

A randomized clinical trial of group medical appointments for patients with chronic neuromuscular disease. A comparison with usual care in terms of quality of life and cost-effectiveness

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To compare group medical appointment as a novel approach in care for chronic neuromuscular patients with conventional outpatient visits, in terms of health outcomes and costs.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neuromuscular disorders
Study type	Interventional

Summary

ID

NL-OMON32749

Source

ToetsingOnline

Brief title

.

Condition

- Neuromuscular disorders

Synonym

Muscle diseases

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: ZONMW

Intervention

Keyword: cost-effectiveness, group medical appointment, neuromuscular disorders, quality of life

Outcome measures

Primary outcome

Primary outcome measure is Quality of Life (Qualy's),

Secondary outcome

secondary outcome measures are Self efficacy, functional activities, patient and partner satisfaction with care and use of care resources.

Study description

Background summary

Most neuromuscular diseases are chronic progressive diseases necessitating periodic specialized care. Currently, these patients attend the out-patient clinic at regular intervals (usually annually), where they are seen in one-to-one patient- physician encounters. It is difficult, however, to fulfill the complex needs of neuromuscular patients in these brief, problem-focused out-patient visits which leave little time for the patient's psychosocial needs, patient education, and patient empowerment. It is possible that the concept of a group medical appointment or group visit give a better opportunity to fulfill this needs.

During a group medical appointment a number of patients and their partners are seen simultaneously by a physician and a specialized nurse or psychologist. Group medical appointments are a series of one on one doctor- patient contacts, in presence of a group fellow patients. This group visit takes 1,5 - 2 hours and substitutes the annual control visit the patients pay to the neurology department. The same items the neurologist attends to in a one on one appointment are attended to during the group medical appointment. The physician has more time to give information to the patient and patients and

partners can ask questions to- and learn from their fellow patients.

Study objective

To compare group medical appointment as a novel approach in care for chronic neuromuscular patients with conventional outpatient visits, in terms of health outcomes and costs.

Study design

A randomised, prospective, controlled study will be performed comparing the effect of group medical appointments with the regular private one-to-one appointments. At least two neurologists will participate, doing the regular outpatient care as well as the group medical appointment.

Intervention

The intervention group takes part in one group medical appointment. This group medical appointment replaces the annual visit to the neurologist of this one patient.

The control group receives care as usual: an individual visit of 20-30 minutes with the neurologist.

Study burden and risks

Patients visit the hospital as often as during usual care. The group medical appointment replaces the annual visit with the neurologist. The group medical appointment takes approximately 90 minutes, while an individual visit takes 20-30 minutes.

The patients are being asked to return a questionnaire four times. At baseline, one week after the visit, 3 months after the visit and 6 months after the visit. This will cost half an hour per questionnaire per patient. The questionnaires are about quality of life, self efficacy, social support, functional activities and use of care.

The potential risks for participants are very small. Possibly patients in the intervention group will feel inhibited to ask all the questions they have for the neurologist. To reduce this risk patients will be asked at the start of the group medical appointment to write a confidentiality form. Also patients will be noticed that there is always the possibility of having a private conversation with the neurologist after the group medical appointment.

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

- Patients are diagnosed with one of the 7 above neuromuscular diseases
- Age > 18 years
- Patients are control patients in care at the department of neurology RUNMC

Exclusion criteria

- Patients with severe hearing problems
- Patients who cannot speak, read or understand the Dutch language well
- Patients who have had a control visit with a neurologist at the neurology department of the RUNMC less than 6 months ago

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	06-02-2009
Enrollment:	270
Type:	Actual

Ethics review

Approved WMO	
Date:	15-01-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL26118.091.08
Other	TC = 1412