Stroke

ORIGINAL CONTRIBUTION

Long-Term Follow-Up of Participants in the Taking Charge After Stroke Randomized Controlled Trial

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BACKGROUND: The take charge intervention—a conversation-based, community intervention to improve motivation, improved independence, and physical health 12 months after stroke in 2 randomized controlled trials with 572 participants. This article reports long-term outcomes for the 400 participants in the TaCAS study (Taking Charge After Stroke).

METHODS: Follow-up study of a New Zealand multicenter, randomized, controlled, parallel-group trial. Outcomes were collected by postal questionnaire or telephone call. The TaCAS study recruited 400 participants discharged after stroke, randomized within 16 weeks to one of 3 groups: 1 session of the take charge intervention, 2 sessions 6 weeks apart, or no sessions (control). This study is of participants still alive and willing to answer a questionnaire 5 to 6 years after their index stroke, undertaken in 2022. The primary outcome was the Physical Component Summary of the Short Form 36, comparing the take charge intervention and control. Secondary outcomes were: Frenchay Activities Index; modified Rankin Scale (mRS); survival; and stroke recurrence. These outcomes were compared with those 12 months after stroke. Analysis was by ANOVA or logistic regression.

RESULTS: Mortality data were available for all 400 participants, and functional data for 204/297 (69%) of survivors. The mean difference (95% CI) in Physical Component Summary between take charge and control groups was 2.8 (−0.8 to 6.5) units, P=0.12, and for independence (modified Rankin Scale score, 0–2) the odds ratio (95% CI) was 0.56 (0.28–1.16), P=0.11, both favoring take charge with similar point estimates to those after 12 months. Differences between take charge and control participants for Frenchay Activities Index scores, survival, and stroke recurrence were small and nonsignificant.

CONCLUSIONS: The clinically significant improvements in physical health and independence for take charge participants, observed at 12 months, were sustained 5 to 6 years after stroke, but no longer statistically significant.

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Key Words: control groups ■ motivation ■ stroke rehabilitation ■ survivors ■ telephone

The take charge (TC) intervention, a conversation-based intervention designed to improve intrinsic motivation, delivered in the early community phase of stroke rehabilitation, improves independence, advanced activities of daily living, and physical health at 12 months. Two randomized controlled trials of size 172 and 400 participants, and an individual participant meta-analysis of all 572 participants, provide strong evidence of benefit with a large effect size. The number needed to treat to have 1 extra person independent at 12 months after stroke is 8.[1,2] This is of a similar magnitude to that for intravenous thrombolysis with alteplase in the first 3 hours after stroke.[3] TC is the only intervention that has been shown to affect these outcomes in people discharged from the hospital after stroke. It is also very cost-effective, saving $US2000 for every patient treated when assessed directly over a 12-month horizon following stroke.[4] The TC intervention is now a

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Nonstandard Abbreviations and Acronyms

mRS	modified Rankin Scale
PCS	Physical Component Summary
TaCAS	Taking Charge After Stroke trial
TC	take charge
TCS	take charge Session

strong recommendation in recent stroke rehabilitation guidelines[5] and, to our knowledge, is being used in clinical services in the United States, Canada, Australia, New Zealand, the United Kingdom, Germany, and other countries. Materials are free to download and available in 7 languages.[6]

Long-term stroke follow-up studies (>2 years after randomization) of randomized controlled trials are rare. This reflects the difficulties in maintaining contact with participants over long periods. Nevertheless, these follow-up data are important to assess whether established medium-term benefits of an intervention are sustained in the longer term. To our knowledge, only 1 other study has assessed functional outcomes in participants who received a randomized intervention multiple years after the initial trial. That study reports 5- and 10-year survival and functional outcomes for survivors of the original 220 participants in a randomized trial of stroke unit versus general medical ward care. In that study, beneficial survival and functional outcome observed after 12 months were sustained at both 5 and 10 years.[7–9]

This study aimed to assess independence, physical health, and advanced activities of daily living, as well as mortality and stroke recurrence, between 5 and 6 years after the initial stroke to explore if the positive outcomes for TC participants after 12 months in the TaCAS study (Taking Charge After Stroke) were sustained.

METHODS

Data Availability

All data will be made available on reasonable request to the corresponding author. This is a cross-sectional follow-up study of the 400 participants enrolled in the TaCAS study, a multicenter randomized controlled parallel-group trial in people discharged to a community setting following hospital admission with acute stroke.[2,10] The study protocol was approved by the Health and Disability Ethics Committee. Per *Stroke* guidelines, for this observational follow-up study, we report against STROBE (Strengthening the Reporting of Observational Studies in Epidemiology). Participants in the initial study were not masked as to treatment allocation. Outcomes for this study were collected remotely, by investigators masked to the original treatment allocation. Questionnaires were administered either by pen and paper through the post, or by telephone with an investigator.

Participants

In the TaCAS study, 400 non-Māori, non-Pacific adults (>16 years) discharged to a community setting after acute stroke and randomized between 2 and 16 weeks after that event, were recruited over 2016/2017 from 7 centers across New Zealand, 4 tertiary and 3 nontertiary centers. Of the initial 400 participants recruited, 2 withdrew and 10 died before the final visit at 12 months, with a 12-month follow-up rate for functional outcomes of 97%. Participants in this follow-up study were survivors who could be contacted and consented to complete a questionnaire.

Sample Size

This was a convenience sample, determined by the original study size and the proportion of survivors willing to participate.

Interventions

No new intervention occurred as part of this follow-up study. The original interventions are described in detail in the TaCAS study main report.[2] Briefly, the TC intervention was delivered face to face in the person's own home 2 to 18 weeks after the initial stroke (mean, 46 days) by a trained facilitator. The facilitators used a nondirective approach, based on self-determination theory,[11] guided by an illustrated workbook,[6] to encourage participants to express what was most important to them and what they most wanted to achieve over the next 12 months, as well as considering concrete first steps to achieve those aims. The overall aim of the session was to promote intrinsic motivation.[12] The session was not time-limited but usually lasted between 45 and 60 minutes. In the initial study, participants were randomly allocated to one of 3 treatment groups: 1 TC session (TCS), 2 TCS 6 weeks apart, and no TCS in a 1:1:1 ratio. Control participants received stroke educational material at the first visit. All participants received usual community rehabilitation.

Outcome Variables

The primary outcome was the Physical Component Summary (PCS) of the Short Form 36, adapted to New Zealand norms, comparing any TC intervention with control.[13] Secondary outcomes were the Frenchay Activities Index, the modified Rankin Scale (mRS) dichotomized to independent (mRS score, 0–2) and dependent (mRS score >2), survival, and stroke recurrence. We planned to compare differences between the groups on each outcome at 5 to 6 years with those observed 12 months after stroke in the TaCAS study. All outcome measures were used in the TaCAS study (Table S1 for the list of measures and time points for the original and current study). All outcome measures have been validated for use in stroke.[14–16]

Data Collection

Data were collected from March to August of 2022, between 5 and 6 years after the initial stroke. Death was established by accessing medical records. Any participants who were not listed as deceased were sent a consent form and questionnaire, which they could complete and return by post. Alternatively, participants could choose a telephone call from an investigator during which informed consent and study questionnaires were completed. If a participant was unable to provide the necessary

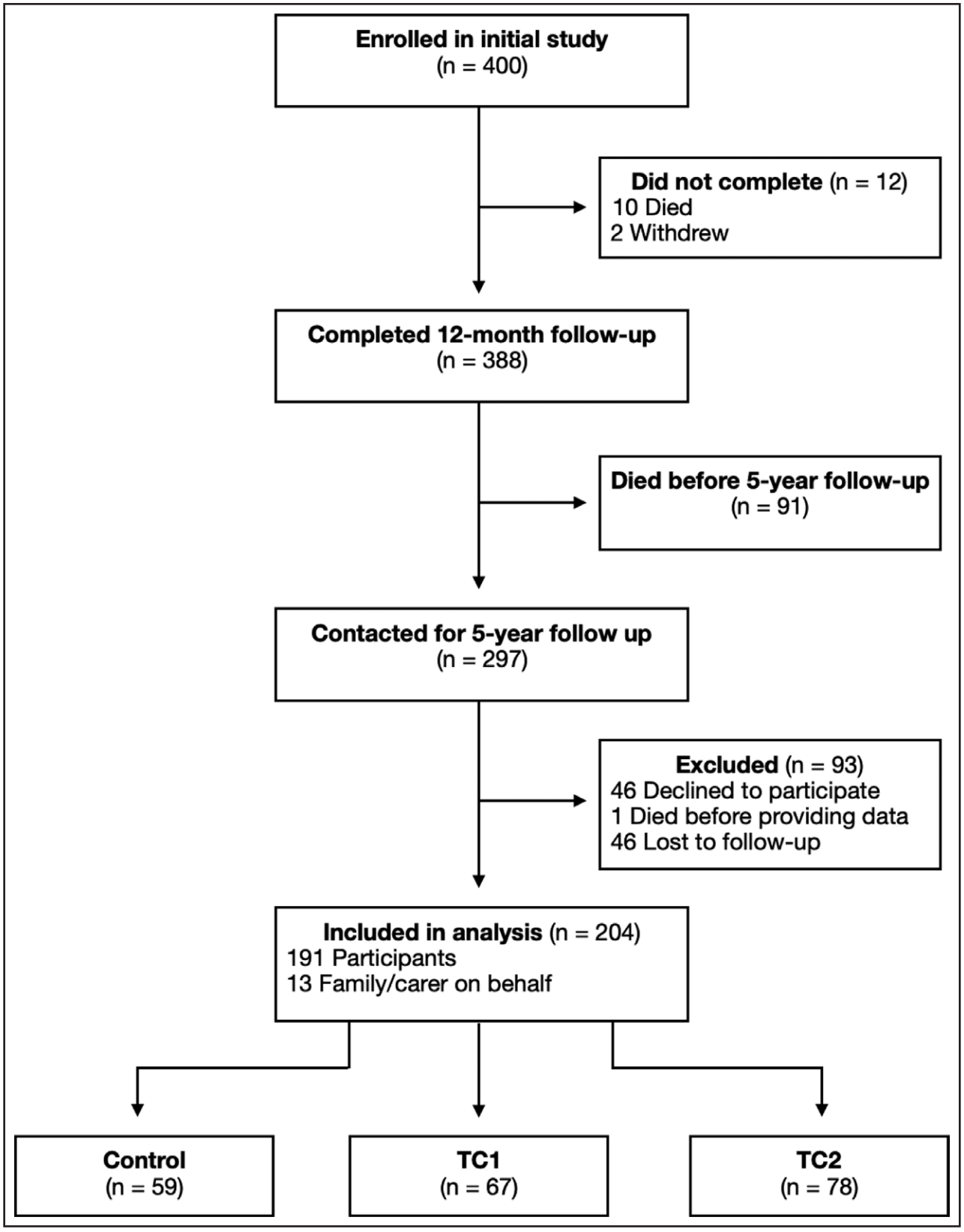

Figure 1. Flow of participants in the TaCAS trial (Taking Charge After Stroke), completed after 12-month follow-up, and the TaCAS-FU trial (Taking Charge After Stroke Follow-Up).
TC1 indicates 1 take charge session only; and TC2, 2 take charge sessions.

information, a carer or family member could complete the mRS alone, either in writing or by telephone, on behalf of the participant. If there was no response from a participant, they were contacted by telephone between 14 and 21 days after their study pack was posted. If uncontactable, participants were subsequently contacted a second and final time between 14 and 21 days after the first follow-up. Failing this contact, the participant was classified as lost to follow-up.

Data Management and Missing Data

Source data from article questionnaires were transcribed by an investigator into a secure REDCap[17] database, and electronic copies of the source data were uploaded alongside. Verbally collected data were input directly into this database. The REDCap database was hosted on the Medical Research Institute of New Zealand servers.

Statistical Analysis

Statistical analyses were prespecified in the study protocol and were intended to match the analyses of the initial study. All analyses were intention-to-treat. The primary outcome measure was the PCS of the Short Form 36. The primary analysis of the primary outcome was ANOVA; all TC versus control. The number of TCS was used in a sensitivity analysis to explore a dose-response relationship with the outcome. The secondary analysis of the PCS of the Short Form 36 was ANCOVA, adjusted for the following baseline variables: Barthel Index score 3 days poststroke, PCS of the Short Form 12, age, gender, and living alone. The 2 prespecified comparisons were all TCS versus control and 2 sessions TCS versus 1 session TCS. The analysis of the Frenchay Activities Index was ANOVA. mRS, survival, and stroke recurrence were analyzed by logistic regression. Statistical Analysis System version 9.4 was used.

RESULTS

The mean (SD) time between initial stroke and consent for this follow-up was 5.7 (0.4) years. Mortality data were available for all the original 400 participants of the TaCAS trial. Of these, 2 withdrew and 10 died by the 12-month follow-up. Of the 388 participants who completed the final visit of the original study, a further 91 died before the 5- to 6-year follow-up (25% mortality overall). Of the remaining 297 participants, 47 chose not to participate, and 46 were lost to follow-up, leaving 204 (69%) of the surviving participants, who provided functional outcome data, with 191 (64%) able to complete the PCS. Loss to follow-up was similar across the 3 arms of the trial. For participants at the 12-month outcome point, 386/388 (99%) provided mRS scores and 381/388 (98%) provided PCS scores. The participant flow is shown in Figure 1. Baseline characteristics of participants at the 5- to 6-year follow-up were broadly similar across the intervention groups, as shown in Table 1.

For the entire cohort, physical health declined from a mean PCS of 45.4 units at 12 months to 40.3 units after between 5 and 6 years of follow-up. Similarly, rates of independence (mRS score, 0–2) fell from 86% at 12 months to 78% after between 5 and 6 years. There were 21/189 (11%) respondents reporting a recurrent stroke, compared with 24/395 (6%) at 12 months.

Table 1. Baseline Characteristics of Follow-Up Study Participants

	Treatment group mean (SD)		
	All	Control	All take charge
Age at randomization, y	69.3 (11.2)	69.9 (11.7)	69.1 (10.9)
Time from stroke, y	5.7 (0.4)	5.7 (0.5)	5.7 (0.4)
PCS SF12 at randomization	41.8 (7.8)	41.1 (9.0)	42.1 (7.2)
	N (%)		
Male	120 (59)	34 (58)	86 (59)
Living alone before the stroke	68 (33)	25 (42)	43 (29)

PCS indicates physical component summary; and SF12, Short Form 12.

Outcomes by treatment allocation, at 5 to 6 years and 12 months follow-up, are summarized in Table 2. Participants who received any TCS had a mean (95% CI) PCS score 2.8 units (−0.8 to 6.5), P=0.12, higher (better) at prolonged follow-up after stroke than participants who received no TCS. This point estimate of the mean difference after 5 and 6 years is almost identical to that observed at 12 months after stroke, although no longer statistically significant (Figure 2). Similarly, the odds ratio (95% CI) for dependency (mRS score, >2) for TC participants compared with controls was 0.56 (0.28–1.16), P=0.11, at the prolonged follow-up, as compared with an odds ratio of 0.55 (0.31–0.99), P=0.045, on the same measure 12 months after stroke (Figure 3). An odds ratio <1 favors the TC intervention. The mean difference (95% CI) in the Frenchay Activities Index between TC and control was 0.8 (−2.0 to 3.7), P=0.57. Fewer participants in the TC groups than control group were dead or reported recurrent stroke by 5 to 6 years; however, the differences were small and not statistically significant. Mean (95% CI) PCS scores increased 1.6 units (−0.4 to 3.6), P=0.11, for each extra TC session received. This is a similar estimate of change to that measured at 12 months, which showed an increase of 1.9 (0.8–3.1), P<0.001, units per extra session received (Figure S1).

DISCUSSION

In this long-term follow-up of a randomized trial after stroke, we were able to assess mortality for all the original participants, and data regarding functional outcomes for 69% of survivors, a mean of 5.7 years after the original stroke. The main finding was that the differences in physical health outcomes and independence, favoring the TC intervention, measured at 12 months after stroke, were sustained at almost 6 years of follow-up. However,

Table 2. Outcomes Between 5 and 6 Years Compared With Outcomes 12 Months After Stroke

	5–6 Years after stroke				12 Months after stroke			
	All, N=191	Control, N=55	All TC, N=136	TC-control	All, N=386	Control, N=130	All TC, N=256	TC-control
	Mean (SD)			Estimate (95% CI)	Mean (SD)			Estimate (95% CI)
PCS	40.3 (11.6)	38.3 (13)	41.2 (10.9)	2.8 (-0.8–6.5); *P*=0.12	45.4 (8.2)	43.4 (10.7)	46.4 (8.4)	2.9 (0.95–4.9); *P*=0.004
FAI	30.6 (9.1)	30 (10.4)	30.8 (8.6)	0.8 (-2.0–3.7); *P*=0.57	30.6 (9.1)	26.0 (10.0)	28.7 (8.5)	2.7 (0.8–4.6); *P*=0.006
	N/N (%)			Odds ratio (95% CI)	N/N (%)			Odds ratio (95% CI)
Alive	297/400 (74)	94/130 (72)	203/270 (75)	1.31 (0.80–2.12); *P*=0.28	390/400 (98)	128/130 (99)	262/270 (97)	1.95 (0.41–9.34); *P*=0.40
mRS <3*	162/203 (80)	43/59 (73)	119/144 (83)	0.56 (0.28–1.16); *P*=0.11	331/387 (86)	103/128 (81)	228/259 (88)	0.55 (0.31–0.99); *P*=0.045
Recurrent stroke	21/189 (11)	7/55 (13)	14/134 (10)	0.80 (0.30–2.1); *P*=0.64	24/395 (6)	10/130 (8)	14/265 (5)	0.61 (0.25–1.45); *P*=0.26

FAI indicates Frenchay Activities Index; mRS, modified Rankin Scale; PCS, Physical Component Summary; and TC, take charge.
*Odds ratio is for dependence (mRS score, >2), meaning a number <1 favors taking charge.

these differences were no longer statistically significant, reflecting participant attrition from mortality and loss to follow-up. The measured 2.8 units difference in physical health approximates the 2.5 to 3 unit minimal clinically important difference for the PCS in people with stroke.[18] A dose-response effect was again observed, with higher PCS scores for participants receiving 2 sessions compared with 1.

To our knowledge, this is the largest long-term follow-up study of a randomized intervention for stroke. Our results show a similar pattern to the stroke unit studies of Indredavik et al[7–9] where a difference observed at 12 months persisted to 5 (and 10) years. Those studies were numerically smaller than ours, with functional outcomes limited to a simple activity of daily living measure, the Barthel Index (treated as a dichotomous variable), obtained from 58 participants at 5 years and 41 participants at 10 years. Our functional data were based on responses from 204 individuals and measured physical health, advanced activities of daily living, and independence, giving a broader picture of outcomes at the International Classification of Functioning levels more appropriate for people living in the community.[19] The confirmation that significant changes at 12 months could be sustained long-term is important for at least 2 reasons. First, it should encourage attempts to maximize outcomes in the first year after stroke, and second, the information can be used in longer-term modeling of outcomes and cost-effectiveness of interventions after stroke.

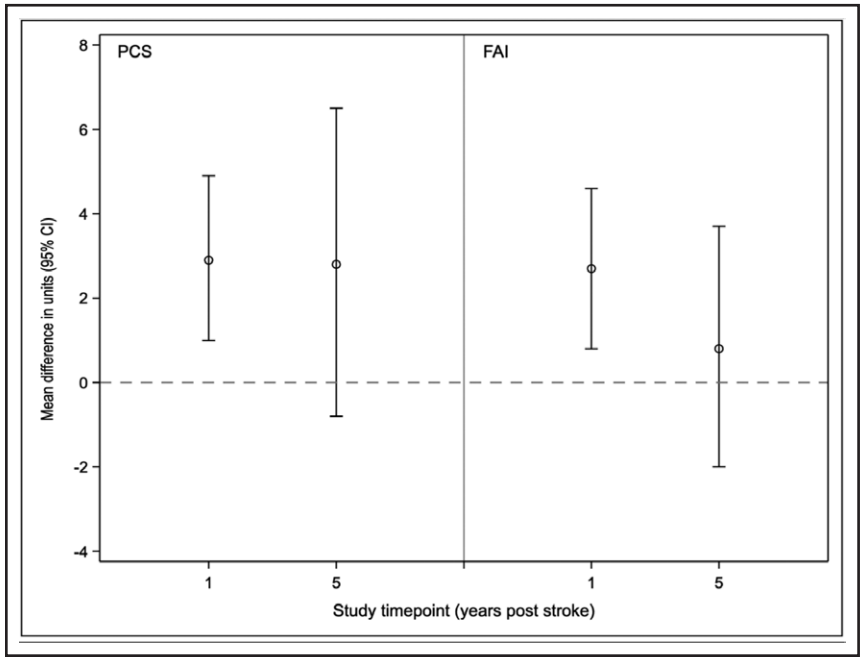

Figure 2. Difference in mean scores takes charge minus control for Short Form 36 Physical Component Summary (PCS) and Frenchay Activities Index (FAI) at 12 months and 5 to 6 years poststroke, shown using point estimates of the mean difference in units and 95% CIs.

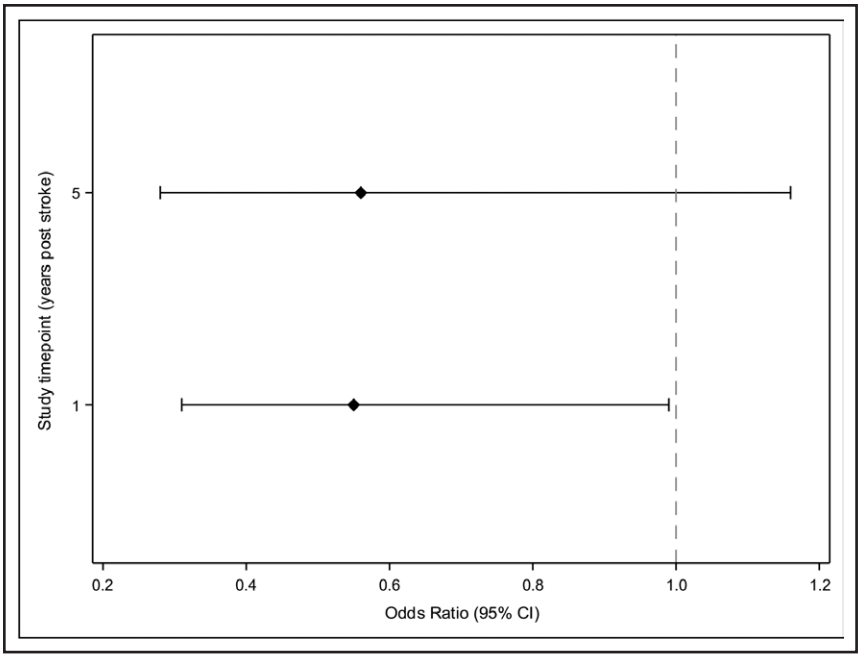

Figure 3. Odds ratios and 95% CIs of being dependent (modified Rankin Scale score, >2), take charge vs control 12 months, and between 5 and 6 years poststroke.
An odds ratio below 1.0 favors taking charge.

The most significant limitation of the study was loss to follow-up, which resulted in a smaller achieved sample size and possible type II error. Nevertheless, we were able to obtain complete survival data, and functional data were obtained from over two-thirds of survivors. Participants in the initial study were not masked to treatment allocation, and participants with more favorable outcomes may have been more likely to respond to the request for follow-up. However, loss to follow-up was distributed evenly between groups, and the similarity in the differences at 12 months and 5 to 6 years between the groups is compelling.

That a low-intensity (1 or 2 sessions) conversation-based intervention delivered in the first 4 months after stroke could have a significant effect on independence and physical health 12 months after stroke may be surprising, but it is supported by sound theory and experimental evidence.[11,12] That the effect could be sustained past 5 years of follow-up seems remarkable. We hypothesize that the TC intervention influences the intrinsic motivation of the individual, leading to permanent behavior change, with the person with stroke taking more responsibility for achieving the outcomes that matter most to them.[12,20,21]

These results strengthen the case for widespread implementation of the TC intervention for people discharged home after stroke. They also underline the potential for psychological interventions in general after stroke to have an important impact on long-term recovery, when combined with usual therapy-based approaches.[12]

ARTICLE INFORMATION

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Disclosures

None.

Supplemental Material

Table S1
Figure S1
STROBE Checklist

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