ISRCTN49706672 https://doi.org/10.1186/ISRCTN49706672

The effects of a community-based exercise therapy programme for young people with cerebral palsy

Submission date
19/03/2012

Recruitment status
No longer recruiting

Registration date
18/04/2012

Overall study status
Completed

Last Edited
25/08/2015

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Cerebral palsy (CP) is a condition that affects a person's muscle control leading to problems with movement, posture and coordination. It is caused by abnormal brain development or damage to the brain either before birth or in early childhood. The severity of the condition and any associated ailments (such as problems with vision, hearing, learning, etc) depend on the extent and location of this damage. Although there is no change to the brain abnormality throughout a person's life, the implication to the way they move and function physically in day-to-day life will change as they develop and age. Therapies such as physiotherapy can help maximize a patient's physical abilities and help them become more independent. Traditionally the focus of therapies and research for people with CP has been on children. When they are school aged they tend to receive comprehensive health care and well structured physiotherapy, but when they turn about 16-18 years old they are discharged from paediatric services. Health care for adults with CP tends to be much less complete, and often doesn't include treatments like physiotherapy. It is common for patients with CP to have big declines in their physical ability in early adulthood. This can have negative impacts on their independence, social life, emotional health and overall well-being. We will all experience a decline in our physical function as we get older, but people with CP seem to experience this at a much younger age (in their 20's or 30's) than people without a disability. For these reasons we think that adolescence and early adulthood is a very important time for patients with CP. They should be taking steps to help manage their disability on their own and hopefully put off this physical decline. To accomplish this, the strategy we are proposing in this research study is to get young people with CP into their local gym to exercise. We will provide them with a combined aerobic and strength training programme and show them how to complete it. Then we will measure how it impacts their physical function and quality of life. The goal is to help reduce any physical declines or even improve physical function when compared to peers with CP who aren't taking part in the programme.

Who can participate?
To take part you need to have cerebral palsy, be between 16 and 25 years old, and live in Lothian or Fife, Scotland.

What does the study involve?
If you take part in the study you will be randomly assigned to either a group that will be taking part in an exercise program or a control group. If you are in the exercise group you will take part in an 18-week exercise training programme. The exercise programme will take place at your local community leisure centre and will include strength exercises as well as aerobic exercises. An experienced physiotherapist will introduce you to the programme showing you how to do the different exercises. The physiotherapist will return for about 3 or 4 other sessions throughout the 18 weeks to check in and adapt the exercises as needed. For the other sessions a fitness instructor from the leisure centre will be available to help you out. For the first 6 weeks you will be expected to attend 3 supervised sessions per week. During weeks 7-12 you will attend 2 supervised sessions per week and will be encouraged to complete 1 more session on your own per week. In the last 6 weeks (13-18) there is no set number of sessions but you will be encouraged to complete 3 sessions per week on your own. We will provide you with a logbook describing the different exercises and ask you to record what you are doing and any comments you have. If you are put in the control group you will not take part in the exercise programme. You'll just continue to do what you would normally be doing. At the end of the 18 weeks when the study is complete you will be given free leisure centre access for 6 months. Regardless of which group you are in, everyone who participates in the study will be asked to also come to Queen Margaret University four times to have your physical function tested. Each assessment will take about 2.5 to 3 hours to complete. These will be done at the beginning of the study, and after 6, 12, and 18 weeks. During the assessment a number of different measures will be recorded. You will complete some questionnaires and be asked to perform activities such as walking, standing from a seat, and going up stairs. Your muscle strength will be measured for a number of muscles in your legs. The flexibility of your ankle, knee and hip will be recorded. Your physical fitness will be tested by having you do a 10 m shuttle run/walk test which is designed specifically for people with CP. We will also do gait analysis. For this, reflective balls (called markers) will be stuck to your legs and hips and you will be asked to walk back and forth in the lab. The markers will allow us to analyse your movement patterns during walking. You will also be given a small (about the size of a matchbook) activity monitor that we will ask you to wear for one week. This will record information on how much you walk, sit and stand throughout a day.

What are the possible benefits and risks of participating?
By taking part in this study you will be given 6 months of free access to your local leisure centre and hopefully some motivation to use it to get/stay fit. There are also indirect benefits for other young adults with CP. This study will help to develop an exercise program to assist young adults in their transition from childhood to adult healthcare and hopefully help improve their quality of life. The assessment procedure involved is a safe and common clinical assessment. However, there exist minimal risks such as the possibility to fall, trip etc. There is a risk of injury during any fitness program. This will be minimized because the physiotherapist will work with you to make sure the exercises are appropriate and a fitness instructor will be available at the leisure centre to help you out and make sure you are doing the exercises properly.

Where is the study run from?
The study is being run at Queen Margaret University, Edinburgh, Scotland. We are working with Edinburgh Leisure, West Lothian Leisure, and East Lothian Leisure to provide you with a facility close to home where you can exercise.

When is the study starting and how long is it expected to run for?
The study is currently underway and we will continue to recruit participants until April 2016.

Who is funding the study?
The study is funded by two charities:

1. The James and Grace Anderson Trust
2. La Fondation Motrice

Who is the main contact?
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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
The effects of a pragmatic community-based exercise therapy intervention on physical fitness, habitual physical activity, self-esteem and quality of life on adolescents and young adults with cerebral palsy: a pilot study

Study objectives
Patients who undergo a community-based individualized exercise therapy program will show improvements in muscle strength, function, and quality of life with respect to baseline measures as compared to peers who do not take part in the exercise program.

On 25/08/2015 the overall trial end date was changed from 31/12/2012 to 01/12/2016.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Lothian NHS Board South East Scotland Research Ethics Committee, 09/03/2011, ref: 11/AL /0044
2. NHS Fife Operational division, 19/04/2011, ref: 11-015 NRA11/NE39 11/AL/0044

Study design
Prospective single-blind parallel-group randomized control trial

Primary study design
Interventional

Secondary study design
Randomised parallel 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
Cerebral palsy

Interventions
Participants will be randomized to either an exercise group or a control group.

Those in the exercise group will be asked to complete an 18-week exercise programme taking place at their local leisure centre. The programme will consist of a combination of aerobic, strength and flexibility exercises. The exercise program will involve three supervised sessions per week during weeks 1-6, two supervised sessions with encouragement to complete a third unsupervised session per week during weeks 7-12, and encouragement to complete three unsupervised sessions per week during weeks 13-28. The control group will continue with their usual activities. All participants will be assessed at baseline and at 6, 12 and 18 weeks.

Intervention Type
Behavioural

Primary outcome measure
The change in Gross Motor Function Measure (GMFM) for dimensions D and E from baseline to 6, 12 and 18 weeks.
The Gross Motor Function Measure was developed to assess children with cerebral palsy. It uses a 4-point scale to rate participants on their ability to complete a motor task.

Secondary outcome measures
1. Body function & structures
1.1. Aerobic fitness based on a 10 m shuttle run/walk
1.2. Maximal isometric muscle strength
1.3. Range of motion at the ankle, knee, and hip.
2. Activity
2.1. Timed up and go (TUG) test - time for a participant to rise from a chair, walk 3 m, return to the chair and sit down again
2.2. Gait Profile Score (GPS) - determined from computerized three-dimensional movement analysis
3. Participation
3.1. Daily physical activity level
3.2. Quality of life, and function in activities of daily living
3.3. Functional Assessment Questionnaire (FAQ)
3.4. Canadian Occupational Performance Measure (COPM)

Measures for the function & structures and activity components will be recorded during all four assessments (baseline and at 6, 12, 18 weeks) while outcomes for the participation component will only be measured twice (baseline and 12 weeks). A Rosenberg Self-Esteem Scale will also be completed, but only at baseline and after completion of the training program.

A small activity monitor (ActivPAL, PAL Technologies Limited, Glasgow, UK) attached to the front of the thigh will be used to assess the amount of physical activity the participants engage in over a 7-day period. The device will record the number of steps, sit-to-stand and stand-to-sit transitions and the time spent walking, standing, or sitting and lying. Quality of life for each participant will be measured using the Short Form 12, a self report survey. The third and forth outcome measures are a self-report survey (FAQ) and a scored patient interview (COPM) respectively, used to assess function during activities of daily living.

Overall study start date
01/03/2011

Completion date
01/12/2016

Eligibility

Key inclusion criteria
1. Diagnosed with spastic cerebral palsy
2. Aged 16 - 25 years
3. Living in Lothian or Fife
4. Discharged from the paediatric service within the last 6 years
5. Able to ambulate with or without aids

Participant type(s)
Patient

Age group
Adult

Sex

Both

Target number of participants
20

Key exclusion criteria
1. Participating or participated in a gym based exercise training program within the last 2 months
2. Receiving regular physiotherapy (more often than 1 session every 4 weeks)
3. Insufficient cognitive ability to give informed consent
4. Medical issues with participating in an exercise program
5. Received Orthopaedic surgery or Botox injections within the last 6 months

Date of first enrolment
01/03/2011

Date of final enrolment
01/04/2016

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Queen Margaret University
East Lothian
United Kingdom
EH21 6UU

Sponsor information

Organisation
Queen Margaret University (UK)

Sponsor details
Queen Margaret University Drive
Musselburgh
East Lothian
Scotland
United Kingdom
EH21 6UU

Sponsor type

University/education

Website
http://www.qmu.ac.uk/

ROR
https://ror.org/002g3cb31

Funder(s)

Funder type
Charity

Funder Name
The James and Grace Anderson Trust (UK)

Funder Name
La Fondation Motrice (France)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request