ISRCTN05017507 https://doi.org/10.1186/ISRCTN05017507

Treatment Of chronic Fatigue in patients with multiple sclerosis by paramedical disciplines

Submission date
10/07/2013

Recruitment status
No longer recruiting

Registration date
05/08/2013

Overall study status
Completed

Last Edited
19/09/2014

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Fatigue is a common and disabling symptom in people with multiple sclerosis (MS), and is considered to be one of the main causes of reduced daily activities and quality of life. Due to the multidimensional character of fatigue in MS it seems obvious to manage fatigue in a tailored, multidisciplinary way. To optimize the management of chronic fatigue in MS, a paramedical multidisciplinary rehabilitation program has been developed. The study's findings should help to optimize the management of fatigue in people with MS.

Who can participate?
The study aims to recruit 48 patients diagnosed with MS and suffering from chronic fatigue.

What does the study involve?
The patients will be randomly allocated to either receive multidisciplinary rehabilitation or a consultation with the MS nurse. Multidisciplinary rehabilitation consists of occupational therapy, physical therapy or social work or any combination of these treatments. Participants who are allocated to the MS nurse consultation are offered the opportunity to receive multidisciplinary rehabilitation once the study is completed.

What are the possible benefits and risks of participating?
Both interventions may have a positive effect on dealing with fatigue in MS, of which the effect of multidisciplinary rehabilitation is expected to be larger. Information obtained from this study may be beneficial for future fatigue management of people with MS suffering from fatigue. No harmful effects are expected for either treatment.

Where is the study run from?
The study was set up by the multidisciplinary care team of the MS centre Amsterdam, VU University Medical Centre Amsterdam.

When is the study starting and how long is it expected to run for?
Patient were recruited between February 2006 and November 2010.

Who is funding the study?
Stichting MS Research, Netherlands.

Who is the main contact?
Dr M. Rietberg, m.rietberg@vumc.nl
Professor Dr. G. Kwakkel

Contact information

Type(s)
Scientific

Contact name
Prof Gert Kwakkel

Contact details
Department of Rehabilitation Medicine
VU University Medical Center
Amsterdam
Netherlands
1081 HV

Additional identifiers

Protocol serial number
04-553 MS

Study information

Scientific Title
Effects of multidisciplinary paramedic rehabilitation on chronic fatigue in multiple sclerosis: A randomised controlled trial

Acronym
TOF

Study objectives
It is hypothesized that individually tailored, multidisciplinary outpatient rehabilitation by paramedical disciplines is more effective in reducing MS related chronic fatigue than consultation by an MS-nurse alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The RCT was approved by the ethics committee of the VU University Medical Centre, Amsterdam (METc VUmc). Registration number 2005/72. date 12-05-2005

Study design

Single centre single blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Multiple sclerosis, fatigue

Interventions
Multidisciplinary paramedical rehabilitation.
Patients assigned to multidisciplinary rehabilitation receive either occupational therapy, physical therapy or social work or any combination of these treatments. The participating disciplines treat MS-related fatigue according to specific treatment programmes.

MS-Nurse consultation
Patients allocated to the control group receive MSnurse consultation based on the Nursing Intervention Classification (NIC)

Double baseline assessment at week -1 and week 0, one assessment post intervention at 12 weeks and a follow-up assessment at 24 weeks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Fatigue assessed using the self report questionnaire Checklist individual strength (CIS-20R): 20 statements for which the participant has to indicate on a 7 point scale ranging from Yes, that is true to No, that is not true to what extent the particular statement applies to him or her, at baseline, 12 weeks and 24 weeks.

Key secondary outcome(s))
1. Modified Fatigue Impact Scale (MFIS): assesses the perceived impact of fatigue on the subscales physical, cognitive and psychosocial functioning during the past 4 weeks. Participants rate on a 5-point Likert scale, ranging from Never to Almost always, their agreement with 21 statements.
2. Fatigue Severity Scale (FSS): a nine-item questionnaire to assess the severity of fatigue and its impact on an individuals daily functioning using a seven-point rating scale. Participants rate their agreement with a statement ranging from one point, reflecting strongly disagree to seven points representing strongly agree, depending on how appropriate they feel the statement applies to them
3. Functional Independence Measure (FIM): measures activities of daily living. It is an 18-item, generic seven-point rating scale to assess physical and cognitive disability in terms of burden of care.
4. Disability and Impact Profile (DIP): is a 39 item self-administered questionnaire regarding activities that may be restricted by a disabling disease. Each item is rated on a 0-10 point scale

for its current disability and for the importance of that disability
5. Multiple Sclerosis Impact Scale (MSIS-29): disease-specific measure of the physical (20 items) and psychological (9 items) impact of MS from the patients perspective. The self-reported instrument measures disease impact due to limitations in the past 2 weeks, scored on 5 levels from not at all to extremely. Scores on the individual items are added and then transformed to a 0100 scale, thereby generating two summary scores (for physical and psychological impact).
6. Impact on Participation and Autonomy (IPA): measures person-perceived participation. The IPA is a generic questionnaire that addresses 2 different aspects of participation: (1) perceived participation, reflected in 31 items in 5 domains (interior and exterior autonomy, family role, social relations and job and education) , and (2) the experience of problems for every aspect of participation, reflected in 8 problem experience scores (mobility, selfcare, activities around the house, looking after money, leisure, social life and relations, helping and supporting other people, paid for voluntary work, education and training).

All measures were assessed at baseline, 12 weeks and 24 weeks

Completion date
01/11/2010

Eligibility

Key inclusion criteria
1. Age > 18 years, either sex
2. Diagnosed with MS according to the criteria of McDonald [Mc Donald 2001] and
3. Suffering from chronic fatigue. Chronic fatigue was defined as being present for any amount of time on at least 50 percent of the days, for more than 6 weeks as agreed on by the Multiple Sclerosis Council for Clinical Practice Guidelines.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Patients were excluded in case of:
1. Current MS relapse
2. Pregnancy
3. Current inflammation (cystitis)

4. Alcohol or substance abuse
5. Physical conditions like muscle spasm or pain, or
6. Depressive symptomatology importantly contributing to fatigue

Date of first enrolment
01/02/2006

Date of final enrolment
01/11/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
Department of Rehabilitation Medicine
Amsterdam
Netherlands
1081 HV

Sponsor information

Organisation
Stichting MS Research (Netherlands)

ROR
https://ror.org/00qeet526

Funder(s)

Funder type
Research organisation

Funder Name
Stichting MS Research (Netherlands) (project number 04-553 MS)

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

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	18/09/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes