

Cost-utility and efficacy of a home-based exercise program in poliomyelitis survivors

Submission date
07/08/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
19/09/2007

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
30/08/2011

Condition category
Infections and Infestations

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Study website

<http://afycav.es/index.php?lang=en>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Study objectives

1. A home-based exercise program is effective in improving health-related quality of life, neuromuscular function and fitness in paralytic poliomyelitis survivors
2. A home-based exercise program is cost-effective compared to usual care in paralytic poliomyelitis survivors

Ethics approval required

Old ethics approval format

Ethics approval(s)

Bioethical Committee of University of Extremadura, approved on 25 May 2006 (ref: 16/2006)

Study design

Randomised controlled trial.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Poliomyelitis

Interventions

Participants will be randomised to the experimental and control groups (usual care). The experimental group of participants will be asked to perform 3 months of home-based physical exercises including two one-hour sessions per week. They will be instructed by a sport sciences graduate to perform progressive (set of 10 to 30 repetitions) strength-resistance exercises (flexion and extension of trunk and limbs; abduction and adduction of shoulder).

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The following will be measured at 0 (before start), 3 (end of exercise period) and 6 months (detraining in intervention group):

1. Health related quality of life (the EQ-5D questionnaire, 15-D instrument and the 36-item Short Form health survey [SF-36])
2. Sanitary costs (consultations, medication, health utilities, cost of program)
3. Back disorders (Roland Morris Scale)
4. Fatigue scale (FSS)
5. Neuromuscular function - isokinetic dynamometry: moment of force and power (root mean square electromyogram [EMGrms])
6. Fitness (strength, flexibility, balance, 6 min walk test, body composition)

Secondary outcome measures

Validity and reliability of instruments (fitness tests that will be used in this sub-population for the first time) in poliomyelitis.

Overall study start date

20/08/2007

Completion date

20/12/2007

Eligibility

Key inclusion criteria

Paralytic poliomyelitis survivors with one (or two) lower limb affected more than twenty years ago, recruited through local associations.

Participant type(s)

Patient

Age group

Not Specified

Sex

Both

Target number of participants

40

Key exclusion criteria

1. Medical contraindication to physical exercise
2. Doing regular physical exercise within 6 month before trial

Date of first enrolment

20/08/2007

Date of final enrolment

20/12/2007

Locations

Countries of recruitment

Spain

Study participating centre

Faculty of Sports Sciences

Caceres

Spain

10071

Sponsor information

Organisation

University of Extremadura (Spain)

Sponsor details

Fitness and Quality of Life Laboratory

Faculty of Sports Sciences

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Sponsor type

University/education

Website

<http://www.unex.es>

ROR

<https://ror.org/0174shg90>

Funder(s)

Funder type

Government

Funder Name

Ministry of Work and Social Affairs (IMSERSO) (Spain) (ref: 118/06)

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