Background and Purpose—This study investigated whether problem-solving therapy (PST) is an effective group intervention for improving coping strategy and health-related quality of life (HRQoL) in patients with stroke.

Methods—In this multicenter randomized controlled trial, the intervention group received PST as add-on to standard outpatient rehabilitation, the control group received outpatient rehabilitation only. Measurements were performed at baseline, directly after the intervention, and 6 and 12 months later. Data were analyzed using linear-mixed models. Primary outcomes were task-oriented coping as measured by the Coping Inventory for Stressful Situations and psychosocial HRQoL as measured by the Stroke-Specific Quality of Life Scale. Secondary outcomes were the EuroQol EQ-5D-5L utility score, emotion-oriented and avoidant coping as measured by the Coping Inventory for Stressful Situations, problem-solving skills as measured by the Social Problem Solving Inventory-Revised, and depression as measured by the Center for Epidemiological Studies Depression Scale.

Results—Included were 166 patients with stroke, mean age 53.06 years (SD, 10.19), 53% men, median time poststroke 7.29 months (interquartile range, 4.90–10.61 months). Six months post intervention, the PST group showed significant improvement when compared with the control group in task-oriented coping ($P=0.008$), but not stroke-specific psychosocial HRQoL. Furthermore, avoidant coping ($P=0.039$) and the utility value for general HRQoL ($P=0.034$) improved more in the PST group than in the control after 6 months.

Conclusions—PST seems to improve task-oriented coping but not disease-specific psychosocial HRQoL after stroke >6-month follow-up. Furthermore, we found indications that PST may improve generic HRQoL recovery and avoidant coping.

Clinical Trial Registration—URL: http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=2509. Unique identifier: CNTR2509.

(Stroke. 2016;47:135-142. DOI: 10.1161/STROKEAHA.115.010961.)

Key Words: adaptation, psychological ▪ problem solving ▪ quality of life ▪ randomized controlled trial ▪ stroke
Materials and Methods

Design and Participants

In this multicenter, randomized controlled trial, patients were randomly allocated to the PST or control group. Patients were assessed at the rehabilitation center or at home at 4 time points: within 3 weeks before the intervention (T0), within 10 days post intervention (T1), and 6 (T2) and 12 (T3) months post intervention.

Patients at 2 departments of Rijnland Rehabilitation Center (Rotterdam and Dordrecht, the Netherlands) and at Ghent University Hospital (Belgium) were approached between March 2011 and August 2013. Patients were included if they (1) had a stroke (including subarachnoid hemorrhage), (2) were aged 18 to 75 years, (3) received outpatient stroke rehabilitation treatment, and (4) were able to participate in group therapy. Patients were excluded if they had progressive neurological disorder, life expectancy ≤1 year, insufficient understanding of the Dutch language, subdural hematomas, moderate or severe aphasia, or partook in excessive drinking or drug abuse.

The study has been approved by the Medical Ethics Committee of the Erasmus University Medical Center and of Ghent University Hospital. Written informed consent was obtained from all participants.

Procedure

Patients were approached by their physiatrist. Patients willing to participate were invited for the baseline measurement. All assessments and data-entry were performed by trained research psychologists who were blinded for group allocation. All tests were administered in a fixed order during all measurements.

The randomization procedure was performed by an independent investigator using an online random number generator; a random block design (block size of 4) was used stratified for the 3 locations. The allocations were kept in sealed opaque envelopes until the baseline measurement. To start the intervention groups, the first 3 patients per location were directly assigned to the PST group. Thereafter, all patients were randomly assigned to the PST or control group. The flow of new patients with stroke was sufficient to continue the group sessions for most of the time. Eleven times, the PST group was complemented with a patient with traumatic brain injury to secure the minimum number of participants per group (n=3). These patients with traumatic brain injury were invited for the PST group only, not for participation in the study.

Intervention: PST

Patients assigned to the intervention group received PST as add-on module to standard rehabilitation, during the last 8 weeks of outpatient treatment. PST is a widely used intervention and was slightly adapted for our study; it was provided in an open group design with predesigned modules including physiotherapy, occupational therapy, psychology, speech therapy, and social work, which were tailored to individual needs.

Outcome Measures

Coping strategy was measured using the Coping Inventory for Stressful Situations.17 This questionnaire consists of 3 scales, each including 16 items, task-oriented, emotion-oriented, and avoidant coping. The items are measured on a 5-point rating scale (range, 1–5). Sum scores are calculated per scale, with higher scores indicating more use of that coping strategy. The questionnaire has been validated in the Netherlands.18 Task-oriented coping was chosen as primary outcome because PST is mainly focused on this coping strategy. Good internal consistency was found (task-oriented: Cronbach α=0.88, emotion-oriented α=0.87, and avoidant: α=0.82).

Problem-solving skills were measured with the short version of the Social Problem Solving Inventory-Revised. This questionnaire consists of 10 questions and contains 5 domains: positive problem orientation, rational problem solving, negative problem orientation, impulsivity/carelessness style, and avoidance style. The items are measured on a 5-point rating scale (range, 0–4). Domain scores are calculated as sum scores. Higher scores indicate more use of a problem-solving skill. The total score is the sum of the positive domains (positive problem orientation and rational problem solving) and the reverse scores of the negative domains (negative problem orientation, impulsivity/carelessness style, and avoidance style), a higher total score indicating better general problem-solving skills. The short version is considered reliable and valid.20 Internal consistency was questionable at T0 (α=0.68) and adequate at follow-up (α=0.71).

HRQoL was measured using the Stroke-Specific Quality-of-Life Scale-12 and the EuroQol EQ-5D-5L. The Stroke-Specific Quality-of-Life Scale-12 is a disease-specific questionnaire, specifically measuring problems related to stroke.21 The short version contains 12 questions and has been validated.22 It provides 2 subscores; Physical and Psychosocial HRQoL, calculated as the mean scores of the scale items (score range, 1–5). Psychosocial HRQoL was chosen as primary outcome measure because PST is a cognitive rehabilitation intervention. Internal consistency of this scale was good (α>0.80). The EQ-5D-5L is a generic questionnaire, allowing comparison of HRQoL between different populations, consisting of 5 items with 5 response categories. These items can be combined into 5^5=3125 health states. For each of these health states, utility scores that range from 0 (death) to 1 (full health) have been established in society. Utilities represent the value of the general public toward the quality of life of different health states.23,24 In this way, the societal value of HRQoL is measured.25 The questionnaire showed adequate internal consistency (α>0.71).

Depression was measured using the Center for Epidemiological Studies Depression Scale. It consists of 20 items (score range, 0–3). A higher total score (range, 0–60) indicates more depressive symptoms, a score of ≥16 is the cutoff value for probable depression.26 The Center for Epidemiological Studies Depression Scale has been validated in the Netherlands.27 Internal consistency was good (α=0.88).

Other Measures

Personality traits were assessed with the Eysenck Personality Questionnaire Brief Version, measuring neuroticism and extraversion. It has been shown internally consistent, reliable, and valid.28 The presence and severity of aphasia were measured using the short version of the Token Test.29 The level of independence was measured with the modified Rankin Scale.30 Comorbidity was assessed using...
the Cumulative Illness Rating Scale. All 4 questionnaires have been validated in the Netherlands. Clinical and demographic characteristics were obtained from patient records and a structured interview at baseline. Education level was classified using a 7-level system; 1 indicates some years of primary education and 7 a university degree or higher.

Sample Size Calculation

For this trial with 4 repeated measurements, expected correlation of 0.70, \( \alpha \) of 0.05, and power of 0.80, we calculated a total required sample size of 132 patients based on the \( F \)-test, to detect a significant difference in HRQoL between the 2 groups. We strived to include

### Table 1. Patient Characteristics of the PST and Control Group

<table>
<thead>
<tr>
<th>Variable</th>
<th>PST (n=88)</th>
<th>Control (n=78)</th>
<th>Test Statistic</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y, mean (SD)</td>
<td>52.17 (9.67)</td>
<td>54.07 (10.73)</td>
<td>T(164)=1.203</td>
<td>0.231</td>
</tr>
<tr>
<td>Sex, male, n (%)</td>
<td>55 (62.5)</td>
<td>33 (42.3)</td>
<td>( \chi^2(1)=6.768 )</td>
<td>0.009</td>
</tr>
<tr>
<td>Education level, high, n (%)</td>
<td>32 (36.4)</td>
<td>26 (33.3)</td>
<td>( \chi^2(1)=0.167 )</td>
<td>0.683</td>
</tr>
<tr>
<td>Partner, no, n (%)</td>
<td>29 (33.0)</td>
<td>16 (20.5)</td>
<td>( \chi^2(1)=3.239 )</td>
<td>0.072</td>
</tr>
<tr>
<td>Side of stroke, left, n (%)</td>
<td>35 (40.7)</td>
<td>29 (39.2)</td>
<td>( \chi^2(1)=0.117 )</td>
<td>0.732</td>
</tr>
<tr>
<td>Type of stroke, ischemic, n (%)</td>
<td>68 (77.3)</td>
<td>53 (70.7)</td>
<td>( \chi^2(1)=1.819 )</td>
<td>0.177</td>
</tr>
<tr>
<td>Time post stroke, ≤1 y, n (%)</td>
<td>77 (87.5)</td>
<td>62 (79.5)</td>
<td>( \chi^2(1)=1.949 )</td>
<td>0.163</td>
</tr>
<tr>
<td>modified Rankin Scale score, dependent, n (%)</td>
<td>26 (29.5)</td>
<td>20 (25.6)</td>
<td>( \chi^2(1)=0.315 )</td>
<td>0.575</td>
</tr>
<tr>
<td>modified Rankin Scale Score, mean (SD)</td>
<td>2.11 (0.73)</td>
<td>2.00 (0.77)</td>
<td>T(164)=0.971</td>
<td>0.333</td>
</tr>
<tr>
<td>Personality (EPQ-BV)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extraversion, mean (SD)</td>
<td>7.03 (3.19)</td>
<td>6.23 (2.60)</td>
<td>T(164)=1.764</td>
<td>0.080</td>
</tr>
<tr>
<td>Neuroticism, mean (SD)</td>
<td>4.09 (3.41)</td>
<td>4.09 (3.30)</td>
<td>T(164)=0.002</td>
<td>0.998</td>
</tr>
<tr>
<td>CIRS score, comorbidity, mean (SD)</td>
<td>5.73 (2.67)</td>
<td>6.77 (3.54)</td>
<td>T(164)=2.152</td>
<td>0.033</td>
</tr>
<tr>
<td>Aphasia severity, mean (SD)</td>
<td>33.06 (2.76)</td>
<td>33.21 (2.53)</td>
<td>T(164)=0.359</td>
<td>0.720</td>
</tr>
<tr>
<td>Currently taking antidepressant medication, n (%)</td>
<td>15 (17.0)</td>
<td>17 (21.8)</td>
<td>( \chi^2(1)=0.599 )</td>
<td>0.439</td>
</tr>
</tbody>
</table>

CIRS indicates Cumulative Illness Rating Scale; EPQ-BV, Eysenck Personality Questionnaire Brief Version; and PST, problem-solving therapy.
200 patients, taking into account potential dropout during the intervention and 1-year follow-up period.

**Statistical Analysis**

All statistical analyses were performed using SPSS version 21.0 for Microsoft Windows. Potential differences between the PST and control group at baseline were analyzed using independent samples t tests for interval variables and χ² tests for categorical variables. Differences in changes over time between the groups were analyzed using linear-mixed models, taking into account the correlation within and between subjects. We performed these repeated measurement analyses for each outcome separately. Unstructured covariance structures were used. The outcomes of the 4 measurement times were entered as dependent variables in each model. Fixed factors in the models were group (PST or control) and time point (T0, T1, T2, and T3) and the interaction between these variables. Each model provided interaction coefficients that represent the mean difference between the groups per time point, using the baseline measurement of the control group as reference. The models were corrected for sex and comorbidity (baseline Cumulative Illness Rating Scale score) because these variables accidently differed between the groups at baseline. P<0.05 were considered statistically significant. Cohen d effect sizes (difference in effect/pooled SD) were calculated.

**Results**

**Study Population**

Of 293 eligible patients approached, 166 provided informed consent. Reasons for nonparticipation were no time, logistical problems, or lack of interest. The flow of patients through the study is presented in Figure 1. During the intervention period, 4 patients dropped out of the PST group (4.5%). During the 1-year follow-up, another 4 patients dropped out of the PST group and 7 were lost in the control group, resulting in equal dropout rates over the total study time in both groups (9.1% and 9.9%, respectively). The average number of PST-sessions completed was 6.5.

The mean age of the total sample was 53.06 years (SD, 10.19), and 53% were men. The median time poststroke was 7.29 months (interquartile range, 4.90–10.61 months). Left-sided stroke was observed in 40.0% and ischemic stroke in 74.2%. Tables 1 and 2 show the patient characteristics and baseline scores of the outcome variables for the PST and control group.

**Effectiveness of PST Compared With Standard Care**

**Coping Strategy**

Figure 2A shows the trajectory of task-oriented coping over the intervention and follow-up time: the primary outcome measure of coping. At 6 months post intervention (T2), significant differences between the groups were found; the PST group improved significantly more >6-month follow-up than the control group (P=0.008; Table 3). The Cohen’s d effect size was 0.43. Figure 2A illustrates that the PST group increased in task-oriented coping, whereas the control group slightly decreased. The improvement in task-oriented coping remained stable ≤12 months after PST although the difference with standard care only showed a trend toward significance after a year (P=0.060). Figure 2B shows a significant difference in the secondary outcome avoidant coping between the PST and control group (effect size, 0.33). The gain in the PST group was not sustained over the 1-year follow-up (P=0.581). Emotion-oriented coping decreased over time in both groups (P=0.004), but the groups did not differ significantly over time (P=0.895).

Looking specifically at problem-solving skills, we found no changes over time and no differences between the groups over time (data not shown).

**Health-Related Quality of Life**

The primary outcome psychosocial HRQoL did not change over the intervention period in any group. Figure 2C shows the course of the secondary outcome utility value of HRQoL. Over the intervention period, both groups improved equally in general HRQoL, after which the curves diverged; the PST group continued to increase, whereas the control group leveled off. Six months post intervention (at T2), the
increase in utility score significantly differed between the PST and the control group (P=0.034). The effect size was 0.34. Between 6 and 12 months post intervention, the utility score in the PST group remained stable, whereas the control group caught up, resulting in equal HRQoL after 12 months (P=0.245).

Depression
In both groups, the depression score, a secondary outcome in this study, significantly decreased over the total follow-up time (P=0.028). Depression score did not differ significantly between the groups over time (P=0.577). The proportion of patients with probable depression decreased from 39.2% at baseline to 32.5% at 1-year follow-up.

Discussion
This study is the first randomized controlled trial assessing the effectiveness of PST, provided as a group intervention during outpatient stroke rehabilitation, on coping strategy and HRQoL. The results suggest that PST positively affects task-oriented coping skills. The results in terms of HRQoL recovery are mixed; the primary disease-specific outcome did not show an effect, whereas the secondary generic outcome did. The expected stagnation in HRQoL recovery after rehabilitation discharge was observed in the control group, whereas the PST group showed continued improvement of the utility value of HRQoL until 6 months after PST, suggesting that adding PST to outpatient stroke rehabilitation succeeded in optimizing HRQoL recovery after discharge.

The finding that stroke-specific psychosocial HRQoL recovery did not improve while the secondary generic HRQoL outcome did is remarkable, as one would expect that a disease-specific outcome is more sensitive than a generic. An explanation can be that PST does more than just improving stroke-related HRQoL problems; newly learned problem-solving skills can be applied in all aspects of life. Another explanation might be a possible measurement issue; we measured psychosocial HRQoL with the short version of the questionnaire. This version has been validated, but may not be sensitive enough to detect small but significant changes.

The effects of PST differed over time; no significant group differences were present directly after the intervention. This may be explained by the fact that both groups received outpatient rehabilitation treatment and were both improving because of the multiple interventions in this standard program. In addition, it may take a while for learning-based interventions to impact psychosocial variables such as coping strategy and HRQoL. Accordingly, after 6 months, PST resulted in increased use of task-oriented and avoidant coping strategies, indicating an improved flexibility in applying different coping strategies, accompanied by improved utility scores. In the literature, avoidant coping often has been associated with negative outcomes like depression and anxiety. However, a recent study on the psychometric properties of the Coping Inventory for Stressful Situations in patients with acquired brain injury showed that avoidant coping was not related with depression and anxiety, whereas emotion-oriented coping was.33 We reported the same relationship in our study population in a previous article; avoidant coping was not different between patients with high and low depression scores.34 The result that avoidant coping increased after PST might be explained by the fact that this scale includes many items on social diversion such as seeking company and talking to others, which are encouraged in a group therapy. Being able to apply both task-oriented and avoidant coping strategies in different situations indicates flexibility, which we consider a positive outcome. The effect sizes on coping and utility were rather small and
find effects. Similar to our intervention, the intervention interventions aimed at coping in patients with stroke did investigated about HRQoL and coping before. However, other HRQoL. In patients with stroke, PST has not been inves-
tigated. These results do not support effects of PST on coping or to affect coping.

We did not find extra effects of PST on depression, whereas earlier PST studies primarily investigated this outcome. Studies in adults with depression presented mixed results; a systematic review and a meta-analysis both found mixed evidence on effects of PST on depression. In patients with stroke, PST resulted in a lower incidence of depression >12-month follow-up, which disappeared using more conservative analysis. Another study showed a reduction in depressive symptoms ≤12 months. The different results of PST on depression might be because of differences in design, diagnosis, type of PST, type of analysis, or type of control group. The studies reporting effects of PST on poststroke depression differed on the study population and used the Hamilton Rating Scale for Depression as outcome measure, which might explain the differences.

This study did show effects on HRQoL and coping strategy. PST effects on HRQoL have been investigated in other patient populations. In breast cancer survivors, HRQoL improved at 12-month follow-up although the PST group was not significantly better than the control group. A pilot study investigating telephone-delivered PST (6-week follow-up) found effects in HRQoL and in active coping, but no control group was included. A study investigating a nurse-led telephone-based PST in patients with chronic obstructive pulmonary disease found no differences on problem-oriented coping between the intervention and the control group. These results do not support effects of PST on coping or HRQoL. In patients with stroke, PST has not been investigated about HRQoL and coping before. However, other interventions aimed at coping in patients with stroke did find effects. Similar to our intervention, the intervention described by Backhaus et al was provided by psychologists, whereas the studies described above without effects on coping were provided by nurses or students. This might point at the importance of a psychologist providing the intervention to affect coping.

Unexpectedly, problem-solving skills did not improve after PST, whereas the intervention was specifically aimed at these skills. Maybe PST improves the use of coping strategy in its broad sense, not just problem-solving, supported by the finding that 2 of the 3 coping strategies improved 6 months post intervention. Another explanation is that a measurement issue might have occurred; the questionnaire measuring problem-solving skills might not be sensitive enough because only 2 questions per subscale are used in the short version. The total score of the short version has been validated, but the longer version is more suitable to detect changes in the domain scores. A drawback of the long version might be difficulty in understanding time-consuming questionnaires for patients with patients stroke, especially as part of an extensive test battery.

The intervention was provided in an open group design, which is new in the field of PST research; in earlier PST studies, the groups were closed or PST was provided individually by telephone. Our results show that an open group design is feasible and effective in outpatient stroke rehabilitation. The low dropout rate in our study supports this conclusion, as well as the positive feedback we received from patients in the PST group.

A limitation of the study might have been the absence of an active control group intervention. We designed this trial in a pragmatic way because it enables us to observe the added value of PST to standard care. The observed effects cannot be simply explained as an effect of additional attention received by the PST group. The effects were found >6 months post intervention, whereas an effect of additional attention would have been present on the short term only. Furthermore, coping skills are also implicitly trained in standard outpatient rehabilitation, which may decrease the contrast between the intervention and the control group. Another limitation might be the generalizability of the results. Because the intervention has been investigated within the outpatient rehabilitation program, we should be careful in generalizing the results to other settings after stroke. Finally, our population reported a relatively high utility score compared with other stroke populations. The finding that this utility score improved after PST suggests that in populations in which there is more to gain (with lower baseline utility scores), the intervention could even be more beneficial.
Summary

PST seems a useful intervention for patients with stroke, which may have added value to standard outpatient rehabilitation. PST seems to improve task-oriented coping, but not disease-specific psychosocial HRQoL >6-month follow-up. Furthermore, we found indication that PST may improve generic HRQoL recovery after stroke and avoidant coping.

Acknowledgments

We thank all participating patients, Wendy Boerboom, Mette Lappöhn, Kim van Driel, Dindra Bouter, Loes Abraham, Chantalle Hartjes, and Lianne Pappell are thanked for performing measurements.

Sources of Funding

This study was funded by the National Initiative Brain and Cognition (NIBc, The Healthy Brain, Program Cognitive Rehabilitation [grant number 05611010], Stichting Coolingsel, and Erasmus MC Cost-Effectiveness Research.

Disclosures

None.

References


Problem-Solving Therapy During Outpatient Stroke Rehabilitation Improves Coping and Health-Related Quality of Life: Randomized Controlled Trial
Marieke M. Visser, Majanka H. Heijenbrok-Kal, Adriaan van't Spijker, Engelien Lannoo, Jan J.V. Busschbach and Gerard M. Ribbers

Stroke. 2016;47:135-142; originally published online November 19, 2015;
doi: 10.1161/STROKEAHA.115.010961

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://stroke.ahajournals.org/content/47/1/135

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published in Stroke can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial Office. Once the online version of the published article for which permission is being requested is located, click Request Permissions in the middle column of the Web page under Services. Further information about this process is available in the Permissions and Rights Question and Answer document.

Reprints: Information about reprints can be found online at:
http://www.lww.com/reprints

Subscriptions: Information about subscribing to Stroke is online at:
http://stroke.ahajournals.org//subscriptions/