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Clinical efficacy and prognostic indicators for lower limb pedalling exercise early after stroke

Submission date
02/11/2009

Recruitment status
No longer recruiting

Registration date
30/11/2009

Overall study status
Completed

Last Edited
14/01/2019

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A stroke is a serious condition where the blood supply to a part of the brain is cut off, usually by a blood clot blocking an artery supplying the brain (ischaemic stroke) or a bleed in the brain (haemorrhagic stroke). A large proportion of stroke victims suffer from long-term complications depending on the area of the brain that is affected, which can affect their ability to move, speak or even their cognitive function (memory loss, difficulty reasoning and confusion). One of the most common complications of a stroke is paralysis (hemiplegia) or weakness (hemiparesis) on one side of the body, particularly the legs. Early after having a stroke, patients are keen to start rehabilitation, such as walking training to strengthen their legs and regain their mobility. However, patients are often unable to take part in such activities as they may be too weak to undertake the repetitive movements required and need a lot of help from therapy staff. Some studies have shown that repetitive motions such as pedalling exercises can help to restore movement patterns helpful to walking recovery. The aim of this study to see whether pedalling exercises on an exercise bike can help patients with severe leg weakness who are unable to take part in active therapy.

Who can participate?
Adults who have had a stroke with severe one-sided leg weakness making them unable to walk or in need of support from two people to do so.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive only conventional physical therapy (CPT). Those in the second group are given access to an adjustable exercise bike. In the first session with the bike, participants are asked to pedal for up to 30 minutes. They are then encouraged to use for up to ten minutes at a time for up to ten days before completing another 30 minute session at the end of the study. At the start of the study and then after the therapy is finished, all participants are examined and complete a number of movement tests in order to find out if there is has been any change to their muscle strength and function.

What are the possible benefits and risks of participating?
Participants benefit from a thorough assessment of their abilities and movement after their

stroke. Participants who take part in the pedalling exercise may experience improved abilities, however this is not certain. There is a small risk that participant may experience some pain or discomfort in the legs while pedalling, however this will be closely monitored and the pace of pedalling will be adapted to each person's abilities.

Where is the study run from?
Norfolk and Norwich University Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2009 to March 2011

Who is funding the study?
University of East Anglia (UK)

Who is the main contact?
Professor Valerie Pomeroy
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Clinical efficacy and prognostic indicators for lower limb pedalling exercise early after stroke: a pilot randomised controlled trial with observer blinding

Acronym
Ped-Ex

Study objectives
UNICAM-assisted upright pedalling (UNICAM-assisted UP), when used as an adjunct to conventional therapy, enhances recovery of lower limb motor function in people with substantial paresis 3 - 30 days after stroke. Is there sufficient evidence of benefit to justify proceeding to larger scale clinical trials?

The trial will also investigate which stroke survivors are most likely to benefit from UNICAM-assisted UP by linking pre-stated prognostic indicators to the ability to pedal or not.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Essex 1 Research Ethics Committee, 27/08/2009, ref: 09/H0301/52
2. Research Governance Approval by East Norfolk and Waveney Research Governance Committee, 24/09/2009, ref: 2009MFE04 [158-09-09]

Study design
Single-centre randomised controlled pilot trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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 with substantial paresis of the lower limb

Interventions
All participants will receive routine conventional physical therapy (CPT) as deemed appropriate by the clinical team. To describe and quantify the routine therapy and consequently improve the ability to replicate in research and clinical practice, a standardised schedule to record details of the conventional treatment will be used.

Control intervention:
Participants allocated to the control group will receive CPT only as described above.

Duration: Baseline and outcomes measures sessions only, times as intervention group

Experimental intervention:
Participants allocated to the experimental group will receive UNICAM-assisted UP in addition to CPT. All experimental participants will be asked to pedal at 50 revolutions per minute (50 rpm) at a comfortable resistance whilst maintaining a heart rate of 85% or below their age-predicted maximum (i.e., less than 220 - age x 0.85 beats per minute). If patients cannot achieve 50 rpm, the research therapist will be guided by their response in setting the maximum rpm. The mean rpm achieved will be recorded for each participant for each intervention session. It is anticipated that few patients this early after stroke will immediately manage ten minutes of pedalling, so the number of minutes pedalled, up to ten minutes, will be recorded.

Duration: Baseline measures x 1 session = 30 minutes, daily pedalling for up to ten minutes for up to ten days = 100 minutes intervention maximum over ten days, outcome measures x 1 session = 30 minutes.

Each intervention session will also involve recording:
1. The pedal crank setting
2. The degree of reciprocal activation of antagonistic muscle groups via EMG
3. The timing of onset and offset of activity in antagonistic muscle groups via EMG
4. The distance pedalled as recorded by the exercise cycle

This description of each intervention session will allow replication of the intervention and information on how to progress the intervention over time in subsequent clinical trials.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Measurement of clinical efficacyis measured using the Motricity Index lower limb section. This is a widely used measure, with established validity and reliability for use after stroke. It is an ordinal score with six measurement levels within each of three categories for the lower limb. The three categories are: ankle dorsiflexion, knee extension, and hip flexion. For each movement, a score of 0, 9, 14, 19, 25, or 33 is given, where 0 is no movement, 19 is full range movement against gravity not against resistance and 33 is normal power.
2. Prognostic indicator measures:
2.1. Site of stroke lesion (determined from scan and liaison with medical team)
2.2. Degree of muscle weakness as measured by the Motricity Index (see clinical efficacy measures)
2.3. Ambulatory Capacity as measured by the Functional Ambulatory Categories: this scale is designed to give detail on physical support needed by patients for walking, so has clinical relevance, and is easy to use. It has established validity and reliability for use after stroke. It is an ordinal scale, patients scoring from 0 - 5, where 0 indicates a patient who is not able to walk or needs help of 2 therapists, and 5 indicates a patient who is independent in ambulation even on stairs.

2.4. Ability to control the trunk as measured by the Trunk Control Test: a short, simple measure of motor loss developed for use after stroke. Patients are asked to do four movements - rolling to their weak side, rolling to their strong side, sitting up from lying down and balancing in a sitting position. Each movement is scored according to ability, either 0, 12 or 25, leading to a total score out of 100. Validity and reliability have been established.

Secondary outcome measures
1. Onset and offset of EMG activity of antagonistic muscle groups during pedalling:
EMG activity will be recorded in quadriceps and hamstring muscles. The EMG system to be used is the Biometrics SX 230, Biometrics, UK. Baseline EMG activity in will be recorded as a voltage at 1,000Hz whilst the participant's foot is resting firmly on a box so that the leg is still and relaxed and the knee is in approximately 5 degrees of flexion, for 30 seconds. This will be undertaken for each leg in turn. EMG data (voltage) will be collected continuously during pedalling for 30 seconds at 50 rpm. EMG data will be rectified and then processed by a Technician. Baseline EMG values will be calculated as the mean ± 3 SD (standard deviations) during the 30 seconds baseline data collection period. Onset of activity in each of the four muscle groups will be defined as the time point during the 360 degree turn at which EMG voltage exceeds the mean baseline value plus 3SD for 20 data points (20 ms). Offset of activity in each of the four muscle groups will be defined as the time point during the 360 degree turn at which EMG voltage falls below the mean baseline value minus 3SD for 20 data points (20 ms). The time point for onset and offset of muscle activity in each of the four muscle groups will also be recorded as a function of the position of the pedal during the 360 degree turn as one channel of the DataLINK will be making recordings of angle of turning synchronously with EMG data. Thus in addition to timing of onset and offset of muscle activity we will also be able to relate this to the position of the pedal and during the 360 degree turn.

2. Reciprocal activation of antagonistic muscle groups during pedalling:
By collection of EMG data as described above. Rectified EMG data for each antagonistic muscle pair will be analysed using the Spearman's correlation coefficient. A r value of 1.0 indicates perfect correlation and therefore complete co-contraction, no reciprocal activation, of an antagonistic muscle pair. Whereas a r value of 0 indicates no correlation and therefore complete reciprocal activation of an antagonistic muscle pair. A negative correlation therefore indicates a better level of reciprocal activation of antagonistic muscle groups.

Overall study start date
01/11/2009

Completion date
30/03/2011

Eligibility

Key inclusion criteria
1. Adults aged 18 years and over, either sex
2. Three to thirty days following a unilateral stroke resulting in unilateral muscle weakness with or without sensory deficit
3. Considered fit to participate by a consultant-led medical team fully engaged with the research process. Participants will have resting oxygen saturations of 95% and above, resting heart rate 90 beats per minute or less and systolic blood pressure of 100 - 160 mmHg.
4. Score of 0, 1 or 2 on the Functional Ambulation Categories. Clinically, this means unable to walk; or need the help of two or more people; or require firm continuous or intermittent support

of one person assisting with weight and balance.
5. Able to sit unsupported for 30-seconds on the edge of a bed with feet on the floor
6. Able to follow a one-stage command i.e. sufficient communication, orientation and memory to participate in this cycling intervention
7. Sat out of bed in a chair or wheelchair at least once for a continual period of 15 minutes, i.e., have appropriate sitting tolerance to participate in this cycling intervention
8. Independently mobile with or without an aid prior to the index stroke

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24 (12 in each trial arm)

Key exclusion criteria
One or more co-existing pathologies contributing to substantial impairment in either lower limb, e.g., osteoarthritis with severe deformity

Date of first enrolment
01/11/2009

Date of final enrolment
01/02/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Norfolk and Norwich University Hospital
Gunthorpe Ward Acute Stroke Unit
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Funder(s)

Funder type
University/education

Funder Name
University of East Anglia (UK) - PhD studentship, funded by an MRC fellowship awarded to Ms Nicola Hancock

Results and Publications

Publication and dissemination plan
The data is to be used in part fulfilment of the requirements for a University of East Anglia PhD by the Chief Investigator, Nicola Hancock, in addition to publications in peer reviewed journals.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	07/03/2011		Yes	No
Results article	observational results	01/12/2017		Yes	No
HRA research summary			28/06/2023	No	No