ISRCTN14527641 https://doi.org/10.1186/ISRCTN14527641

The effect of coordinative training on balance and walking ability in ataxic people with acute cerebral stroke

Submission date
19/05/2016

Recruitment status
No longer recruiting

Registration date
27/05/2016

Overall study status
Completed

Last Edited
17/04/2020

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] 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. Around 80% of strokes are ischemic strokes, in which the arteries that supply the brain with oxygen become narrowed or blocked, causing severely reduced blood flow (ischemia). As we age, a gradual build-up of a sticky substance called plaque can build-up in these arteries. An acute cerebral stroke is a type of ischemic stroke in which these arteries become blocked suddenly by a blood clot, reducing blood flow to the brain (cerebral perfusion) and starving it of oxygen. This can lead to serious complications, depending on which part of the brain is deprived of oxygen and for how long. A common complication of acute stroke is ataxia, in which the patient loses full control of their bodily movements. Patients with ataxia suffer from disturbance of balance and coordination. This leads to exceedingly uncontrolled, swaying movements. This study is investigating a new physical therapy approach called the Doris-Broetz-Concept, which aims to help improve balance (both when still and moving), coordination skills and to reduce fear of stiffness. The aim of this study is to find out whether the Doris-Broetz-Concept is more effective at improving balance and coordination in people with acute stroke than standard physiotherapy.

Who can participate?
Adults who have had a stroke and are suffering from, ataxia and balance problems.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive ten 45 minute sessions of standard physiotherapy over 16 days. This involves taking part in active exercises including balance training, gait (walking) training), core stability and training in everyday activities (activities of daily living). Those in the second group take part in ten 45 minute sessions of physical therapy using the Doris-Broetz-Concept over 16 days. This involves a range of exercises which are completed with a physical therapist while trying to stop the body becoming stiff by swaying. Participants in both groups are also given home exercises to complete (15 minutes per day) every day during the physical therapy and for four weeks

afterwards. At the start of the study and then again after the physical therapy (around 16 days) and 12 months later, participants in both groups complete a number of physical tests in order to find out if their balance and coordination have improved.

What are the possible benefits and risks of participating?
Participants may benefit from a quicker recovery if they receive the coordinative training, however this cannot be guaranteed. The journey to the Innsbruck Medical University for Follow-up, the assessments and the treatment are seen as a slight risk to the patient and so they are insured for this. During the assessments and therapy the patient is always safeguarded by the principal investigator or the physical therapist to minimise risks.

Where is the study run from?
Innsbruck Medical Hospital (Austria)

When is the study starting and how long is it expected to run for?
December 2015 to March 2018

Who is funding the study?
Innsbruck Medical Hospital (Austria)

Who is the main contact?
Mrs Patricia Brugnara
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Contact information

Type(s)
Public

Contact name
Mrs Patricia Brugnara

Contact details
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Innsbruck
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6020

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AN2016-0078 361/4.10

Study information

Scientific Title
The effect of coordinative training on postural impairment and gait ataxia in people with acute cerebral stroke - a single-blind randomized controlled pilot trial

Acronym
GLAAS

Study objectives
Null hypothesis:
There is no significant difference between coordinative training (Doris-Broetz-Concept) and usual physical therapy to change balance in people with acute stroke

Experimental hypothesis:
There is a significant difference between coordinative training (Doris-Broetz-Concept) and usual physical therapy to change balance in people with acute stroke

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethikkommission Der Medizinischen Universität Innsbruck, 24/06/2016, ref: AN2016-0078 361/4. 10

Study design
Single-blind randomized controlled pilot 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
Ataxia after acute cerebral stroke

Interventions
After baseline examination and physiotherapy testing, participants will be randomly allocated to one of two groups (A or B). Allocation concealment will be conducted by an independent

researcher working at Innsbruck University Hospital. He will fabricate sealed envelopes according to the randomization list and group allocation, one for each participant, and will inform the physical therapist of the proper group.

Treatment group A: Participants receive ten 45 minute sessions of physical therapy according to current practice. Treatment will include active exercises including balance training, gait training, core stability and training of ADL's (activities of daily living). The exercises will differ in difficulty depending on the patient. Further information about the exercises involved can be found via http://broetz-physiotherapie.de/ataxia_coordinative_physiotherapy_broetz.pdf

Treatment group B: Participants receive ten 45 minute sessions of coordinative training (based on the Doris-Broetz-Concept). This treatment involves a range of exercises to improve static and dynamic balance control and coordination skills and to reduce fear and stiffness. The main aims of this therapy method is to define goals based on problems in daily living, “Sway – don't make yourself stiff”, exercise every day, coordinative challenging movements, doing lots of repetitions by having variation. The exercises differ in difficulty depending on the patient.

For participants in both groups, a home exercise program is also given to be completed by the patient for 15 minutes every day, starting on day 2. Home exercise should be continued for another four weeks after post-intervention testing. Participants are followed up at 12 months.

Intervention Type
Other

Primary outcome measure
Balance is measured using the Berg Balance Scale (BBS) at baseline, day 16+/-2 (= post-intervention) and at 12 month (follow-up).

Secondary outcome measures
1. Core Stability and trunk control is measured using the Trunk Control Test (TCT) at baseline, day 16+/-2 (= post-intervention) and at 12 month (follow-up)
2. Walking ability is measured using the Functional Ambulation Categories (FAC) at baseline, day 16+/-2 (= post-intervention) and at 12 month (follow-up)
3. Walking speed is measured using the Timed up and go Test (TuG) at baseline, day 16+/-2 (= post-intervention) and at 12 month (follow-up)
4. Independence in activities of daily living is measured using the Scores of Independence for Neurologic and Geriatric Rehabilitation (SINGER) at baseline, day 16+/-2 (= post-intervention) and at 12 month (follow-up)
5. Quality of life is measured using the EQ 5D 3L at baseline, day 16+/-2 (= post-intervention) and at 12 month (follow-up)

Overall study start date
15/12/2015

Completion date
31/03/2018

Eligibility

Key inclusion criteria

1. First acute cerebral stroke
2. Aged 18 years and over
3. Resident of Tyrol
4. Ataxia of gait and/or stance and/or sitting and/or positive heel-shin slide (assessed with "Scale for the Assessment and Rating of Ataxia - SARA"): score of at least 1 point in SARA
5. Berg Balance Scale (BBS) < 50 points
6. Written informed consent
7. Male and female participants

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Cerebral stroke in case history
2. Comorbidity which would restrain the participation (e.g. life expectancy less than 12 month, alcohol or drug abuse)
3. Modified Rankin Scale (mRS) ≥ 5
4. Any physical or mental condition the investigator believes would not allow safe participation in the study or would complicate assessment of outcomes (e.g. dementia, cardiac insufficiency, severe Aphasia, people having a procurator appointed, etc.)
5. Pregnancy
6. People fulfilling military service

Date of first enrolment
01/06/2016

Date of final enrolment
01/12/2016

Locations

Countries of recruitment
Austria

Study participating centre

Innsbruck Medical Hospital
Department of Neurology
Stroke Unit
Anichstraße 35
Innsbruck
Austria
6020

Sponsor information

Organisation
Innsbruck Medical Hospital

Sponsor details
Department of Neurology
Anichstraße 35
Innsbruck
Austria
6020

Sponsor type
Hospital/treatment centre

Website
www.tirol-kliniken.at

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Innsbruck Medical Hospital

Results and Publications

Publication and dissemination plan
1. The participants will be informed about the study results after analysis completion
2. Findings from the study will be presented at scientific conferences and will be published in an appropriate scientific journal

Intention to publish date

31/12/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		15/04/2020	17/04/2020	No	No