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

**Contact name**
Dr C Annema

**Contact details**
University Medical Center Groningen
Department of Integrated Care
P3.264
P.O. Box 30001
Groningen
Netherlands
9700 RB
+31 (0)50-3611490
j.h.annema@ccznn.umcg.nl

## Additional identifiers

**Protocol serial number**
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

## Study type(s)
Quality of life

## 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(s)
Quality of life

### Key secondary outcome(s))
1. Depression
2. Quaity of care
3. Care giver strain
4. Cost efficacy

### 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

### Healthy volunteers allowed
No

### Age group
Not Specified

### Sex
Not Specified

### 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)

### 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

### 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 |