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Exercise training for the treatment of post-thrombotic syndrome: the EXPO pilot trial

Submission date 09/05/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/05/2008	**Overall study status** Completed	
Last Edited 25/01/2011	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
MCT-82338

Study information

Scientific Title
Exercise training for the treatment of post-thrombotic syndrome: a multicentre, two-arm randomised controlled parallel trial

Acronym
EXPO

Study objectives
In our proposed pilot trial, we will randomise patients with post-thrombotic syndrome (PTS) to:
1. A six-month exercise training program designed to improve leg strength, leg endurance, leg flexibility and general cardiovascular fitness (Active Training), or
2. An Attention Control group

Our feasibility objectives are to assess levels of patient eligibility, consent, adherence and retention. Our scientific objectives are to obtain estimates of effect size associated with Active Training, by describing within-subject change over six months in quality of life (QOL), severity of PTS, calf strength, calf flexibility and exercise capacity (time-on-treadmill) in the Active Training and Attention Control groups. Our results will inform the design of a large, multicentre trial of exercise training to treat PTS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the Sir Mortimer B. Davis Jewish General Hospital (Canada) approved on the 13th October 2006 (ref: 06-080).

Study design
Multicentre, two-arm randomised parallel trial with outcome assessor and data analyst blinding

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Post-thrombotic syndrome

Interventions
Active Training:
Six-month exercise training program designed to improve leg strength, leg endurance, leg flexibility and general cardiovascular fitness.

Attention Control:
Six-month program consisting of:
1. Standardised one-hour education session on PTS (what PTS is, why patients get it, how to manage it; exercise will be kept 'neutral', i.e., not specifically addressed) given by a trained thrombosis nurse-educator not involved with the assessment of study outcomes, and
2. Monthly phone contacts by the same thrombosis nurse to 'check in' with the patient, ask about their PTS and provide support

Contact for public queries:
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Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Feasibility indicators (measured throughout trial):
1. Proportion of patients screened who are eligible to participate in the trial
2. Proportion of eligible patients who consent to participate in the trial
3. Proportion of subjects who are adherent with the intervention
4. Proportion of subjects who complete the trial

Key secondary outcome(s))
1. Venous disease-specific, measured at baseline, 3 months and 6 months
2. Generic QOL, measured at baseline, 3 months and 6 months
3. Severity of PTS (Villalta PTS Scale), measured at baseline, 3 months and 6 months
4. Leg (triceps surae) strength, measured at baseline, 3 months and 6 months
5. Leg flexibility, measured at baseline, 3 months and 6 months
6. Time-on-treadmill, measured at pre-randomisation and 6 months

Completion date
30/09/2008

Eligibility

Key inclusion criteria
1. Aged 18 - 75 years, either sex
2. Previous unilateral deep vein thrombosis (DVT) diagnosed using standardised ultrasound or venographic criteria
3. PTS in same leg as previous DVT (Villalta PTS Scale score greater than 4)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
All

Key exclusion criteria
1. Acute DVT within previous six months
2. Contra-indications to exercise training, e.g. arthritis of lower extremities, angina, symptomatic chronic obstructive lung disease, congestive heart failure, severe claudication, poor balance
3. Expected lifespan less than six months or general medical condition that would make study unfeasible, e.g. advanced cancer or cardiopulmonary disease
4. Pregnancy or lactation
5. Open venous leg ulcer
6. Not conversant in either English or French
7. Geographic inaccessibility which precludes participation
8. Unwilling or unable to provide signed informed consent
9. Screening (i.e. pre-randomisation) exercise stress test (Bruce Ramp protocol) demonstrating uncontrolled hypertension, ischaemia, or arrhythmia (such patients will be referred for appropriate medical evaluation)

Date of first enrolment
01/03/2006

Date of final enrolment
30/09/2008

Locations

Countries of recruitment
Canada

Study participating centre
Sir Mortimer B. Davis Jewish General Hospital
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Sponsor information

Organisation
Sir Mortimer B. Davis Jewish General Hospital (Hôpital Général Juif Sir Mortimer B. Davis) (Canada)

ROR
https://ror.org/056jjra10

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-82338)

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?
Results article	results	11/01/2011		Yes	No