Rehabilitation & Capability Care in NMD

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The quality of life of adult patients with NMD can be enhanced by providing capability care in comparison to usual care.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Muscle disorders
Study type	Interventional

Summary

ID

NL-OMON24397

Source
Nationaal Trial Register

Brief title
ReCap-NMD

Condition

- Muscle disorders

Synonym
FSHD and DM1

Health condition

facioscapulohumeral dystrophy (FSHD) and myotonic dystrophy type 1 (DM1)

Research involving
Human

Sponsors and support

Primary sponsor: Prinses Beatrix Spierfonds
Source(s) of monetary or material Support: Prinses Beatrix Spierfonds

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

Difference in the Canadian Occupational Performance Measure (COPM) between both groups (corrected for the value at baseline).

Secondary outcome

Secondary outcomes: Difference between both groups in the the ICEpop CAPability measure for Adults (ICECAP-A), Utrecht Scale for Evaluation of Rehabilitation Participation (USER-P), the EuroQol-5D-5L (EQ-5D-5L), the Medical Outcome Study Short-Form-36 (SF-36) and the Capability Set for Work Questionnaire (CSWQ) score. Other study parameters: Audio recordings of consultations with the healthcare professionals and the multidisciplinary team meetings, medical reports, questionnaire on resources and personal characteristics, interviews with patients and partners, focus groups with healthcare professionals.

Study description

Background summary

High quality care of patients with inheritable neuromuscular diseases (NMD) requires a multi-faceted personalized approach. The capability approach provides a new conceptualization of wellbeing focusing on a) the real opportunities that patients have to be and do things they have reason to value and b) the dynamic interaction between access to resources (e.g., medication, aids), personal characteristics, physical and social environment, and such opportunities. In this study we want to investigate whether providing care based on the capability approach (capability care) has an added value in the rehabilitation of patients with NMD.

Study objective

The quality of life of adult patients with NMD can be enhanced by providing capability care in comparison to usual care.

Study design

T0: baseline, just before intervention. T1: 6 months after T0

Intervention
One group of patients will receive usual rehabilitation care. The other group of patients will receive care based on the capability approach (capability care). Health care professionals will be trained to apply the capability approach in consultation and care to identify a) capabilities of patients and b) barriers or promoting factors of patients' capabilities. The health professionals learn how to support the patient in thinking about capabilities. It is expected that one of the main changes is that the consultations will help patients in reflection on what really matters to them, how their chronic illness interferes with achieving desired ends, and how rehabilitation can help the patient to address this.

Contacts

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Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: - confirmed diagnosis of FSHD or DM1 by neurologist - 18 years or older - a current rehabilitation aim - in a mentally stable condition - sufficient mastery of the Dutch language to participate in conversation with the health care providers and research assistant and to fill in questionnaires - informed consent (written) Patients that have been treated previously and have new rehabilitation aims can be included.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: - patients that have one of the following comorbidities: o active or previously major psychotic, psychiatric or depression episodes o acquired brain injury (e.g. stroke, traumatic brain injury) o severe cognitive problems (e.g. severe dementia) in which case the rehabilitation treatment is affected and/or patients are not able to fill out the questionnaires o a limited life expectancy (e.g. due to cancer)

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-11-2020
Enrollment:	60
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO

Date:	15-09-2020

Application type:	First submission
Review commission:	METC Oost-Nederland
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Study registrations

Followed up by the following (possibly more current) registration

ID: 49384
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8946
CCMO	NL72794.091.20
OMON	NL-OMON49384

Study results