

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 25/08/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/09/2023	Condition category Circulatory System	<input type="checkbox"/> 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?

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Contact information

Type(s)

Public

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

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Study participating centre

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

Modena

Italy

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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, in the framework of Region-University Program - Area 2 'Clinical Governance' 2013

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes