ISRCTN24868616 https://doi.org/10.1186/ISRCTN24868616

The use of aerobic exercise to augment training of motor skill in stroke rehabilitation

Submission date
14/01/2011

Recruitment status
No longer recruiting

Registration date
05/04/2011

Overall study status
Completed

Last Edited
06/06/2025

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
A stroke occurs when the blood supply to part of the brain is cut off. The injury to the brain can lead to weakness or paralysis in one side of the body. The aim of this study is to find out whether a combination of aerobic exercise and motor skill training is better than motor skill training only in the rehabilitation of stroke patients. In this study we will use Constraint Induced Movement Therapy (CIMT) for the motor skill training, which involves rehabilitation of the weaker hand while restraining the stronger hand.

Who can participate?
Patients aged 18 and over who had their first stroke 3 or more months ago.

What does the study involve?
Patients are randomly allocated to either the control group or the intervention group. The control group carry out CIMT for 5 hours and 30 minutes a day over 10 days. The intervention group, in addition to CIMT for about 4 hours and 45 minutes per day, also perform aerobic exercise, consisting of cycling on an exercise bike twice a day for 4 x 5 minutes with 1 minute of rest between. The total duration of training is the same for both groups. Both groups also use a restraint for the stronger hand 90% of the time they are awake to prevent them from using it. Motor skill and hand grip strength are measured at 1 - 7 days before the start of the rehabilitation and 1 day after it has finished.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Umeå University (Sweden)

When is the study starting and how long is it expected to run for?
January 2011 to September 2024

Who is funding the study?
1. County Council of Södermanland (Sweden)

2. National Stroke Association (Sweden)
3. Insamlingsstiftelsen för Strokeforskning i Norrland (Sweden)
4. Legitimerade sjukgymnasters riksförbund, Minnesfonden (Sweden)
5. Norrbacka-Eugeniastiftelsen (Sweden)

Who is the main contact?
Staffan Eriksson

Contact information

Type(s)
Scientific

Contact name
Mr Staffan Eriksson

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SE-631 88

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
The use of aerobic exercise to augment training of motor skill in stroke rehabilitation: a randomised controlled trial

Study objectives
Our hypothesis is that the effect of a motor skill training program on motor skill performance, in persons with stroke, is enhanced if the training program is complemented with aerobic exercise.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board in Umeå, reference number (date): 09-104M (09/06/2009), with additional approval 2010/314-32M (27/12/2010), 2011-244-32M (14/07/2011), and 2012-235-32M (05/06/2012)

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Stroke rehabilitation

Interventions
We wanted to investigate if a combination of aerobic exercise and training of motor skill is better than motor skill training only in rehabilitation of stroke patients. In this study we will use CIMT in stroke patients as a model to test this hypothesis. The ordinary work with CIMT at 10 clinics will be utilized to provide the training of motor skill. In CIMT the training regimen is individualized for each patient. A period of CIMT at these clinics consists of 14 consecutive days, 10 weekdays at the clinic and 2 weekends away from the clinic. During the 10 weekdays the patients carry out CIMT at the clinic and a restraint is used 90% of the time they are awake to prevent them from using the non-paretic hand. During the 2 weekends the patients do not visit the clinic and no CIMT or other training is encouraged apart from that they use a restraint 90% of the time.

Patients will consecutively be allocated to either control group or intervention group through randomisation. The control group will during the 10 weekdays carry out CIMT for 5 hours and 30 minutes a day. The intervention group will in addition to CIMT perform aerobic exercise immediately in the morning and after lunch during the 10 weekdays. Aerobic exercise will be conducted as cycling on a stationary bicycle. The intervention group also trains 5 hours and 30 minutes each day which includes cycling and CIMT. Hence, the intervention group will carry out CIMT for about 4 hours and 45 minutes each weekday and also twice a day carry out cycling for 4 x 5 minutes with 1 minute of rest between intervals. The aerobic exercise will be performed prior to the CIMT. They will be cycling at an exertion level corresponding to 13 on the Borg RPE-scale. On weekdays, in both groups, the total duration of training will be 5 hours and 30 minutes and they will also use a restraint for the non-paretic hand 90% of the time they are awake. During the weekends the patients in both groups will submit to the same regimen using a restraint of their non-paretic hand for 90 % of the time when awake.

Test procedure:
Outcome measures will be tested at 1 - 7 days before start of intervention, i.e. baseline, and at day 1 after intervention.

Intervention Type
Behavioural

Primary outcome(s)
Motor skill by BL-motor assessment, at baseline and after intervention

Key secondary outcome(s))
1. Motor skill by Twenty-five Hole Peg Test, at baseline and after intervention
2. Hand grip isometric strength by dynamometer, at baseline and after intervention
3. Cognitive ability by MMSE, at baseline and after intervention
4. Effect of CI-therapy by BL-motor assessment (BLMA), Twenty-five Hole Peg Test (THPT), hand grip isometric strength by dynamomter, at basline and after intervention

5. Effect of CI-therapy, by BLMA and THTPT, with regard to age, sex, motor skill at baseline, time since stroke and whether stroke affects dominant hand
6. The effect of the participants expectation (Likert-type scale) of the effect of CI-therapy on the effect of CI-tharapy by BLMA and THPT, at basline and after intervention
7. If motivated, in a secondary analysis of our primary outcome and secondary outcomes 1-6, we will adjust for clinic and in this analysis we will exclude clinics contributing with less than four participants
8. Concurrent validity of THPT by BLMA and Fugl-Meyer assessment
9. Test-retest reliability of THPT

Completion date
30/09/2024

Eligibility

Key inclusion criteria
1. An approval from the patient's physician
2. Aged 18 years and over, either sex
3. First time stroke
4. Stroke ≥3 months ago
5. BL-motor assessment score less than or equal to 45
6. Able to pick up and release a tennis ball 3 times in 1 minute
7. Mini-mental state examination (MMSE) score greater than or equal to 24
8. Able to cycle on a stationary bicycle 4 x 5 minutes with 1 minute rest between intervals at an exertion level corresponding to 13 on Borgs RPE-scale

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
45

Key exclusion criteria
1. Participants in both groups missing 3 hours or more of training
2. Participants in the intervention group missing more than one session of aerobic exercise, or from two or more interrupted aerobic exercise sessions lacking the same amount of aerobic exercise.
3. Other brain injury than stroke, e.g. intracranial haemorrhage caused by aneurysmal rupture or

trauma
4. Neurological disorder such as Parkinson's disease or peripheral nerve damage
5. Stroke affecting brainstem and/or cerebellum
6. Previous participation in constraint-induced movement therapy (CIMT)
7. Current participation in other stroke treatment directed at motor skill
8. Injection of anti-spasticity drugs into upper extremity musculature within the past 3 months

Date of first enrolment
24/01/2011

Date of final enrolment
12/09/2024

Locations

Countries of recruitment
Sweden

Study participating centre
Avesta Lasarett
Geriatriska rehabiliteringsenheten
Avesta
Sweden
774 82

Study participating centre
Rmonthagen
Öppenvårdsrehab, stroke och hjärnskaderehab Solidenvägen 58
Östersund
Sweden
831 83

Study participating centre
Sjukhuset i Arvika
Sjukgymnastiken i Arvika
Rackstavägen
Arvika
Sweden
671 80

Study participating centre
Länssjukhuset Ryhov
Rehabmedicin/sjukymnastik

Hus T1
Jönköping
Sweden
551 85

Study participating centre
Norrlands universitetssjukhus
Geriatriska kliniken
Umeå
Sweden
901 85

Study participating centre
Blekingesjukhuset
Arbetsterapin
Karlskrona
Sweden
37185

Study participating centre
Paramedicin
Geriatrik/rehab Borlänge sjukhus
Box 731
Borlänge
Sweden
781 27

Study participating centre
Sjukgymnastiken Korpen
Brömsebroväg 8
Box 1254
Visby
Sweden
621 23

Study participating centre
Vrinnevisjukhuset
Rehab öst Vrinnevi
Norrköping
Sweden
601 82

Study participating centre
Rörelse och hälsa
Dag/hemrehab
Brigadgatan 22
Linköping
Sweden
587 58

Sponsor information

Organisation
Umeå University (Sweden)

ROR
https://ror.org/05kb8h459

Funder(s)

Funder type
Government

Funder Name
County Council of Södermanland (Sweden)

Funder Name
National Stroke Association (Sweden)

Funder Name
Insamlingsstiftelsen för Strokeforskning i Norrland (Sweden)

Funder Name
Legitimerade sjukgymnasters riksförbund, Minnesfonden (Sweden)

Funder Name
Norrbacka-Eugeniastiftelsen (Sweden)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes