Non-surgical treatment of Carpal Tunnel Syndrome by means of Mechanical Traction: a Randomized Clinical Trial. The MT-CTS project

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

Summary

ID

NL-OMON38578

Source
ToetsingOnline

Brief title
MT-CTS project

Condition

- Neurological disorders NEC

Synonym
Carpal Tunnel Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg

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

Intervention

Keyword: Carpal Tunnel Syndrome, Mechanic Traction

Outcome measures

Primary outcome

The primary study parameter is:

- self-reported symptom severity and functional status

Secondary outcome

The secondary study parameters are:

- Quality of life

- absenteeism from work

- resource utilisation behaviour

Study description

Background summary

Carpal Tunnel Syndrome occurs in up to 5-8% of the general population and up to 11% of the working population. Apart from the patient inconvenience, Carpal Tunnel Syndrome is associated with tremendous economic burden: the direct financial implications of management and the indirect burden of absenteeism from the workplace.
Current treatment, such as cortisone injections or surgery have a risk of complications. A promising non-invasive treatment is mechanical traction / rotation by the Phystrac apparatus. Although over 5000 patients in the Ntherlands have been treated already in regular care by the Phystrac apparatus, until now no randomised controlled trial has been performed to evaluate the effectiveness of the Phystrac in people with Carpal Tunnel Syndrome.

Study objective

The aim of this study is to investigate the effectiveness of the Phystrac in people with Carpal Tunnel Syndrome.

The primary research question is:
- Is there evidence that Phystrac might be an additional non-invasive option of treating CTS patients with regard of clinical outcome?

The secondary research questions are:
- To what extent contributes Phystrac to decrease the number of days of sick leave?
- To what extent contributes Phystrac to improvement of quality of life?
- To what extent contributes Phystrac to less resource utilisation behaviour?

Study design

The current study has a Randomised Controlled Trial design with one year follow up. The Phystrac intervention will be compared with care as usual.

Intervention

The intervention consist of mechanical traction / rotation using the Phystrac apparatus. Each session has a duration of 20 minutes. Treatment sessions are twice a week during 6 weeks.

Study burden and risks

No risk is associated with participating in the study. The Phystrac is classified into risk class 1. All participants are asked to fill out a questionnaire four times during a year. Participants allocated to the intervention group will have a 20 minutes treatment twice a week during 6 weeks.

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 who fulfil the criteria of diagnosis of CTS.
- aged between 18 - 80 years, compos mentis
- being physically capable of visiting the outpatient clinic twice a week in Venlo
- being capable to sit in an upright position for 20 minutes in a standard chair
- not intending to move outside the area within 3 months after inclusion

Exclusion criteria

- not understanding Dutch appropriately
- other known (rare) cause of neuropathy
- suffering from severe psychiatric disorders such as personality disorder, schizophrenia, bipolar disorder

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2013
Enrollment:	200
Type:	Anticipated

Medical products/devices used

Generic name:	Traction apparatus PHYSTRAC GT10
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	14-08-2013
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL44692.008.13