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

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The main research question of this study is:Is client-centred occupational therapy according to the Occupational Performance Process Model more effective than usual-care occuaptional therapy in patients with multiple sclerosis?

Ethical review	Approved WMO
Status	Pending
Health condition type	Demyelinating disorders
Study type	Interventional

Summary

ID

NL-OMON30557

Source
ToetsingOnline

Brief title
Muscot

Condition

- Demyelinating disorders

Synonym
MS, multiple sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Stichting MS Research

Intervention

Keyword: Client-centred practice, Clinical Trial, Multiple Sclerosis, Occupational Therapy

Outcome measures

Primary outcome

The focus of the study is on the client, and primary and secondary outcomes are assessed at this level. The primary outcome measures are:

- Disability Impact Profile (DIP). This questionnaire is commonly used to assess health-related quality of life in patients with MS and has adequate clinimetric properties.

- Impact on Participation and Autonomy (IPA). This questionnaire was developed to assess the impact of chronic neurological diseases on outdoor and indoor autonomy, family role and social relations and also has adequate clinimetric properties.

Secondary outcome

Secondary outcome measures at the client level include measures for the severity of MS (using the EDSS), client-centred therapeutic outcome (Canadian Occupational Performance Measure, COPM), dexterity (9-hole peg test, 9HPT), generic health-related quality of life (SF36), fatigue (MFIS), pain (PES) and cognitive functioning (PDQ).

The quality of the client-therapist interaction as experienced by the client and the therapist will be assessed using the Quote-EEE questionnaire.

Therapy compliance will be measured using a diary. Using this diary, the extent to which patients comply with therapeutic advice will be assessed. Additionally, no-shows, cancellation and rescheduling of therapeutic

appointments will be inventoried.

Additionally, an inventory of treatment goals is made, and the duration (in weeks) and intensity (number of therapeutic sessions, frequency of sessions) of OT are measured.

At the level of the therapist, an inventory is made of the level of compliance with OPPM and attitude towards client-therapist interactions. Additionally, demographic information on the therapist will be collected.

At the level of the institution, data will be collected on the organisation of care for MS patients, including any care received from other health care professionals (physiotherapists, clinicians, psychologists) within a multidisciplinary setting.

Study description

Background summary

Occupational therapy (OT) is an integral part of the care for MS patients. Severe functional disability and reduced social participation are commonly experienced by patients with MS. OT is aimed at reducing functional disability and improving social participation, thus resulting in increased autonomy and quality of life of patients.
Currently, there is a movement towards client-centred approach to OT. The theoretical benefit is that therapy is tailored to the patient*s needs and will therefore result in a bigger improvement in autonomy and quality of life than regular OT. However, so far this theoretical advantage has not been established in scientific research.
This application describes a cluster-randomised trial investigating the efficacy of client-centred OT based on the Occupational Performance Process Model (OPPM) as compared to usual care OT, in patients with Multiple Sclerosis (MS).

Study objective

The main research question of this study is:

Is client-centred occupational therapy according to the Occupational Performance Process Model more effective than usual-care occuaptional therapy in patients with multiple sclerosis?

Study design

This is a clustered randomised trial (CRT). Randomisation will take place at the level of the cluster. The clusters are the participating hospitals and rehabilitation centres. This means that all participating OT's within the same centre are randomised into the same treatment condition. Likewise, all clients who receive treatment from the same therapist fall within the same treatment group. To ensure the comparability of the experimental and control group, the randomisation will be stratified for type of institution (i.e. hospital or rehabilitation centre).
Measurements will be made at the level of the institution, therapist and client, with the focus of the study on the client level (see 'primary study parameters' below). Data from clients will be collected prior to the start of treatment (baseline) at 4 months (post-treatment), and at 8 months (follow-up). A test assistant will be responsible for the client data collection.
The test assistant and the clients themselves will be blinded to their treatment allocation. Due to the nature of the intervention, OT's will not be blinded.

Intervention

The experimental intervention comprises OT according to the OPPM.
Clients treated by OT's from the experimental group will receive OT according to the OPPM. This means that problem identification, treatment goal setting, treatment planning and execution, and goal evaluation will be performed in a client-centred manner as described by the OPPM. This is a flexible, yet focused, framework to guide the therapist and client through seven stages of a collaborative, outcome-oriented process. The process starts with the identification, validation and prioritising of occupational performance issues. This is followed by selecting the appropriate theoretical approach (stage 2), the identification of strengths, resources and environmental conditions (stage 3 and 4), the negotiation (stage 5) and implementation (stage 6) of action plans to reach targeted outcomes. The process concludes with the evaluation of the outcomes (40).
Prior to the inclusion period, all OT's in the experimental group will receive a two-day course in client-centred practice according to the OPPM, provided by the NVE. Subsequently, OT's will be asked to implement this in clinical practice. Initial experiences will be evaluated in a booster session provided six weeks after the course. The client inclusion period will start following this reinforcement session. Additional booster sessions will be planned every

six months for the duration of the project's data collection period.
The control group of OT's will provide regular OT to their patients. They will be notified beforehand that after the conclusion of this study they will be invited to take the OPPM-course at no cost.

Study burden and risks

All patients included in this trial will receive occupational therapy. with the associated burden and risks equal to those in the normal therapeutic setting. The measurements for this study comprise questionnaires, interviews and a physical examination specifically intended to assess the severity of MS. All measurements will be performed in the participant's home setting. In total, these measurements will take 4 hours, divided over three spearate occasions (baseline, and 4 and 8 months follow-up).

All participants have a referral for occupational therapy and will receive therapy accordingly.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Clients are eligible for inclusion if they have an existing diagnosis of MS; a new referral for OT with no previous OT treatment in the six months preceding inclusion; and age between 18 and 75.

Exclusion criteria

Exclusion criteria are: major depression; refusal to provide informed consent; and insufficient control of the Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2007
Enrollment:	280
Type:	Anticipated

Ethics review

Approved WMO
Application type: First submission
Review commission: METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL15178.029.06