

Efficacy of a thumb opponens splint on manual dexterity in patients with Hereditary Motor and Sensory Neuropathy: a pilot study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Peripheral neuropathies
Study type	Interventional

Summary

ID

NL-OMON32255

Source

ToetsingOnline

Brief title

Thumb opponens splint in HMSN

Condition

- Peripheral neuropathies

Synonym

Charcot-Marie-Tooth disease, Hereditary Motor and Sensory Neuropathy

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Charcot-Marie-Tooth Disease, Hand, Hereditary Motor and Sensory Neuropathies, Splints

Outcome measures

Primary outcome

Manual dexterity assessed with the Sollerman hand function test. The Sollerman test consists of 20 unilateral and bilateral subtests, each comprising a task considered to be an activity of daily living. The tasks reflect the most common handgrips used in daily life. The time necessary to perform the task and the quality of movement of the hand are recorded (test administration time 30-60 min).

Secondary outcome

Manual dexterity assessed with the Functional Dexterity test (FDT). The FDT provides information regarding the patient's ability to use the hand for functional daily tasks that require a 3-jaw-chuck prehension between the fingers and the thumb. An advantage of this test is that it requires a minimum amount of time for administration (15 seconds to 2 minutes).

Perceived physical functioning of the upper extremity, assessed using the Dutch language version of the Michigan Hand Outcomes Questionnaire (MHOQ-DLV). The MHOQ is a self-administered questionnaire. The mean time required to complete the questionnaire is 10 minutes.

Occupational performance assessed with the Canadian Occupational Performance Measure (COPM). The COPM is a measure of a client's self-perception of

occupational performance in the areas of self-care, productivity and leisure.

Outcome measures of the COPM are: client's most important problems in occupational performance and a total score for performance and a total score for satisfaction for these problems.

Perceived usability of the splint will be assessed with a questionnaire specifically designed for the purpose of the study.

Study description

Background summary

Hereditary motor and sensory neuropathy (HMSN) also known as Charcot-Marie-Tooth disease type, forms a heterogeneous group of slowly progressive diseases of the peripheral nerve. HMSN presents with distal muscle weakness and atrophy usually starting in the foot and leg muscles. In a later stage the hand may be affected. Although in the literature and clinical practice the attention lies predominantly on the problems of the lower extremity, many HMSN patients present with affected hand function, loss of manual dexterity and perceived limitations in upper extremity related activities.

In our society people value the use of their hands and loss of hand function may have a substantial effect on their lives. Manual dexterity is furthermore of utmost importance for daily activities. Previous study has showed that the ability to oppose the thumb is a major determinant of impaired manual dexterity. This finding helps target intervention strategies like the use of a short thumb opponens splint to improve manual dexterity and preserve or enhance daily life functioning of patients with HMSN.

Study objective

Purpose of this study is to assess the feasibility, tolerability of a short thumb opposition splint and the initial efficacy of this splint on manual dexterity and perceived limitations in activities in patients with HMSN1a. Additionally, the responsiveness of the 3-item version of the Sollerman test and its associations with hand function and perceived limitations in upper extremity related activities of patients with HMSN1a are assessed.

Study design

a prospective self-controlled experimental study

Intervention

The intervention consists of a custom made short thumb opponens splint for the dominant hand. Patients will wear the splint during 6 weeks.

Study burden and risks

Participants will visit the department of Rehabilitation of the AMC 3 times. During the first visit, manual dexterity will be assessed with 2 different tests, questionnaires will be administered and in a semi-structured interview problems in daily activities will be inventoried. The splint will be made and instructions for use will be given to the participant.

One week after the first visit, the fitting of the splint will be checked and if necessary the splint will be adapted. During the third visit (after 6 weeks) manual dexterity with the use of the splint will be assessed and the questionnaires will be administered. A potential risk of wearing the thumb opponens splint is the occurrence of pressure ulcers. During the second visit, this will be monitored and in case of a pressure ulcer the splint will be readapted.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Diagnosis of HMSN confirmed by DNA or electrophysiological study;

Age between 18 and 70 years;

Loss of opposition (kapandji score < 3)

Impaired manual dexterity (Sollerman test score <80)

Exclusion criteria

Other disabling disorders in the medical history that might influence hand function of the dominant hand;

Difficulty comprehending the Dutch language;

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 15-02-2008

Enrollment: 10

Type: Anticipated

Medical products/devices used

Generic name:	Opposition splint
Registration:	No

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	NL21464.018.08