Efficacy of client-centred occupational therapy in patients with multiple sclerosis: a cluster-randomised trial

Submission date	Recruitment status No longer recruiting	Prospectively registered		
16/01/2007		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
16/01/2007	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
14/01/2021	Nervous System Diseases			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Efficacy of client-centred occupational therapy in patients with multiple sclerosis: a cluster-randomised trial

Acronym

MUSCOT

Study objectives

Client-centred occupational therapy according to the Occupational Performance Process Model will be more effective in improving daily functioning and societal participation of patients with multiple sclerosis than usual-care occupational therapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised, controlled, parallel group, double blinded, multicentre trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Multiple sclerosis (MS)

Interventions

Experimental intervention: client-centred occupational therapy according to the Occupational Performance Process Model (OPPM).

Control intervention: usual-care occupational therapy.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. Disability Impact Profile (DIP) questionnaire
- 2. Impact on Participation and Autonomy (IPA) questionnaire

At baseline) and after four and eight months follow-up.

Secondary outcome measures

- 1. Evaluation of Client-Centred Process (ECGP) questionnaire
- 2. Quality of Care through the patient's eyes (QUOTE-EEE) questionnaire
- 3. Canadian Occupational Performance Measure (COPM)
- 4. Nine-Hole Peg Test (9-HPT) Dexterity measure
- 5. Fatigue (Modified Fatigue Impact Scale [MFIS]) questionnaire
- 6. Pain (Pain Effects Scale [PES]) questionnaire
- 7. Cognitive functioning (Perceived Deficits Questionnaire [PDQ]) questionnaire
- 8. Generic Health-related Quality of Life (Short Form health survey [SF-36]) guestionnaire

At baseline, and after four and eight months follow-up.

Overall study start date

01/01/2007

Completion date

31/12/2009

Eligibility

Key inclusion criteria

- 1. Diagnosed Multiple Sclerosis
- 2. New referral for occupational therapy
- 3. Age between 18 and 75 years

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

280

Total final enrolment

Key exclusion criteria

1. Major depression

Date of first enrolment

01/01/2007

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

Netherlands

Study participating centre VU University Medical Center

Amsterdam Netherlands 1007 MB

Sponsor information

Organisation

VU University Medical Center (The Netherlands)

Sponsor details

Department of Rehabilitation Medicine P.O. Box 7057 Amsterdam Netherlands 1007 MB

Sponsor type

Hospital/treatment centre

Website

http://www.vumc.nl/english/

ROR

https://ror.org/00q6h8f30

Funder(s)

Funder type

Research organisation

Funder Name

Stichting MS Research (The Netherlands)

Alternative Name(s)

Dutch Multiple Sclerosis Research Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Netherlands

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?
Results article	results	01/09/2013	14/01/2021	Yes	No