ISRCTN22635159 https://doi.org/10.1186/ISRCTN22635159

Case Management for people with Multiple Sclerosis

Submission date	Recruitment status	[_] Prospectively registered
22/11/2006	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/11/2006	Completed	[_] Results
Last Edited	**Condition category**	[_] 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

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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
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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