Original Contribution

Efficacy and Safety of Individualized Coaching After Stroke: the LAST Study (Life After Stroke)

A Pragmatic Randomized Controlled Trial

Torunn Askim, PhD; Birgitta Langhammer, PhD; Hege Ihle-Hansen, MD, PhD; Mari Gunnes, MSc; Stian Lydersen, PhD; Bent Indredavik, MD, PhD; on behalf of the LAST Collaboration Group*

Background and Purpose—The evidence for interventions to prevent functional decline in the long term after stroke is lacking. The aim of this trial was to evaluate the efficacy and safety of an 18-month follow-up program of individualized regular coaching on physical activity and exercise.

Methods—This was a multicentre, pragmatic, single-blinded, randomized controlled trial. Adults (age ≥18 years) with first-ever or recurrent stroke, community dwelling, with modified Rankin Scale <5, and no serious comorbidities were included 10 to 16 weeks poststroke. The intervention group received individualized regular coaching on physical activity and exercise every month for 18 consecutive months. The control group received standard care. Primary outcome was the Motor Assessment Scale at end of intervention (18-month follow-up). Secondary measures were Barthel index, modified Rankin Scale, item 14 from Berg Balance Scale, Timed Up and Go test, gait speed, 6-minute walk test, and Stroke Impact Scale. Other outcomes were adverse events and compliance to the intervention assessed by training diaries and the International Physical Activity Questionnaire.

Results—Three hundred and eighty consenting participants were randomly assigned to individualized coaching (n=186) or standard care (n=194). The mean estimated difference on Motor Assessment Scale in favor of control group was −0.70 points (95% confidence interval, −2.80, 1.39), *P*=0.512. There were no differences between the groups on Barthel index, modified Rankin Scale, or Berg Balance Scale. The frequency of adverse events was low in both groups. Results from International Physical Activity Questionnaire and training diaries showed increased activity levels but low intensity of the exercise in the intervention group.

Conclusions—The regular individualized coaching did not improve maintenance of motor function or the secondary outcomes compared with standard care. The intervention should be regarded as safe. Despite the neutral results, the health costs related to the intervention should be investigated.

Clinical Trial Registration—URL: https://www.clinicaltrials.gov. Unique identifier: NCT01467206.

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See related article, p XXX

Most patients experience significant improvement in function during the first weeks and months after stroke, and the functional level achieved 3- to 6-month poststroke is strongly associated with long-term outcome.[1,2] However, stroke survivors are at risk of functional decline in the long term and few survive for 5 years without hospital readmission.[3]

Task-oriented and intensive exercise in the acute and subacute phases after stroke has been shown to give optimal recovery and a good prognosis for return to an independent life at home.[4] Cardiorespiratory training has also been shown to reduce disability during or after usual stroke care.[5,6] Furthermore, physical activity and exercise are highly recommended in the chronic phase to sustain functions gained in rehabilitation and as part of

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From the Department of Neuromedicine and Movement Science (T.A., M.G., B.I.) and Regional Centre for Child and Youth Mental Health and Child Welfare, Department of Mental Health (S.L.), Faculty of Medicine and Health Science, NTNU: Norwegian University of Science and Technology, Trondheim; Department of Physiotherapy, Oslo and Akershus University College, Norway (B.L.); Sunnaas Rehabilitation Hospital, HF, Nesoddtangen, Norway (B.L.); Department of Medicine, Vestre Viken Hospital Trust, Bærum Hospital, Drammen, Norway (H.I.-H.); and Department of Medicine, Stroke Unit, Trondheim University Hospital, Norway (T.A., B.I., M.G.).

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*A list of all LAST Collaboration Group participants is given in the Appendix.

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Correspondence to Torunn Askim, PhD, Faculty of Medicine and Health Science, NTNU: Norwegian University of Science and Technology, PO Box 8905, 7491 Trondheim, Norway. E-mail torunn.askim@ntnu.no

long-term secondary prevention to reduce the risk of recurrent stroke and other vascular events. However, these recommendations are mainly based on expert opinions and extrapolated results from studies in primary prevention.[7] Although little is known about how well community-dwelling stroke survivors comply with these recommendations, people with stroke seem less active than their age-matched peers.[8] Hence, development of new interventions is needed to help stroke survivors achieve a more active lifestyle to maintain the functional levels achieved during stroke unit treatment and early poststroke rehabilitation.

A systematic review of the literature provides some evidence that tailored counseling improves participation in physical activity after stroke.[9] However, only 1 study has followed patients for >12 months, showing that regular phone calls in addition to counseling of physical activity every 3 to 6 months did not significantly increase activity levels.[10] The authors hypothesized that the lack of individualized coaching on a more regular basis might explain the neutral result.[10] Therefore, the aim of the present study was to investigate whether a long-term intervention program of regular individualized coaching on physical activity and exercise increased activity levels to maintain optimal motor function, independence in activities of daily living, balance, walking ability, and health-related quality of life. We also aimed to investigate safety and compliance to the intervention. Our primary hypothesis was that individualized coaching would be better than standard care in maintaining motor function at 18-month follow-up.

Materials and Methods

The LAST study (Life After Stroke) was conducted in accordance with the institutional guidelines and was approved by the Regional Committee of Medical and Health Research Ethics (REC no. 2011/1427). Because of Norwegian regulations and conditions for informed consent, the data set is not publicly available. The study was registered with Clinicaltrials.gov. Full details of this study protocol have been published elsewhere.[11]

Study Design and Participants

This was a pragmatic, single-blinded, parallel-group, randomized controlled trial performed at 2 centers in Norway: Trondheim University Hospital and Bærum Hospital, in close collaboration with the primary healthcare service in the municipalities of Trondheim, Asker, and Bærum. The study lasted from October 18, 2011, to January 15, 2016.

All patients treated at the stroke unit at the participating hospitals were screened for inclusion and consecutively recruited at the outpatient clinic at 3 months (10–16 weeks) poststroke. Patients who agreed to participate underwent an initial assessment before randomization and a follow-up assessment 18 months later.

Eligible participants were aged ≥18 years, had confirmed first-ever or recurrent stroke (infarction or intracerebral hemorrhage), had been discharged from hospital or inpatient rehabilitation and were community dwelling with a modified Rankin Scale (mRS) score <5, had no serious comorbidities that made it difficult to perform the intervention, and were capable of providing consent.

Exclusion criteria were serious medical comorbidity with short life expectancy, cognitive deficits as evaluated by the Mini-Mental State Examination <21 points (or <17 points for patients with aphasia), contraindication to participation in motor training, or inclusion in another study.

Randomization and Masking

Participants were stratified according to stroke severity (mRS >2 points), age ≥80 years, and recruitment site. They were randomly assigned (1:1), in blocks of 2 and 4, to an intervention group receiving regular individualized coaching on physical activity or to a control group receiving standard care. A group of well-trained research assistants, blinded to the treatment allocation, screened patients for eligibility and did all assessments face-to-face at inclusion and at 18-month follow-up. Randomization was performed by a web-based randomization system developed and administered by the Unit of Applied Clinical Research, Faculty of Medicine, Norwegian University of Science and Technology, Trondheim, Norway.

Intervention and Control

Standard Care

All eligible participants underwent evidence-based comprehensive stroke unit treatment in the acute phase and further rehabilitation after discharge from hospital, including a 3-month follow-up visit at the outpatient clinic in accordance with the Norwegian guidelines on stroke treatment.[12] The rehabilitation after discharge from hospital usually consists of 45 minutes of physiotherapy at moderate intensity per week performed in the patient's home, at an outpatient clinic, or during inpatient rehabilitation. Rehabilitation is often limited to the first 3 months for patients with mild to moderate strokes but can last for up to 6 months for patients with the most severe strokes and for selected patients even longer. After the end of rehabilitation, patients and their families have to take responsibility for further physical activity and exercise. Participants randomized to the control group received standard care.

Regular Individualized Coaching

Participants randomized to the intervention group were given, in addition to standard care, a follow-up program comprising monthly individualized coaching by a physiotherapist for 18 consecutive months after inclusion. As a starting point, participants were asked to complete a standardized questionnaire to register their individual physical activity preferences[13] and to list 1 to 3 individual goals using Goal Attainment Scaling.[14] Based on the preferences and goals, a schedule for physical activities and exercise was set for the next month. The exercise needed to last 45 to 60 minutes and include 2 to 3 periods of vigorous activity once a week while the physical activity needed to last 30 minutes 7 days a week.[15] Vigorous activity was defined as a rating of 15 to 17 on the Borg scale of perceived exertion.[16] To comply with the weekly exercise, participants were offered participation in several existing outpatient, private, and community-based treatment groups, individual physiotherapy, or home training if preferred.

Furthermore, participants were trained in how to complete the training diary and record the amount and intensity of each day's activities. The training diaries were reviewed, and the schedule was reassessed according to individual needs, including progression for the next month.

The first 6 meetings were performed face-to-face in the participants' home; in the next 6 months, every second meeting could take place as a phone meeting, and during the final 6 months, 4 of the 6 meetings could take place as a phone meeting.

Outcomes

The primary outcome was motor function at 18 months after inclusion assessed by Motor Assessment Scale (MAS).[17] Developed for persons with stroke, the scale consists of 8 functional tasks ranging from rolling from supine to side lying to advanced hand activities. The advantage of MAS is that it covers all basic motor functions and has frequently been used in previous stroke trials.[18] MAS has shown good measurement properties, and the reliability and validity of the Norwegian translation of the scale have been ensured.[19]

Secondary outcomes were the Barthel index[20] and mRS[20] to assess independence in activities of daily living, item 14 from Berg Balance Scale[21] and Timed Up and Go test[22] to assess balance, 10-meter maximum gait speed,[23] and the 6-minute walk test[24] to assess walking ability, and the Stroke Impact Scale 3.0[25] to assess health-related aspects of quality of life at 18 months. Further secondary outcomes

were EQ-5D-5L, Fatigue Severity Scale, one item on fatigue from the HUNT3 (third Nord-Trøndelag Health Study) questionnaire, Hospital Anxiety and Depression Scale, Mini-Mental State Examination, Trailmaking A and B, and Caregiver Strain Index.[11]

Adverse Events

Information about new cardiovascular and cerebrovascular events, serious falls, fractures, or any event of syncope or dizziness with unknown reason, resulting in hospitalization, was collected from the Norwegian Patient Registry. Information about deaths was collected from the hospital records or next-of-kin.

Compliance

Compliance with the intervention was assessed by combining information from the training diaries with information recorded by the physiotherapists. Participants who performed at least 210 minutes of physical activity (30 minutes 7 days a week) and 45 minutes of exercise every week for 80% of the weeks (19 of 24 weeks) within every 6-month period were considered compliers. Compliance was also calculated for those who complied with the general recommendations, that is, 150 minutes of physical activity per week.[26] The Borg scale was used to report intensity levels of physical activity and exercise. The proportion of participants who attended at least 50% of the meetings face-to-face within every 6-month period has also been reported.

The amount and intensity of physical activity performed by the participants in both groups were recorded using the International Physical Activity Questionnaire[27] at 6-, 12-, and 18-month follow-up. International Physical Activity Questionnaire provides information about energy costs (metabolic equivalent task) for walking, moderate intensity, and vigorous intensity activity during the past 7 days. Please see Tables I and II in the online-only Data Supplement.

Statistical Analyses

Sample size estimation was based on previous data from 2 comparable populations.[28,29] Difference of 10% between the groups was considered clinically significant. The intervention group was expected to maintain its initial mean MAS score (38.4 points) at 18-month follow-up while a 10% reduction was expected in the control group at the same time point (34.6 points). The SD was estimated as 10.6 points. Based on these assumptions, a sample size of 170 in each group was needed to achieve a statistical power of 90% with significance level

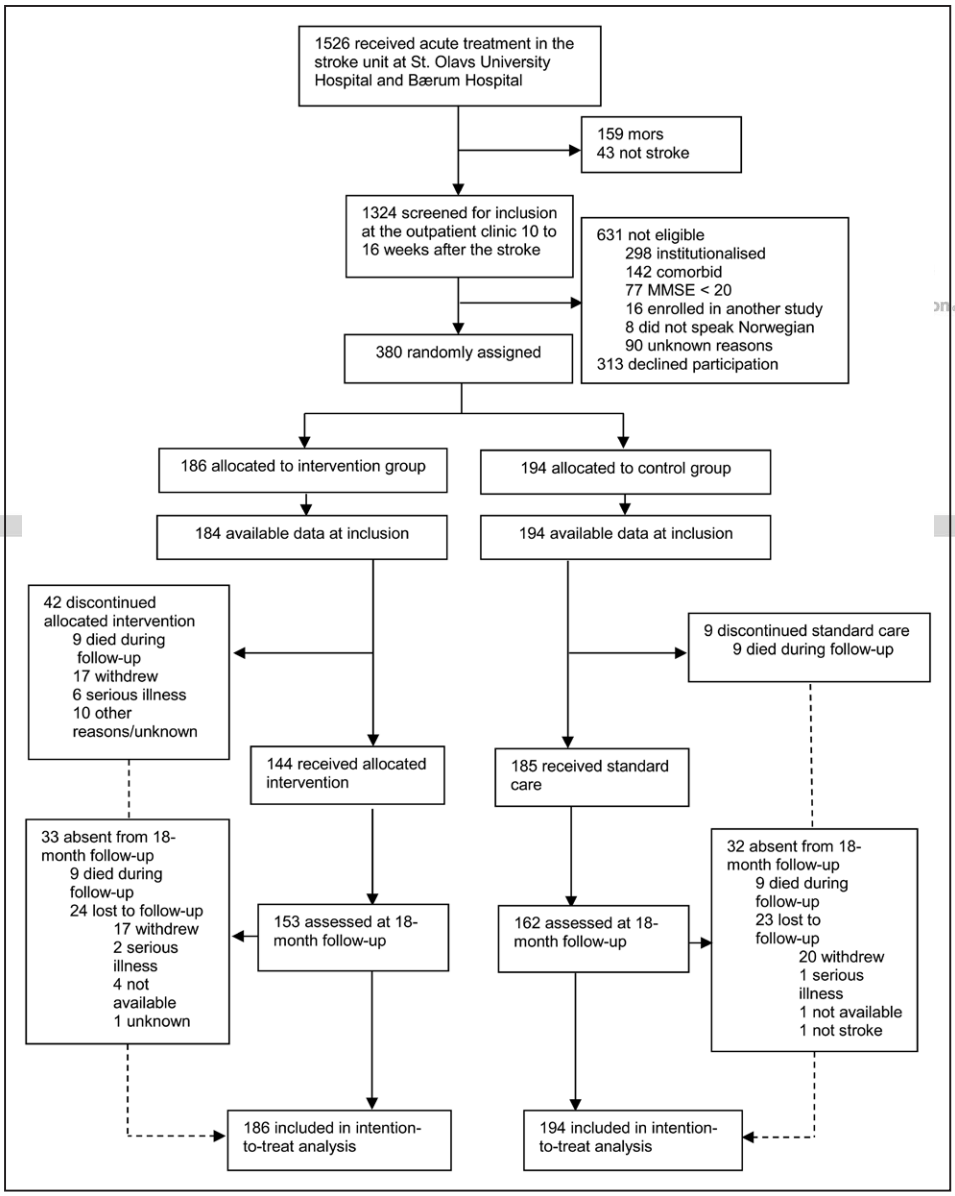

Figure 1. Trial profile. MMSE indicates Mini-Mental State Examination.

α=0.05. Assuming that 15% of the participants might drop out during the course of the study, a target of 390 participants was set.

The primary end point was motor function measured by MAS at 18-month follow-up. We used ANCOVA for primary and secondary end points, with measurement at 18 months as dependent variable, and treatment group, sex, hospital site, stroke severity, age, and measurement at baseline as covariates. The Mann–Whitney *U* test was used for data that were not normally distributed.

We were aiming for an intention to treat analysis approach. For instrument scales with no more than half of the items missing, the missing values were singly imputed using the expectation–maximization algorithm on these. In the primary analysis, participants who had died before follow-up were imputed as zero on all scales except mRS, Timed Up and Go test and Stroke Impact Scale. We used multiple imputation to impute all other missing values, with m=100 imputations as recommended by van Buuren.[30] A sensitivity analysis was done to determine whether participants who were dead at 18 months affected the outcome.

Prespecified subgroup analyses were performed according to the stratification variables (stroke severity [mRS 0–2 versus 3–4], age <80 years, and recruitment site) in addition to sex and cognitive status (Mini-Mental State Examination <25), with a separate ANCOVA for each subgroup.

Results

Between October 18, 2011, and June 30, 2014, 1324 individuals were screened for inclusion. The follow-up assessments were completed January 15, 2016. In total, 380 consenting participants were included and randomly assigned to the intervention group (n=186) or to the control group (n=194). The most common reasons for exclusion were refusal (23.6%) or institutionalization (22.4%). A total of 153 participants in the intervention group and 162 participants in the control group were assessed at 18 months. The flow of participants is shown in Figure 1.

Demographic and baseline characteristics were similar in both groups (Table 1). Both groups declined on primary outcome, MAS at 18 months, relative to baseline (2 points versus 1.3 points in the intervention group and control group, respectively); however, there were no differences between the groups (adjusted between-group mean difference estimate: −0.70 points [95% confidence interval, −2.80, 1.39], *P*=0.512; Table 2). Regarding secondary outcomes, there were no significant differences between the groups except a greater improvement on Timed Up and Go test in the control group (7.05 seconds [95% confidence interval, 2.86, 11.25], *P*=0.001).

The sensitivity analysis showed that participants who died during follow-up did not affect the outcome.

There was no evidence of effect on the primary outcome for any of the prespecified subgroups (Figure 2).

Adverse Events

The safety measures showed no differences in adverse events between the groups (Table 3). However, there were 39% more hospital admissions because of vascular events, when all cerebrovascular and cardiovascular events were summed up, in the control group compared with the intervention group (28 versus 17 events; *P*=0.110).

Compliance

Table I in the online-only Data Supplement shows that 43% to 59% of those who completed the training diaries complied with 210 minutes per week in each 6-month period while 60% to 64% complied with 150 minutes per week. The corresponding numbers for compliance to 45 minutes of weekly exercise ranged from 50% to 54% for the 18-month period. The actual number of compliers increased during follow-up.

Table II in the online-only Data Supplement shows that participants in the intervention group were more active in

Table 1. Baseline Demographic and Clinical Characteristics

	Intervention Group (n=186)	Control Group (n=194)
Age, y, mean (SD)	71.7 (11.9)	72.3 (11.3)
≥80	44 (23.7)	53 (27.3)
<80	142 (76.3)	141 (72.7)
Sex		
Female	82 (44.1)	67 (34.5)
Male	104 (55.9)	127 (65.5)
Time from stroke, d mean (SD)	111.3 (24.5)	112.0 (17.2)
NIHSS, mean (SD)	1.5 (2.3)	1.6 (2.5)
<8	181 (97.3)	188 (96.9)
8–16	5 (2.7)	6 (3.1)
>16	0	0
mRS, mean (SD)	1.45 (1.08)	1.44 (1.10)
mRS=0	34 (18.3)	38 (19.6)
mRS=1	78 (41.9)	80 (41.2)
mRS=2	36 (19.4)	35 (18.0)
mRS=3	32 (17.2)	34 (17.5)
mRS=4	6 (3.2)	7 (3.6)
Living condition		
Living with someone	130 (69.9)	143 (73.7)
Living alone	56 (30.1)	51 (26.3)
Stroke type		
Infarction	172 (92.5)	174 (89.7)
Hemorrhage	14 (7.5)	20 (10.3)
MMSE, mean (SD)	27.8 (2.3)	27.9 (2.6)
≥25	164 (88.2)	176 (90.7)
<25	22 (11.8)	18 (9.3)
Comorbidity		
Stroke	29 (15.6)	38 (19.6)
Transient ischemic attack	20 (10.8)	18 (9.3)
Myocardial infarction	19 (10.2)	28 (14.4)
Heart failure	3 (1.6)	6 (3.1)
Atrial fibrillation	32 (17.2)	43 (22.3)
Hypertension	90 (48.4)	109 (56.2)
Diabetes mellitus	25 (13.4)	29 (14.9)
Lung diseases	19 (10.2)	25 (12.9)

Values are n (%) unless stated otherwise. MMSE indicates Mini-Mental State Examination; mRS, modified Rankin Scale; and NIHSS, National Institutes of Health Stroke Scale.

Table 2. Baseline and Follow-Up Outcome Measures by Group

	Intervention Group (n=186)		Control Group (n=194)		Between Group Differences	
	Baseline Mean (SE)	18-Month Follow-Up Mean (SE)	Baseline Mean (SE)	18-Month Follow-Up Mean (SE)	Adjusted Coefficient Estimate (95% CI)*	*P* Value
Primary outcome						
Motor Assessment Scale†	41.9 (0.50)	39.9 (0.88)	41.7 (0.53)	40.4 (0.81)	−0.70 (−2.80, 1.39)	0.512
Secondary outcomes‡						
Barthel index†	96.4 (0.05)	90.2 (0.18)	96.1 (0.066)	90.2 (0.16)	−0.41 (−4.96, 4.14)	0.860
Modified Rankin Scale	1.45 (0.056)	1.28 (0.117)	1.44 (0.079)	1.33 (0.11)	−0.03 (−0.30, 0.25)	0.860
Berg Balance Scale, item 14†	2.55 (0.11)	2.63 (0.12)	2.52 (0.10)	2.71 (0.10)	−0.10 (−0.33, 0.13)	0.391
Timed Up and Go test, s	12.3 (0.57)	19.5 (2.16)	16.1 (2.25)	12.9 (0.69)	7.05 (2.86, 11.25)	0.001
Gait speed, m/s†	1.28 (0.04)	1.01 (0.06)	1.35 (0.05)	1.07 (0.07)	−0.03 (−0.17, 0.10)	0.625
Six-minute walk test, m†	391.1 (12.5)	371.6 (14.4)	389.1 (16.7)	372.2 (18.8)	−1.38 (−34.6, 31.8)	0.935
Stroke Impact Scale, over all recovery		72.8 (2.67)		73.5 (2.58)	−0.95 (−7.58, 5.68)	0.778

CI indicates confidence interval.

*Adjusted estimates after controlling for age, sex, stroke severity (modified Rankin Scale at inclusion), hospital site and baseline Motor Assessment Scale, Barthel index, modified Rankin Scale, Berg Balance Scale (item 14), Timed Up and Go test, gait speed, and 6-minute walk test as appropriate.

†Participants who died before follow-up were given a test score of zero at 18-month follow-up.

‡EQ-5D-5L, Fatigue Severity Scale, one item on fatigue from the third Nord-Trøndelag Health Study questionnaire, Hospital Anxiety and Depression Scale, Mini-Mental State Examination, Trailmaking A and B, and Caregiver Strain Index showed no differences between the groups. Details will be reported and discussed elsewhere.

terms of vigorous activity compared with the control group at 6-month (*P*=0.009), 12-month (*P*=0.016), and 18-month follow-up (*P*=0.033). Moderate activity and walking time were only significantly higher at 6-month (*P*=0.005) and 12-month follow-up (*P*=0.001).

Discussion

Contrary to our hypothesis, we could not demonstrate that individualized coaching was better than standard care in maintaining motor function, as measured with MAS, at 18 months. Nor did the secondary outcomes show any benefit of the intervention. The compliance measures showed that stroke survivors receiving regular individualized coaching were more active than participants receiving standard care, and the safety measures showed no differences in adverse events between the groups.

The major strength of the present study was the pragmatic randomized controlled study design with few inclusion and exclusion criteria and an intervention applicable in a wide range of settings, strengthening the external validity of the results. The high-quality treatment given as part of standard care to participants in both groups should also be regarded as a strength even though it might have contributed to reducing the ability to achieve significant differences between the groups. The low number of participants lost to follow-up, which was slightly lower than assumed in our sample size estimation, was also a strength.

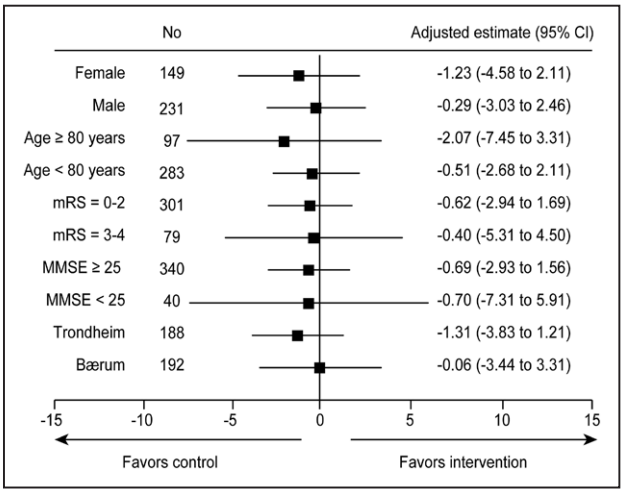

Figure 2. Subgroup analysis for Motor Assessment Scale at 18-mo follow-up. CI indicates confidence interval; MMSE, Mini-Mental State Examination; and mRS, modified Rankin Scale.

Table 3. Safety Outcomes

	Intervention Group (n=186)	Control Group (n=194)	*P* Value
Death	9 (4.8)	9 (4.6)	0.909
Myocardial infarction	4 (2.2)	4 (2.1)	0.745
Other cardiovascular events	4 (2.2)	10 (5.2)	0.120
Recurrent stroke	7 (3.8)	12 (6.2)	0.279
Transient ischemic attack	5 (2.6)	5 (2.6)	0.946
Any vascular event	17 (9.1)	28 (14.4)	0.110
Unspecific cerebral symptoms	7 (3.8)	5 (2.6)	0.509
Fracture	11 (5.9)	11 (5.6)	0.919
Fall	3 (1.6)	4 (2.1)	0.745

Values are n (%).

A weakness of the study was the lack of repeated measurements of motor function and secondary outcomes during follow-up. Another limitation was the lack of detailed and regular information about physical activity and exercise performed by the control group. However, the rationale for not recording such information was to reduce the risk of contamination of the intervention to the control group and because the training diaries were an important part of the individualized coaching given to the intervention group.

The use of a self-reported measure of physical activity and exercise might also be regarded as a weakness. It is well-known that people may overestimate their activity levels when self-reported measures are used, and we cannot exclude the possibility that the participants in the intervention group have tended to overestimate their activity levels more than the controls. Objective measures, such as activity monitors, are recommended for used in future research. However, independent of the choice of method, participants in both groups might be prone to the Hawthorne effect, that is, changing their behavior as a motivational response to the attention received through the assessment.[31]

The neutral results might also be explained by a possible ceiling effect shown by the primary outcome and the large number of participants with mRS score of 0 or 1 at inclusion. There are many pros and cons to consider when choosing a primary measure. MAS was chosen in the present study because it covers the whole range of motor activities and because it was validated in Norwegian.[19] Another advantage of MAS was the good responsiveness demonstrated for the mobility items (balanced sitting; sitting to standing; walking).[32] However, in future research, an instrumental ADL (Activities of Daily Living) measure, like the Nottingham Extended ADL Scale, might be more suitable as a primary outcome in this population.

Despite significantly better Timed Up and Go test score in the control group, this trial should be interpreted as neutral. This difference was probably driven by 5 extreme cases (Timed Up and Go test >60 seconds) at follow-up.

The frequency of all vascular events was low in both groups, demonstrating that the intervention was safe. A nonsignificant trend toward more vascular events in the control group might indicate a possible benefit of the intervention in secondary prevention. This result should be interpreted with caution because a recent systematic review found no effect of lifestyle interventions on cardiovascular event rate after ischemic stroke.[33] However, the follow-up periods were probably too short to reveal such effect. It is important to notice that we only recorded serious adverse events in the present study. We cannot exclude the possibility that the frequency of other events might have been different between the groups.

The results from International Physical Activity Questionnaire indicate that the participants mainly complied with the intervention while information from the training diaries indicates that the exercise was not as intensive as intended. This finding was in contrast to the ExStroke Pilot Trial,[10] underscoring the importance of regular individualized coaching that includes systematic goal setting; agreement on a personalized training program; and use of training diaries, which were not part of standard care. It is well-known that changing lifestyle takes time, and it will be of interest in future research to investigate whether this intervention has resulted in a persistent active lifestyle or whether the participants depend on continuous coaching to maintain their activity levels.

Our results do not support the introduction of individualized coaching in the clinic to improve motor function in people with minor impairments after stroke. Still, more research is needed to investigate the effect of health coaching after stroke on other outcomes, such as the long-term risk of new vascular events. To overcome the heterogeneity challenge and improve the compliance, the coaching should probably be even more personalized and multimodal. It is also possible that an earlier commencement of the intervention, increased intensity, and a longer follow-up period are needed.

Conclusions

The LAST study has shown that regular coaching did not result in better maintenance of motor function or improvement on the secondary outcomes compared with standard care. The intervention should be regarded as safe. Despite the neutral results, the health costs related to the intervention should be investigated.

Appendix

The LAST Collaboration Group: Torgeir Engstad, Jon Magnussen, Anne Hansen, Rune Schjørlien, Stian Engen, Randi Moxnes Osmundnes, Anne-Britt Olerud, Camilla Knudsen, Trine Hansen, Walburga Schroeter, Gro Stensrud Fjelldal, Kristin Hovde, Kristine Helen Reneflot, Lisa Wennberg, Ole Petter Norvang, Ailan Phan, John Bjørn Storvoll, Brede Ørjaset, Marianne Syvertsen, Ingvild Berger, Anne Eitrem Dahl, Christine Lundemo Sandø, Veronica Kjølstad, Alexander Hansen, Helene Kværne Vileid, Maren Hjelle Giddal, Julie Bernhardt, Peter Langhorne.

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Disclosures

None.

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Efficacy and Safety of Individualized Coaching After Stroke: the LAST Study (Life After Stroke): A Pragmatic Randomized Controlled Trial

Torunn Askim, Birgitta Langhammer, Hege Ihle-Hansen, Mari Gunnes, Stian Lydersen, Bent Indredavik and on behalf of the LAST Collaboration Group

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SUPPLEMENTAL MATERIAL

Table I. Compliance with physical activity (PA) and exercise

	1-6 months	7-12 months	13-18 months
Physical activity, n	135	123	112
Participants complying with 210 minutes of PA per week, n (%)	58 (43.0)	58 (47.2)	66 (58.9)
Borg scale (6-20) during physical activity, mean (SD)	12.3 (1.3)	12.3 (1.5)	12.7 (1.7)
Participants complying with 150 minutes of PA per week, n (%)	81 (60.0)	75 (61.0)	72 (64.3)
Borg scale (6-20) during physical activity, mean (SD)	12.4 (1.4)	12.6 (1.6)	12.7 (1.7)
Exercise, n	133	124	113
Participants complying with 45 minutes of exercise per week, n (%)	66 (49.6)	71 (57.3)	61 (54.0)
Borg scale (6-20) during exercise, mean (SD)	14.0 (1.7)	14.3 (1.6)	14.2 (1.9)
Individualised coaching, n	150	138	120
Participants attending ≥ 50% of the meetings face-to-face, n (%)	132 (88.0)	64 (46.4)	46 (38.3)

Table II. Results from International physical activity questionnaire (IPAQ) at 6, 12 and 18 months' follow-up

	Intervention group		Control group		
	n	Median(Q1, Q3)	n	Median(Q1, Q3)	p-value*
IPAQ at 6 months					
Vigorous (MET-min/week)	152	0.0(0.0, 1440.0)	166	0.0(0.0, 660.0)	0.009
Moderate (MET-min/week)	153	792.0(120.0, 1200.0)	159	693.0(0.0, 960.0)	0.005
Walking (MET-min/week)	151	480.0(396.0, 1386.0)	160	240.0(297.0, 1386.0)	0.081
IPAQ at 12 months					
Vigorous (MET-min/week)	136	0.0(0.0, 960.0)	150	0.0(0.0, 480.0)	0.016
Moderate (MET-min/week)	129	480.0(120.0, 1440.0)	137	240.0(0.0, 720.0)	0.001
Walking at least (MET-min/week)	137	792.0(421.0, 1386.0)	138	240.0(186.0, 1386.0)	0.018
IPAQ at 18 months					
Vigorous (MET-min/week)	133	0.0(0.0, 1020.0)	144	0.0(0.0, 240.0)	0.033
Moderate (MET-min/week)	127	240.0(0.0, 720.0)	133	240.0(0.0, 1350.0)	0.554
Walking (MET-min/week)	118	693.0(198.0, 1386.0)	126	643.0(198.0, 1386.0)	0.551

Q1: First quartile; Q3: Third quartile, *Mann-Whitney U test