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Title: Circuit class or seven day therapy for increasing intensity of rehabilitation after stroke.

Protocol of the CIRCIT trial.

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Conflicts of Interest Disclosures

None to declare

Key words:

Stroke, rehabilitation, therapy, clinical trial
Summary

Rationale There is strong evidence for a dose-response relationship between physical therapy early after stroke and recovery of function. The optimal method of maximizing physical therapy within finite health care resources is unknown.

Aims To determine the effectiveness and cost-effectiveness of two alternative models of physical therapy service delivery (7 day per week therapy services or group circuit class therapy over 5 days a week) to usual care for people receiving inpatient rehabilitation after stroke.

Design Multicenter, 3-armed randomized controlled trial with blinded assessment of outcomes.

Study A total of 282 people admitted to inpatient rehabilitation facilities after stroke with an admission Functional Independence Measure score within the moderate range (total 40-80 points or motor 38-62 points) will be randomized to receive one of three interventions; usual care therapy over 5 days a week, standard care therapy over 7 days a week, or group circuit class therapy over 5 days a week. Participants will receive the allocated intervention for the length of their hospital stay. Analysis will be by intention-to-treat.

Outcomes The primary outcome measure is walking ability (six-minute walk test) at 4 weeks post-intervention with 3 and 6 month follow-up. Economic analysis will include a costing analysis based on length of hospital stay and staffing/resource costs and a cost-utility analysis (incremental quality of life per incremental cost, relative to usual care). Secondary outcomes include walking speed and independence, ability to perform activities of daily living, arm function, quality of life and participant satisfaction.
Introduction

Following a stroke, getting enough physical activity-based therapy is essential to promote recovery of functional abilities (1) and to maintain cardiovascular and metabolic health (2). Despite this knowledge, studies around the world show that people receiving rehabilitation services after stroke spend very little time engaged in physical activity (3-5). Provision of rehabilitation services is expensive; it is therefore vital that novel methods of providing a greater amount of activity-based therapy are investigated for both effectiveness in terms of functional recovery, cost to service providers and cost-effectiveness. Circuit class therapy (CCT) – where people receive activity-based therapy in groups of up to 6 participants supervised by 1 to 2 staff members – has been shown to be a highly effective means of providing a greater amount of therapy time to people receiving inpatient stroke rehabilitation compared to traditional therapy, and has the potential to be a cheaper and more cost-effective option (6). While there is strong evidence supporting the effectiveness of CCT for improving walking ability in people later after stroke; (7) the effectiveness of this approach in inpatient rehabilitation facilities has yet to be established. In Australia, many rehabilitation centers are moving toward a 7 day a week model of therapy delivery to maximize therapy time (increase dosage), despite the lack of evidence of the effectiveness of this approach (8) and likely increase in costs involved. It is still unclear whether increased therapy delivered during the week will be more cost effective than therapy delivered across 7 days or whether either the clinical outcomes of such approaches will justify the additional resources required.

This aim of the CIRCIT (Circuit class therapy for Increasing Rehabilitation Intensity of Therapy after stroke) trial is to compare the effectiveness, costs and cost-effectiveness of different models of delivering a greater dosage of activity-based therapy to people after stroke. Our primary hypotheses are 1) providing CCT (5 days a week) will lead to improved walking ability compared to usual care therapy (5 days a week), 2) providing 7 day per week
therapy will lead to improved walking ability compared to usual care therapy, and 3) providing CCT (5 days a week) will lead to improved walking ability compared to 7-day week therapy. Our secondary hypothesis is that CCT will be cheaper and more cost-effective than 7-day week therapy. Further hypotheses relate to the impact of CCT and 7-day week therapy on the ability to perform activities of daily living (ADLs), arm function, quality of life and length of hospital stay.

**Study design**

CIRCIT is a 3-armed, multicenter pragmatic randomized controlled trial with blinded assessment of outcomes and six month follow-up. Within 1 week of admission to a rehabilitation facility (or 1 month after stroke onset) participants will be randomly allocated to receive one of 3 methods of physiotherapy service delivery:

1. Usual care therapy
2. 7 day per week therapy
3. CCT

Participants will receive the allocated form of physiotherapy service delivery from the day after randomization and for the duration of their stay in the rehabilitation facility. Therapy provided after discharge will be monitored, but not standardized. The trial will be run in at least 6 rehabilitation facilities in 2 Australian states. Figure 1 demonstrates the trial flow.

**Ethics**

Ethical approval has been received from the Human Research Ethics Committees of Flinders Medical Centre, Royal Adelaide Hospital and The Queen Elizabeth Hospital covering all recruitment sites in South Australia. Prior to the trial commencing at additional sites, all appropriate ethical approval will be obtained.

**Patient population – inclusion and exclusion criteria**
People admitted to a participating rehabilitation facility with a diagnosis of stroke (hemorrhagic or infarct) with a Functional Independence Measure (FIM) total score of between 40 and 80 points or motor subscale score of between 38 and 62 points will be invited to participate. Stroke survivors with moderate disability (defined by these FIM score ranges) show the greatest degree of functional recovery (9) and are most likely to benefit from increasing the dose of activity-based therapy. People who were not able to walk independently prior to their stroke for any reason will be excluded (prior use of a walking aid is acceptable). Participants will provide informed consent or proxy-consent will be sought from the appropriate third party as required.

**Baseline measures**

Baseline measures will be collected by the blinded assessor within 1 week of admission to rehabilitation. Data to be collected will include demographic details (age, gender), previous function (walking ability, co-morbidities, living arrangements), date of stroke, date of admission to rehabilitation, stroke classification (Oxfordshire Stroke Classification) and details (imaging results, side of stroke, first or recurrent event), visual fields assessment, Mini-mental State Examination (MMSE), ability to perform activities of daily living (FIM), walking ability (6 minute walk test [6minWT]), walking speed, Functional Ambulation Classification [FAC]) and arm function (Wolf Motor Function Test [WMFT]). See Table 1 for the schedule of assessment procedures.

**Randomization**

Participants who meet the inclusion criteria and consent to take part in the trial will be randomized on a one to one basis, stratified by hospital site to receive either 5 days a week therapy, 5 days a week CCT or 7 days a week therapy. The randomization schedule was computer-generated.
Following the baseline assessment, the on-site investigator will call a central phone-in service, answered by a person independent to the study, to obtain group allocation. This person is the only one with access to the allocation schedule and she has no other role in the trial.

**Intervention**

The comparison of interest in this trial is mode and intensity of physical therapy delivery, as opposed to content of therapy. Thus, the key differences between the intervention arms of the trial are (a) total therapy time per week and (b) whether sessions are delivered on an individual basis or in a group setting. The content of therapy sessions will be similar. In all therapy sessions exercises will be progressed according to standard practice, including by increasing number of repetitions, weights, duration of practice and increasing complexity of tasks.

**Usual care therapy**

Participants randomized to receive usual care therapy will receive all physical therapy according to local site standard practice. This may include individual therapy sessions, hydrotherapy (with a one therapist to one patient ratio) and group therapy as long as this is part of usual care. The total duration of usual care therapy will be no more than 90 minutes per day, 5 days a week (450 minutes per week).

**7 day per week therapy**

Participants randomized to receive 7 day a week therapy will receive physical therapy on both Saturday and Sunday for the duration of their inpatient stay, as well as the usual five days of the working week. The duration of therapy sessions provided on the weekend will be matched to that provided during the preceding week. The total duration of 7 day a week therapy will be no more than 90 minutes, 7 days a week (630 minutes per week).

**Circuit class therapy (CCT)**

This trial aims to assess an alternative model of providing physical therapy to people receiving rehabilitation post-stroke. Thus, participants randomized to the CCT arm of the trial
will receive CCT as an alternative to usual care; ie CCT sessions will replace all other physiotherapy sessions. Participants will receive CCT for up to 3 hours per day, usually in two 90-minute sessions morning and afternoon. Circuit class therapy will involve groups of at least 3 (ideally 4 to 6) participants and will be staffed by both qualified (physiotherapists) and unqualified staff (therapy assistants and physiotherapy students) with no more than one staff member per three participants. If there are less than 3 trial participants allocated to the CCT group at any one time, the CCT group will be augmented with non-trial patients with mobility issues. According to best evidence, (10,11) exercises included in the CCT sessions will be task-specific, largely activity-focused (as opposed to impairment-focused) with an emphasis on repetition and feedback. For each participant, exercises will be individually prescribed and progressed in terms of both complexity and intensity (number of repetitions, resistance and duration). Therapy will be aimed at improving mobility as well as (where appropriate) use of the hemiparetic arm. Therapists providing CCT will be pre-trained and will be provided with ongoing support and advice as well as a written manual. For a more complete description of the content of CCT please refer to Appendix 1, English et al (6). The total duration of CCT will be up to 180 minutes per day, 5 days a week (900 minutes per week).

The integrity of interventions delivered at each site will be monitored by prospective collection of data regarding therapy time and content which will be regularly reviewed, as well as a system of regular onsite audits.

**Primary outcomes**

The primary outcome measure is walking ability as measured by the 6minWT at 4 weeks after randomization. The 6minWT was chosen as current evidence suggests that the greatest benefit of CCT is in improving walking capacity (7) and this test measures a construct that is meaningful to people with stroke. The 4-week time point for the primary outcome measure was chosen to be commensurate with the average length of hospital stay for rehabilitation (12)
and because there is evidence for the effectiveness of a 4-week package of CCT intervention delivered in addition to usual care therapy in the sub-acute rehabilitation setting (13).

Secondary outcomes

Secondary outcomes will provide a broader picture of functional ability and economic implications. They are:

- Functional walking ability as measured by the FAC (14), walking speed and the Stroke Impact Scale (SIS) (15).
- Ability to perform ADLs as measured by the FIM (16)
- Arm function as measured by the WMFT (17).
- Quality of life as measured by the Assessment of Quality of Life (AQoL) instrument (18). Data from the AQoL will also be used for the economic analyses.
- Participant satisfaction as measured by the Hopsat questionnaire (19).
- Complications, including adverse events will be monitored for all trial participants. These may include (but are not limited to) worsening of stroke symptoms, falls (including those not resulting in injury), angina or myocardial infarction.
- Resource utilization including costs involved with therapy provision (therapist time, therapy equipment, essential discharge equipment such as walking aids).
- Length of hospital stay (LOS) as measured by the number of overnight stays in the rehabilitation facility. External barriers to discharge (waiting for essential home modifications or placement in residential care facility) will be documented.
- All primary and secondary outcome measures (except participant satisfaction) will be administered by the blinded assessor at baseline, 2 and 4 weeks (+/- 2 days) after randomization and at 3 and 6 months (+/- 1 week) after randomization. To avoid the risk of un-blinding, the participant satisfaction questionnaire will be administered by a local therapist, not directly involved in the participant’s therapy.
Data monitoring body

The trial will be overseen by a Steering Committee consisting of all members of the investigating team including onsite therapy staff. A Data Safety Monitor who is independent of the trial will review un-blinded data in regards to all adverse events and complications regularly and will advise the Steering Committee if safety issues arise.

Sample size

Sample size estimates were based on the ability to detect a between group difference of 116m in the 6minWT (standard deviation of 112m) between the CCT and usual care arms of the trial (13). In the absence of published data regarding the effect of 7 day week therapy and considering the dose-response relationship between therapy time and outcome (1) we conservatively estimate the change in the 7 day week therapy arm will be half that seen in the CCT 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 will provide at least 80% power to test for differences between CCT and usual care, 7 day therapy and usual care and CCT and 7 day therapy. Allowing for a 20% drop out rate, we aim to recruit 282 participants.

Planned statistical analyses

Reporting will follow the CONSORT statement for pragmatic randomized controlled trials. Baseline characteristics of patients in the three treatment arms will first be described using means and SEMs for continuous variables (or non-parametric equivalent) and counts and percentages for categorical variables. The treatment arms will be examined for comparability at baseline with respect to demographic and prognostic factors. An intention-to-treat analysis will be performed. One-way analysis of variance (ANOVA) with a Sidak post hoc procedure will be used to test for between group differences on the primary and secondary outcomes at 4 weeks. Should the outcome measures prove to be not normally distributed, either a transformation will be attempted, or a Kruskal Wallis H-test will be used followed by post hoc comparisons. Changes in outcome measures over time will be explored using linear
mixed effects models. As the sample size will be relatively small, testing for confounding will be undertaken using the change in co-efficient method and adjusted analyses undertaken when required.

**Economic evaluation**

The economic analysis will involve i) a simple comparison of the mean cost of therapy which will include personnel costs of therapists and therapy assistants (therapy AND planning time), ii) mean length of hospital stay and iii) incremental cost per differential change in patient outcome (as described above) for (a) 7 day a week therapy versus usual care (5-days a week therapy), (b) Circuit class therapy versus usual care and (c) Circuit class therapy versus 7 day a week therapy. Costs of therapy will include the time to deliver physiotherapy services to the participants (personnel costs) including costs for organization of sessions (prospectively collected), equipment cost and hospital stay, costed at published per diem or diagnostic-related group rates). Interpretation of results will consider both the functional outcomes and differences in costs between the three arms of the trial.

**Study organization and funding**

Administration and data management activities will be conducted through the International Centre of Allied Health Evidence at the University of South Australia. This trial is funded by the National Health and Medical Research Council of Australia (grant number 631904) and is registered with the Australian and New Zealand Trial Registry (ACTRN12610000096055).

**Recruitment**

Recruitment to the trial commenced in July 2010. By February 2011, 44 participants had been randomized to the trial.

**Summary**

Currently circuit class therapy is being used in various ways in rehabilitation settings around Australia without clear evidence of its effectiveness. Similarly, many Australian rehabilitation centers have, or are considering implementing weekend therapy services at a significant
additional cost to the health care system, without clear evidence of the effectiveness or cost-effectiveness of such a service. This trial will be the first to provide rigorous evidence on the effectiveness, cost and cost-effectiveness of both CCT and 7 day per week therapy for stroke survivors receiving inpatient rehabilitation, relative to usual care.

Improved functional outcomes for people post stroke has significant health and welfare implications for both the individuals, their significant others and the community sector. In addition to the potential to improve functional outcomes, CCT has the potential to lead to reduced LOS (6,7,13) which could ‘free up’ hospital beds for other patients. In 2006 there were 5,205 stroke patients discharged from rehabilitation facilities in Australia (20). If 50% of these were eligible for CCT, even a modest reduction in LOS would release several thousand bed-days for alternative use.

With the ageing population and the rising incidence of stroke, the outcome of this trial has the potential to benefit a large section of the population, both in Australia and internationally. If our results are positive in favor of either CCT and/or 7 day a week therapy, we will have scientific evidence to support changes to the provision of therapy in rehabilitation units. If the results do not support either approach being more effective or cost-effective to usual care, it will provide the evidence to support the status quo and avoid potentially costly and difficult changes in practice.
References


All people admitted to participating rehabilitation centers with a diagnosis of stroke will be assessed for eligibility.

Potential participants included if they:
- are able to walk independently prior to their stroke
- have a FIM total score of 40-80 points or motor score of 38-62 points
- give informed consent

Included participants randomized

- Usual care therapy
  - 2 week assessment
  - 4 week assessment
  - 3 month assessment
  - 6 month assessment
- 7-day week therapy
  - 2 week assessment
  - 4 week assessment
  - 3 month assessment
  - 6 month assessment
- Circuit class therapy
  - 2 week assessment
  - 4 week assessment
  - 3 month assessment
  - 6 month assessment
**Table 1 – Schedule of assessments**

<table>
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<th>Assessment</th>
<th>Screening</th>
<th>Baseline</th>
<th>Week 2</th>
<th>Week 4</th>
<th>Discharge</th>
<th>3 months post-stroke</th>
<th>6 months post-stroke</th>
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<td>Length of hospital stay</td>
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</table>

1 = Site main investigator  2 = blinded assessor  3 = treating therapy staff  4 = research assistant

*FIM scores will be determined in consultation with members of the treating team (excluding the treating physiotherapist)

**or proxy responses provided by carer

OSC = Oxfordshire stroke classification, MMSE = mini-mental state exam, 6mWT = six minute walk test, FAC = functional ambulation classification, FIM = functional independence measure, WMFT = Wolf motor function test, SIS = Stroke impact scale, AQoL = Australian quality of life scale, Hopsat = satisfaction with hospital care, SAE = serious adverse events, AE = adverse events