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Can exercise reduce disability in peripheral neuropathy?

Submission date
30/08/2012

Recruitment status
No longer recruiting

Registration date
06/12/2012

Overall study status
Completed

Last Edited
21/11/2018

Condition category
Nervous System Diseases

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

Plain English summary of protocol
Background and study aims
Many people with inflammatory immune mediated neuropathies (IN) experience long term activity limitation (or disability) and may need health and social services as well as informal care from family or friends. Long term management varies but observational studies suggest that exercise may improve activity limitation. The aim of this study is to establish the efficacy and cost effectiveness of a tailored home exercise programme (tHEP) in 54 people with stable inflammatory neuropathy compared to information and usual care only.

Who can participate?
Adults with a diagnosis of Guillain Barré syndrome (GBS), chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) or paraproteinemic demyelinating neuropathy (PDN) who have had no changes in their symptoms or treatment in the last six months. Participants should also be able to walk at least 10 metres, with or without walking aids.

What does the study involve?
Participants will be randomised to either the tailored exercise group or the advice group. Participants in the advice group will receive information about exercise and usual care. Participants in the tailored exercise group will have an assessment with a physiotherapist who will prescribe an exercise regime based on their specific requirements and preferences, incorporating aerobic and strengthening exercise. Participants will complete questionnaires measuring fatigue, strength, endurance, mood, health beliefs, and quality of life at baseline, after 12 weeks and then after 12 months. Demographic data and information regarding service use, informal care and health status
will also be collected and used to evaluate cost effectiveness of the intervention. Some participants will be invited to take part in semi-structured interviews to investigate the acceptability of the tailored home exercise programme (tHEP) and factors affecting adherence to it.

What are the possible benefits and risks of participating?
Participants will be observed undertaking exercise. In addition participants undertaking exercise who have residual weakness or sensory loss that places specific joints at biomechanical risk of injury or imbalance, will be referred for orthotic prescription prior to exercise.

The burden on participants will differ between intervention and usual care groups. However, all participants will experience the burden of the time demand in completing study questionnaires.

Where is the study run from?
The study is taking place at various NHS hospitals across the UK, primarily in the South East and West Midlands.

When is the study starting and how long is it expected to run for?
The study is expected to start recruiting in September 2012 and recruitment will close in December 2013.

Who is funding the study?
Guillain Barré Syndrome Support Group, grant ref: GBS2011/8

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
GBS2011/8

Study information

Scientific Title
Observer blind randomised controlled trial of a tailored home exercise programme versus usual care in people with stable inflammatory neuropathy

Acronym
Home-based exercise for Inflammatory Neuropathy Trial (HINT)

Study objectives
Many people with inflammatory immune mediated neuropathies (IN) experience long term activity limitation (or disability) and may need health and social services as well as informal care from family or friends. Long term management varies but observational studies suggest that exercise may improve activity limitation. Following a systematic literature review and a pilot feasibility study the proposed randomised controlled assessor blind trial aims to establish the efficacy and cost effectiveness of a tailored home exercise programme (tHEP) on activity limitation in 54 people with stable IN compared to information and usual care only. The tHEP will be based on physiotherapy assessment and participants preferences and will incorporate aerobic and strengthening exercise. The primary outcome of improving activity limitation and secondary outcomes of fatigue, strength, endurance, mood, health beliefs, and quality of life will be assessed at baseline, after completion of the intervention or usual care and at 12 months. Demographic data and information regarding service use, informal care and health status will also be collected and used to evaluate cost effectiveness of the intervention. Semi-structured interviews with a purposive sample of people from the exercise group will investigate the acceptability of the tHEP and factors affecting adherence to it.

Null hypothesis: There will be no difference in the primary outcome of disability as measured by the Overall neuropathy limitations scale (ONLS)or Rasch Overall Disability Scale (RODS) between participants with IN undertaking a tailored home exercise programme (tHEP) and those receiving usual care.

Alternative hypotheses: The primary outcome of disability as measured by the Overall neuropathy limitations scale (ONLS) or Rasch Overall Disability Scale (RODS) will be better for participants with IN undertaking a tHEP than those receiving usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES - London City and East, 15/05/2012, ref: 12/LO/0155

Study design
Multi-centre randomised controlled researcher-blind trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Guillain Barré syndrome (GBS), chronic inflammatory demyelinating polyradiculoneuropathy (CIDP), paraproteinemic demyelinating neuropathy (PDN)

Interventions
Participants will be randomised to either the tailored exercise group or the advice group.

Participants in the advice group will receive information about exercise and usual care.

Participants in the tailored exercise group will have an assessment with a physiotherapist who will prescribe an exercise regime based on their specific requirements and preferences, incorporating aerobic and strengthening exercise.

Intervention Type
Behavioural

Primary outcome(s)
1. Overall neuropathy limitations score (ONLS)
2. Rasch Overall Disability Scale (R-ODS) score

Measured at end of intervention (12 weeks) and 12 months.

Key secondary outcome(s))
All secondary outcome measures except the client service receipt inventory (CSRI) are to be assessed at end of intervention and 12 month follow-up:

1. Fatigue (Fatigue severity scale - FSS)
2. Mood (Hospital anxiety and depression scale - HADS)
3. Quality of life (medical outcomes short form 12 - SF12)
4. Level of physical activity (International physical activity questionnaire - IPAQ)
5. Health beliefs (brief illness perception questionnaire - IPQ)
6. Self-efficacy (Self-efficacy for exercise scale - SSE)
7. Adherence (Exercise adherence rating scale (EARS) modified version of Medication adherence rating scale)

The CSRI will be assessed at baseline and 12 month follow-up when cost utility (quality adjusted life years (QALYs) derived from Euroquol (EQ5D) will be evaluated.

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. Are adults with stable motor neuropathy with or without sensory neuropathy, as a result of GBS, CIDP or PDN diagnosed using established criteria (and where PDN is defined as the combination of a demyelinating neuropathy, serum antibodies to myelin associated glycoprotein, and an IgM monoclonal gammopathy with no evidence of haematological malignancy)
2. Are able to walk 10 metres, with or without walking aids
3. Are at least 1 year since onset if they have GBS
4. Have no change in self reported disability, immunotherapy or medication for neuropathic pain in the previous 6 months (except dose of azathioprine must not have changed for 12 months). Patients receiving regular intravenous immunoglobulin (IVIg) or plasma exchange will be assessed at the same time points after treatment to avoid fluctuations due to time since last treatment.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. They score zero on the primary outcome measure
2. They have any other unstable medical conditions that
2.1. Affect activity limitation
2.2. Prevents them from exercising
2.3. Would make it unsafe to exercise
3. They are pregnant
4. Adults who are unable to consent for themselves
5. Are not able to understand spoken and/or written English or not able to communicate responses to questionnaires

Date of first enrolment
15/09/2012

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King's College London
London
United Kingdom
SE1 1UL

Sponsor information

Organisation
King's College London (UK)

ROR

https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
Guillain Barré Syndrome Support Group (UK) ref: GBS2011/8

Results and Publications

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?
Protocol article	protocol	21/08/2015		Yes	No