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Fitness intervention trial post-stroke (FITS): Enhancing walking endurance using home rehabilitation programs

Submission date 18/11/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 18/11/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 17/09/2008	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

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-66794

Study information

Scientific Title

Acronym
FITS

Study objectives
The specific clinical hypothesis to be tested is that, over a one year period, persons assigned to the general fitness 'cycle' group will experience a greater increase in functional exercise capacity compared with the 'walking' group and that consequently the cycle group will achieve a higher quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board, McGill, Faculty of Medicine, Montreal, Québec (Canada), 29/11/2002.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Stroke

Interventions
Group 1 is assigned to The Disability-Tailored Walking Competency Home Program:
We have devised a series of mobility-related tasks that can be easily and safely carried out at home without ongoing professional supervision. These tasks are similar to those used in our recent laboratory-based study but have been adapted for the home environment. A physical therapist, based on his or her evaluation of the participant, will choose a number of these tasks for the home program and train subjects to carry out these tasks safely and effectively in their own homes. The choice will depend on the capacity of each person and the home environment. Each person will be visited at home on a regular basis to adjust the program as needed. Persons will be instructed to try to carry out a minimum of 15 minutes of exercise per day. Each task is designed to be carried out for a minute with a one minute rest between exercises. Brisk walking will be recommended to complete the 15 minute time recommendation. Progression will be to more difficult tasks and then by adding weights or repetitions. The aim is to build up to one-half hour of exercise per day including walking.

Group 2 is assigned to The Home Cycling Program: Participants will be given a time and intensity graded program at an intensity that is comfortable and tolerable for the individual. The individual will be encouraged to augment, gradually, either the time of cycling per day or the work of cycling, always keeping within the limits of comfort and tolerability. Participants will also be given a target heart rate threshold to try and meet but not to exceed. This will be based on their response to the stress test and will most likely be between 50% and 70% of maximum

age-predicted heart rate. The aim is to build up to one-half hour of cycling per day. All bicycles will be equipped with electronic monitoring of speed, distance, and heart rate.

Trial details received 12 Sept 2005

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Walking endurance (6 minute walk test [6MWT]) measured at 12 months after recruitment

Key secondary outcome(s))
1. Health Related Quality of Life (HRQOL)
2. Gait Speed
3. Balance
4. Community Re-Integration
5. Stroke Specific Quality of Life
6. Fatigue
7. Depression
8. Anxiety
9. Anger

Completion date
30/04/2008

Eligibility

Key inclusion criteria
1. Verified stroke requiring hospital admission (based on clinical and radiological evidence)
2. Aged 50 years and older, either sex
3. Ability to walk a minimum of 10 meters independently, using an aid or orthotic, with or without supervision
4. Less than one year since the last cerebrovascular event at the time of recruitment
5. Discharge from active rehabilitation (usually around 3 to 4 months post-stroke but not less than 1 month) into the geographic study area of greater Montreal and greater Halifax

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Severe cognitive deficits as evaluated by the Telephone Version of the Mini-Mental State Examination such that the subject does not understand their participation in the study
2. Receptive aphasia as evaluated by the Canadian Neurological Scale or the treating speech therapist
3. Illness or disability precluding participation in either rehabilitation intervention
4. Failure to pass a standard cardiology orientated history and physical examination complemented by a baseline screening exercise stress test

Date of first enrolment
01/04/2003

Date of final enrolment
30/04/2008

Locations

Countries of recruitment
Canada

Study participating centre
Royal Victoria Hospital
Montreal
Canada
H3A 1A1

Sponsor information

Organisation
McGill University (Canada)

ROR
https://ror.org/01pxwe438

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-66794)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration