ISRCTN05245917 https://doi.org/10.1186/ISRCTN05245917

Effects of highly specialized rehabilitation of patients with multiple sclerosis

Submission date
09/05/2012

Recruitment status
No longer recruiting

Registration date
06/06/2012

Overall study status
Completed

Last Edited
27/09/2021

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Multiple sclerosis (MS) is a complex, chronic and progressive disease where rehabilitation services offer important support to patients. Few MS rehabilitation programs have been shown to provide health improvements to patients in a cost-effective manner. The aim of this study is to assess the effect in terms of changes in quality of life from a highly specialized, individually planned and coherent rehabilitation program for people with MS.

Who can participate?
Patients with MS referred to the two Danish Sclerosis hospitals for a 4-week rehabilitation program.

What does the study involve?
Participants will be randomly allocated to either advanced admission (within 2 months) or usual admission (after an average waiting time of 8 months).

What are the possible benefits and risks of participating?
The results of the study would be relevant for further development of the MS rehabilitation services and for discussions about the design and contents of such services. The results will also be relevant for health authorities with responsibility for providing and financing rehabilitation services. We believe that there are no risks of participating in the study.

Where is the study run from?
The two Danish Sclerosis Hospitals at Haslev and Ry, Denmark.

When is the study starting and how long is it expected to run for?
Patient recruitment ran from March 2012 to March 2013. Data collection is expected to be completed summer 2014.

Who is funding the study?
The Sclerosis Hospitals and the Danish Multiple Sclerosis Society (Denmark).

Who is the main contact?
Prof Jan Sørensen

Contact information

Type(s)
Scientific

Contact name
Prof Jan Sørensen

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effects of highly specialized rehabilitation of patients with multiple sclerosis: a randomized controlled trial of personalized, targeted and multidisciplinary interventions

Study objectives
The primary aim of the study is to assess the effect of personalized, targeted and multidisciplinary interventions in terms of changes in disease-specific quality of life measures.

As secondary aims the study aims at answering the following questions:
1. To what extent are the observed effects maintained 6 and 12 months after discharge?
2. How do different dimensions of quality of life, functional abilities and more specific measurements of sleep, daily activities, gait, balance and urinary retention correlate?
3. Which individual goals were set before the start of the rehabilitation?
4. What functions and priorities are at the focus of the individualized rehabilitation program?
5. What specific and measurable actions are included in the individual rehabilitation program?
6. What effect does the rehabilitation process have on the individual goals and priorities at discharge?

7. To what extent do patients maintain and integrate coping, immediately after discharge?
8. Which resource use and costs occur at the individual rehabilitation program for patients and their relatives, and for the rest of the healthcare system?
9. What is the relationship between the obtained effects and costs, 6 months after discharge?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Scientific Ethics Committee of Region Sealand (Region Sjælland, Kvalitet og Udvikling, DK-4180 Sorø), 07/02/2012, ref: journal no. 1-01-0002-07 (experiment SJ-281)
2. Registered with the Danish Data Agency (Datatilsynet, Borgergade 28,5, DK-1300 Copenhagen K), ref: journal no. 2011-41-6751

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Multiple sclerosis

Interventions
Patients who fulfil the inclusion criteria and have signed the consent form will be randomised to either the intervention group, which includes early rehabilitation (after less than 2 months from referral), or the control group, who are provided with rehabilitation after the usual waiting time (approximately 8 months after referral).

When admitted both groups will receive a personalized, targeted and multidisciplinary hospital-based rehabilitation program organized during four weeks of continuous hospitalization. The rehabilitation team is composed based on the patient's individualised needs and may include a neuro-psychologist, clinical psychologist, occupational therapist, physiotherapist, nutritional therapist or dietitian, nurse, healthcare assistant, nursing assistant and social worker. Symptomatic drug therapy is organized or administered as part of the effort after the usual guidelines and overall judgment by the neurologist.

The patient's counselor is responsible for the content of the patient's program and should oversee that it contributes to the work of the team and patient, works towards the agreed objectives and milestones, and that needed adjustments are made during hospitalization. The counselor and patient evaluate the program, for example by weekly conversations and at discharge. According to the patient's desire, relatives and other team members may participate in one or more of the talks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Changes in Multiple Sclerosis Impact Scale version 2 (MSIS-29) and Functional Assessment of Multiple Sclerosis (FAMS) measured at baseline, at the start of the intervention, at intervention completion, 1, 6 and 12 months after baseline.

Secondary outcome measures
1. Mastery: Health Education Impact Questionnaire (heiQ)
2. Generic Quality of Life: EQ-5D and 15D
3. Expanded Disability Status Scale score (EDSS)
4. Resource consumption and costs for hospitals sclerosis for patients and their relatives, and for the rest of the healthcare service

Measured at baseline, at the start of the intervention, at intervention completion, 1, 6 and 12 months after baseline.

Overall study start date
01/03/2012

Completion date
30/06/2013

Eligibility

Key inclusion criteria
Study participants will be recruited among all patients who are referred to the 4-week individual rehabilitation program during March 2012 to June 2013. Patients who are referred for a shorter rehabilitation program or theme courses are not eligible for the study.

Participants must meet the following inclusion criteria:
1. Aged between 18 and 65 years
2. Diagnosis of multiple sclerosis (MS): relapsing remitting, primary or secondary progressive MS
3. Expanded Disability Status Scale (EDSS) score ≤ 7.5
4. Can use a PC or have support/relative who can
5. Ability to read and understand sufficient Danish to understand instructions both orally and in writing, and having completed a consent form

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2 x 200

Key exclusion criteria
1. MS disease duration less than 6 months (the period from diagnosis to referral)
2. Experienced relapse within 3 months before the neurological appraisal
3. Recipient of sclerosis-specific hospital-based rehabilitation within the last 6 months
4. Cognition score, Kurtzke's Functional Systems (KFS) > 2 or cognitive limitations which hinder completion of self-reported questionnaires and/or giving informed consent
5. Moderate to severe depression; severe heart or lung disease
6. Drug or alcohol abuse
7. Any other illness that can impede participation in the study

If participants develop a disease that might impair their participation in the study they will be excluded from the study at that time.

Date of first enrolment
01/03/2012

Date of final enrolment
01/03/2013

Locations

Countries of recruitment
Denmark

Study participating centre
Centre for Applied Health Services Research and Technology Assessment
Odense
Denmark
DK-5000

Sponsor information

Organisation
The Danish Sclerosis Hospitals (Denmark)

Sponsor details
Ringstedvej 106
Haslev
Denmark
DK-4690

Sponsor type
Hospital/treatment centre

Website
http://temp.scleroseforeningen.dk/sclerosecentrene,-d-,dk.aspx

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Sclerosis Hospitals (Denmark)

Funder Name
Scleroseforeningen

Alternative Name(s)
Danish Multiple Sclerosis Society, Danish MS Society

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Denmark

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/09/2012		Yes	No
Results article		01/12/2020	27/09/2021	Yes	No