

Real-Time Foot Clearance Biofeedback to Assist Gait Rehabilitation Following Stroke: a Randomised Controlled Trial Protocol

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Abstract

Background The risk of falling is significantly higher in people with chronic stroke and it is, therefore, important to design interventions to improve mobility and decrease falls risk. Minimum Toe Clearance (MTC) is the key gait cycle event for predicting tripping-falls because it occurs mid-swing during the walking cycle where forward velocity of the foot is maximum. High forward velocity coupled with low MTC increases the probability of unanticipated foot-ground contacts. Training procedures to increase toe-ground clearance (MTC) have potential, therefore, as a falls prevention intervention. The aim of this project is to determine whether augmented sensory information via real-time visual biofeedback during gait training can increase MTC. **Methods** Participants will be over 18 years, have sustained a single stroke (ischaemic or hemorrhagic) at least 6 months previously, able to walk 50 metres independently and capable of informed consent. Using a secure web-based application (REDCap) 150 participants will be randomly assigned to either no-feedback (Control) or feedback (Experimental) groups, all will receive 10 sessions of treadmill training for up to 10 minutes at a self-selected speed over five to six weeks. The intervention group will receive real-time, visual biofeedback of MTC during training and will be asked to modify their gait pattern to match a required "target" criterion. Biofeedback is continuous for the first six sessions then progressively reduced (faded) across the remaining four sessions. Control participants will walk on the treadmill without biofeedback. Gait assessments are conducted at baseline, immediately following the final training session and then during follow-up, at 1, 3 and 6 months. The primary outcome measure is MTC. Monthly falls calendars will also be collected for 12 months from enrolment. **Discussion** The project will contribute to understanding how stroke-related changes to sensory and motor processes influence gait biomechanics and associated tripping risk. The research findings will guide our work in gait rehabilitation following stroke and may reduce falls rates. Treadmill training procedures incorporating continuous real-time feedback may need to be modified to accommodate stroke patients who have greater difficulties with treadmill walking.

Background

Stroke affects more than 60,000 Australians every year with 50% unable to walk one week following the event¹. Impaired walking impacts independence by reducing the ability to perform everyday activities and limiting community participation^{2, 3}. Falls risk is significantly higher in people with chronic stroke⁴ and approximately 50% of people living at home after a stroke will fall within 12-months¹¹, with up to half sustaining multiple falls. Furthermore, in community dwelling people with stroke, up to 77% of falls occurred during walking. While there has been considerable research investigating falls risk management for older people generally, high-risk groups such as those who have had a stroke have not been extensively studied with respect to targeted falls prevention. Traditional exercise-based falls prevention programs are useful for the general older adult community but are not effective in people with stroke. For example, Batchelor et al. found that a multifactorial intervention including a home-based balance and strength program did not reduce falls in people with stroke¹². Another study confirmed that a group and home-based exercise program incorporating balance and strength training did not reduce falls¹³. This

suggests that alternative, targeted treatments to reduce falls risk in people with stroke are urgently needed.

Stroke adversely affects sensorimotor function and muscle strength, inhibiting the capacity to activate appropriate muscles and increasing the risk of contact between the foot and either the supporting surface or objects on it. Said et al. 21 found, for example, that stroke participants who had difficulty in stepping over small obstacles (4-cm high) had greater falls rates. The key gait variable for predicting tripping-falls is Minimum Toe Clearance (MTC), an event mid-swing in the walking cycle⁶⁻⁹. Low MTC increases the probability of unanticipated foot-ground contacts⁸. Given that tripping directly results from unsuccessful toe clearance, previous research with both young and older populations has focussed on toe trajectory control during walking^{7-9, 17-19}. Training individuals to increase MTC, therefore, has potential as a falls prevention intervention.

The aim of this project is to determine whether real-time biofeedback of toe clearance during gait training can significantly minimize tripping risk in people with stroke. We will test the efficacy of real-time biofeedback as an intervention to increase MTC using a RCT design incorporating both a training or “acquisition” phase with biofeedback. Retention tests will be conducted to confirm *learning*, as demonstrated by the longer-term or “relative permanence” of the targeted behaviour.

The primary objective is to determine whether real-time biofeedback of MTC during gait training will significantly increase MTC in people with stroke. We will also determine whether changes in MTC achieved on a treadmill transfer to overground walking. It is hypothesised that, compared to no-biofeedback training, visual biofeedback of foot clearance parameters during gait training will significantly increase toe-ground clearance (MTC), and MTC during biofeedback training will be retained in the longer term. It is also hypothesized that increases in MTC demonstrated in treadmill training will transfer to overground walking, such that tripping-risk in people with stroke is significantly reduced.

Methods

This single-blinded parallel group randomised controlled trial (RCT) with 1: 1 randomisation will assess the effects of biofeedback on MTC following gait training. It will conform to CONSORT guidelines and has been registered on the Australian and New Zealand Clinical Trials Registry (ANZCTR): ACTRN12617000250336. Ethics approval for the study was obtained from Austin Health, Melbourne Health and Victoria University Human Research Ethics Committees. Informed consent procedures include the provision that participants clearly understand that they are free to withdraw at any time without providing a reason. The study design flowchart is shown in Figure 1.

Insert Figure 1 About Here

Patient population

Eligibility criteria for participants

Participants will be over 18 years, have sustained a single stroke (ischaemic or hemorrhagic) at least 6 months previously, able to walk 50 metres independently with or without a single point stick and capable of providing informed consent. Exclusion criteria are: (i) an ankle foot orthosis, (ii) neurological, orthopaedic, cardiac, respiratory or other medical conditions in addition to stroke that impact their ability to walk on a treadmill, (iii) over 158 kg body mass (due to the weight limit of the harness) and (iv) visual problems or severe visual-spatial neglect. Participants will not be receiving physiotherapy for their walking or lower limbs while enrolled in the study.

Participant recruitment study settings

Recruitment sites include Heidelberg Repatriation Hospital (Austin Health), the Royal Melbourne Hospital (Royal Park Campus) and Western Health. Interested parties can also self-refer in response to advertising. Gait assessments and training are conducted at the Heidelberg Repatriation Hospital (Department of Physiotherapy) and the Victoria University (Footscray Park) Biomechanics Laboratory.

Randomisation

Randomisation to participant group will be performed by the project coordinator using a secure, web-based Research Electronic Data Capture (REDCap) tool hosted at Victoria University⁵⁰. The participant group allocation will then be e-mailed to the intervention therapist with the subject heading Randomisation of (Participant ID). Participants will be coded and only available to authorized project personnel.

Blinding

Clinical Physiotherapists will be involved in assessment but blinded to group allocation and training sessions. Blinded Clinical Physiotherapists will conduct clinical assessments and collect falls-related data. Biomechanical gait assessors who conduct the movement analysis are, similarly, blinded to group allocation to ensure that all assessment personnel are blinded as to the participant's group assignment. Physiotherapists and Biomechanists delivering the gait training are required to know the patient's group assignment.

Intervention

All participants, both controls and those in the feedback intervention group, will walk on the treadmill following an identical schedule of training sessions. Self-selected walking speed will be determined following treadmill familiarization with a Physiotherapist during the first clinical assessment visit. This self-selected walking speed will be recorded and each treadmill walking session will be conducted at the same walking speed. All participants wear a safety harness when treadmill walking and continue for up

to 10 minutes with rest breaks as required. Previous research by the authors had determined 10 minutes to be comfortable maximum for this population^{29, 30}. Participants will wear the same comfortable shoes for all walking activities.

Participants randomized to the intervention group undertake biofeedback gait-training using a real-time display of the affected limb's swing phase trajectory, with toe clearance and the associated MTC event clearly shown. Motion analysis markers will be attached to the shoe and other body segments to calculate toe clearance parameters in real-time as per the established protocol⁷. *Target* MTC will be calculated as baseline MTC plus 1 SD. The feedback group will be asked to move their affected limb such that MTC falls between target MTC mean+0.5SD and target MTC-0.5SD, projected as parallel lines on a screen in front of the treadmill^{35, 36}. If baseline MTC cannot be calculated, target boundaries will be set using the *maximum* Toe Clearance (TC) with instructions to control foot motion within that target band. Borg Ratings of Perceived Exertion will be recorded after each session.

Biofeedback is presented for the first six sessions then progressively reduced (faded) across the remaining four sessions. During fading one third of the initial feedback will be available at the beginning of session seven, one third in the middle for session eight, one third at the end of session nine, and finally one tenth at the beginning and one tenth at the end of session ten. As indicated above the control group will walk under the same conditions without either feedback or any instructions concerning their gait control. Adherence to the gait training program will be reflected in the number of training sessions successfully completed, and the research team will monitor any non-adherence.

Outcome Measures

Assessments

A clinical assessment is conducted on the first visit (Baseline) in order to describe the study population. Clinical assessments for global function, lower limb strength, gait speed and falls risk are repeated following the final training session and at one-, three- and six-months post training. Clinical measures undertaken by the Research Physiotherapists will include:

- Functional Independence Measure (FIM)³⁷, a measure of global function;
- Timed Chair Stand Test³⁹, an indicator of lower limb strength;
- Timed 10 metres Walk Test³⁸, an assessment of gait speed;
- Step Test⁴⁰, a balance measure that identifies stroke patients with a risk of falls;
- Sensory Testing (light touch, pinprick and sensory extinction);
- Star cancellation test; to screen for visual-spatial neglect⁵¹;

- Stroke Rehabilitation Assessment of Movement (STREAM)⁴¹, measures voluntary movement and mobility in people with stroke;
- Tardieu scale⁴², to assess spasticity in gastrocnemius and soleus;
- Six minute walk test⁴³, a measure of walking endurance;
- Falls Risk for Older People in the Community (FROP-Com). The FROP-Com has previously been used to identify falls risk in people with stroke¹².

Gait assessment trials are conducted at baseline, after the final training session (a minimum of 20 minutes following final training) and one-, three- and six-months later. These gait data are collected during treadmill and overground walking by biomechanics personnel blinded to group allocation. During overground walking assessments (pre and post training) participants walk at preferred speed along an 8m walkway. Kinematic (position/time) data are captured using a three dimensional motion analysis system (Optotrak®, NDI, Canada) with clusters of infrared markers fixed to the toe of the shoe, and the shank, thigh and pelvis segments. Bony landmarks on the foot, ankle, knee and hip are identified using virtual markers and used with the clusters in order to construct a model of the joints and segments. This enables kinematic data, including joint angles, to be calculated. Foot plantar pressures and centre of pressure excursion (COPE) are captured to assess gait stability using the Pedar foot pressure insole (Novel, Germany), an in-shoe system that measures plantar pressure distribution within the shoe.

Primary outcomes

The primary outcome variables from the motion analysis, MTC magnitude and variability, will be assessed using biomechanical assessment data at baseline and post-training, which occurs immediately following the final training session after a minimum of 20 minutes rest. Retention MTC data at 1, 3 and 6 months for the affected limb will determine whether the target MTC, ie baseline MTC plus 1 SD, has been maintained after visual biofeedback training has concluded. The precise probability of tripping due to foot-ground contact will be computed by statistically modelling the MTC histogram⁸.

Secondary outcomes

To supplement the MTC data, gait kinematics (secondary outcome variables) will be used to assess gait training effects on gait speed, stance/swing times, and joint angles at key events, foot-contact, toe-off and MTC of the affected and unaffected limb. Baseline and retention clinical data will show how falls risk measures were influenced by feedback training. The association between the clinical tests and the biomechanical variables will be shown by correlating tripping probability and clinical measures. Medio-lateral and anterior-posterior foot pressure (COPE) shifts will reveal biofeedback effects on gait stability. A further secondary outcome is the number of falls following training. These data will be collected via monthly falls calendars for 12 months from enrolment in the study as illustrated in the SPIRIT study-timeline (Figure 2).

Insert Figure 2 About Here

Sample size calculations

In determining sample sizes, for the between-group comparisons, to detect differences in MTC a medium effect size ($ES=f=0.25$) between the group effects (No-Feedback vs Feedback) across the two time points (Baseline and post-training) a total of 126 or 63 per group is required (G*Power 47 calculation, 2x2 repeated measures design, $\alpha=0.05$, power =0.85, correlation=0.7). To allow 20% drop out we shall initially recruit 75 participants per group (N=150). This sample size will also allow detection of a 1SD increase in MTC of the biofeedback group, compared to their pre-training. The probability of tripping⁸ calculated using the pilot (stroke) participants' data suggests that a 1 SD (0.77cm) increase in MTC will result in significant reduction in the risk of tripping on small (1 - 2 cm) obstacles. A 0.77 cm increase in MTC represents approximately a 50% gain in minimum ground clearance (mean MTC = 1.4 cm) that is shown by our modelling to represent a substantial decrease in tripping risk, i.e., the probability of contacting an obstruction of a given height.

Data management and statistical analysis

All data will be stored via REDCap, an application specifically designed for the safe storage of clinical research data, for 7 years. Only research personnel associated with the study will have access to the data and it will not be available to external agencies. Optotrak, IMU and Pedar data will be coded so no personal information will be identified in the data. De-identified data will also be stored on a secure drive at the University. The patient's gait kinematics are monitored as the project progresses to confirm no adverse effects of gait training, such as increased tripping risk. External auditing is not required in this study because all experimenters are trained to identify and record adverse events.

MTC data obtained from the treadmill walking will be analysed using two intervention group comparisons and repeated measures ANOVA of the intervention groups and change scores, with post-hoc comparisons where relevant. Walking speed will be used as a co-variate due to its influence on MTC data. The between subject factor will be treatment group (No-feedback and Feedback) with Time (pre-training baseline, post-training, 1-month, 3-month and 6-month) being the within-subject factor.

- 1) Between-group comparisons of MTC post-training will reveal effectiveness of the biofeedback gait training method in improving MTC.
- 2) The within-subject analysis of the Feedback group will reveal the biofeedback effects on MTC by comparing each participant's after intervention (post-training) data to that obtained in retention conditions i.e., MTC data at 1-month (short-term retention), and at 3-month, 6-month (long-term retention).

3) MTC data collected during overground walking during retention conditions will determine whether any changes in MTC are translated to overground walking.

Discussion

This innovative study will evaluate the impact of augmented sensory information for improving gait function, specifically foot-ground clearance, via visually presented biofeedback. The research findings will contribute to the broader falls prevention initiative by demonstrating the effectiveness of toe clearance biofeedback in making walking safer. It will also confirm whether faded feedback enhances learning by demonstrating how performance is affected immediately following training and whether it can be retained in the long term. If shown to be effective, there will be opportunities for biofeedback-training applications to other gait-impaired clinical populations. The project's findings will contribute to understanding how stroke-related changes to sensory and motor processes influence the tripping risks of everyday walking. The protocol is, however, limited to people with chronic stroke capable of walking on a treadmill due to the continuous real-time feedback used for gait training.

Trial status

Recruitment began on 27/4/2017 with Protocol Version 6 dated 16/09/2016. Protocol Version 8 dated 20th June 2018 is currently in use following minor amendments not affecting the implementation of the project protocol. Recruitment is expected to be completed by 31/12/2020. Any important protocol modifications will be formally communicated to relevant parties by the chief investigator, and the Protocol Version updated.

Abbreviations

MTC: Minimum Toe Clearance; FIM: Functional Independence Measure; FROP-Com: Falls Risk for Older People in the Community; RTC: Randomised Control Trial; COPE: Centre of Pressure Excursion; SD: Standard Deviation; ES: Effect Size.

Declarations

Ethics approval and consent to participate

Ethics approval for the study was obtained from Austin Health, Melbourne Health and Victoria University Human Research Ethics Committees. The approving HREC is Austin Health. HREC/15/Austin/516. Written informed consent is obtained from all participants using the procedures mandated and approved by the above institutional research ethics committees. The blinded assessor (clinical physiotherapist) will obtain informed consent during the first visit for clinical assessment. Patients are fully informed that they are free to withdraw at any time without providing a reason.

Consent for publication

Not applicable.

Availability of data and materials

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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National Health and Medical Research Council (NHMRC) Approval number Approval number GNT1105800. The NHMRC has no role in the study design, collection, analysis and interpretation of data or manuscript writing.

Authors' contributions

Conception of the study: RB, CS, MG, PL, WS, FK. Drafting the manuscript: RB, WS, LJ. Critical review of the manuscript: CS, MG, PL, LJ, FK. All authors read and approved the manuscript.

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Confidentiality

All participants will be assigned a code. The list of participants and codes and all data will be stored via REDCap. No identifying information will be published.

Dissemination plans

Study findings will be presented as conference abstracts, poster presentations and scientific publications. The principal investigator will collaborate with all co-investigators to prepare manuscripts for submission.

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Figures

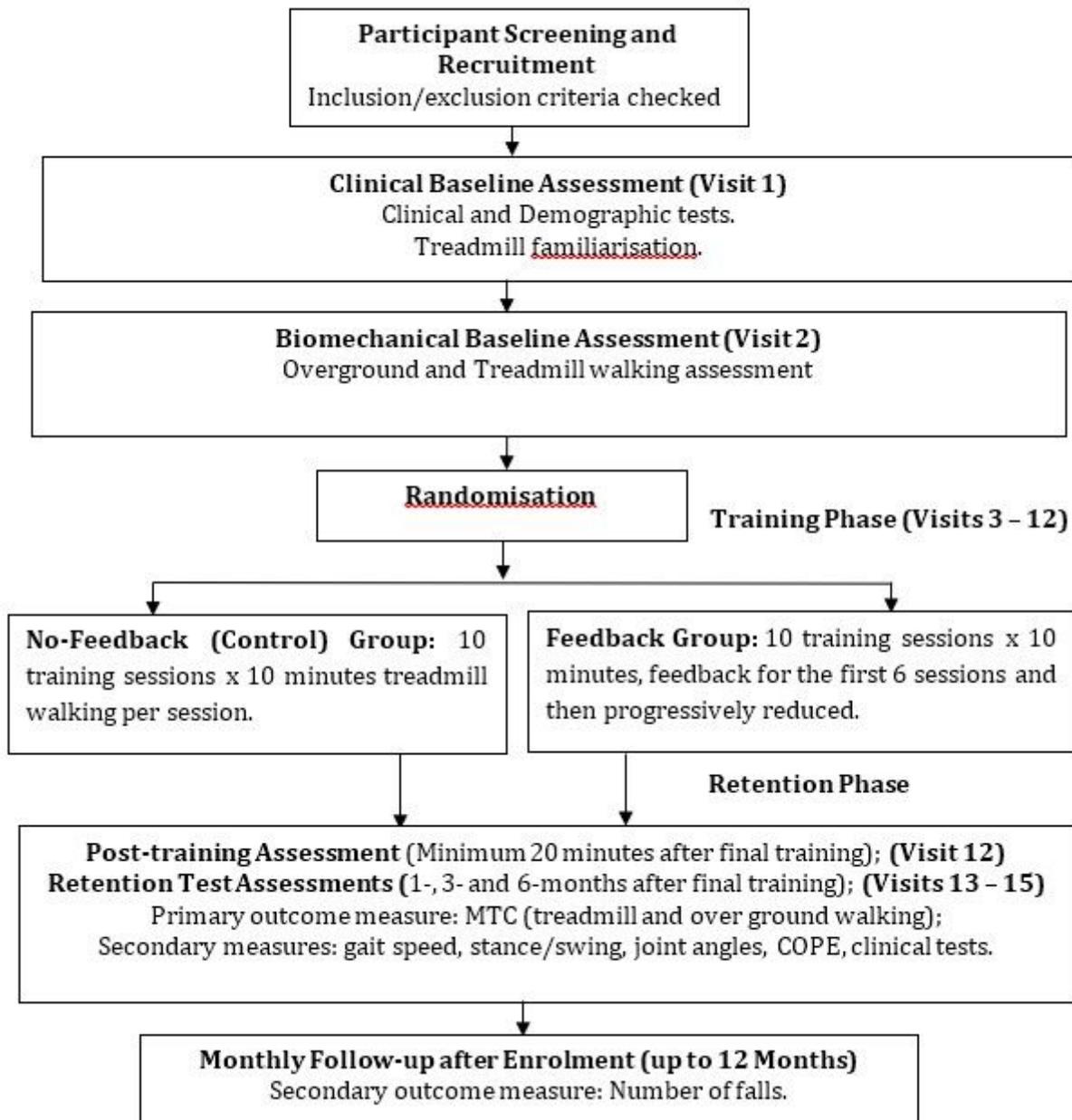


Figure 1

Study design flowchart.

TIMEPOINT	STUDY PERIOD								
	Recruit	Gait Biom. Baseline	Training Phase		Post – Training Retention Phase				Follow-up (12 months)
	-2 Week	-1 Week	T1-T6	T7-T10	20 min following T10	1 month	3 months	6 months	Monthly
RECRUITMENT:									
Eligibility screen	X								
Informed consent	X								
Clinical tests	X								
Treadmill practice	X								
INTERVENTIONS:									
No-Feedback Control Group		X	X	X	X	X	X	X	
Feedback Group		X	X	<i>Fade</i>	X	X	X	X	
ASSESSMENTS:									
Gait Biom. Vars.		X	X	X	X	X	X	X	
Min. Toe Clearance		X	X	X	X	X	X	X	
COPE, Clinical tests		X			X	X	X	X	
Borg Scales			X	X	X	X	X	X	
Falls Calendars									X

Figure 2

SPiRiT study-timeline. T1 to T10 gait training sessions of (up to) 10 min treadmill walking. Feedback (FB) group given visual feedback display of minimum toe clearance (MTC), No-Feedback group given no gait-related information. Gait Bio. Baseline: Gait biomechanics variables for overground and treadmill walking. Fade: MTC information reduced progressively for FB group. COPE: Centre of Pressure Excursion. Gait stability assessment from plantar pressures. Clinical Tests, Borg Scales and Falls Calendars: see text.

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