Case Management for people with Multiple Sclerosis

Submission date	Recruitment status No longer recruiting	Prospectively registered		
22/11/2006		[X] Protocol		
Registration date	Overall study status Completed Condition category	Statistical analysis plan		
22/11/2006		Results		
Last Edited		☐ Individual participant data		
16/08/2010	Nervous System Diseases	Record updated in last year		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR762; ABR NL13248.042.06

Study information

Scientific Title

Randomised Controlled Trial on the effectiveness of a Dutch patient advocacy case management intervention among severely disabled Multiple Sclerosis patients

Acronym

CMMS

Study objectives

- 1. People with Multiple Sclerosis who receive care by a case manager experience a better quality of life and quality of care compared with people with MS who receive care as usual.
- 2. Caregivers of people with Multiple Sclerosis who receive care by a case manager experience a better quality of life compared with caregivers of people with MS who receive care as usual.
- 3. Healthcare cost for people with MS will increase during the first year in which they receive case management; in the long term costs will decrease.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Medical Ethics Review Board of the University Medical Center Groningen (ref: METc2006. 140, ABR form NL13248.042.06).

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Multiple sclerosis (MS)

Interventions

Patients will be randomised to

1. Case management: consisting of home visits twice a year by a Nurse practitioner or Nurse specialist MS. During the home visit the neurological examination is performed and the health status (physically, mentally and socially) of the person with MS is investigated as well as the impact of the disease on the lives of the person with MS and his/her caregiver.

Based on this investigation a care plan will be developed. Realisation of the goals set in the care plan is monitored by the case manager.

2. Control group: People with MS receive care as usual. They will visit their Neurologist at the outpatient clinic once or twice a year (or more if indicated).

Both groups consist of 50 persons with MS and 30 caregivers. The intervention will take place during 15 months.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Quality of life

Secondary outcome measures

- 1. Depression
- 2. Quaity of care
- 3. Care giver strain
- 4. Cost efficacy

Overall study start date

10/08/2006

Completion date

31/01/2008

Eligibility

Key inclusion criteria

People with MS

- 1. Who have an Expanded Disability Status Scale (EDSS) score between 4.5 and 8.5
- 2. Treated in the University Medical Center of Groningen

Caregivers:

Partner with MS who is participating in the research directly involved in care fot the person with MS

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

160

Key exclusion criteria

- 1. Residents of nursing homes
- 2. Partipation in other research projects

Date of first enrolment

10/08/2006

Date of final enrolment

31/01/2008

Locations

Countries of recruitment

Netherlands

Study participating centre University Medical Center Groningen

Groningen Netherlands 9700 RB

Sponsor information

Organisation

University Medical Center Groningen (UMCG) (Netherlands)

Sponsor details

Department of Neurology P.O. Box 30001 Groningen Netherlands 9700 RB

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/03cv38k47

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Medical Center Groningen (Netherlands) - Internal funding

Funder Name

Icare (Netherlands) - an organisation for home care (cooperation partners)

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	27/05/2010		Yes	No