Circuit class therapy or 7-day week therapy for increasing rehabilitation intensity of therapy after stroke (CIRCIT). A randomised controlled trial

Cover title: Circuit class and 7-day week therapy after stroke

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Abstract

Background and aims:

To determine the effectiveness of two alternative models of increased physiotherapy service delivery (7-day week therapy or group circuit class therapy 5 days a week) to usual care.

Method:

Three-armed randomised controlled trial with blinded assessment of outcome. People admitted with a diagnosis of stroke, previously independently ambulant and with a moderate level of disability were recruited. 'Usual care' was individual physiotherapy provided 5 days a week. 7-day week therapy was usual care physiotherapy provided 7 days a week. Participants in the circuit class therapy arm of the trial received physiotherapy in group circuit classes in two 90-minute sessions, 5 days a week. Primary outcome was distance walked on the 6-minute walk test at 4 weeks post-randomisation.

Results:

283 participants were randomised; primary outcome data were available for 259 (92%). In the 7-day arm participants received an additional 3 hours of physiotherapy and those in the circuit class arm an additional 22 hours. There were no significant between-group differences at 4 weeks in walking distance (p=0.72). Length of stay was shorter for 7-day (mean difference -2.9 days, 95% confidence interval [CI] -17.9 to 12.0) and circuit class participants (mean difference -9.2 days, 95% CI -24.2 to 5.8) compared to usual care, but this was not significant.

Conclusions: Both 7-day therapy and group circuit class therapy increased physiotherapy time, but walking outcomes were equivalent to usual care.

Clinical Trial Registration:

URL:https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12610000096055 Unique identifier: ACTRN12610000096055.

Introduction

People in hospital after stroke in Western countries receive between 15 and 60 minutes of physiotherapy per day (1, 2). Evidence from clinical trials (3, 4) and neuroplasticity literature (5, 6) suggests that more therapy time will lead to improved functional recovery after stroke. However, this hypothesis has not been tested within a robust clinical trial to date, and the most effective and cost-effective means of providing increased therapy time is not known. Two alternative models for increasing the amount of physiotherapy are group circuit class therapy and 7-day week therapy.

Only around 30% of rehabilitation facilities in Australia currently provide weekend physiotherapy services (7). Two randomised controlled trials (RCTs) of additional Saturday physiotherapy services (6-days versus 5-days week therapy) have been conducted. In both, participants had mixed diagnoses, with between 10% (8) and 16% (9) of the sample diagnosed with stroke. In both trials small (3 and 2 days respectively), but non-significant, reductions in length of hospital stay were found. In one trial, participants who received 6-day week therapy were also found to have greater independence at discharge from hospital (9), although the mean between group difference of 2 points on the Functional Independence Measure (FIM) was well below the minimal clinically important difference of 22 points (10). There are however, no RCTs testing the effectiveness of 7-day week therapy compared to 5-day week therapy for people with stroke.

Group circuit class therapy involves stroke survivors receiving physiotherapy services in a group setting with a ratio of staff to participants of no more than 1:3. With the group nature of the approach, people with stroke are able to spend more time in physiotherapy sessions within existing staffing levels. Circuit class therapy has been shown to be effective in increasing therapy time (11) for people receiving inpatient rehabilitation after stroke. To date there are eight published RCTs investigating the effectiveness of circuit class therapy, four

involving participants >6 months after stroke, and four involving participants in the subacute phase (< 6 months post-stroke) (3). In the one RCT involving participants receiving inpatient rehabilitation (12), participants received circuit class therapy in addition to usual care physiotherapy. All other trials were conducted in outpatient settings and compared circuit class therapy to no therapy, or sham intervention. These trials were recently synthesised in a meta-analysis by Veerbeek et al. (3), who showed a significant, homogenous effect size in favour of circuit class therapy for improving walking capacity (distance walked on the 6-minute walk test), and, to a lesser extent, walking speed. The effect of circuit class therapy on improving walking ability was strongest for people at least 6 months post stroke.

Aims

Given ongoing pressures to improve the efficiency and cost-effectiveness of models of stroke care, we wanted to examine the effectiveness of group circuit class therapy *as an alternative model* of physiotherapy service delivery to people receiving in-hospital rehabilitation in the subacute post-stroke period, as well as test the comparative effectiveness of 7-day versus 5 days a week therapy. To this end, the aim of this trial was to investigate the effectiveness, in terms of physiotherapy time and clinical outcomes, of two alternative models of increasing physiotherapy dosage after stroke.

The primary hypotheses of the study were:

(1) providing physiotherapy in group circuit classes (5 days a week) will lead to improved walking ability compared to usual care physiotherapy (5 days a week) at 4 weeks post-randomisation (primary outcome)

(2) providing 7-day a week physiotherapy will lead to improved walking ability compared to usual care physiotherapy at 4 weeks post-randomisation, and

(3) providing physiotherapy in group circuit classes (5 days a week) will lead to improved walking ability compared to 7-day a week physiotherapy at 4 weeks post-randomisation.

Results of the cost-effectiveness sub-study will be the topic of a future paper.

Methods

This was a 3-armed RCT with concealed allocation and blinded assessment of outcome. A computer-generated randomisation sequence was blocked to ensure equal numbers for each arm in each block of 15. Randomisation was concealed by use of a central telephone service administered by staff not involved in the trial. Participants were recruited from one of five stroke rehabilitation centres in three states within Australia. Trained assessors who were unaware of participant group allocation assessed participants at baseline, 4 weeks, 3 and 6 months post-randomisation. The trial was registered with the Australian and New Zealand Trial Registry (ACTRN12610000096055). Ethical approval was obtained from the University of South Australia Human Research Ethics Committee (Protocol P380-09) and from the ethics committees governing each recruitment site.

Participants

Full details of the trial protocol are published elsewhere (13). Briefly, participants were people with stroke admitted to inpatient rehabilitation facilities with moderate disability (FIM total score between 40 and 80 points or motor subscale score of between 38 and 62 points) (14). Either participants provided informed consent themselves, or proxy consent was obtained from an appropriate third party.

Interventions

From the time of admission to rehabilitation until randomisation, participants received usual care physiotherapy. From the next working day after randomisation, participants received the allocated model of physiotherapy service delivery for the duration of their inpatient stay. The comparison of interest in this trial was the amount of physiotherapy time provided to people with stroke (13). Therefore the content of therapy sessions was similar between intervention

arms, and the key differences were the time scheduled for therapy and the mode of therapy delivery (individual versus group).

Usual care therapy

Participants randomised to usual care received physiotherapy according to local site standard practice. For three of the five sites, this was individual sessions provided 5 days a week. At two of the recruitment sites usual care involved a combination of daily individual physiotherapy sessions augmented for some people by group physiotherapy provided between 1 and 4 times a week. In two of the five sites, usual care therapy included weekend therapy for some, but not all patients.

7-day week therapy

Participants randomised to receive 7-day a week therapy received physiotherapy on both Saturday and Sunday for the duration of their inpatient stay, in addition to the usual 5 days of the working week. The duration of therapy sessions provided on the weekend was matched to that provided during the preceding week. Additional staffing was required to deliver the 7-day week therapy.

Circuit class therapy

Participants received circuit class therapy for up to 3 hours per day, usually in two 90-minute sessions, morning and afternoon. Circuit class therapy involved groups of at least three (and up to six) participants and was staffed by physiotherapists, assistants and physiotherapy students with no more than one staff member to three participants. Where there were less than three trial participants randomised to the circuit class arm of the trial at any given time, non-trial patients with mobility issues were included in circuit class therapy sessions. Training of trial staff in the provision of circuit class therapy included a half-day workshop conducted at each recruitment site before commencement of the trial. A written manual and ongoing advice and support was provided by the trial manager. Circuit class therapy sessions were not

run according to a strict protocol. Training was intended to guide therapists in how best to adapt their usual practices to providing therapy within the semi-supervised, group nature of circuit class therapy sessions. Therapists were encouraged to prescribe exercises and activities that were task-specific, included part- as well as whole- practice of tasks, with an emphasis on repetition and feedback. Circuit class therapy was provided within existing staffing levels at all sites.

Fidelity measures

We monitored the integrity of the interventions provided by asking physiotherapists to record details of each therapy session at the end of each session. Therapy data included the duration of the session, reasons for missed or shortened sessions, number of staff involved, and in the case of circuit class therapy, the total number of patients per class. Therapists' recall of time spent in specific activities within therapy sessions has been proven inaccurate (15). Therefore we collected data on the content of therapy sessions by video-taping therapy sessions of all available participants on selected days during four time periods (16). The time periods and specific days on which therapy sessions were videoed were based on research assistant staff availability.

Outcomes

All outcomes were assessed by a trained assessor who was blinded to group allocation. All assessors were physiotherapists who received specific training in the outcome measures collected. To preserve blinding, all assessments took place in a location remote to the usual therapy area within the rehabilitation centres. Once discharged, participants returned to the rehabilitation centre for assessments. All outcomes were assessed at baseline, 4 weeks after randomisation, and at 3 and 6 months after randomisation (with the exception of the Stroke Impact Scale (SIS) and the Australian Quality of Life (AQoL) scale which were not collected at baseline).

Demographic data collected included gender, age, time of stroke, history of previous stroke and other co-morbidities, side of stroke lesion, Oxfordshire Stroke Classification, cognitive function (Mini-mental State Assessment) and screening for visual inattention (star cancellation test).

Primary outcome

The primary outcome measure was the 6-minute walk test using a standard protocol at 4 weeks post-randomisation. The 6-minute walk test is a valid and reliable measure of walking capacity (17) and previous trials have demonstrated that circuit class therapy is particularly effective for improving walking capacity after stroke (3). Participants were provided with physical assistance of up to 2 people to complete the 6-minute walk test. Where the test was unable to be attempted for safety reasons, a score of 0m was recorded.

Secondary outcomes

Walking speed – was measured using a stop watch over the middle 5 metres of a 9 metre walkway (18). The first 9 metres walked in the 6-minute walk test was used to assess walking speed.

Degree of independence in walking – was measured using the Functional Ambulation Classification (FAC) (19). This ordinal scale rates how much physical assistance a person needs to safely walk from a score of 0 (2 people required to assist, or not safe to attempt) to 5 (independent and safe, including over outdoor surfaces and stairs).

Independence in activities of daily living was assessed using the FIM (20) which, according to the guidelines, was scored by the multidisciplinary team.

Arm function was assessed using the Wolf Motor Function test (WMFT), mean time score (21).

Self-reported physical function – was assessed using the SIS physical subscale (22).

Length of hospital stay – was measured by the number of overnight stays in the rehabilitation facility.

Health related quality of life was measured using the AQoL tool (23).

Complications and adverse events were monitored throughout the trial for all participants. An independent data safety monitor reviewed unblinded data with regard to adverse events and complication rates annually during the trial.

Resource utilisation data, including costs of providing therapy, equipment, length of stay and other costs were collected for the purposes of economic evaluation which will be reported separately.

Sample size

Based on a previous RCT, we predicted a between group difference of 116m (SD 112m) on the 6minWT between the circuit class therapy and usual care arms of the trial (13). We conservatively estimated the difference in the 7-day week therapy arm compared to usual care would be half that seen in the circuit class therapy arm. Based on two-sided independent t-tests with Type I error set at 0.025 to allow for multiple testing, a sample size of 75 per arm was required to provide at least 80% power to test for differences between circuit class therapy and usual care, 7-day therapy and usual care and circuit class therapy and 7-day therapy. Importantly, this sample size was sufficient to detect the minimal clinically important difference of 50m on the 6mWT (24). Allowing for a 20% drop out rate, we aimed to recruit 282 participants.

Data analysis

Data were examined for normality using the Shapiro-Wilk test. As data for all outcome measures were not normally distributed at either baseline or 4 weeks, they were analysed using non-parametric statistics. To address the primary hypothesis of between group differences in walking capacity we conducted a Kruskal-Wallis test. Secondary analyses

included testing for between group differences at 4 weeks using the chi-squared statistic for the FAC categories, and Kruskal-Wallis tests for all other secondary outcomes. Linear mixed effects modelling was used to examine change scores between groups between baseline and 4 weeks for the 6-minute walk test, gait speed, FIM (total), FIM (motor), and WMFT (time score). In particular, the group-time interaction effect was used to formally test any intervention effect. Linear effects mixed modelling explicitly adjusts for baseline scores by modelling change scores for all participants. Analyses were first conducted with no imputation of missing data (reported). We then applied multiple imputation (Stata 13 mi command with multivariate normal approach), which did not alter the significance of the results. Analyses were conducted using SPSS Statistics 21 and Stata 13.

Results

Between July 2010 and June 2013, 283 participants were randomly assigned to usual care (n=94), 7-day week therapy (n=96) and circuit class therapy (n=93). During this time approximately 1,031 people with stroke were admitted to the participating rehabilitation centres. Reasons for exclusion included: admission FIM score outside of the eligible range (n=489); not independent in walking prior to stroke (n=12); did not consent (n=135); medically unstable (n=32); and planned length of rehabilitation stay of less than 2 weeks (n=23). The reason for exclusion was not documented in 57 cases. Of the 283 included participants, 13 did not complete the 4-week assessment (5 lost to follow-up, 8 withdrawals due to death [n=2], poor health [n=2] or refused assessment [n=4]), see Figure 1.

Intervention fidelity

Over the 4-week period, participants in the usual care arm received a mean of 15.1 ± 6.7 hours of physiotherapy, 7-day week therapy participants received a mean of 18.2 ± 6.0 hours of physiotherapy and circuit class therapy participants received a mean of 37.3 ± 12.5 hours of physiotherapy. These differences were significant between all three groups ($p<0.001$ for

circuit class therapy v usual care and circuit class therapy v 7-day therapy; p=0.044 for usual care v 7-day therapy), and are reported in full elsewhere (25). The average number of participants per circuit class session was 3.9 ± 1.5. Four usual care participants received additional weekend therapy (mean 1.65 [1.23] hours total weekend therapy per participant). A total of 79 therapy sessions (34 usual care and 45 circuit class therapy) were videoed. Details about the content of therapy sessions are published elsewhere (15,16).

There were 13 documented cases of variation to the intervention protocol. Reasons included reducing frequency of physiotherapy input while awaiting residential care placement (n=6), or on medical orders (n=1), infectious conditions preventing group therapy (n=2), or not tolerating the group environment (n=1). In the circuit class arm of the trial, 3 participants only received one circuit class therapy session per day due to either fatigue (n=2) or to allow adequate time for other therapies (n=1).

Table 1 presents the demographics of the sample. Groups were balanced at baseline in regards to age, sex, stroke type, lesion location and FIM scores. The mean time between stroke onset and randomisation was 28.1 ± 21.5 days and was similar across groups.

Adverse event data are reported in Table 1. The data safety monitor determined that no serious adverse events were related to the intervention, with the exception of one calf haematoma of unknown cause. Despite the semi-supervised nature of the circuit class sessions, there were only 4 falls during therapy sessions reported in this group. None of the reported falls in therapy time for any participants caused injury requiring intervention.

Double data entry was conducted for a randomly selected sample of participants (10% of total sample). There were 13 errors identified within the 1860 data points re-entered (0.7% error rate).

Outcomes

At baseline 75 (26.6%) participants could not complete the 6-minute walk test, even with the assistance of 2 people. At 4 weeks, 13 (5.0%) could not complete the assessment. This contributed to 6-minute walk test data being highly skewed at both time points. Table 2 summarises all outcome measures.

Between group differences at 4 weeks post-randomisation

At 4 weeks, distances walked on the 6-minute walk test for each participant group were: usual care median 105.5m (IQR197.5), 7-day median 108.0m (IQR 145.0), circuit class therapy median 116.0m (IQR 179.0). There were no significant between group differences at 4 weeks. Similarly, there were no significant differences between groups at 4 weeks in walking speed, independence in walking (FAC), independence in activities of daily living (FIM), arm function (WMFT timed tasks), self-reported physical function (SIS-physical) or quality of life (AQoL), see Table 2. Length of rehabilitation stay did not differ significantly between groups (p=0.643), although compared to usual care, participants in the 7-day arm of the trial had a mean 2.9 days shorter length of stay (95% CI -17.9 to 12.0) and participants in the circuit class arm of the trial had a mean 9.2 days shorter length of stay (95% CI -24.2 to 5.8).

Change over time and between group differences in change scores

Results of the linear mixed effects model for the 6-minute walk test found that neither of the two interaction terms (7 day versus usual care, p=0.899; circuit class versus usual care, p=0.344) were statistically significant, implying no intervention effect. When the interaction terms were removed from the model, a statistically significant time effect demonstrated that participants in all three groups walked significantly further on the 6-minute walk test at 4 weeks compared to baseline ($p<0.001$), however, there were no statistically significant differences between groups. Similarly, the interaction effects for gait speed, FIM total, FIM motor and WMFT time scores were not statistically significant ($p>0.05$), implying no effect

of the intervention. However, for each of these measures, all groups improved significantly between baseline and 4 weeks ($p<0.001$).

Discussion

A recent large meta-analysis of clinical trials (3) and a meta-regression analysis of individual data from clinical trials (4) both concluded that more therapy time would lead to improvements in stroke recovery. Our study is the only adequately powered, high quality randomised controlled trial that has tested this assumption in a clinical environment. It is also the first RCT to examine the use of group circuit class therapy as an alternative model of service delivery, and the first RCT of 7-day week physiotherapy for people receiving in-hospital rehabilitation after stroke. Despite the substantial increase in therapy time (an extra 3 hours over 4 weeks for 7-day week participants and an extra 22 hours over 4 weeks for circuit class therapy participants) there were no differences between groups in walking ability, arm function or activities of daily living at 4 weeks post-randomisation. This neutral trial result has important implications for clinical practice.

The results of a meta-analysis of 20 RCTs of a range of therapy interventions published by Kwakkel (26) suggested there was a threshold of at least an extra 16 hours of additional therapy time provided in the first 6 months after stroke that was needed to show improvement in outcome. In a recent update of this meta-analysis, including 80 trials of different physiotherapy dosage this threshold estimate was adjusted to a minimum of 17 hours (3). In our study this minimum threshold of increased therapy time was not just met but exceeded, with no apparent benefit in functional outcome. Two factors may go some way toward explaining this unexpected result.

Firstly, the influence of time alone on recovery of function may have confounded results. Subgroup analyses within the meta-analysis by Veerbeek et al. (3) showed that the effect of increased therapy time provided less than 6 months after stroke was not significant for many

outcomes (activities of daily living, walking capacity, arm function), although a significant effect remained for walking speed. Therefore, the evidence for more therapy time leading to improved functional outcomes is strongest for stroke survivors who are more than 6 months post-stroke. Our participants were on average 28 days post-stroke at baseline. The rate of recovery after stroke appears to be fastest in the first 3 to 6 months (27, 28). The relative influence of time alone and therapy input is difficult to ascertain in rehabilitation trials where all participants receive some form of therapy and there have been very few trials conducted early after stroke involving a control group which receives no therapy input. However, a recent Cochrane review (29) included 55 such trials, 44 of which were conducted in China. In all of these trials, significant benefit was found in favour of those receiving rehabilitation. While there were considerable risks of bias noted in these trials, this does provide some evidence that rehabilitation provides additional benefit above natural recovery. The meta-data review by Lohse and colleagues (4) supports this view. In their model, they found that amount of therapy was a significant predictor of outcome, regardless of timing post-stroke (4). Clearly, the relative influences of time alone and therapy input on post-stroke recovery are likely to be complex. Our trial was not powered to undertake sub-group analyses. The interrogation of multiple large, robust datasets using meta-analytical approaches are required if we are to better understand this relationship.

The variability in our study sample may have also influenced results. As we were aiming to maximise the generalizability of the results, we wanted to determine whether circuit class therapy or 7-day week therapy was beneficial for most stroke survivors in rehabilitation. Therefore, our inclusion and exclusion criteria were kept deliberately broad and our final sample was more heterogeneous and lower functioning than participants in other circuit class therapy (3) or 7-day week therapy trials (8, 9).

The content of therapy sessions – that is, what participants actually did during therapy time – was a likely factor in the observed outcome of the trial. The video-taped therapy sessions collected as a measure of trial fidelity were analysed in detail and have been published elsewhere (15, 16). As expected the content of each therapy session was similar in terms of the types of activities and exercises undertaken by the participants. However, despite the significantly longer average duration of circuit class therapy sessions (73 minutes compared to 35 minutes for usual care sessions), participants spent the same amount of time practising walking; 12 minutes in the usual care sessions and 11 minutes in the circuit class therapy sessions. The extra therapy time in circuit classes was spent resting (additional 14 minutes), in activities involving the affected upper limb (additional 5 minutes), in activities performed in a sitting or lying position (additional 9 minutes), and in standing activities (additional 5 minutes). While this is only a snapshot of all of the therapy sessions provided within the trial, it suggests that the dose of walking practice may have been similar between the arms of the trial. Therefore, while circuit class therapy was effective at increasing the amount of time spent in physiotherapy sessions, it did not appear to be effective at increasing the amount of time spent practicing walking. Further work is also required to optimise the intensity (amount of practice) that stroke survivors are able to achieve during physiotherapy sessions.

Evidence from studies investigating the drivers of positive neuroplasticity suggest that the *type* of practice is as important as the amount of practice – salience, relevance, variety and the right level of difficulty are all essential components (30). While both circuit class therapy and 7-day week therapy can increase the *opportunities* for an increase in the amount of practice, we also need to know more about what the most effective exercises and activities are for stroke survivors to perform during physiotherapy sessions for promoting recovery of function, and how to optimally tailor and progress these exercises according to individual need. The semi-supervised nature of circuit class therapy presents unique challenges to

therapists to be able to prescribe exercises and activities for their patients that are sufficiently challenging enough, yet safe to perform semi-independently.

Our trial is the first to examine the effectiveness of 7-day week therapy services for stroke survivors within a RCT. We found equivalent benefit in this approach in terms of walking ability, arm function or length of hospital stay. It is important to note this trial was conducted within sub-acute rehabilitation facilities and participants were on average 28.1 (21.5) days post-stroke at the time of randomisation. The benefit of providing additional weekend physiotherapy services to people early after stroke remains largely untested, but may be an important factor in increasing therapy intensity early after stroke (31). The question of rehabilitation services in general being available over the weekend (for discharge/admission) and the potential value for patients in terms of increasing activity were beyond the scope of this trial.

Strengths and limitations

While there were no statistically significant differences between groups, participants in the circuit class arm of the trial walked further on the 6-minute walk test compared to both usual care and 7-day week participants. This suggests the possibility that our trial may have been under-powered. Our sample size calculations were based on the best available evidence about expected effect of circuit class therapy on walking capacity in the subacute period after stroke (12). However, these data were based on a single centre RCT, and included participants who were all able to walk at baseline (12). Therefore, our sample size may have been overly optimistic.

Few previous physiotherapy dosage studies have included detailed description of the content of physiotherapy sessions provided. The detailed analysis of the content of therapy provided within this trial (32) allowed further insights into the results. In all, an estimated 80 physiotherapists were involved in providing therapy in the trial, across five sites and three

states of Australia. Thus, the therapy provided can be considered generalizable to current practice in Australia.

As this was a trial delivered within existing service settings and physiotherapy practice, the content of the therapy sessions was not proscribed. The actual planning and prescription of activities and exercises was the responsibility of the treating therapists, all of whom were experienced practitioners. The research question was about the delivery model, not the content of the physiotherapy sessions. We aimed to answer the question "should circuit class therapy or 7-day week therapy be used as the primary mode of physiotherapy service delivery?" Based on the trial results, in regards to walking ability, we found that that neither circuit class therapy nor 7-day week therapy was superior to usual care physiotherapy. There are equivalent benefits, in terms of walking ability, arm function or length of stay, in providing therapy over 7-days, or in circuit classes for people receiving rehabilitation early after stroke. Providing therapy in group circuit classes and over 7-days does lead to a significantly greater amount of physiotherapy time being provided, but increasing time spent in therapy alone does not translate to improvements in outcome. This is possibly because the extra therapy time did not translate to more time in walking practice during, and outside of therapy sessions. Close attention needs to be paid to the type and level of activities and exercises that stroke survivors perform during therapy sessions if functional outcome is to be improved.

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Conflict of interest

The authors declare no conflicts of interest.

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Table 1 Baseline characteristics of participants.

Characteristic N(%) or mean ± SD, range	**Whole sample (n=283)**	**Usual care (n=94)**	**7-day week therapy (n=96)**	**Circuit class therapy (n=93)**
Age (years)	69.9 ± 12.7	68.2 ± 13.5	71.9 ± 12.0	70.0 ± 12.9
	23 to 93	23 to 91	38 to 91	34 to 93
Males	167 (59.0%)	52 (55.3%)	59 (61.5%)	56 (60.2%)
Females	116 (41.0%)	42 (44.7%)	37 (38.5%)	37 (39.8%)
First stroke	229 (81.0%)	75 (80.6%)	78 (81.3%)	76 (83.5%)
Side of stroke lesion				
Left	119 (42.0%)	38 (40.4%)	41 (42.7%)	40 (43.0%)
Right	142 (50.2%)	46 (48.9%)	47 (49.0%)	49 (63.4%)
Brainstem	5 (1.8%)	3 (3.2%)	2 (2.1%)	0 (0%)
Combination	11 (3.9%)	4 (4.3%)	4 (4.2%)	3 (3.2%)
No lesion on imaging	3 (1.1%)	1 (1.1%)	2 (2.1%)	0 (0%)
Unknown	3 (1.1%)	2 (2.1%)	0 (0%)	1 (1.1%)
Stroke type (Oxfordshire Stroke Classification)		93	94	90
TACI	41 (14.5%)	15 (16.1%)	9 (9.6%)	17 (18.9%)
PACI	108 (38.2%)	31 (34.4%)	40 (42.6%)	37 (41.1%)
LACI	49 (17.3%)	16 (17.2%)	20 (21.3%)	13 (14.4%)
POCI	20 (7.1%)	11 (11.8%)	5 (5.3%)	4 (4.4%)
Haemorrhage	54 (19.1%)	18 (19.4%)	19 (20.2%)	17 (18.9%)
Unknown	11 (3.9%)	2 (2.2%)	1 (1.1%)	2 (2.2%)
Time between stroke and randomisation to trial	28.1 ± 21.5	28.7 ± 17.4	25.0 ± 17.2	30.9 ± 28.2
	5 to 197	8 to 121	6 to 133	5 to 197
Previous walking				

ability				
Independent	227 (80.2%)	75 (80.9%)	75 (78.1%)	77 (83.4%)
Independent with walking aid	55 (19.1%)	19 (20.2%)	21 (21.9%)	15 (16.3%)
Unilateral spatial neglect	54 (19.9%)	13 (14.4%)	19 (20.4%)	22 (25.0%)
Star cancellation test score ≤ 44				
MMSE	23.9 ± 5.7 1 to 30	24.7 ± 4.5 3 to 30	23.6 ± 6.0 1 to 30	23.7 ± 5.9 6 to 30

Table 2 Primary and secondary outcomes at baseline

Characteristic N(%) or mean ± SD, range	**Whole sample (n=283)**	**Usual care (n=94)**	**7-day week therapy (n=96)**	**Circuit class therapy (n=93)**
Primary outcomes				
6-min walk test (m) Median ± IQR, range	33.4 ± 106.0 0 to 400	31.3 ± 120.0 0 to 280	38.8 ± 93.2 0 to 360	33.0 ± 110.4 0 to 400
Secondary outcomes				
Gait speed (m/s) Median ± IQR, range	0.17 ± 0.43 0 to 1.20	0.14 ± 0.47 0 to 1.20	0.17 ± 0.36 0 to 0.91	0.16 ± 0.44 0 to 1.00
Functional Ambulation Classification n (%) n=283		1.1 ± 1.3 1.2 0 to 5	1.1 ± 1.4 1.2 0 to 5	1.0 ± 1.4 0 to 4
Score 0	150 (53.0%)	47 (50.0%)	50 (50.2%)	53 (57.0%)
Score 1	28 (9.9%)	7 (7.4%)	12 (12.5%)	9 (9.7%)
Score 2	48 (17.0%)	22 (23.4%)	15 (15.6%)	11 (11.8%)
Score 3	40 (14.1%)	14 (14.9%)	12 (12.5%)	15 (15.1%)
Score 4	15 (5.3%)	3 (3.2%)	6 (6.3%)	6 (6.5%)
Score 5	2 (0.7%)	1 (1.1%)	1 (1.0%)	0 (0%)
FIM total (n=283) Median ± IQR, range	66.0 ± 22.0 40 to 112	67.5 ± 23.5 40 to 103	65.0 ± 22.5 40 to 112	65.0 ± 18.0 40 to 98
FIM motor (n=283) Median ± IQR, range	40.0 ± 22.0 15 to 78	40.8 ± 13.4 15 to 68	40.4 ± 13.6 16 to 78	40.2 ± 12.1 18 to 64
WMFT mean time	57.9 (108.9)	45.9 (90.2)	66.6 (107.3)	63.0 (109.6)

(secs) n=270 Median ± IQR, range	1.4 to 121	1.37 to 121	1.8 to 121	1.72 to 121
Adverse events				
All adverse events	49	12	16	21
Serious adverse events	16	6	6	4
Falls during physiotherapy sessions	8	0	4	4
Total number of falls	18	1	7	10

Table 3 Outcomes at 4 weeks for participants randomised to usual care, 7-day week therapy or circuit class therapy. Means and standard deviations

	Usual care therapy	7-day week therapy	Circuit class therapy	p value (Kruskal-Wallis test)
Primary outcome				
6-min walk test (m) (n=261) Median ± IQR, range	105.5 ± 197.5 0 to 99.9	108.0 ± 145.0 0 to 563	116.0 ± 179.0 0 to 450	0.997
Secondary outcomes				
Gait speed (m/s) (n=258) Median ± IQR, range	0.48 ± 0.67 0.0 to 2.08	0.42 ± 0.54 0 to 2.77	0.48 ± 0.60 0 to 1.66	0.967
FAC n (%) (n=259)				
Score 0	16 (18.2%)	13 (14.8%)	18 (21.7%)	0.709*
Score 1	7 (8.0%)	4 (4.5%)	4 (4.8%)	
Score 2	15 (17.0%)	10 (11.4%)	10 (12.0%)	
Score 3	10 (11.4%)	17 (19.3%)	16 (19.3%)	
Score 4	24 (27.3%)	24 (27.3%)	17 (18.3%)	
Score 5	16 (18.2%)	20 (22.7)	18 (21.7%)	
FIM total score (n=261)	96.0 ± 36.0 49 to 126	100.0 ± 33.5 41 to 125	93.0 ± 35.8 46 to 125	0.439
FIM motor score (n=261)	67.5 ± 33.0 23 to 93	69.0 ± 30.0 22 to 91	64.0 ± 33.8 23 to 91	
WMFT (mean time) (secs) (n = 248) Median ± IQR, range	27.6 (109.0) 2 to 121	12.6 (65.0) 2 to 121	16.8 (99.0) 2 to 121	0.45
SIS – Physical Domain score (n = 206) Median ± IQR, range	49.0 (41.4) 8.3 to 99.4	51.0 (39.0) 15.4 to 95.9	45.9 (36.9) 9.7 to 100	0.864
SIS – recovery score (% recovery) (n = 242)	50.0 (40.0) 0 to 90	50.0 (40.0) 10 to 100	50.0 (30.0) 0 to 100	0.681

Median ± IQR, range				
AQoL overall score (n = 241) Median ± IQR, range	0.24 (0.47) -0.2 to 1.0	0.2 (0.40) -0.2 to 1.0	0.22 (0.38) -0.3 to 1.0	0.991
LoS (actual discharge date) days (n=265) Median ± IQR, range	55.0 ± 49.0 14 to 240	45.0 ± 38.0 14 to 460	46.0 ± 38.0 13 to 118	0.643

*Chi-squared statistic

Figure 1 – CONSORT statement flow chart