ISRCTN75290225 https://doi.org/10.1186/ISRCTN75290225

Patient Therapeutic Education (PTE) in the rehabilitation process of stroke patients: improving self management and fostering transition from hospital to community

Submission date
02/07/2015

Recruitment status
No longer recruiting

Registration date
25/08/2015

Overall study status
Completed

Last Edited
05/09/2023

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Stroke is the second leading cause of death and the first cause of long-term neurological disability worldwide. Several rehabilitation programs have been proven to be effective but patients often feel unprepared to deal with long-term problems, especially at the end of the rehabilitation program. Therapeutic Patient Education (TPE) aims to improve awareness and self-management of the consequences of the disease. Currently the best way to integrate TPE interventions into the rehabilitation process is not known. The aim of this study is to design and standardize a structured TPE intervention for stroke patients in a very early phase after stroke, and specifically in a rehabilitation hospital setting. The impact of the intervention on patient empowerment, care continuity, quality of life and social reintegration is also assessed. The third aim is to analyze the feasibility of such an intervention in terms of costs, workload, acceptability and satisfaction of patients and caregivers.

Who can participate?
First stroke patients with mild/moderate to severe disability.

What does the study involve?
Patients admitted to Rehabilitation Unit 1 (Bologna) receive the usual care for stroke. Patients admitted to Rehabilitation Unit 2 Reggio E.-AO and Rehabilitation Unit 3 Modena-AUSL receive the TPE intervention. All participants complete questionnaires and will be assessed at hospital admission, at discharge and 1 month after discharge.

What are the possible benefits and risks of participating?
The benefits associated with taking part in our study are: improvements in self-management of disability, psychological well-being, caregiver burden, physical functioning and ambulatory function. No significant risks are expected for participants. Participants can consult a psychologist if needed.

Where is the study run from?
The study will run from three Physical Medicine and Rehabilitation Units in Italy:
1. Physical Medicine and Rehabilitation Unit of St. Orsola Malpighi Hospital, Bologna
2. Physical Medicine and Rehabilitation Unit of IRCCS Santa Maria Nuova, Reggio Emilia
3. Rehabilitation Medicine Unit of St. Agostino–Estense Baggiovara New Hospital, Modena

When is the study starting and how long is it expected to run for?
June 2014 to July 2017

Who is funding the study?
The Regional Agency for Health and Social Care, Regione Emilia Romagna, in the framework of Region-University Program - Area 2 'Clinical Governance' 2013.

Who is the main contact?
Mariangela Taricco, MD
mariangela.taricco@aosp.bo.it

Contact information

Type(s)
Public

Contact name
Dr Mariangela Taricco

ORCID ID
http://orcid.org/0000-0002-4028-1877

Contact details
Via Albertoni, 15
Bolgna
Italy
40138
+39 (0)51 2142286
mariangela.taricco@aosp.bo.it

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Patient Therapeutic Education (PTE) in the rehabilitation process of stroke patients: improving self management and fostering transition from hospital to community. A non-randomized clinical trial

Study objectives
The Therapeutic Patient Education (TPE) will be more effective than treatment as usual (TAU) in first stroke patients with mild/moderate to severe disability assessed at hospital admission, at discharge and 1 months after discharge.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Hospital Trust St. Orsola Malpighi of Bologna, of the Hospital Trust Santa Maria Nuova of Reggio Emilia and of the Hospital Trust St. Agostino–Estense Baggiovara, 11/02/2014, CODE Ec: LAY/2013

Study design
Non-randomized clinical trial with concurrent controls

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
First stroke patients with mild/moderate to severe disability

Interventions
The project will be run in two phases:

Phase 1:
1. Design and standardization of the therapeutic education intervention; the intervention will be based on the Chronic Disease Self Management Program which will be adapted and tailored to the specific needs of stroke patients in the early rehabilitation phase.
2. Training of Program leaders, who will be health workers of the Rehabilitation Units involved in the Project as well as lay-leaders.
Both the design of the Program and the Training will be realized by a group of health care professionals of the Rehabilitation Units coordinated by a T-group Trainer of the Chronic Disease Self Management Program, assisted by a psychologist.

The intervention will consist of both individual interactions between patients and health care professionals, and group sessions, led by trained health care professionals and lay leaders.

Phase 2:
1. A non-randomized controlled study will be performed in three Rehabilitation Units in the Emilia Romagna Region; the Units are selected on the basis of similarities of the stroke rehabilitation pathway adopted. Patients admitted to Rehabilitation Unit 1 (Bologna) will receive 'usual care'; patients admitted to Rehabilitation Unit 2 Reggio E.-AO and Rehabilitation Unit 3 Modena-AUSL will receive the experimental intervention.
2. A feasibility assessment study will be conducted with special emphasis on the training costs, educational intervention costs, organizational impact, workload, satisfaction of both users and health care professionals.

Intervention Type
Behavioural

Primary outcome measure
Self-efficacy, measured using the Stroke Self-efficacy Questionnaire at the end of treatment and at follow-up

Secondary outcome measures
1. Health-related quality of life, measuring using SF-12
2. The ability to perform daily living activities, measured using the Modified Barthel Index
3. The presence and severity of depression, measured using the Geriatric Depression Scale
4. The caregiver’s burden, measured using the Caregiver Strain Index
5. Patient/caregiver satisfaction, measured using a self-report visual analog scale
6. Mobility, measured using the Short Physical Performance Battery
Measured at the end of treatment and at follow-up

Overall study start date
15/06/2014

Completion date
30/07/2017

Eligibility

Key inclusion criteria
1. Patients who suffered a first stroke at the admission to hospital rehabilitation phase (age >18)
2. Having a caregiver as reference person
3. Mild/moderate to severe disability (modified Barthel Index <70/100)
4. Communication disability from absent to mild (Communication Disability Scale <3)
5. Informed consent form signed both by patient and caregiver

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
240 stroke survivors, 120 for each intervention

Total final enrolment
185

Key exclusion criteria
1. Previous stroke episodes
2. Severe cognitive impairment (MMSE<15/30, Communication Disability Scale > or=3)
3. Life threatening diseases
4. No consent to participation

Date of first enrolment
01/10/2014

Date of final enrolment
14/06/2015

Locations

Countries of recruitment
Italy

Study participating centre
Physical Medicine and Rehabilitation Unit of St. Orsola Malpighi Hospital
Bologna
Italy
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Study participating centre
Physical Medicine and Rehabilitation Unit of IRCCS Santa Maria Nuova
Reggio Emilia
Italy
-

Study participating centre

Rehabilitation Medicine Unit of St. Agostino–Estense Baggiovara New Hospital
Modena
Italy
-

Sponsor information

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

Sponsor details
Viale Aldo Moro 21
Bolgna
Italy
40127

Sponsor type
Government

ROR
https://ror.org/02edavb98

Funder(s)

Funder type
Government

Funder Name
Regional Agency for Health and Social Care, Regione Emilia Romagna, in the framework of Region-University Program - Area 2 'Clinical Governance' 2013

Results and Publications

Publication and dissemination plan
The results of this study, comparing therapeutic patient education and treatment as usual in patients with stroke, will be disseminated via peer-reviewed publications and conference presentations.

Intention to publish date
01/07/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Laura Dallolio (laura.dallolio@unibo.it).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2020	12/05/2021	Yes	No
Protocol article		31/08/2021	05/09/2023	Yes	No