 = 0.14$	NS
No	20	21		
Tactile inattention, n				
Yes	8	7	$\chi^2 = 0.05$	NS
No	29	29		
Barthel Index, mean (SD)	70 (25)	78 (28)	t = 1.29	NS
MMSE, median (IQR)	30 (30-27)	30 (30-27)	W = 0.09	NS

MMSE = Mini-Mental State Examination; IQR = interquartile range (Q3 -Q1) ; t = t test (unpaired); W = Wilcoxon rank sum test; NS = not significant (p > 0.05).

group got a lower decision post-training. This “changes in decision” from pre- to post-training was significantly different between the groups in favor of the experimental group (see table E-2 on the *Neurology* Web site).

*At follow-up.* Fifty-two subjects performed the follow-up assessment in CARA. Univariate and multivariate logistic regression analyses did not reveal any variable as significant predictor of dropout. There was also no significant difference between the median improvement in the on-road test from pre- to post-training for the 11 dropouts in the experimental group (median = 34) and the 10 control dropouts (median = 38) (see table 3). These imply that the occurrence of dropout was not related to any of the neurologic variables or performance in the pre- or post-training predriving assessments.

The differences between groups in the on-road test and the three-class decision at follow-up were not significant. However, when the legal implications of the three-class decision (pass/fail classification) between groups were compared (table 4), there was a significant difference. Nineteen (73%) of the 26 experimental subjects passed and legally could resume driving as compared with only 11 (42%) of the 26 control subjects. The outcome of the intent-to-treat analyses using post-training scores revealed significant differences between the groups in the on-road test, three-class decision, and pass/fail classification, all in favor of the experimental group.

*Effect of simulator training on driving performance.* Simulator training significantly improved performance in most variables evaluated in the simulator in the experi-

**Table 2** Median, interquartile range, mean, and SD of variables in experimental (n = 37) and control (n = 36) groups before and after training and improvements after training

Variable	Experimental, n = 37	Control, n = 36	Test statistic	p Value
Binocular acuity, median (IQR)				
Pretraining	10 (8–10)	10 (7–10)	W = -0.16	0.87
Post-training	10 (8–10)	9 (8–10)	W = -1.47	0.14
Pre–post-training difference	0 (0–0)	0 (0–0)	W = -0.22	0.82
Kinetic vision, median (IQR)				
Pretraining	60 (4–7)	5.5 (4–7)	W = -0.54	0.59
Post-training	7.0 (5–8)	7.0 (5–8)	W = -0.32	0.75
Pre–post-training difference	1.0 (0–2)†	1.0 (0–2)†	W = 0.17	0.86
Useful field of view, mean (SD)				
Pretraining	21.48 (24.36)	27.92 (25.27)	t = 1.11	0.27
Post-training	15.14 (15.55)	18.82 (20.83)	t = 0.86	0.39
Pre–post-training difference	6.35 (14.72)‡	9.10 (16.00)‡	t = 0.76	0.45
Dot cancellation time, mean (SD)				
Pretraining	546.65 (222.13)	596.60 (214.07)	t = 0.97	0.34
Post-training	516.05 (213.75)	568.26 (190.54)	t = 1.09	0.28
Pre–post-training difference	30.60 (167.36)	27.56 (192.65)	t = -0.07	0.94
Dot cancellation error, mean (SD)				
Pretraining	32.47 (41.00)	26.83 (31.00)	t = -0.65	0.52
Post-training	16.05 (28.48)	16.43 (30.17)	t = 0.05	0.96
Pre–post-training difference	15.54 (31.37)‡	10.11 (20.63)‡	t = -0.88	0.38
Dot cancellation false positives, median (IQR)				
Pretraining	0 (0–0)	0 (0–1)	W = 0.71	0.48
Post-training	0 (0–0)	0 (0–0)	W = 0.65	0.52
Pre–post difference	0 (0–0)	0 (0–0)	W = 0.23	0.82
Square matrix (direction), mean (SD)				
Pretraining	23.69 (10.53)	21.11 (11.90)	t = -0.97	0.34
Post-training	27.08 (8.38)	24.51 (10.48)	t = -1.15	0.25
Pre–post-training difference	4.03 (8.30)‡	3.31 (6.28)‡	t = -0.42	0.68
Square matrix (compass), mean (SD)				
Pretraining	14.75 (10.02)	12.77 (7.95)	t = -0.92	0.36
Post-training	19.62 (9.90)	17.11 (8.38)	t = -1.16	0.25
Pre–post-training difference	5.27 (7.69)‡	4.22 (7.69)‡	t = -0.58	0.56
Road sign recognition, mean (SD)				
Pretraining	4.61 (3.17)	4.74 (2.91)	t = 0.18	0.86
Post-training	6.89 (2.89)	5.49 (2.94)	t = -2.05	0.04
Pre–post-training difference	2.41 (2.66)‡	0.72 (2.49)	t = -2.79	0.007‡
On-road test, median (IRQ)				
Pretraining	116.0 (74–172)	122.5 (50–172)	W = -0.57	0.57
Post-training	181.0 (121–196)	167.0 (96–191)	W = -1.77	0.08
Pre–post-training difference	34.0 (2–59)*	11.0 (0–53)*	W = -0.74	0.46

\*  $p \leq 0.05$ .

†  $p \leq 0.025$ .

‡  $p \leq 0.007$ .

IQR = interquartile range (Q1–Q3); W = Wilcoxon rank sum test; t = t test (unpaired).

**Table 3** Frequencies in three-class decision of fitness to drive solely based on performance in “on-road test” at pre- and post-training for 73 subjects that completed training

Classes of decision	Pretraining		Post-training	
	Experimental	Control	Experimental	Control
Fit to drive	3	4	16	7
Temporarily unfit to drive	7	6	11	15
Unfit to drive	27	26	10	14
	$\chi^2 = 0.23, p = 1.00$		$\chi^2 = 4.79, p = 0.09$	

mental group (table 5). The difference in excessive speed from pre- to post-training was not significant in spite of 14 experimental subjects who had no speeding excesses pre-training but had between two and four excesses post-training. Difference in faults committed at traffic lights from pre- to post-training was also not significant.

Multiple regression analyses revealed that improvements in individual items evaluated during the on-road test at post-training were predictable by improvements in some variables evaluated in the simulator. In most cases, the variance explained by the model was low. The best prediction was observed for “position on the road at speed less than 50 kilometers per hour” by a combination of excessive speed and number of pedestrians hit ( $R^2 = 0.34, n = 37$ ). Use of mechanical parts (handling and use of steering wheel or steering spinner knobs, brake and accelerator pedals) was best predicted by a combination of number of pedestrians hit, run time, and total faults committed in the simulator driving task ( $R^2 = 0.22, n = 37$ ).

Improvement in the overall performance in the on-road test from pre- to post-training could not be significantly predicted by improvement in any of the variables or combination of variables evaluated in the simulator. However, improvement in overall performance in the on-road test performed during the official driving assessment 6 to 9 months poststroke (follow-up) was individually and significantly predicted by improvement in total number of collisions, excessive speed, and pedestrians hit. The variance explained by a combination of these three variables was moderate ( $R^2 = 0.59, n = 26$ ).

Outcome of univariate logistic regression analyses to identify subgroups of subjects in both group that benefited more from the training programs revealed academic qualification ( $p = 0.026$ ), side of lesion ( $p = 0.048$ ), and the Barthel Index ( $p = 0.043$ ) scores as individual predictors of marked improvement in the experimental group. Multivariate logistic regression analyses produced a combination of academic qualification and Barthel Index score as the best predictive model of improvement in the experimental

group. Data exploration showed that 8 of the 10 experimental subjects that improved from “unfit to drive” decision at pretraining to “fit to drive” at post-training (two-level improvement) had both high academic qualification (tertiary education) and high Barthel Index scores ( $\geq 75$ ). No neurologic evaluation or predriving assessment variable was retained as a significant predictor of improvements in the control group.

**Discussion.** After 15 hours of standardized simulator-based training, subjects in the experimental group significantly improved in most variables evaluated in the simulator and in many variables of the predriving assessment. These findings are in agreement with those of another study<sup>7</sup> in subjects with closed head injuries following 16 hours of structured simulator training. Control subjects significantly improved their performances in many variables of the predriving assessment after driving-related cognitive training as well, a finding that had also been reported in a previous study.<sup>4</sup> Despite specific training using 40 different road sign cards in the control group, performance in the test was only significantly better after training in the simulator. The road sign recognition test involved correctly matching 12 of 19 traffic sign cards to 12 traffic situation cards. This outcome reinforces the motor learning principle that there is greater amount of positive transfer of learning when a skill is trained in a similar context in which it is performed.<sup>22</sup>

The median difference in improvement in the on-road test from pre- to post-training was 23 points more in the experimental group. This difference corresponded to 15.7% of the total score range (49 to 196), which is clinically important. Still, between-group difference in the test at post-training only approached conventional level of significance. The unexpected large variability in changes in driving performance after training reduced the power of the study. However, significantly more subjects in the experimental group as compared with control subjects improved in the three-class decision of driving fitness from pre- to post-training. At follow-up, significantly more experimental subjects than control subjects also passed the official predriving assessment and were legally allowed to resume driving. These findings suggest that some crucial factors in the simulator training may have led to positive changes in on-road performance and driving fitness

**Table 4** Frequencies and comparison of pass/fail classifications derived from three-class decisions of fitness to drive at follow-up between experimental and control groups

Classification	Experimental	Control	Test statistic	$p$ Value
Pass (fit to drive)	19 (19)	11 (11)	$\chi^2 = 5.04$	0.03
Fail (temporarily unfit to drive + unfit to drive)	7 (4 + 3)	15 (9 + 6)		

**Table 5** Median and interquartile range of performance in pre- and post-training assessment in simulator for 37 subjects in experimental group

Variable	Pretraining		Post-training		Test statistic	p Value
	Median	IQR	Median	IQR		
Collisions, n	1	0–5	0	0–0	W = 3.11	0.0005
Pedestrians hit, n	2	1–2	0	0–1	W = 8.05	0.0001
Excessive speed, n	0	0–0	0	0–1	W = -0.41	0.84
Traffic light faults, n	0	0–1	0	0–0	W = 1.97	0.15
Total faults, n	7	6–9	0	0–3	W = 7.87	0.0001
Run time, s	1,302	1,122–1,463	1,180	1,074–1,254	W = 3.60	0.0001

IQR = interquartile range; W = Wilcoxon signed rank test.

decisions in several subjects. The simulator training program in this study involved use of appropriate adaptations when required, real steering wheel and brake and accelerator pedals, and driving through simulated scenarios similar in nature and complexity to real-life on-road traffic situations and demands. It is therefore logical that some aspects of the on-road tests that were trained in the simulator such as lane tracking at moderate speed (<50 km/h) and use of mechanical parts (handling and use of steering wheel or steering spinner knobs, brake and accelerator pedals) were predictable by improvements in simulator tasks. In most cases, the variance explained by the predictive models was low, which cast doubt on the amount of transfer of some learned skills in the simulator to real-life driving. It is also possible that the effect of training in the simulator requires time to consolidate. Overall performance in the on-road test administered about 3 months post-training was predicted with better accuracy by improvements in some simulator tasks than the performance immediately after training.

Not all stroke patients benefited equally from the simulator-based training program. Those with left-sided brain lesion improved better than the right-sided brain lesion patients. Only one patient with a left-sided lesion was not eligible for inclusion in the study as a result of very severe aphasia. Therefore, the finding that left-sided lesion was an individual predictor of benefit from the training program is probably not because patients with large left hemispheric lesions or aphasia were excluded. The finding is also in agreement with studies that have reported that right-sided stroke patients are more difficult to train<sup>23,24</sup> because they often demonstrate more cognitive and visual problems that affect driving performance.<sup>12,25</sup>

A combination of high academic qualification and limited level of overall disability were the major determinants of better improvement in the experimental group. Fairly good motor ability was an important factor in the effective use of the mechanical parts of the simulator. Appreciation of the simulated driving scenario was also necessary for an effective learning process. Motivation to return to

prestroke routine, which had been observed in highly educated persons with less physical disability after stroke,<sup>26</sup> is believed to have played a major role in this cohort of patients as well. Despite more subjects with very high qualification, level of education did not seem to play a significant role in determining benefits from the training program received by the control subjects. The fidelity of the simulator, which gave the simulator-based training a sort of face validity, may have further motivated experimental subjects to maximally benefit from the training program.

The dropout rate at follow-up (28.8%) was high in spite of encouragements to perform the legally required assessment. Dropouts occurred at random and did not seem to have an adverse effect on the findings. Subjects were recruited early on in the rehabilitation (subacute) phase and may have underestimated the difficulty in resuming driving. Still, many patients (especially in the experimental group) that performed the follow-up assessment retained the improved performance observed immediately after the training. This demonstrates the long-term effect of the intervention and suggests the usefulness of implementing a driving training program in the active rehabilitation phase after stroke. Patients with severe poststroke deficits should be allowed more time to physically recover before being included in such training programs.

To the best of our knowledge, this is the first randomized controlled trial of its type. Though control subjects received driving-related cognitive training instead of placebo in order to motivate all subjects alike, simulator-based driving training of stroke patients was shown to be better. There were no significant differences between groups in all the variables assessed at pretraining. Therefore, recovery and progress during the duration of the study were expected to be similar in both groups. However, in such a long-term follow-up study, it is possible that the results may be influenced by other factors (known and unknown) rather than the intervention alone. The fact that some variables, especially “level of overall disability,” were not repeated at follow-up is a weakness of the study.

It would be interesting to see similar studies set

up in other rehabilitation centers to determine the generalizability of the findings in this study. New studies should not be difficult to set up as the simplest version of the simulator system used is easily available, affordable (\$15,000 or less), and requires a regular office space (10 ft square). Future studies are also needed to determine the effect of driving training in other neurologic conditions such as Parkinson disease and early stage dementia.

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