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Effectiveness of adaptive physical activity combined with therapeutic patient education in stroke survivors at 12 months.

Submission date
13/03/2015

Recruitment status
No longer recruiting

Registration date
29/04/2015

Overall study status
Completed

Last Edited
18/01/2019

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Stroke is a serious, life-threatening medical condition that usually happens when a blood clot or haemorrhage cuts of the blood supply to an area of the brain. Symptoms vary according to how much of the brain is affected and where in the brain the stroke occurs, but includes paralysis, muscle weakness and speech difficulties. A stroke can also have an impact on the sufferers emotions and can lead to anxiety, depression and personality changes. It is the second leading cause of death and leading cause of long-term neurological disability worldwide. Several rehabilitative interventions (or programmes) have proved to be successful in treating the effects of stroke. They have significantly improved walking speed, physical fitness, balance and reduced the risk for falls, fractures, and further decline in mobility. Recent studies have shown that the degree in which a person is physically active after a stroke affects how disabled the person is. However, there was not enough information to draw reliable conclusions about the impact of fitness training on quality of life or mood. One exercise program that proved to work in improving physical functioning and psychological well-being is the Adaptive Physical Activity (APA), a community-based exercise program for chronic stroke survivors. The effectiveness of APA intervention in combination with Therapeutic Patient Education (TPE) was also investigated in a recent large clinical study in which APA-TPE was compared with treatment as usual (TAU). However, the long-term benefits of the APA TPE are still unknown. The aim of the present study is to find out how well 12 months of Adaptive Physical Activity (APA) combined with Therapeutic Patient Education (TPE) worked in treating stroke survivors.

Who can participate?
Adults (aged at least 18) with a confirmed diagnosis of stroke in the previous 3 to 18 months and able to walk 25m.

What does the study involve?
Participants are allocated (non-randomly) to either the experimental group or control group. Those in the experimental group receive 16 APA sessions and 3 sessions of TPE. Those in the control group receive their usual care. Patients are assessed in terms of distance they are able to walk, how well they are able to perform normal day-to-day activities, whether they feel

depressed and the severity of any depression, and their overall perception of how well they have recovered from the stroke 4 months after the beginning of the study. Each participant is also followed up 12 months later to see whether they have suffered any medical complications and what health services they had used in that time.

What are the possible benefits and risks of participating?
Benefits associated with taking part in our study: improvement of physical functioning, ambulatory function, and psychological well-being in patients with stroke. Risks associated with taking part in our study: no significant risk is expected for participants at the APA-TPE program. Physical rehabilitation is supervised by physical therapists. A previous study indicated that no serious adverse clinical events occurred during the APA exercise classes.

Where is the study run from?
The Physical Medicine and Rehabilitation Unit of Sant'Orsola Malpighi Hospital and Physical Medicine and Rehabilitation Unit of IRCCS Santa Maria Nuova in Italy.

When is the study starting and how long is it expected to run for?
January 2009 to May 2012

Who is funding the study?
Regional Agency for Health and Social Care, Regione Emilia-Romagna (Italy)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Study information

Scientific Title

Effectiveness of adaptive physical activity combined with therapeutic patient education in stroke survivors at 12 months: a non-randomized clinical trial

Study objectives
The Adaptive Physical Activity (APA) combined with Therapeutic Patient Education (TPE) treatment is more effectiveness than treatment as usual in stroke survivors with mild to moderate hemiparesis recruited after discharge from the hospital, 3 to 18 months after the stroke event

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Hospital Trust Sant'Orsola Malpighi of Bologna and of the Hospital Trust Santa Maria Nuova of Reggio Emilia, 09/09/2009, ref: EFG/2009/01

Primary study design
Interventional

Study design
Non-randomized clinical trial with concurrent controls

Study type(s)
Other

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

Interventions
The experimental intervention, adapted from the Adaptive Physical Activity (APA) for stroke, developed in Italy and combined with Terapeutic Patient Education (TPE), consisted of 3 group sessions of interactive TPE and 8 weeks of twice-weekly APA exercise sessions. The TPE sessions, held by a physician and physical therapist, involved patients, family, and caregivers. The content included an overview of stroke risk factors, the potential for recovery, how to cope with disabilities, and the benefits of a healthy lifestyle, including APA exercises. The APA exercises include mobility, balance and stretching. TAU comprised recommendations provided in the letter of discharge and two follow-up visits in a year. Two follow-ups were conducted at 4 months by face-to-face interview and at 12 months by telephone interview by blinded assessors.

Intervention Type
Behavioural

Primary outcome(s)
Change in gait endurance (distance walked) from baseline to 4 months, measured using the 6-minute walk test (6MWT).

Key secondary outcome(s)
1. The change in the ability to perform activities of daily living measured using the modified Barthel Index
2. The change in the mobility measured using the 6MWT, Short Physical Performance Battery (SPPB), Berg Balance Scale (BBS) and Motricity Index

3. The change of the caregiver's burden measured using the Caregiver Strain Index
4. The presence and severity of depression measured using the Geriatric Depression Scale
5. The change in the health-related quality of life measured using the 12-item Short-Form Health Survey (SF-12)
6. The patients' overall perception of their recovery from acute strokes measured using a self-reported visual analog scale (VAS), with a score from 0 to 100

Secondary outcomes included the change of the above mentioned measures from baseline to 4 months and the change from baseline to 12 months of the following measures: Modified Barthel Index; Caregiver Strain Index; Geriatric Depression; SF-12. Moreover, at 12 month follow-up medical complications (presence of falls, fractures, stroke recurrence) and health services utilization (access to the Emergency Department, number of hospitalizations, specialty medical examinations and rehabilitative treatments) were recorded.

Completion date
31/05/2012

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. A confirmed diagnosis of stroke according to the World Health Organization's definition in the previous 3 to 18 months, with mild to moderate hemiparesis
3. Ability to walk 25 m independently (with or without an assistive device such as a cane)
4. Discharged home from a rehabilitation center
5. No need to continue physical therapy
6. Informed consent to participate in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Severe cognitive impairment (Mini-Mental State Examination [MMSE] <15/30 and/or a score >3 on the Disability Communication Scale),
2. Severe heart failure or other medical conditions preventing participation in low-intensity exercise,
3. Co-morbidity (Cumulative Illness Rating Scale [CIRS]: index of comorbidity >3),
4. Severe perceptual disorders (ie, deafness or blindness).

Date of first enrolment
01/11/2009

Date of final enrolment
31/05/2012

Locations

Countries of recruitment
Italy

Study participating centre
Physical Medicine and Rehabilitation Unit of Sant'Orsola Malpighi Hospital
Via Pietro Albertoni, 15
Bologna
Italy
40138

Study participating centre
Physical Medicine and Rehabilitation Unit of IRCCS Santa Maria Nuova
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Sponsor information

Organisation
Regional Agency for Health and Social Care, Regione Emilia-Romagna

ROR
https://ror.org/02edavb98

Funder(s)

Funder type
Government

Funder Name
Regional Agency for Health and Social Care, Regione Emilia-Romagna

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2016	18/01/2019	Yes	No