

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

Submission date 14/01/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/04/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/06/2025	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

Contact details
FoU-centrum Sörmland
Kungsgatan 41
Eskilstuna
Sweden
SE-631 88

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

Motor skill by BL-motor assessment, at baseline and after intervention

Secondary outcome measures

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 dynamometer, at baseline and after intervention
5. Effect of CI-therapy, by BLMA and THPT, 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-therapy by BLMA and THPT, at baseline 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

Overall study start date

24/01/2011

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

46

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

Rmönthagen

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/sjukgymnastik

Hus T1

Jönköping

Sweden

551 85

Study participating centre

Norrlands universitetssjukhus

Geriatriska kliniken

Umeå

Sweden

901 85

Study participating centre

Blekingesjukhuset

Arbetssterapin

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)

Sponsor details
Community Medicine and Rehabilitation
Department of Physiotherapy
Umeå
Sweden
SE-901 87

Sponsor type
University/education

Website

<http://www.umu.se/english>

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

Publication and dissemination plan

To be confirmed at a later date

Intention to publish date

30/06/2025

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not expected to be made available