



Effectiveness of task-oriented circuit training on the motor performance of ischaemic stroke patients: a study protocol for randomised clinical trial

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ABSTRACT

Stroke is one of the most common causes of disability and death worldwide. With the rapidly growing stroke survivor population, it is crucial to identify an effective method for their healthcare. Recovery from stroke is followed by physiotherapy to promote rehabilitation. Task-oriented circuit training is designed to improve stroke patients' overall functioning during rehabilitation. This research aims to assess the effectiveness of task-oriented circuit training compared with conventional physiotherapy. The investigators have planned an 8-week parallel, two-arm, prospective, randomised clinical study. Participants will be enrolled from eight branches of the centre for the rehabilitation of the paralysed (CRP). We have planned to recruit 506 stroke survivors via a 1:1 random assignment procedure for 24 months. As a main objective, the Action Arm Research Test and the Timed Up and Go will be used to test upper and lower limb motor function. The secondary objectives will include daily living and balance activities, which will be evaluated using the Barthel Index and the Berg Balance Scale. The post-test and follow-up data will be collected after 8 and 12 weeks. The final analysis will include dropouts and treatment side effects. This study has been granted ethical approval by the Ethics Review Committee of the CRP (CRP-R&E-0401-357). All activities and interventions will be carried out following the Helsinki Declaration of 2020. The findings will be published in peer-reviewed journals and disseminated at international conferences. Trial registration number: CTRI/2023/09/057907 (21 September 2023) (Prospectively registered).

INTRODUCTION

Stroke is a neurological disorder in which a thrombus blocks or ruptures blood vessels in the brain, causing hemiplegic paralysis.¹ On a global scale, there are more than 12.2 million occurrences of stroke, with 60% of ischaemic strokes.² In a lower to middle economic country like Bangladesh, stroke has already proven itself as a major disabling non-infectious disease with

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Task-oriented circuit training (TOCT) effectively improves motor performance in ischaemic stroke patients by focusing on task-specific, repetitive activities. It enhances limb functions, gait and independence, but more research is needed to assess its long-term impact.

WHAT THIS STUDY ADDS

⇒ This study contributes to the growing evidence on the effectiveness of TOCT by evaluating its impact on motor performance in ischaemic stroke patients through a randomised clinical trial. It addresses gaps in understanding the long-term efficacy, optimal intensity and broader applicability of TOCT, providing valuable insights for improving stroke rehabilitation practices.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study may inspire research on TOCT's long-term benefits, promote its adoption in clinical practice and influence policy to enhance stroke rehabilitation programmes through evidence-based interventions.

a prevalence of 11.4 per thousand.³ Approximately 80% of individuals who have had a stroke are estimated to have a motor disability on one side of their body.⁴ Rehabilitation techniques aim to restore problem-solving and motor skills to become independent.^{5,6} Neuroplasticity is a unique brain characteristic that enables the neural network to modify its physiology on a cellular level in response to various internal and external stimuli.⁷ Task-oriented circuit training (TOCT) is a sequence of motor training that capitalises on neuroplasticity by immersing patients in diverse functional tasks with increasing degrees of complexity.⁸ TOCT holds multiple exercises, including task-specific training and circuit training intensity. Many authors have evaluated the impact of TOCT

specifically designed for either upper limb^{9 10} or lower limb.^{11–13}

Motor rehabilitation strategies, such as constraint-induced movement therapy,¹⁴ motor imaging techniques⁴ and task-oriented approaches,^{8 10 15} have shown efficacy in rehabilitating patients who had a stroke. Although several researchers have proposed different approaches for task-oriented training, a limited number have focused on conducting it in a circuit manner and designing the treatment approach for the complete hemiparetic side. In contrast, our goal is to establish TOCT as an approach requiring patients to use their hemiparetic limbs. In TOCT, participants use their eyesight, balance and proprioception. This multimodal stimulation enhances brain connections and improves motor learning and neuroplasticity.⁷ Furthermore, gradual complex activities are projected to boost these attributes. The goal of our large-scale investigation from different locations will increase the generalisability of the suggested therapy and assist rehabilitation professionals in adjusting and evolving their treatment approaches to address a range of stroke-related motor deficits.

Therefore, our research aims to assess the efficacy of TOCT compared with conventional physiotherapy in treating ischaemic stroke patients. The specific objectives are (1) to explore the sociodemographic features of stroke patients; (2) to test the comparability of baseline

characteristics of two groups at pretest; (3) to assess the influence of TOCT on upper and lower extremity motor function and (4) to assess the impact on daily tasks and balance at post-test and follow-up.

METHODS

Study design

Randomly selected participants will participate in a double-blinded, randomised clinical trial. Participants will be allocated to either the TOCT or conventional physiotherapy group. The study will follow SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines (table 1). After 8 weeks of treatment, the TOCT group will be compared with the conventional physiotherapy group.

Trial sites

Ischaemic stroke patients will be randomly recruited from eight centre for the rehabilitation of the paralysed (CRP) branches all over Bangladesh. Information will be documented after eligibility screening. They will be allocated to either the TOCT or conventional physiotherapy group on a 1:1 ratio through a random allocation procedure. Participants and outcome assessors will be blinded throughout the entire trial.

Table 1 Summary of the standard method and data collecting procedure outlined in the Standard Protocol Items: Recommendation for Interventional Trials-2013 guideline

	Entrance	Group allocation	Postallocation		
Time point	-T ₁	T ₀	T ₁	T ₂	T ₃
Enrolment					
Screening for eligibility	✓				
Informed consent		✓			
Demographic assessment			✓		
Group assignment		✓			
Intervention					
TOCT		✓	↔		
Conventional treatment		✓	↔		
Clinical tools					
ARAT			✓	✓	✓
TUG			✓	✓	✓
BI			✓	✓	✓
BBS			✓	✓	✓
MAS			✓		
FAC			✓		
PHQ-9			✓		
GAD-7			✓		

ARAT, Action Arm Research Test; BBS, Berg Balance Scale; BI, Barthel Index; FAC, Functional Ambulation Categories; GAD-7, Generalised Anxiety Disorder-7; MAS, Modified Ashworth Scale; PHQ-9, Patient Health Questionnaire-9; T₀, group allocation; T₁, prestudy enrolment; T₁, baseline recording before intervention; T₂, measurements recorded at 8 weeks after recording T₁; T₃, follow-up measurements recorded at 12 weeks after recording T₁; TOCT, Task Oriented Circuit Training; TUG, Time Up and Go.

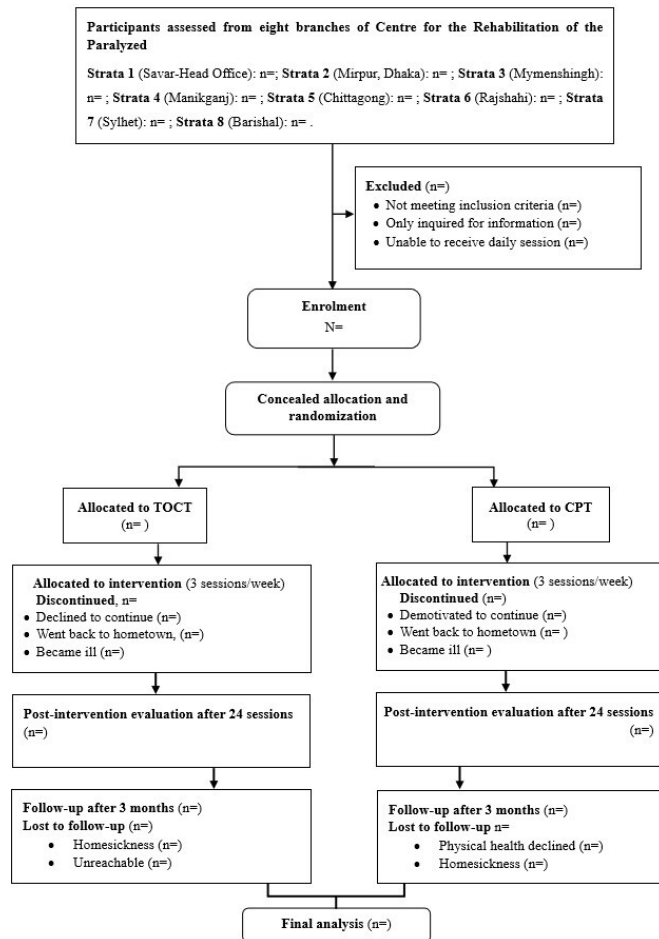


Figure 1 Flow diagram for participant recruitment.

Sample size calculation

The sample size calculation was done using ClinCalc software. The trial needs 404 participants to achieve the expected minimum clinically relevant difference for the Action Arm Research Test (ARAT) (23.71 ± 17).¹⁶ Group 1 had a mean of 23.71, and group 2 had 28.18. Therefore, the absolute difference was 4.742, which was determined by a clinical improvement of at least 20% from baseline. Considering an enrolment ratio of 1:1 and statistical power of 80%, the probability of type II error would be 0.84 (expressed as the beta number), and the type I error rate, often known as the alpha value, would be adjusted to 0.05. Each group will comprise 202 ischaemic stroke patients, totalling 404 participants. We expect to enrol 253 patients for every group, assuming a 20% dropout.

Participant recruitment and screening

All patients with ischaemic stroke, verified by CT or MRI, will be assessed for eligibility. The study shall obtain written permission from eligible participants during the recruitment process. After receiving consent, baseline evaluation and blinded random group allocation will commence. Consolidated Standards of Reporting Trials guidelines advocate a clear and comprehensive reporting of outcomes. Therefore, the results should be assessed and reported accordingly (figure 1). Treatment

will begin immediately after allocation. The 24-month recruiting procedure spans from November 2023 to May 2025.

Eligibility criteria

Inclusion criteria

1. Ischaemic stroke survivors with neurological deficit.¹⁷
2. The age of the patient ranges from 35 to 70 years.⁹
3. Duration of stroke from 1.5 to 6 months.¹⁷
4. Can walk 10 m independently or using an aid or orthotic with or without supervision or aid.¹⁸
5. Functional ambulation category Score of at least grade-3.¹⁸
6. Limited arm motor function, yet able to reach and grip.¹⁴
7. Patients who had only one event of stroke in either the left or right cerebral hemisphere.¹⁹
8. Both male and female participants will be included.⁸
9. Patients who are willing to participate.¹⁸

Exclusion criteria

1. A patient suffering from unstable cardiac condition, severe hypertension, congestive heart failure, aphasia and cognitive impairments for which exercises are contraindicated.
2. Patients with progressing neurologic illness and other health issues affecting walking abilities.¹⁹

Randomisation procedure

The study will recruit eligible participants by stratified random sampling. The trial sites will be regarded as strata. Each trial site will get a prerandomised sequence of patient IDs based on diverse block sizes to reduce the predictability of group allocation. Participants meeting the inclusion criteria will be discreetly assigned to treatment groups using the 'rand' function in Microsoft Excel 2023. Participants will be assigned to parallel treatment groups in a 1:1 ratio.

Blinding

Trial participants and outcome assessors will be blinded to group allocation. The consent form will state this information. An impartial trial assistant will monitor participant eligibility and report to the trial management via a WhatsApp group. The trial manager will convey the data of eligible patients and their group assignments to treatment providers via a separate WhatsApp group. On arrival of baseline documents, the treatment provider will enclose the document in an envelope and affix a patient ID. Two independent outcome assessors, devoid of interpersonal relationships, will be designated for each study location. A trial coordinator and an impartial monitoring team will supervise the research. Blinding will be maintained throughout the study to eliminate any bias. The TOCT group and the conventional physiotherapy group will get treatment in two distinct rooms on separate levels to prevent trial contamination.

Health professional involvement

Participants will get treatment from 20 stroke rehabilitation specialists with a minimum of 5 years of expertise. According to the criterion, therapists must be at least a CRP-certified Junior Consultant. Outcome assessors must have at least 1 year of experience working in a neurology unit. Outcome assessors and treatment providers will get training from a CRP-certified consultant physiotherapist at each trial site. Treatment providers will provide treatment to patients based on their designated treatment group.

Intervention

Conventional physiotherapy group

Participants of the conventional physiotherapy group will receive conventional physiotherapy. Conventional physiotherapy includes stretching, balance practices, core stability exercises, functional exercises, muscle activation techniques and sensory integration techniques. The patients will receive 45 min of conventional physiotherapy, 3 times per week, lasting 8 weeks.

TOCT group

The TOCT protocol has 10 workstations that will be used sequentially to provide task-oriented training (table 2). 2 min for each of the nine workstations and 5 min for one specific workstation make up the TOCT procedure. A 1 min rest period will be implemented before each workstation to prevent tiredness. This treatment protocol will last for 33 min and will be repeated three times/week for 8 weeks.

Outcome measurements and assessment points

Primary outcome

Motor function of upper limb

The ARAT will assess upper limb motor function. The ARAT consists of subscales that assess grasp, grip, pinch and general movement abilities. The scale comprises 19 tests. The intra-class correlation coefficient (ICC) values for grab, grip, pinch, general movement and overall score are 0.98, 0.96, 0.95 and 0.98, respectively.²⁰ This indicates the scale's excellent reliability.

Motor function of lower limb

Timed Up and Go (TUG) will assess lower limb motor function. Patients will sit in a standard chair with 10 feet marked. The time for the stated distance and return to the chair will be recorded. The TUG test is an extremely reliable (ICC1=0.95 and ICC2=0.96) study tool for measuring lower limb motor function.²¹

Secondary outcome

Activities of daily living

The Barthel Index (BI) has 10 components, with each item being given a score ranging from 0 (indicating functional incompetence) to 100 (indicating functional competence). BI has been evaluated and shown to be reliable (ICC≥0.96).²²

Balance

The Berg Balance Scale (BBS) will evaluate balance using specified activities. The 14-item scale uses a range of five ordinal scores, ranging from 0 to 4, to assess each item. The intra-rater reliability (ICC=0.95) for BBS was determined to be sufficiently reliable.²³

Study procedure and data collection

After the initial evaluation, participants' sociodemographic and clinical parameters will be collected for baseline data. Each study site will have two outcome assessors. After initial evaluations, pretest data will be gathered, and participants will be randomly allocated to groups. 8 weeks after the initial assessment, outcome assessors will gather post-test data. A follow-up evaluation will be done after 12 weeks. As a global standard for experimental studies, the trial will be conducted by adhering to SPIRIT-2014 criteria (table 1).

Safety measures and adverse reaction management

Although it is likely the therapy will not result in any significant negative effects, the monitoring team will carefully observe for any unexpected occurrences during and after the intervention and quickly inform appropriate specialists. If serious adverse responses occur during the trial, the principal investigator shall inform the ethical review board and be included in the study's final publication.

Data management

Baseline data will be collected after obtaining consent from the participants. After random allocation, post-test data will be gathered after 8 and 12 weeks (table 1). Data quality will be maintained by checking files for errors and omissions. An appointed data curator will preserve all of the participants' confidential information data collection materials, including hard and soft copies. Participants' confidential information will be kept within password-protected databases. Each participant will get an ID number to encrypt data. A secret list of identifying numbers will be preserved from disguised data. Statisticians will use disguised data and pool findings to maintain confidentiality.

Monitoring

A monitoring team consisting of two people from every study site who are not directly participating in the experiment will be formed. Each trial site's monitoring team will review data daily. Their duties will include overseeing the execution of the plan, any adverse effects and the recruitment of individuals into the study groups. After data collection, the trial supervisor, main researcher and investigators will get the final data. After the trial, each author will have full access to the encoded content. In addition, they will examine the data and do a temporary analysis. If any alterations are made to the research protocols or treatment techniques, the principal investigator should notify the CRP ethical review board.

Table 2 The TOCT protocol

Station-1: reaching activities ²⁶	Description: sitting at a table and reaching in different directions. Progression: increase object distance and complexity progressively. Duration: 2 min
Station-2: Object-related reach to grasp practice in trunk restrained position ²⁷	Description: Sagittal trunk movement, sitting by a table. Body belts will limit displacement and rotation. It involves repeated arm unimanual and bimanual activities. Reach-to-grasp tasks will use items of various sizes, weights and shapes. Progression: 1. Progress is made by increasing task repetition, object size and weight. 2. Progress by increasing the height and distance of the object. Duration: 5 min
Station-3: Sit to Stand ¹⁹	Description: Sit on various chair heights. Progression: 1. Increase speed until it can complete within 30 s, then decrease seat height. 2. Increase the complexity of the workstation Duration: 2 min
Station-4: Swiss ball squats ¹⁹	Description: Start by standing and sitting at a selected level. Progression: 1. Progress the squatting while keeping the thigh parallel to the ground 2. Progress by adding weight to hands. 3. Progress by increasing squat hold duration. Duration: 2 min
Station-5: Self-sway ¹⁹	Description: Start close to the wall, sway forward and backward from ankles. Progression: Gradually standing away from the wall. Duration: 2 min
Station-6: Stepping ²⁶	Description: Stepping forward, backwards and sideways on the floor. Progression: 1. Progress by walking in the forward, backward, and sideways orientations onto blocks of varying heights. 2. Gradually increase the height of blocks. Duration: 2 min
Station-7: Calf raises ¹⁹	Description: Begin with both calf raises and lowering while maintaining a standing posture. Progression: Increase speed. Progress to single calf raise. Progress to jumps. Duration: 2 min
Station-8: Marching in place ¹⁹	Description: Start marching with hand support. Progression: 1. Marching with a weight. 2. Marching with no hand support. 3. Marching on a mini trampoline. Duration: 2 min
Station-9: Tandem walk ¹⁹	Description: Walk with feet on the floor. Progression: 1. Progress by altering heel and toe walking. 2. Progress further by decreasing speed. 3. Walk looking forward and crossing your arms. Duration: 2 min
Station-10: Walking in on different surfaces (rough surface, smooth surface and foam) ²⁸	Description: Start forward and sideway walking. Progression: 1. Start with an even surface. 2. Progress to backward walking 3. Progress walks on carpet, foam and rough surface Duration: 2 min
TOCT, task-oriented circuit training.	

Analysis plan

A statistician will use SPSS (V.22) to analyse encoded data. The normal data distribution will be evaluated using

the Kolmogorov-Smirnov test, the Shapiro-Wilk test, the bell curve, kurtosis and skewness. Descriptive statistics, such as mean and SD, will be used for continuous data.

Categorical data will be presented as frequency and percentage. To evaluate the similarity between the two groups and endpoint differences, we will use the independent samples t-test or Mann-Whitney U test, depending on the data distribution. The Wilcoxon or paired sample t-test will be used to complete the analysis within each group. One-way analysis of variance (ANOVA) or Friedman's ANOVA will be used to study treatment superiority among three measures, followed by post hoc analysis. The dropout data will be assessed using intention-to-treat analysis.

Dissemination

A symposium will present the study's findings to physiotherapists, academics and healthcare professionals. A genuine study will be published in a database-indexed peer-reviewed publication to disseminate the findings. Additionally, physiotherapists will get protocol-based therapeutic training on TOCT. The study's findings will be published as an open-access issue, ensuring everyone can access them regardless of financial standing. Such initiatives attempt to enhance stroke survivors' rehabilitation.

DISCUSSION

Stroke leads to motor deficits in the upper and lower extremities, and restoring these disabilities remains a key objective for rehabilitation specialists.²⁴ TOCT is a treatment approach involving specialised training sessions focused on specific tasks, considering the appropriate dosage and progression. This technique uses the principles of neuroplasticity by emphasising functional tasks.¹⁴ This treatment closely relates to the techniques used by professional physiotherapists who specialise in disorders of the brain, especially stroke. Many authors have tried to evaluate the effects of TOCT on upper and lower limbs separately.^{10 24 25} Nevertheless, no research has directly compared the effectiveness of the TOCT for both limbs with conventional therapy. To make appropriate therapeutic judgements throughout the patient's rehabilitation period, physiotherapists must be informed with randomised clinical trials, since the available data are currently limited. Our goal is to establish TOCT as a rehabilitation strategy that can improve the overall functioning of stroke survivors. This study has been carefully planned to provide a sample size sufficient to detect treatment effects while extending the results to a broader population and minimising any possible biases.

In summary, the study compares the effectiveness of TOCT over conventional therapy. The results of this research will assist medical professionals in making informed therapeutic decisions by providing information regarding the most efficient treatment strategy for patients who had a stroke throughout their reintegration phase after a stroke. Our training programme considers fatigue, which may arise as the session progresses. We have designed therapy progression to increase the difficulty of the sessions and improve rehabilitation outcomes.

We will make sure that there are sufficient intervals of rest between each station. The research will provide important insight for stroke patients, encouraging them to make educated decisions about their treatment.

In summary, this research will compare TOCT with standard stroke physiotherapy using both upper and lower limbs through a single trial. The research will involve a large number of stroke survivors, enhancing generalisability. The trial will emphasise many outcomes, including upper and lower limb motor functions, daily living activities and balance. Additionally, we intend TOCT to be recognised as a straightforward and uncomplicated therapeutic procedure for rehabilitation specialists. The focus on reproducing real-life clinical practice strengthens the study's relevance and usability.

Trial status

This randomised clinical trial has not recruited any participants yet.

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Contributors Conceptualisation: FarJS, MFH and MRK. Methodology: FarJS, MFH and MRK. Software: MUB. Investigation: FarJS, MFH, MUB, AHK, MAH and MRK. Writing-original draft: FarJS and MUB. Writing-review and editing: MFH, AHK, MAH, MEA, FarJS and MRK. Visualisation: MUB, AD and AHK. Supervision: MFH, AHK, MAH and MRK. Project administration: MAH, AD, SMS, FarJS and HOR. Guarantor: FarJS.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval The study received retrospective approval from the corresponding institute's Ethics Review Committee of Centre for the Rehabilitation of the Paralysed (CRP) on 15 November 2021 (Approval Number: CRP-R&E-0401-357). The Declaration of Helsinki-compliant ethics will be followed. Participants must provide written informed permission before entering the study. Participation will be voluntary, and quitting will not affect their regular treatment. The gathered data will be protected from unauthorised users. Investigators will be prohibited from acquiring confidential data. Post-trial care will be provided for any adverse events.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data sharing not applicable as no datasets generated and/or analysed for this study. Once the research is completed, the data will be accessible to ensure transparency. The dataset analysed in the study can be obtained from the corresponding author on a reasonable request.

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