The YOU CALL–WE CALL Randomized Clinical Trial Impact of a Multimodal Support Intervention After a Mild Stroke

Annie Rochette, PhD; Nicol Korner-Bitensky, PhD; Duane Bishop, MD; Robert Teasell, MD; Carole L. White, PhD; Gina Bravo, PhD; Robert Côté, MD; Teri Green, PhD; Louise-Hélène Lebrun, MD; Sylvain Lanthier, MD; Moira Kapral, MD, MSc; Mark Bayley, MD

Background—Comparison of a multimodal intervention WE CALL (study initiated phone support/information provision) versus a passive intervention YOU CALL (participant can contact a resource person) in individuals with first mild stroke.

Methods and Results—This study is a single-blinded randomized clinical trial. Primary outcome includes unplanned use of health services (participant diaries) for adverse events and quality of life (EuroqoL-5D, Quality of Life Index). Secondary outcomes include planned use of health services (diaries), mood (Beck Depression Inventory II), and participation (Assessment of Life Habits [LIFE-H]). Blind assessments were done at baseline, 6, and 12 months. A mixed model approach for statistical analysis on an intention-to-treat basis was used where the group factor was intervention type and occasion factor time, with a significance level of 0.01. We enrolled 186 patients (WE=92; YOU=94) with a mean age of 62.5±12.5 years, and 42.5% were women. No significant differences were seen between groups at 6 months for any outcomes with both groups improving from baseline on all measures (effect sizes ranged from 0.25 to 0.7). The only significant change for both groups from 6 months to 1 year (n=139) was in the social domains of the LIFE-H (increment in score, 0.4/9±1.3 [95% confidence interval, 0.1–0.7]; effect size, 0.3). Qualitatively, the WE CALL intervention was perceived as reassuring, increased insight, and problem solving while decreasing anxiety. Only 6 of 94 (6.4%) YOU CALL participants availed themselves of the intervention.

Conclusions—Although the 2 groups improved equally over time, WE CALL intervention was perceived as helpful, whereas YOU CALL intervention was not used.


Key Words: affect • life support care • patient participation • quality of life • rehabilitation • secondary prevention

Mild stroke, typically defined as a stroke with no or slight motor impairment or a high level of independence in personal activities of daily living, accounts for the majority of all strokes. Its prevalence is expected to rise with demographic changes and increased use of thrombolysis and other preventive interventions. Traditionally considered a subgroup of patients with stroke without sequelae, there is increasing evidence that these patients experience negative consequences on quality of life, participation, that is, accomplishment of daily activities and social roles, and mood, and they have a higher risk of stroke recurrence.

In most circumstances, individuals with a mild stroke are discharged home directly from acute care without referral for rehabilitation. Several qualitative studies have shown that information and support are needed, and the timing and type of information required vary along the poststroke trajectory. Yet, within the current healthcare system, individuals with mild stroke have limited access to adequate information and support, even in the face of mounting evidence that education and support improve mental health and stroke knowledge.

Therefore, this trial involving individuals experiencing a first mild stroke aimed to determine whether a low-cost, multimodal support intervention (WE CALL) offered for 6 months would be effective compared with the availability of a resource person (YOU CALL) for 6 months after stroke in reducing unplanned use of the healthcare system for adverse events and in improving quality of life after intervention (6 months) and at 1-year follow-up. Secondary outcomes included participation...
WHAT IS KNOWN

- Individuals with a mild stroke, representing the majority of all stroke severity, are typically discharged home directly from acute care without referral for rehabilitation.
- Traditionally considered a subgroup of patients with stroke without sequelae, increasing evidence shows that these patients experience negative consequences on quality of life, participation, and mood.

WHAT THE STUDY ADDS

- We randomized 186 patients to a proactive series of calls from trained hospital staff (WE CALL) versus the standard of care whereby contact with medical staff was initiated by patients (YOU CALL).
- Qualitatively, the WE CALL intervention was perceived as reassuring; supporting increased insight and problem solving and decreasing patients’ anxiety.
- Quantitatively, no differences in adverse events or quality of life, as assessed by the Euroqol-5D, were found at 6 or 12 months.
- Despite the majority of patients receiving little poststroke rehabilitation, a substantial proportion of participants reported daily challenges in mobility, relationships, work, and recreation at both 6 and 12 months.

level, depressive symptoms, and planned use of health services for health promotion and secondary prevention.

Methods

Design
This is a multicenter randomized clinical trial, with intervention delivered during the first 6 months after stroke and assessments performed pre-intervention, immediately after intervention, and at 1 year (International Standard Randomized Controlled Trial, ISRCTN95662526). Approval was obtained from the Research Ethics Committee of the participating acute care hospitals. Full details of the study protocol, including sample size estimates, have been published, with minor changes (ie, increased number of recruitment sites and decreased sample size). The intended sample size was 384 subjects including sociodemographic characteristics. Participants then underwent random allocation. An information package was sent to each participant by regular mail. It included a short list of trustworthy websites about stroke and a frequency calendar with an example of what they should be documenting (type of health service used, reason to use it, and whether it was unplanned or planned). Each participant also received an explanation about their group allocation (YOU/WE CALL) and a reminder of what it meant to be in that particular group.

Procedure
Between October 2008 and April 2011, a site-designated nurse (who was not the treating clinician) undertook daily chart reviews of all new stroke admissions to identify individuals who sustained a first mild stroke and, if potentially eligible, completed the Comorbidity Index. All screened individuals were contacted by phone in the first month after stroke by a trained assessor who confirmed eligibility, requested consent, and, for those who agreed, completed baseline measures including sociodemographic characteristics. Participants then underwent random allocation. An information package was sent to each participant by regular mail. It included a short list of trustworthy websites about stroke and a frequency calendar with an example of what they should be documenting (type of health service used, reason to use it, and whether it was unplanned or planned). Each participant also received an explanation about their group allocation (YOU/WE CALL) and a reminder of what it meant to be in that particular group.

Intervention Protocols

YOU CALL
YOU CALL participants were provided with the name and phone number of a trained healthcare professional (THCP) who was not involved in providing the WE CALL intervention, whom they were free to contact should they feel the need. The THCP was instructed to answer the participant’s queries on those topics initiated by the participant but not to probe further on other potential issues.

WE CALL
WE CALL participants received a multimodal (telephone, Internet, and paper) support intervention. Telephone interactions focused on any new or ongoing issues, as well as 6 key areas, including family functioning and individualized risk factors. Call frequency initiated by the THCP was weekly for the first 2 months, biweekly during the third month, and monthly for the past 3 months. Additional written information on stroke management was provided as needed (by regular mail, e-mail, or Internet such as referring to www.strokeengine.ca family site). Participants were referred to local community services as necessary and directed to their family doctor when they experienced health problems.

Outcomes

The primary outcome, unplanned use of health services for an adverse event, was collected daily by way of a frequency calendar. Other researchers have similarly used calendars with success with older individuals with high reliability between self-reported and administrative data on health-service use. The Quality of Life Index, a reliable measure that is responsive to change in stroke, and the Euroqol-5D, which is recommended by the Canadian Agency for Drugs and Technologies in Health, were used to assess quality of life. Secondary outcomes were planned use of health services collected with the frequency calendar, depressive symptoms quantified using the Beck Depression Inventory II (BDI-II), and participation measured with the Assessment of Life Habits (LIFE-H 3.1). All outcomes were collected by assessors blind to group allocation.

Participants

All adults who sustained a first mild stroke defined as a score >8.5/11.5 on the Canadian Neurological Scale (where a higher score indicates mild or no deficit) or a modified Rankin Score between 0 and 2 on admission and who were discharged home within 3 weeks of the index event were invited to participate. Other inclusion criteria included telephone access, ability to understand basic instructions and express basic needs, and ability to communicate in English or French. Individuals with moderate or severe cognitive deficits (based on clinical judgment) and those who experienced another stroke before baseline measures were completed were excluded.

Randomization
Once baseline measures were completed, participants were allocated randomly, by way of sealed envelopes, using stratified block randomization, to 1 of 2 groups: YOU CALL or WE CALL. Randomization was stratified by sites and by the level of comorbidity (no or low comorbidity versus moderate to high as indicated by a score ≥4 on the Comorbidity Index). The research member in charge of randomization was not involved in the assessment or intervention.

Setting
Participants were recruited from 11 acute care hospitals located in urban and rural areas across 4 Canadian provinces.

Participants

All adults who sustained a first mild stroke defined as a score >8.5/11.5 on the Canadian Neurological Scale (where a higher score indicates mild or no deficit) or a modified Rankin Score between 0 and 2 on admission and who were discharged home within 3 weeks of the index event were invited to participate. Other inclusion criteria included telephone access, ability to understand basic instructions and express basic needs, and ability to communicate in English or French. Individuals with moderate or severe cognitive deficits (based on clinical judgment) and those who experienced another stroke before baseline measures were completed were excluded.
Documentation Related to the Intervention

The intervention content, including topics addressed and interventions provided during each YOU CALL/WE CALL contact, was documented by the THCP. For example, if the participant expressed concerns about his/her diet as a risk factor for a second stroke, the content of the discussion was noted and any intervention provided. This might include the THCP assisting the participant in finding solutions by providing information as needed or by suggesting that the participant consult a dietician. The duration of each telephone contact and the total number of contacts were recorded.

Statistical Analyses

Baseline characteristics of the sample are presented using descriptive statistics. We used a mixed model approach on an intention-to-treat basis, where the group factor was type of intervention and the occasion factor was time. The primary end point for analysis was the postintervention assessment at 6 months. Effect sizes (ES) of the differences with a 95% confidence interval were calculated. The ES reported are based on parameter estimates.

The primary outcome was analyzed using a mixed model approach. The 2 groups (between subject factor) were compared at 2 time points (6 months and 1 year) instead of 3 time points (baseline, 6 months, and 1 year). In this specific model, we were interested in the effect of group at 6 months. In the case where we used the mixed model on variables with baseline measures, we were specifically interested in the interaction effect between the group and the time at 6 months (or 12 months depending on the question).

Furthermore, descriptive data about the YOU CALL and WE CALL interventions are reported, as well as a qualitative content analysis of the participants’ comments on the WE CALL intervention at the 6-month call.

Results

The Figure describes participant flow. The numbers of participants who could not be reached for assessment are comparable between groups. Sociodemographic characteristics of the participants can be found in Table 1. There were no significant differences between the 2 groups at baseline for all variables, including outcomes.

### Table 1. Participant Characteristics at Baseline by Group

<table>
<thead>
<tr>
<th></th>
<th>Total Sample (n=186)</th>
<th>YOU CALL (n=94)</th>
<th>WE CALL (n=92)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>Mean±SD (range)</td>
<td>62.5±12.5</td>
<td>63.2±12.4</td>
</tr>
<tr>
<td></td>
<td>(31–92)</td>
<td>(34–88)</td>
<td>(31–92)</td>
</tr>
<tr>
<td>≤65 y, n (%)</td>
<td>102 (54.8)</td>
<td>47 (50.0)</td>
<td>55 (59.8)</td>
</tr>
<tr>
<td>No. of days hospitalized</td>
<td>Mean±SD (range)</td>
<td>5.9±4.4 (0–23)</td>
<td>5.2±3.8 (0–21)</td>
</tr>
<tr>
<td></td>
<td>24/166 (14.5)</td>
<td>12/82 (14.6)</td>
<td>12/84 (14.3)</td>
</tr>
<tr>
<td>Comorbidity score (/90)</td>
<td>Mean±SD (range)</td>
<td>3.5±4.3 (0–24)</td>
<td>3.8±4.8 (0–24)</td>
</tr>
<tr>
<td></td>
<td>116 (62.4)</td>
<td>57 (60.6)</td>
<td>59 (64.1)</td>
</tr>
<tr>
<td>Female gender, n (%)</td>
<td>79 (42.5)</td>
<td>44 (46.8)</td>
<td>35 (38.0)</td>
</tr>
<tr>
<td>Type of stroke, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ischemic</td>
<td>172 (92.5)</td>
<td>87 (92.6)</td>
<td>85 (92.4)</td>
</tr>
<tr>
<td>Hemorrhagic</td>
<td>10 (5.4)</td>
<td>5 (5.3)</td>
<td>5 (5.4)</td>
</tr>
<tr>
<td>Other</td>
<td>4 (2.1)</td>
<td>2 (2.1)</td>
<td>2 (2.2)</td>
</tr>
<tr>
<td>Side of stroke, n (%)</td>
<td>76 (42.7)</td>
<td>42 (45.7)</td>
<td>34 (39.5)</td>
</tr>
<tr>
<td>Left</td>
<td>92 (51.7)</td>
<td>44 (47.8)</td>
<td>48 (55.8)</td>
</tr>
<tr>
<td>Bilateral</td>
<td>10 (5.6)</td>
<td>6 (6.5)</td>
<td>4 (4.7)</td>
</tr>
<tr>
<td>Schooling, n (%)</td>
<td>19 (10.3)</td>
<td>12 (13.0)</td>
<td>7 (7.6)</td>
</tr>
<tr>
<td>Primary</td>
<td>69 (37.5)</td>
<td>34 (37.0)</td>
<td>35 (38.1)</td>
</tr>
<tr>
<td>Secondary</td>
<td>96 (52.2)</td>
<td>46 (50.0)</td>
<td>50 (54.3)</td>
</tr>
<tr>
<td>Primary occupation, n (%)</td>
<td>78 (41.9)</td>
<td>36 (38.3)</td>
<td>42 (45.7)</td>
</tr>
<tr>
<td>Working</td>
<td>93 (50.0)</td>
<td>50 (53.2)</td>
<td>43 (46.7)</td>
</tr>
<tr>
<td>Other</td>
<td>15 (8.1)</td>
<td>8 (8.5)</td>
<td>7 (7.6)</td>
</tr>
</tbody>
</table>

* n values vary because of missing data.

Primary and Secondary Outcomes

Although 98.8% of participants visited their family doctor or a specialist in the first 6 months (ie, during active intervention), <20% received rehabilitation services (17.3% saw a physiotherapist, 17.3% an occupational therapist, 6.8% a speech language pathologist). We found no significant differences between the 2 groups on any of the primary outcomes, that is, unplanned use of health services and quality of life (Table 2) with the 2 quality of life measures improving significantly for both groups (ES between 0.25 and 0.37) between baseline and 6 months after stroke. Similarly, although there were improvements in all of the secondary end points between baseline and 6 months for both the YOU and WE groups, no between-group differences were identified for any of the secondary outcomes (Table 3).

Despite improvements in participation level (LIFE-H total score), time effect for entire sample P<0.001; ES, 0.7), at the end of interventions (6 months after stroke), 51% of participants were still facing daily challenges (score on the LIFE-H <9/9 indicating a difficulty in accomplishing the activity or the social role or needing technical or human assistance for...
accomplishment) in mobility (including driving), 25.5% in their relationships (including sexual relationships), 44.7% in working, and 61.4% for recreation.

At the 1-year assessment (6 months after intervention), the only significant change from the 6-month assessment for both groups combined was in the social domains (relationships, work, and recreation) of the LIFE-H (increment in score=0.4/9±1.3; ES, 0.3 [95% confidence interval, 0.03–0.57]). Yet 15.9% were still facing daily challenges in their relationships, 33.7% in working, and 48.5% in recreation.

YOU and WE CALL Intervention Results

Few participants (6/94) used the YOU CALL intervention. Three participants called in the first 3 months, whereas the other 3 called between months 3 and 6. The average length of a YOU CALL telephone contact was 10.8±7.4 minutes with an extra mean indirect time used by the THCP of 23.8±28.5 minutes to complete various aspects of follow-up, including finding and sending information to the participant or providing links to local community resources. Most (5/6) participants asked for advice about stroke prevention. Other issues included sleep problems (n=1), questions on the best activity level to avoid exertion (n=1), and concerns expressed about changes in mood (n=1): “back home two weeks now, back to work, mood swings, getting anxious more quickly than before, part of me has changed. I can’t put my finger on it. Why am I like this? I am worried. Changes in my mood concern me.”

Participants randomized to the WE CALL intervention were reached 78.4% of the time after a minimum of 3 attempts at each different planned time point. If a participant could not be reached at a given planned time point (eg, month 1 to week 2), the THCP would try again at the next planned time point (eg, month 1 to week 3). The mean length of time spent in direct contact was 14.1±9.5 minutes, with an additional 10.3±5.4 minutes of indirect time.

WE CALL participants commented post-intervention on their perceptions about the intervention, and these comments, as noted by the THCP, can be grouped under 3 main themes: (1) appreciation of support (25 comments), “calls would help my mood and I had the impression that someone cared for me; “it help a lot,…<I> felt supported” and “I appreciated being able to talk to someone other that family or doctor to answer questions or get advice” and “I was glad someone called as I would not have done it <called>”;(2) intervention helped in problem solving (7 comments), “intervention enabled talking through to find a solution” or “talking to someone brought up other questions making me read and become more informed”; and (3) intervention increased insight (11 comments), “intervention made me more conscious about the process I was going
through”; “intervention made me reflect about my health status”; or “I paid more attention to different aspects in my life which could be affected by a stroke.”

Discussion

Our results suggest no significant group differences on the 2 primary outcomes: unplanned use of health services for an adverse event and quality of life. Also, we did not find significant group differences on the secondary outcomes: planned use of health services, depressive symptoms, and participation. At first glance, these findings may be interpreted as suggesting that the 2 interventions are equally effective or equally noneffective, but both groups improved on most parameters and equally used healthcare resources because of factors other than group assignment. However, on further analyses of the interventions, the YOU CALL process of having the patient reach out when they had questions/concerns proved to be rather ineffective as a post-discharge follow-up strategy. In initiating this trial, we assumed based on our previous work that individuals with a mild stroke represent a relatively neglected patient population, who have questions and concerns about topics such as secondary prevention, sleeping, driving, working, relationships, and recreation. Yet the majority of those who were left to voluntarily call never availed themselves of the intervention. This finding suggests that the somewhat common practice of providing a telephone number to a patient/family on discharge after stroke may, while providing the appearance of follow-up, be ineffective. Indeed, one of the qualitative findings of our study came from spontaneous comments by those in the WE CALL intervention, where a number indicated their appreciation of the routine calls and further remarked that they would not have otherwise reached out with their questions or challenges.

The absence of significant differences between groups cannot be explained by sample size, although it was reduced from what was initially planned as we ended with sufficient power (80%) to detect between-group differences. Could it be that the WE CALL intervention was insufficient? Indeed, we found an important proportion of participants at both the 6- and 12-month evaluation who were still faced with daily challenges in mobility, relationships, work, and recreation. The majority indicated receiving little in the way of poststroke rehabilitation. There is some evidence that group-based cardiac rehabilitation programs could be adapted to assist in risk factor management and secondary prevention of stroke. This more hands-on approach combined with remote support could change the outcomes desired. Given that there is a growing body of evidence about the sequelae of mild stroke, including changes in cognition, fatigue, decreased quality of life, and psychosocial issues, we would argue that these low rates of service provision by rehabilitation specialists do not reflect patient need. We acknowledge that traditional rehabilitation services would need to be reorganized to meet specific mild stroke

| Table 3. Secondary Outcomes by Group and Time (Comparing 6 Mo With Baseline) |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|
|                                 | Baseline        | 6 Mo (n=149)    | Between-Group   |
|                                 | You (n=94)      | We (n=92)       | Difference      |
| Planned use of health services,* mean (SD) | 0 (0) | 0 (0) | 5.6 (4.2) | 6.4 (5.3) | 0.24 n/a |
| BDI-II Score >13/63 (potentially depressed), n (%) | 10 (10.6) | 15 (16.3) | 7 (9.1) | 6 (8.3) | 0.27 −2.72 (8.5) |
| P Value                          |                |                |                |                | <0.001 |
| ES (95% CI)                      |                |                |                |                | 0.3 (0.03–0.57) |
| LIFE-H (/9)                      |                |                |                |                | |
| Total score Mean (SD)            | 7.1 (1.1) | 7.3 (1.1) | 8.0 (0.9) | 8.0 (0.8) | 0.61 0.84 (1.2) |
| P Value                          |                |                |                |                | <0.001 |
| ES (95% CI)                      |                |                |                |                | 0.7 (0.37–1.03) |
| Activity score Mean (SD)         | 7.6 (0.8) | 7.7 (0.9) | 8.1 (0.7) | 8.2 (0.7) | 0.53 0.55 (0.7) |
| P Value                          |                |                |                |                | <0.001 |
| ES (95% CI)                      |                |                |                |                | 0.8 (0.47–1.13) |
| Social role score Mean (SD)      | 6.5 (1.6) | 6.8 (1.5) | 7.8 (1.3) | 7.9 (1.2) | 0.30 1.21 (1.6) |
| P Value                          |                |                |                |                | <0.001 |
| ES (95% CI)                      |                |                |                |                | 0.8 (0.47–1.13) |

BDI-II indicates Beck Depression Inventory II; CI, confidence interval; ES, effect size; and LIFE-H, Assessment of Life Habits.

*Nonparametric test reskewed distribution (median test, χ²).
†Average differences between 6 mo and baseline (SD) for total sample and P value with effect size as there were no group differences.

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References


Disclosures

None.

Sources of Funding

This work was supported by funding from Canadian Stroke Network, a Center of Networks of excellence of the Canadian Institute of Health Research.

Clientele needs,10 yet the importance of specialized medical follow-up after stroke10 is now recognized, and best practice guidelines for stroke41 recommend that all patients admitted for an acute stroke be assessed by rehabilitation professionals.


Guidelines for the Economic Evaluation of Health Technologies. Ottawa, Canada: Canadian Agency for Drugs and Technologies in Health; 2006.


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Circ Cardiovasc Qual Outcomes. 2013;6:674-679; originally published online November 12, 2013;
doi: 10.1161/CIRCOUTCOMES.113.000375

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