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Long term Individual Fitness Enablement

Submission date	Recruitment status	[_] Prospectively registered
22/08/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/10/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/08/2012	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Miss Charlotte Winward

Contact details
Movement Science Group
School of Life Sciences
Oxford Brookes University
Gipsy Lane
Headington
Oxford
United Kingdom
OX4 0BP

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
0530006

Study information

Scientific Title

Acronym
LIFE

Study objectives
To determine whether a personalised targeted progressive exercise programme delivered in community facilities with a Physical Activity Provision Support System (PAPSS) is effective in increasing physical activity levels in neurological participants when compared with a waiting list control group.

Participants will be adults with a diagnosis of Muscular Dystrophy, Multiple Sclerosis, Parkinson's Disease, Cerebral Palsy, Motor Neurone Disease with no contraindications to exercise. The Oxford Radcliffe NHS Trust, The Nuffield Orthopaedic Centre NHS Trust, City Hospital Birmingham and University Hospital Birmingham are the regional centres for neurological and neuromuscular care and analysis reveals 45 people with each condition could easily be recruited over a period of 2.5 years.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Narional Research Ethics Service Oxfordshire Research Ethics Committee (REC) on the 5th July 2007 (REC reference number: 07/H0606/81).

Study design
Randomised controlled trial with blinded assessments at 0, 3 and 6 months. Interventions every 3 months.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Chronic neurological or neuromuscular disorder

Interventions

There will be two groups in the study:
1. An immediate exercise intervention group
2. A waiting list control group who will receive the exercise intervention after a wait of three months

Thus all participants will receive the exercise intervention for three months. During the exercise intervention period all participants will receive the exercises delivered within a Physical Activity Support System (PASS).

An assessor blinded from group allocation will assess all individuals. Individuals in both groups will be assessed at 0, 3 and 6 months. The waiting list group will act as a control group during the first part of the study. Comparisons of treatment and waiting list control during the first three months will determine whether or not the intervention is effective.

The exercise and Physical Activity Support System (PASS) intervention:
1. Exercises:
Therapeutic exercises will be delivered by fitness professionals at Inclusive Fitness Initiative (IFI) accredited gyms in local authority leisure centres under the mentorship of specialist physiotherapists in Oxfordshire (Jane Freebody, Charlotte Winward) and Birmingham (Nicola Brittle). Physiotherapists will be supported by the research team Dr Helen Dawes in Oxfordshire and Dr Andrew Soundy in Birmingham.

Details of the IFI initiative are available at http://www.inclusivefitness.org/. This is an initiative aimed at increasing participation under the auspices of the English Federation of Disability Sport supported in 2001 by grant of £1 million from the Sport England Lottery Fund towards a total project cost of £1.3 million. Local authority partners contributed further funding of £0.3 million. IFI facilities offer a wide range of benefits to disabled customers, including: 'Facilities that have undertaken both physical and communication access improvements, staff that have a high level of training, an opportunity to exercise in a truly inclusive environment and access to healthy lifestyle choices'.

As part of the intervention participants will be assessed by the fitness professional for a suitable programme and a profile created taking into consideration each participant's family, social background, their hopes, health and fitness needs. An intervention will be created to address participant's requirements. Interventions will typically include components of endurance, muscle strength, flexibility and cardiovascular fitness. Exercise sessions will normally last up to one hour and components be programmed at an appropriate intensity, duration, frequency and progression according to exercise prescription principals.

2. The Physical Activity Support System (PASS):
The PASS will include information, practical advice and physical support from a physiotherapist for both the participants with neurological conditions and the health and fitness professionals involved in physical activity provision. A physiotherapist will provide support so that therapeutic exercises of the participant's choice can be safely and effectively delivered.

Each participant will be supported by the physiotherapist at their initial fitness assessment and up to 5 subsequent attendances, though this number of sessions may vary between participants. It is expected the number of support sessions will be an integral aspect of measuring the support system. A physiotherapist will then provide the fitness trainer and participant with phone/web based contact as required.

Participants will receive full reimbursement for transport and gym costs for their attendance during the three-month intervention period. Participants will be encouraged to continue exercising at the end of the 3 month period, but funding will no longer be available. Local initiatives, such as exercise prescription and discounted membership schemes to support continued exercise participation will be explored as appropriate at this point.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary outcome measure will be the Physical Activity questionnaire in the Elderly (PASE), which is a participant and carer completed measure of activity and community mobility. This will be measured at 0, 3 and 6 months.

Secondary outcome measures
Secondary measures will be measured at 0, 3 and 6 months, and will include:
1. Physical activity participation as measured by the number of sessions attended. The number will be determined from the computerised attendance data at the IFI centres and attendance diaries kept by the trainer
2. Home mobility step counts measured by accelerometer readings over an 8-day period
3. Community activity level will be measured with a long term ambulatory activity monitor that will be worn on the leg for 8 days (full 168 hour week and only removed for bathing). This method of ambulatory monitoring provides essential information relating to the actual level of activity (and hence a good measure of functional ability) as measured by step counts and time spent sitting or lying compared to walking
4. Isometric muscle strength (lower limb: hip flexors, extensors, abductors, quadriceps, hamstrings, ankle dorsiflexors and plantarflexors; upper limb: biceps and triceps) and hand grip. Muscle testing will be carried out in standardised validated manner and include three isometric contractions with a wall mounted myometer (MIE Medical Instruments, UK) for each muscle group or dynamometer (handgrip) (MIE Medical Instruments, UK)
5. Leg power and speed will be recorded using a 'leg power meter' (Medical Laboratory Workshops, Nottingham)
6. The General Health Status questionnaire (36-item short form health survey [SF-36]) and quality of life measure (Euro-Quality of life instrument [EQ-5D])
7. Weight (kg)
8. Barthel Index
9. The Fatigue Severity Scale (FSS)
10. Falls' questionnaire for neurological and neuromuscular populations
11. 2 minute and 10 metre mobility test. During walking tests movement profiles (cadence and step times) will be evaluated by a triaxial accelerometer
12. Fitness test (modified Sjostrand incremental test) - 2 minute initial unweighted cycle and then 1 minute incremental increases in resistance until paticipants wish to stop. During exercise, expired air, heart rate, blood pressure and rating of perceived exertion will be taken
13. Age, height and medication will be recorded
14. Cognitive function will be measured using Short Orientation-Memory-Concentration Test

Overall study start date

01/10/2007

Completion date
01/12/2009

Eligibility

Key inclusion criteria
All individuals with:
1. A diagnosis of a chronic neurological or neuromuscular disorder
2. Aged sixteen years and over
3. No cognitive, sensory or psychological impairments precluding full engagement with training and experimental paradigm
4. Able to participate for the study period
5. Able to stand and walk 10 metres using any aid or assistance

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Our aim is 100 participants

Key exclusion criteria
All individuals:
1. Unable to meet the inclusion criteria, or those unwilling or unable to undertake the programme
2. With additional impairments (e.g. orthopaedic) restricting mobility or any contraindications to exercise

Date of first enrolment
01/10/2007

Date of final enrolment
01/12/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Movement Science Group
Oxford
United Kingdom
OX4 0BP

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
National Institute for Health Research Central Commissioning Facility
PO Box 407
Teddington
United Kingdom
TW11 0XX
+44 (0)20 8943 8990
Farheen.Shafiq@nihr-ccf.org.uk

Sponsor type
Government

Website
http://www.nihr-ccf.org.uk

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
Department of Health (UK) (ref: 0530006)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2011		Yes	No