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A randomized controlled trial to assess the psychosocial effects of early exercise engagement in patients diagnosed with transient ischaemic attack and mild, non-disabling stroke

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Abstract

Objective: To examine the effect of an early exercise and education programme on psychosocial health of transient ischaemic attack (TIA) and mild, non-disabling stroke patients.

Design: Randomized, parallel-group, clinical trial.

Setting: Hospital and academic institution.

Participants: A total of 55 newly diagnosed transient ischaemic attack/mild stroke patients (Mean[SD]; 69[11]y).

Intervention: Participants were randomized to either an eight-week, twice weekly, 90-minute exercise and education programme (experimental group) or to a usual care control group.

Main measures: Psychosocial measures (SF-36, Hospital Anxiety and Depression Scale, Profile of Mood States, International Physical Activity Questionnaire, Stroke Awareness Questionnaire) were assessed at baseline and eight-week and 12-month follow-up.

Results: The experimental group demonstrated improvements in the Physical Component Score (Mean[SD]; 44.1[11.7] to 47.4[11.3]%), Vitality (46.5[12.4] to 54.2[14.2]%), Physical Functioning (45.6[10.7] to 51.9[14.7]%), Role Physical (38.7[10.8] to 43.1[13.6]%) and Global Health (49.1[10.3] to 54.4[13.6]%) from the SF-36, at the eight-week follow-up assessment ($P<0.05$). There were no further changes in these measures between the eight-week and 12-month follow-up assessment ($P>0.05$). The experimental group demonstrated a greater awareness of the signs and symptoms associated with stroke ($P<0.05$). There were no differences in the Mental Component Score (SF-36), the Hospital Anxiety and Depression Scale or the International Physical Activity Questionnaire between treatment groups ($P>0.05$).

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Conclusion: Early engagement in an exercise and education programme may improve physical health perceptions in transient ischaemic attack/mild stroke patients. However, secondary prevention exercise and education programmes warrant further research with regards to their effects on perceptions of mental health in this population group.

Keywords
Transient ischaemic attack, psychosocial health, physical exercise, long-term follow-up

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Introduction

Transient ischaemic attacks (TIAs) are ischaemic brain attacks with focal cerebral or retinal symptoms that last <24 hours, usually <1 hour. Individuals classified with a non-disabling stroke have minor residual symptoms, which are managed by the same treatment paradigm as TIA. Many people who present with a TIA and mild/non-disabling stroke have predisposing modifiable vascular risk factors, such as hypertension, tobacco use, diabetes mellitus, hyperlipidaemia, obesity and physical inactivity.[1] Recent empirical evidence has demonstrated the physiological benefits of regular exercise participation for patients diagnosed with TIA or mild/non-disabling stroke.[2–4] Importantly, the short-term improvements in vascular health (blood pressure, blood lipid profile) and aerobic fitness[2–4] may be sustained over a prolonged period (≤14 months postdiagnosis).[5]

Although physical activity is an effective and pertinent component of secondary prevention care for those with TIA/stroke, psychosocial parameters are important constructs that require further consideration. As sustainable, long-term behaviour change is related to autonomous motivation, general expectancy, and self-efficacy,[6] the ongoing impact of TIA/stroke may be measured by changes in an individual's emotional and social well-being.[7] However, the psychosocial sequelae post-TIA/stroke is often underestimated.[3] Indeed, impairments in health-related quality of life may be observed in these individuals even when residual deficits are not apparent.[8] Factors such as post-stroke depression, anxiety, poor social support, and poor coping strategies are consistent determinants of poor health-related quality of life, and are considered to be contributory factors that may limit recovery and rehabilitation.[9,10] To date, the acute changes in anxiety and depression[11] and health-related quality of life[3,11] are the only psychosocial factors that have been examined following the implementation of an exercise programme soon after TIA/stroke diagnosis.

The purpose of this study, therefore, is to assess the effect of an exercise and education programme, implemented soon after TIA or mild/non-disabling stroke diagnosis, on psychosocial health outcomes in both the short- and long-term. Data presented in the current study pertains only to the psychosocial assessments reported from a larger randomized controlled trial.[5] It was hypothesized that benefits in psychosocial markers would be observed in the short-term, and that these positive changes would be sustained over the course of a 12-month period.

Methods

Participants

Participants were eligible if: (i) TIA or a mild/non-disabling stroke diagnosis was within 7 days of symptom onset, as determined by a specialist stroke physician according to New Zealand's TIA/stroke guidelines;[12] (ii) if the patient resided within the local District Health Board; and (iii) if they did not meet the following exclusion criteria: unstable cardiac conditions, uncontrolled diabetes mellitus, severe claudication, oxygen dependence, significant dementia, inability to communicate in English,

or unable to take part in exercise. Participants complied with drug treatment and standardized therapy in accordance with stroke physician recommendations (as detailed elsewhere).[2,5] The sample size requirements are detailed elsewhere,[6] but calculations were based on the following: power = 80%, $\alpha = 0.05$, participant drop-out rate = 25%.

The clinical trial was conducted through the Neurology Department of a large metropolitan hospital. All participants volunteered to take part in the study and provided informed consent. The study was ethically approved by New Zealand's Central Regional Health and Disabilities Ethics Committee and registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12612000567820). The study was undertaken in accordance with the ethical standards of the Declaration of Helsinki.

Study design

The study was a single-centre, randomized, parallel-group clinical trial. Patients who met study inclusion criteria were invited to participate in a baseline assessment that included a health history questionnaire, a vascular risk assessment, tests for aerobic fitness, and psychosocial questionnaires. Identical follow-up assessments were undertaken at eight weeks and 12 months. Data presented in the current study pertains only to the psychosocial assessments (for additional information on participant adherence, recurrent TIAs, vascular risk factors, etc., see Faulkner et al.[2,5]).

On completion of the baseline assessment, participants were randomized to either the experimental group (exercise and education intervention) or to a usual care control group. The randomization schedule was computer generated using a basic random number generator.[5] Details of the randomized group were given on a piece of paper contained within sequentially numbered, opaque, sealed envelopes. The allocation sequence was prepared by an investigator with no other involvement in the clinical trial. The allocation sequence was concealed from outcome assessors and data analysts. However, participants and the health and exercise practitioner were aware of group allocations during the intervention.

Those individuals randomized to the experimental group took part in two 90-minute exercise sessions and one 30-minute education session per week for eight weeks. The exercise sessions incorporated: (i) 30 minutes of aerobic exercise, and (ii) 60 minutes of resistance training, core-stability, and postural exercises. During the aerobic exercise participants exercised between 50 and 85% of their age-predicted maximum heart rate during cycle and treadmill (walking) exercise (15 minutes each). The exercise intensity was increased by ~5% each week. Blood pressure, heart rate, and subjective perception of exertion were measured prior to, during, and following each bout of aerobic exercise. The resistance training incorporated exercises such as alternate arms biceps curl, shoulder press, lateral raise, calf raise, and squats; all performed with either a swiss ball or buso ball.

The education sessions involved a didactic group discussion to facilitate patients with a greater sense of understanding and management of their condition. The education programme was designed so that the health and exercise practitioners could teach, discuss, and reinforce behaviours that are known to facilitate healthy behaviour change. These sessions were constructed in line with the health belief model for behaviour change, and focused on vascular risk factors, stroke prevention, nutrition, blood pressure, adherence to medication, stress management, and emotional and behavioural changes after TIA. The control group received standard secondary prevention and educational information from the hospital (e.g. leaflets from the Stroke Foundation on discharge).

Psychosocial measures

The participants' psychosocial health was assessed by the same blinded outcome assessor at baseline, and eight-week and 12-month follow-up assessments. A standard battery of clinical tests were implemented, including the Short-Form 36 (SF36), Hospital Anxiety and Depression Scale, the Profile of Mood States, International Physical Activity Questionnaire, and the Stanford Medical Centre Stroke Awareness Questionnaire.

The SF-36 is a valid and reliable quality of life survey,[13,14] which consists of 36 health and well-being questions grouped into eight subscales: Vitality, Global Health, Role Physical, Physical Functioning,

Bodily Pain, Role Emotional, Social Functioning, and Mental Health. The SF-36 also derives a psychometrically based Physical and Mental Health Component Score. It is a widely used measure to assess health-related quality of life in patients with stroke. The Hospital Anxiety and Depression Scale has been used extensively across illness groups where it is well-validated and reliable.[15] The Hospital Anxiety and Depression Scale consists of 14 questions; seven associated with the feeling of anxiety and seven with the concept of depression. The Profile of Mood States[16] is a validated inventory that assesses six dimensions of the mood construct: anger, confusion, depression, fatigue, tension, and vigour.[17] The International Physical Activity Questionnaire is a valid and reliable instrument used for monitoring physical activity and inactivity.[18,19] The Stroke Awareness Questionnaire provides 10 questions related to the signs, symptoms, and risk factors associated with stroke.

Data analyses

The primary outcome measure for this study was the SF-36 component scores. Secondary outcome measures included the SF-36 subdomains, Hospital Anxiety and Depression Scale, the Profile of Mood States, International Physical Activity Questionnaire, and the Stanford Medical Centre Stroke Awareness Questionnaire.

Demographical and clinical comparisons between the experimental group and the control group were performed with independent sample *t*-tests and chi-square tests, as appropriate. Separate two-factor repeated-measures analysis of variance with time (baseline, eight-week follow-up, 12-month follow-up) as the within-subjects factor, and treatment option (experimental vs. control) as the between-subjects factor, were performed for each psychosocial questionnaire. Where statistical differences were observed, post-hoc analyses for multiple comparisons were conducted (*t*-tests; Tukey's Honestly Significant Difference). Data is reported as mean (SD) of groups, mean (SD) difference within groups, and mean (95% CI (confidence interval)) difference between groups. For the International Physical Activity Questionnaire, to account for differences at baseline, analysis of covariance was used to assess leisure time activity and sitting time activity during the follow-up assessments. Partial eta squared (η_p^2) was used as a measure of effect size, with 0.0099, 0.0588, and 0.1379 representing a small, medium, and large effect.[20] Data were analysed using the statistical package SPSS for Windows, version 21.

Results

Figure 1 demonstrates participant recruitment and adherence. A total of 55 individuals took part in the three assessment sessions. Participant demographics and clinical characteristics for both the experimental and control group are reported in Table 1.

SF-36

When analysing the Physical Component Score and Mental Component Score, a significant difference between treatment options (experimental vs. control) was observed for the Physical Component Score ($P < 0.01$; $\eta_p^2 = 0.105$). Tukey's HSD revealed a significant increase in the Physical Component Score between the baseline assessment and the assessment at eight-weeks for the experimental group but not for the control group (Table 2). Similar findings were reported for the following SF-36 sub-domains: Vitality ($\eta_p^2 = 0.092$), Global Health ($\eta_p^2 = 0.080$), Role Physical ($\eta_p^2 = 0.062$) and Physical Functioning ($\eta_p^2 = 0.085$) (all $P < 0.05$; Table 2). For the experimental and control groups, there were no differences in the above SF-36 markers between the eight-week and 12-month assessments (all $P > 0.05$; Table 2).

Hospital Anxiety and Depression Scale

There were no differences in participants' anxiety and depression between the treatment groups (all $P > 0.05$; Table 2).

Profile of mood states

A significant difference between treatment options (experimental vs. control) was observed for Fatigue ($P < 0.01$; $\eta_p^2 = 0.102$). Post-hoc analysis

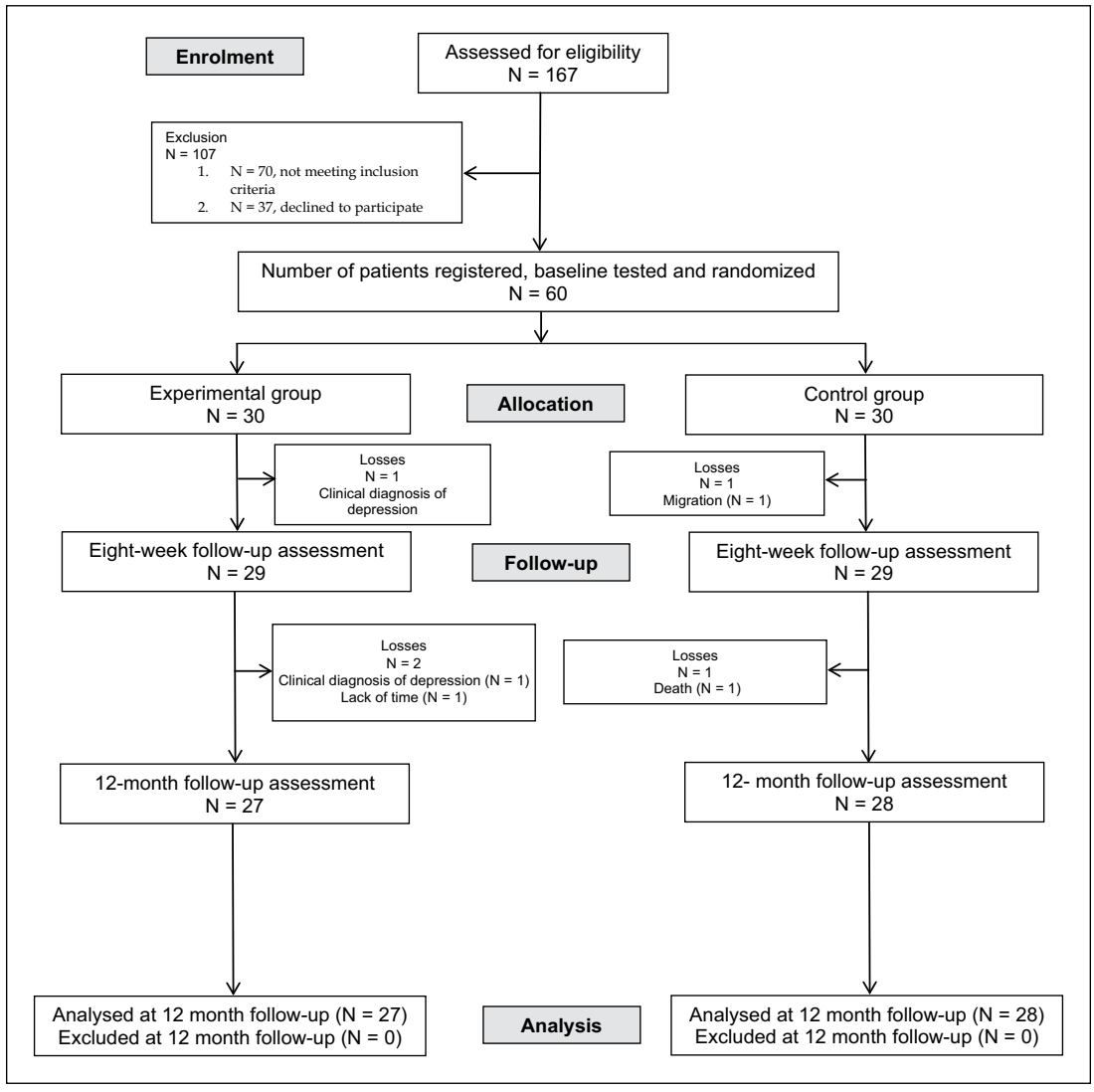

Figure 1. Design and flow of participants through the trial.

demonstrated a significant decrease in Fatigue scores for the experimental group between the eight-week assessment and the 12-month follow-up, but an increase for the control group (Table 3). For the remaining domains of the Profile of Mood States, there were no differences between treatment options ($P > 0.05$; Table 3).

Stroke Awareness Questionnaire

A significant difference between treatment options (experimental vs. control) was observed for the Stroke Awareness Questionnaire ($P < 0.05$, $\eta_p^2 = 0.070$, Table 3). Post-hoc analysis revealed that the experimental group demonstrated a greater overall awareness of the signs and symptoms of stroke than the control group (7.6 (1.1) vs 6.9 (1.1), respectively).

International Physical Activity Questionnaire

Analysis of covariance demonstrated significant changes in total leisure time activity, the amount of walking and vigorous activity completed during

Table 1. Baseline demographics and clinical characteristics of participants randomized to the experimental and control groups, and who completed all three psychosocial assessments (baseline, eight-week follow-up, 12-month follow-up).

		Experimental		Control		Significance
		n	%	*n*	%	
Participants (*n*)		27	53	28	47	
Age (years)		65 ±11		68 ±10		NS 0.2
Weight (kg)		76.6 ±14.1		79.7 ±15.2		NS 0.8
Body mass index (kg/m^2)		28.3 ±4.3		28.7 ±5.1		NS 0.8
Gender (*n*)	Male	15	56	14	50	NS 0.5
	Female	12	44	14	50	
Descent (*n*)	European	24	89	24	86	NS 0.8
	Maori	1	4	0	0	
	Pacifika	1	4	2	7	
	Asian	1	4	1	4	
	Indian	0	0	1	4	
Stroke classification	TIA	16	59	17	61	NS 0.9
	Mild, non-disabling stroke	11	41	11	39	
	Anterior infarction	15	56	14	50	NS 0.7
Diagnostic category	Posterior infarction	7	26	10	36	
	Uncertain territory	5	18	4	14	
Lifestyle factors	Current smoker	2[a]	7	2[b]	8	NS 0.9
	Previous smoker	18	67	15	54	NS 0.1
	Activity status: Sedentary	9	33	7	25	NS 0.8
	Light	10	37	13	46	
	Moderate	7	26	7	25	
	Vigorous	1	4	1	4	
Medication	Statins	23	85	24	86	NS 0.8
	Antithrombotic	24	90	22	79	NS 0.4
	ACEI	8	30	12	40	NS 0.1
	Diuretics	7	26	11	39	NS 0.2
	Calcium blockers	9	33	6	25	NS 0.5
	Beta blockers	6	22	6	21	NS 0.9
	Anticoagulants	2	7	3	13	NS 0.6
	Other Antihypertensives	2	7	1	3	NS 0.6
	Mean medication use	2.91 ±1.09		2.83 ±1.04		NS 0.8

Patients assessed for eligibility ($n = 167$) at the Hospital included the following demographics; age: 70 ±13 years; gender: male $n = 93$ [56%], female $n = 74$ [44%]; ethnicity: European $n = 137$ [82%], Maori $n = 12$ [7%], Pacifika $n = 9$ [5%], Asian $n = 6$ [4%], Indian $n = 3$ [2%].

[a]Current smokers who smoke between 0.5 and 1.0 pack per day.

[b]Current smokers who smoke <0.5 pack per day.

ACEI: angiotension converting enzyme inhibitors; NS: non-significant; TIA: transient ischaemic attack.

leisure time, and for total sitting time, regardless of an individual's treatment group (all $P<0.05$). Post-hoc analysis demonstrated a significant decrease in physical exertion, and a significant increase in sitting behaviour between the eight-week and 12-month follow-up assessment for both conditions (Table 4).

Table 2. SF36 summary and single item scores at baseline, eight-week follow-up, and 12-month follow-up for the experimental and control groups. Data are reported as mean (SD) of groups, mean (SD) difference within groups, and mean (95% CI) difference between groups with *P* values.

Outcome	Groups		Difference within groups								Difference between groups	
	Baseline		Eight-week follow-up		12-month follow-up		Eight-week follow-up minus baseline		12-month follow-up minus baseline		Eight-week follow-up adjusted for baseline	12-month follow-up adjusted for baseline
	EXP	CON	EXP	CON	EXP	CON	EXP	CON	EXP	CON	EXP – CON	EXP – CON
Physical Component Score	44.1 (11.7)	43.4 (8.3)	47.4 (11.3)[a]	40.2 (10.1)	48.5 (12.1)	40.7 (9.6)	3.3 (7.0)	–3.3 (6.4)	4.4 (9.7)	–2.7 (8.7)	6.6 (3.0 to 10.1), $P<0.001$	7.0 (2.0 to 12.0), $P<0.01$
Mental Component Score	48.6 (12.5)	47.9 (11.3)	52.0 (15.1)	50.9 (11.9)	55.3 (12.4)	51.2 (9.3)	3.3 (7.6)	3.1 (8.8)	6.6 (7.9)	3.3 (10.7)	2.2 (–4.2 to 4.6), $P>0.05$	3.3 (–1.7 to 8.4), $P>0.05$
Mental Health	52.3 (10.6)	52.1 (9.7)	55.5 (12.8)	53.9 (8.8)	54.5 (12.0)	53.9 (7.5)	3.2 (12.2)	2.2 (5.9)	2.2 (8.7)	1.8 (8.8)	1.0 (–4.0 to 6.0), $P>0.05$	0.4 (–4.4 to 5.2), $P>0.05$
Social Functioning	48.1 (12.7)	45.1 (11.7)	51.3 (13.5)	44.3 (11.5)	54.7 (13.8)	45.7 (10.7)	3.3 (16.5)	–0.7 (14.4)	6.7 (8.7)	0.6 (15.5)	4.0 (–4.1 to 12.2), $P>0.05$	6.1 (–0.7 to 12.9), $P>0.05$
Global Health	49.1 (10.3)	48.3 (10.9)	54.4 (13.6)[a]	47.4 (11.2)	53.4 (10.7)	46.4 (11.3)	5.3 (9.9)	–1.0 (7.6)	4.3 (8.8)	–1.9 (7.6)	6.3 (1.7 to 11.0), $P<0.01$	6.2 (1.8 to 10.7), $P<0.01$
Role Physical	38.7 (10.8)	35.5 (10.5)	43.1 (13.6)[a]	35.4 (10.0)	46.9 (12.9)	35.5 (9.4)	4.4 (19.0)	0.0 (8.4)	8.2 (11.9)	0.0 (9.4)	4.4 (–3.3 to 12.1), $P>0.05$	8.2 (2.4 to 14.0), $P<0.01$
Role Emotional	41.3 (14.0)	39.1 (13.3)	48.1 (15.4)	42.6 (14.1)	50.6 (14.4)	41.7 (12.8)	6.8 (14.0)	3.1 (12.4)	9.3 (9.8)	2.6 (14.2)	3.7 (–3.3 to 10.7), $P>0.05$	6.7 (0.7 to 13.3), $P<0.05$
Vitality	46.5 (12.4)	49.1 (10.5)	54.2 (14.2)[a]	49.9 (10.6)	54.9 (11.5)	52.1 (8.7)	7.7 (8.9)	0.6 (5.6)	8.3 (7.4)	3.0 (8.6)	7.1 (3.2 to 11.0), $P<0.001$	5.3 (1.0 to 9.6), $P<0.05$
Bodily Pain	53.8 (13.3)	55.2 (9.4)	52.7 (12.5)	51.3 (9.0)	52.4 (11.2)	51.1 (9.8)	–1.1 (10.8)	–4.3 (8.8)	–1.4 (9.1)	–4.1 (13.0)	3.2 (–2.0 to 8.4), $P>0.05$	2.7 (–3.4 to 8.8), $P>0.05$
Physical Functioning	45.6 (10.7)	44.9 (8.2)	51.9 (14.7)[a]	43.7 (10.0)	49.6 (12.2)	44.7 (8.3)	6.2 (10.3)	–1.4 (4.8)	4.0 (8.7)	–0.1 (6.6)	7.6 (3.4– to 1.9), $P<0.001$	4.1 (–0.1 to 8.3), $P<0.05$

CON: control group; EXP: experimental group.

[a]Significant difference in the rate of change (baseline to eight-week follow-up) in the outcome measure between treatment options (experimental vs. control) ($P<0.05$).

Table 3. Hospital Anxiety and Depression Scale, Profile of Mood States and Stroke Awareness Questionnaire scores at baseline, eight-week follow-up, and 12-month follow-up for the experimental and control groups. Data are reported as mean (SD) of groups, mean (SD) difference within groups, and mean (95% CI) difference between groups with *P* values.

	Outcome	Groups						Difference within groups				Difference between groups	
		Baseline		Eight-week follow-up		12-month follow-up		Eight-week follow-up minus baseline		12-month follow-up minus baseline		Eight-week follow-up adjusted for baseline	12-month follow-up adjusted for baseline
		EXP	CON	EXP	CON	EXP	CON	EXP	CON	EXP	CON	EXP – CON	EXP – CON
Hospital Anxiety and Depression Scale	Anxiety	6.2 (4.0)	5.9 (3.1)	5.3 (2.9)	5.4 (3.8)	5.7 (4.0)	5.5 (3.1)	–0.8 (2.5)	0.7 (3.5)	–0.8 (9.7)	–0.9 (2.6)	–1.5 (–3.2 to 0.2), *P*>0.05	0.1 (–1.4 to 1.6), *P*>0.05
	Depression	4.1 (4.1)	3.9 (3.5)	3.3 (2.9)	3.9 (3.0)	3.5 (3.7)	3.6 (3.2)	–0.8 (2.5)	0.2 (2.6)	–0.2 (3.1)	–0.6 (3.0)	–1.0 (–2.4 to 0.4), *P*>0.05	0.4 (–1.3 to 2.1), *P*>0.05
Profile of Mood States	Vigor	9.5 (6.4)	9.2 (5.6)	11.7 (6.6)	10.8 (4.3)	11.9 (6.0)	12.4 (3.8)	2.4 (4.8)	2.0 (4.7)	2.4 (5.6)	3.5 (5.4)	0.5 (–2.1 to 3.1), *P*>0.05	–1.1 (–4.1 to 2.0), *P*>0.05
	Depression	3.4 (5.1)	4.7 (7.9)	2.3 (3.5)	4.3 (7.2)	3.6 (4.4)	3.3 (5.1)	–1.1 (3.6)	–0.4 (3.4)	1.5 (5.1)	–1.5 (5.3)	–0.7 (–2.6 to 1.3), *P*>0.05	3.0 (0.1 to 5.9), *P*<0.05
	Confusion	3.2 (3.2)	3.7 (5.6)	3.5 (4.1)	3.8 (4.5)	4.4 (3.3)	3.3 (3.4)	0.3 (2.4)	0.3 (3.0)	1.4 (2.9)	–0.1 (3.4)	0.0 (–1.5 to 1.5), *P*>0.05	1.5 (–0.3 to 3.2), *P*>0.05
	Tension	4.3 (4.3)	4.5 (5.1)	4.0 (4.7)	3.9 (4.7)	2.7 (2.7)	4.7 (3.8)	–0.3 (3.7)	–0.6 (3.5)	1.2 (4.5)	–1.4 (3.7)	0.3 (–1.6 to 2.3), *P*>0.05	2.6 (0.3 to 4.9), *P*<0.05
	Anger	2.4 (4.0)	3.7 (6.8)	3.0 (5.2)	3.0 (5.5)	4.1 (6.0)	2.9 (5.5)	0.7 (3.5)	–0.6 (3.1)	3.4 (7.7)	–0.8 (4.6)	1.3 (–0.5 to 3.1), *P*>0.05	4.3 (0.8 to 7.7), *P*<0.05
	Fatigue	6.1 (6.1)	4.4 (5.3)	5.6 (6.4)	4.6 (4.3)	4.7 (4.1)[a]	6.8 (4.3)	0.2 (4.4)	0.6 (4.2)	3.4 (3.9)	3-0.2 (5.3)	–0.4 (–2.7 to 2.0), *P*>0.05	3.6 (1.0 to 6.2), *P*0<0.05
Stroke Awareness Questionnaire	Number of correct answers	7.0 (1.8)	6.9 (1.9)	8.0 (1.2)	7.2 (1.1)	7.7 (1.4)	6.8 (1.6)	1.0 (1.5)	0.3 (1.9)	0.7 (1.5)	0.2 (1.8)	0.7 (–0.2 to1.7), *P*>0.05	0.4 (–0.5 to 1.4), *P*>0.05

CON: control group; EXP: experimental group.

[a]Significant difference in the rate of change (eight-week to 12-month follow-up) in the outcome measure between treatment options (experimental vs. control) (*P*< 0.05).

Table 4. Mean (±SD) scores from the International Physical Activity Questionnaire. Values are reported for the experimental and control group during the follow-up assessments (eight-week and 12-month follow-up).

Outcome	Eight-week follow-up			12-month follow-up		
	EXP	CON	EXP + CON	EXP	CON	EXP + CON
Leisure time_walk activity (min/wk)	410 (463)	366 (430)	389 (443)	314 (412)	161 (402)	241 (411)[a]
Leisure time_ moderate activity (min/wk)	328 (376)	105 (249)	221 (337)	226 (587)	94 (278)	163 (465)
Leisure time_vigorous activity (min/wk)	494 (631)	127 (587)	342 (626)	342 (928)	102 (339)	222 (701)[a]
Total leisure time activity	1232 (952)	585 (788)	911 (818)	958 (1481)	485 (985)	731 (1066)[a]
Sitting time (min/wk)	2161 (1091)	2298 (1113)	2227 (1092)	2547 (1348)	2649 (1119)	2595 (1231)[a]

CON: control group; EXP: experimental group;
[a]Significant difference in outcome measures between eight-week and 12-month follow-up assessments ($P < 0.05$).

Discussion

The current study demonstrates that participation in an eight-week exercise and education programme soon after TIA or mild/non-disabling stroke diagnosis may elicit improvements in psychosocial health. In this study, the overall Physical Component Score increased as a result of exercise participation (5%). Individuals randomized to the exercise programme also reported increases in their perceived Vitality (14.2%), Physical Functioning (12.2%), Role Physical (10.0%), and Global Health (9.7%). These findings support past research that has previously demonstrated the utility of the SF-36 in monitoring perceived improvements in patients diagnosed with stroke,[21,22] particularly with the subscales of Vitality and General Health.[21] As physiological improvements (blood pressure and blood lipid profile, body composition, aerobic fitness) were also reported for this participant sample,[2,5] it is likely that the perceived improvements in these SF-36 physical domains were directly related to perceived changes in physical appearance and overall fitness.[23] Encouragingly, the improvements observed at the eight-week follow-up assessment for the SF-36 (Physical Component Score, Vitality, Physical Functioning, Role Physical, Global Health) were maintained to the 12-month follow-up period (Table 2). This is relevant as for an individual to sustain behaviour change, they must continue to engage in lifestyle modifications once the stimulus (i.e. the exercise and education programme) has been removed.

The education sessions were constructed in line with the health belief model for behaviour change, and focused on stroke prevention, nutrition, blood pressure, adherence to medication, and stress management. Participants randomized to the experimental group demonstrated a greater awareness of the signs, symptoms, and risk factors associated with stroke (Table 1), although it was not conclusive that this was directly related to their involvement in the exercise and education programme. Previous research has demonstrated that almost 40% of patients are unaware of the signs, symptoms, and risk factors for stroke,[24] while 46% of patients with three or more risk factors do not perceive themselves to be at risk from stroke.[25] As the time to treatment is paramount in TIA and stroke, and as those that experience a TIA are a high risk group for recurrent events,[26] it is evident that individuals need to be educated to seek appropriate medical attention when stroke symptoms arise.[27]

Participants randomized to the exercise programme reported a large decrease in perceived Fatigue (POMS) between the eight-week and 12-month follow-up assessment (–16% vs. +33%, for EXP and CON, respectively). Fatigue is a

frequent and often disabling post-stroke sequelae.[28] It is likely that the levels of fatigue observed at the eight-week assessment reflects a combination of the usual fatigue associated with stroke and the sustained effort associated with participating in an exercise intervention. At 12 months, the lower perception of fatigue for the experimental group likely reflects their reduced participation in leisure time activities and increased sitting behaviour (Table 4).

As physical inactivity and sedentariness are two factors that increase the risk of stroke and TIA,[26] complementary strategies need to be considered within the follow-up period to ensure appropriate daily levels of physical exertion are achieved. Previous research has regularly demonstrated that physical activity[29,30] and self-regulatory resources[31] typically decline if no follow-up support is provided. As such, the question of how to foster and to assess the long-term maintenance of all of the implemented outcome measures requires further consideration.[32] For example, future research should consider the benefits of including 'booster' sessions in the follow-up period to assist in the promotion and maintenance of exercise and other lifestyle strategies beyond the initial treatment.[33] The inclusion of 'booster' sessions, such as telephone-delivered intervention sessions, have been shown to improve action planning, self-efficacy, and satisfaction within the postrehabilitation phase.[32]

The exercise and education programme had no statistical influence on participants' short- or long-term Mental Component Score from the SF-36 (Table 2). Similar findings were observed for the Hospital Anxiety and Depression Scale (no change in anxiety or depression scores) and the Profile of Mood States (no change in confusion, tension, or anger scores). Previous research has suggested that some SF-36 subscales, especially the scales for General Health and Social Functioning, have limited reliability and validity when administered to stroke patients, and that the two summary scores (Physical and Mental Component Score) may inadequately reflect stroke patients' physical and mental health.[34,35] It is noteworthy, however, that the trial was not powered to identify statistical differences in these variables. The lack of power and limited sample size means that the generalizability of the study findings may be questioned. Future research should consider implementing a larger randomized controlled trial, with sufficient statistical power to detect differences in these informative psychosocial markers.

It is important to highlight that the specific design of the intervention may be considered to be a limiting factor in determining the major contributor to the observed changes in psychosocial health outcomes. As the intervention was a composite of both exercise and education, it is difficult to distinguish whether the changes in psychosocial markers were resultant on an increase in structured physical activity (exercise effect), improved education (educational effect), or a combination of both.

In conclusion, early engagement in an exercise and education programme may lead to some perceived psychosocial benefits for TIA and mild/non-disabling stroke patients. The positive changes in perceived physical health (Physical Component Score, Physical Functioning, etc.) are in keeping with past research into the physiological effects of early exercise engagement. Importantly, some of the evident short-term benefits were shown to be maintained for 12 months, lending support to the development and implementation of a lifestyle-modification programme for TIA and mild/non-disabling stroke patients.

Clinical message

- Early exercise engagement has psychosocial benefits for individuals diagnosed with TIA or mild/non-disabling stroke.
- Improvements in perceived health and well-being (Vitality, Physical Functioning, Global Health) may be reported on completion of an exercise and education programme.
- Improvements in perceived health and well-being (Vitality, Physical Functioning, Global Health) may be maintained for 12 months following an exercise and education programme.

Conflict of interest

The author declares that there is no conflict of interest.

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