The Dutch Injection versus Surgery TRIal in Carpal Tunnel Syndrome patients

-DISTRICTS-

a multicenter open-label randomized controlled trial comparing two treatment strategies

Dutch CTS study group

PROTOCOL TITLE 'The Dutch Injection versus Surgery TRIal in Carpal Tunnel Syndrome patients'

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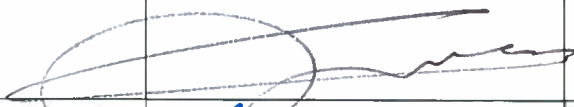
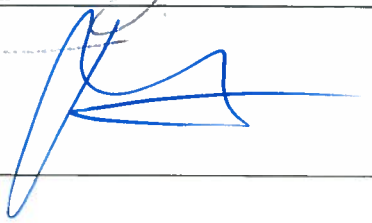
Head of Department: ***Prof. dr. Y.B.W.E.M. Roos***		1-2-2018
Coordinating Investigator: ***Prof. dr. R.M.A. de Bie***		1-2-2018

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LIST OF ABBREVIATIONS AND RELEVANT DEFINITIONS

AE	**Adverse Event**
AMC	**Academisch Medisch Centrum**
AR	**Adverse Reaction**
BCTQ	**Boston Carpal Tunnel Syndrome Questionnaire**
CBO	**Centraal BegeleidingsOrgaan**
CRF	**Case Report Form**
CRU	**Clinical Research Unit**
CTS	**Carpal Tunnel Syndrome**
CTS-6	**6-item carpal tunnel symptoms scale**
eCRF	**Electronic CRF**
EMG	**Electrodiagnostic testing**
GCP	**Good Clinical Practice**
IC	**Informed Consent**
METC	**Medisch Ethische Toetsing Commissie**
NVN	**Nederlandse Vereniging voor Neurologie**
QALY	**Quality-adjusted life year**
SAE	**Serious Adverse Event**
SPC	**Summary of Product Characteristics**
Sponsor	**The sponsor is the party that commissions the organisation or performance of the research, for example a pharmaceutical company, academic hospital, scientific organisation or investigator. A party that provides funding for a study but does not commission it is not regarded as the sponsor, but referred to as a subsidising party.**
STZ	**Stichting Topklinische Ziekenhuizen**
WMO	**Wet Medisch-wetenschappelijk Onderzoek met Mensen**
ZBC	**Zelfstandig BehandelCentra**

SUMMARY

Rationale: carpal tunnel syndrome (CTS) is the most common peripheral neuropathy. The optimal treatment strategy is still unknown. This results in considerable practice variation in the treatment of CTS.

Objective: the objective is to investigate if initial surgical treatment of CTS results in a better outcome and is more cost-effective when compared to initial treatment with a steroid injection.

Study design: multicenter open-label randomized controlled trial.

Study population: adult patients with CTS.

Intervention: one strategy starts with surgical treatment and the other strategy starts with a steroid injection. The choice for possible subsequent treatments is at the patient and physician's discretion.

Main study parameters/endpoints: the primary objective is to assess if the treatment strategy starting with a surgical treatment results in a higher rate of recovery compared to starting treatment with a steroid injection. Recovery is defined as having no or mild CTS symptoms as measured with the 6-item carpal tunnel symptoms scale. Follow-up is 18 months.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: surgical treatment and steroid injections for CTS have been widely used treatments and patients will not be exposed to additional risks. The patient has to fill in eight self-report questionnaires in the course of 18 months. We estimate that this may take 4 hours (4x 0,7hrs + 4x 0,3hrs).

1. INTRODUCTION AND RATIONALE

Carpal tunnel syndrome (CTS) is the most common peripheral neuropathy and is characterized by pain, paresthesia, numbness, and weakness of the affected hand. The cause of CTS is entrapment of the median nerve at the wrist. There are no universally accepted criteria for diagnosing CTS. Electrodiagnostic testing (EMG) and sonography are both accurate tools to confirm the diagnosis.[1] The overall prevalence rate of electrophysiologically confirmed CTS in the Netherlands is 9.2% in women and 0.6% in men.[2] There are approximately 300,000 patients with CTS in The Netherlands.[3] Estimated costs for absenteeism due to CTS are 26,5 million euro/year.3 Treatment options for CTS include splinting, steroid injections, and surgical decompression.[4 5 6 7]

Splinting is effective in the short term. A Dutch study showed that 54% of CTS patients with nocturnal splinting had a general improvement after 3 months.[6] In the same study 75% experienced an improvement of symptoms in the long term, but 41% of patients had also received surgery by that time.[6] The conclusion of the study was that surgery resulted in better outcome than splinting.

Steroid injections have been proven to be efficacious in the short term and are relatively safe.[8] A Dutch study showed that 25% of patients had a persistent effect of a steroid injection after one year.[9] Another Dutch study showed that 67% of patients initially treated with a steroid injection required additional surgery within one year.[10] This was confirmed by a Swedish study in which more than 70% of patients that had a steroid injection for CTS needed surgery within the following year. Ninety-two percent of the patients allocated to placebo needed surgery within the first year.[8] Results of another study suggest that a second injection is as effective as the first one, but long-term prospective data are missing.[11]

Surgical treatment is efficacious in most patients. The reported efficacy however varies. In a pooled analysis of 209 studies (32,936 surgeries), 75% of patients considered their condition as improved, much better, or cured.[12] There is no difference in effectiveness between open carpal tunnel release and endoscopic release.[13]

In line with the above, a systemic review also suggested that surgical treatment is more effective than non-surgical interventions for relieving symptoms of CTS.[14] **Fout! Bladwijzer niet gedefinieerd.**However, most neurologists initiate treatment with a steroid injection because they consider this very easy to perform and safe. Often, a second steroid injection is performed if the result of the first injection proved to be unsatisfactory. If symptoms remain or

reoccur, patients are referred for surgical treatment. Because of the high frequency of persisting or reoccurring symptoms, this strategy may result in postponement of the more effective treatment, that is surgical treatment, which could lead to unnecessary health loss, work absenteeism, and costs. Patients with severe CTS are often primarily treated surgically,[7] though the best treatment strategy for severe CTS is also not known.

The lack of comparative knowledge regarding the best treatment strategy for CTS, that is starting with a surgical treatment or starting treatment with a steroid injection, is reflected in the concept NVN-guideline for CTS (2016), which states no preference for one of the two strategies.[15] All of the above contributes to the considerable practice variation in the treatment of CTS.[16] The objective of this study is therefore to assess the efficacy and cost-effectiveness of a treatment strategy starting with a surgical treatment compared to starting treatment with a steroid injection.

2. OBJECTIVES

2.1 Primary objective

The primary objective is to assess:

if the treatment strategy starting with a surgical treatment results in a higher recovery rate 18 months later when compared to starting treatment with a steroid injection.

2.2 Secondary objectives

Secondary objectives are to compare the treatment strategy that starts with a surgical treatment to the treatment strategy that starts with a steroid injection regarding:

A) time to recovery during 18 months of follow-up;

B) number of patients recovered at different time points during 18 months follow-up;

C) level of symptom severity at different time points during 18 months follow-up;

D) hand functioning at 18 months;

E) pain scar or palm at different time points during 18 months follow-up;

F) patient's global perception of recovery at 18 months;

G) patient satisfaction at 18 months;

H) quality of life at 18 months;

I) number of additional treatments during 18 months follow-up;

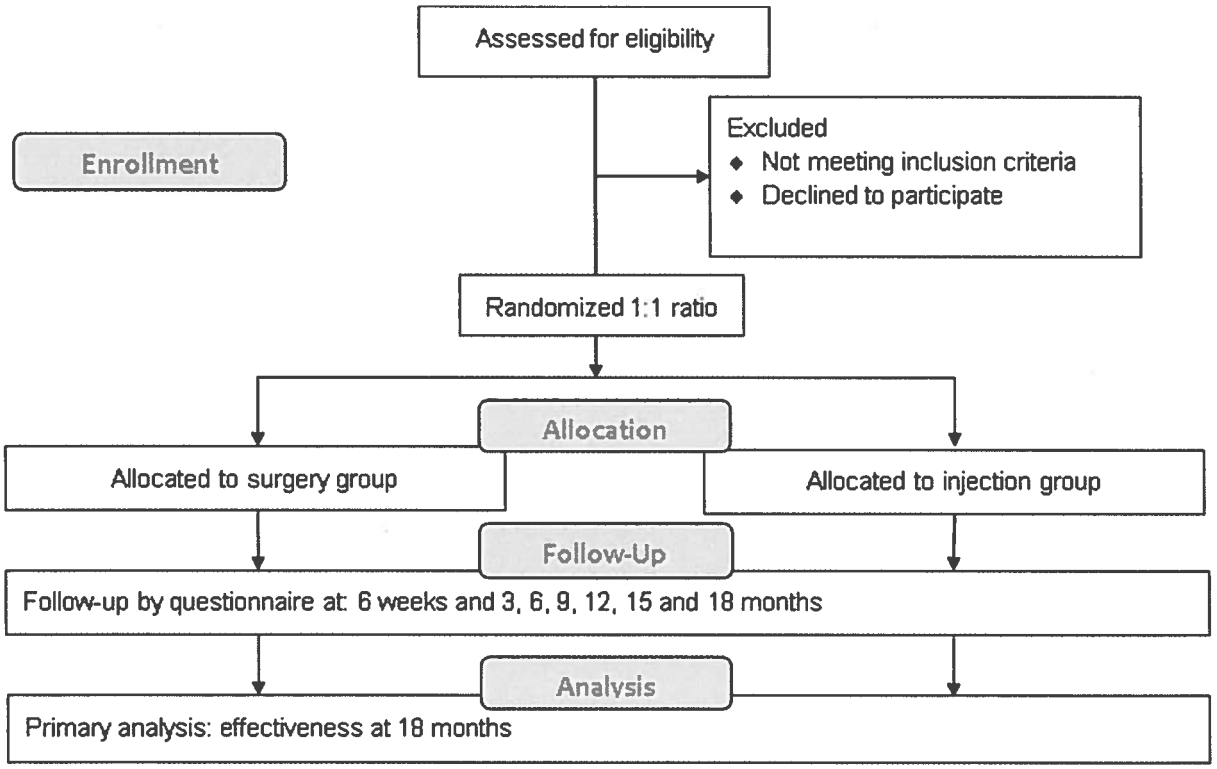
J) adverse events during 18 months follow-up;

K) use of care and health-related costs during 18 months follow-up.

3. STUDY DESIGN

The study is a multicenter open-label randomized controlled trial (Figure 1). The inclusion period will be 18 months. The follow-up of each patient is 18 months from randomization. The approximately 30 participating centers consist of university medical centers, STZ–hospitals (Stichting Topklinische Ziekenhuizen), general hospitals, and ZBC's (Zelfstandig behandelcentra) in the Netherlands.

Figure 1. Study flowchart



Secondary analysis:

- time to recovery
- number of patients recovered at different time points
- level of symptom severity at different time points
- hand functioning at 18 months
- pain scar or palm during 18 months of follow-up
- patient's global perception of recovery at 18 months
- patient satisfaction at 18 months
- quality of life at 18 months
- number of additional treatments
- number of adverse events
- use of care and health-related costs

4. STUDY POPULATION

4.1 Population (base)

The overall prevalence of electrophysiologically confirmed CTS in the Netherlands is 9.2% in women and 0.6% in men.[2] General practitioners will refer patients with clinically suspected CTS to one of the at least 30 participating neurological outpatient clinics. All participating hospitals have special outpatient clinics for CTS, each treating more than 400 patients per year. This results in approximately 18,000 potential participants if the inclusion period is 1.5 years (30x400x1.5). We need 940 participants, which is 5.2% of the potential participants.

4.2 Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- 18 years or older at time of examination;
- clinically suspected CTS;
- symptoms being present for at least 6 weeks;
- electrophysiological or sonographic confirmed CTS according to the Dutch 'carpal tunnel syndrome guideline'*;[17]
- treatment within 6 weeks after inclusion;
- the patient can only be included for the treatment of one hand if both hands are eligible; this will be the hand with the most severe complaints or the dominant hand if both hands are equally affected.
- surgery and injection are both considered as potential treatments for the CTS related symptoms**.

* There is no consensus about findings with sonography in CTS. The current opinion of the DUTCH CTS study group is that a cross-sectional area of more than 11 mm^2 is abnormal and thus confirms a clinical suspicion of CTS. We recommend that the CSA of the wrist is also recorded.

** Patients with secondary CTS due to a known underlying cause including (but not limited to): diabetes mellitus, rheumatoid arthritis, thyroid disease and a history of ipsilateral wrist fracture/trauma or surgery are allowed to participate in the DISTRICTS. This only if the treating physician considers both surgery and injection as effective treatments.

4.3 Exclusion criteria

A subject who meets any of the following criteria will be excluded from participation in this study:

- follow-up not possible;
- a previous history of surgery for CTS on the ipsilateral wrist;
- an injection for CTS in the ipsilateral wrist less than one year ago;
- previously participating in the DISTRICTS;
- clinical or neurophysiological suggestion of another diagnosis, like:
  - cervical radiculopathy;
  - cervical myelopathy;
  - brachial plexopathy including thoracic outlet syndrome;
  - mononeuropathies, such as pronator teres syndrome;
  - polyneuropathy, including Hereditary Neuropathy with Liability to Pressure Palsies;
  - complex regional pain syndrome;
- unable to comprehend Dutch self-report questionnaires;
- legally incompetent adults;
- pregnancy;
- no informed consent.

4.4 Sample size calculation

To date, there are no reliable data available regarding recovery in case of strategies that may include different treatments. We conservatively estimate that after 18 months 70% of patients in the surgery group and 60% of patients in the injection group are recovered.[10 12] A difference in recovery after 18 months of 10% is considered a minimal clinical important difference. A Fisher's exact test with a 0.05 two-sided significance level will have 80% power to detect the difference between a proportion of 0.70 (recovery after primary surgery) and a proportion of 0.60 (recovery after initial steroid injection) when the sample size in each group is 376 (752 patients in total). Anticipating on a 20% attrition rate, we will include (376 / 0.80 =) 470 patients per treatment group; 940 patients in total.

5. TREATMENT OF SUBJECTS

5.1 Investigational product/treatment

Patients will be randomly assigned to two treatment strategies. One strategy consists of starting with a surgical treatment (surgery group). The other strategy consists of starting with a steroid injection proximal to the carpal tunnel (injection group). If needed, these treatments can be followed by any additional treatments within the 18 months of follow-up such as a second injection or surgical treatment. Independent of the initial treatment performed, patients will receive the usual care at the discretion of their physician.

Surgery group — A certified surgeon or a qualified resident will perform the surgical treatment. As we choose to stay as close as possible to daily practice, participating center will continue to refer patient to their surgeon of choice, whether this be a neurosurgeon, plastic surgeon or other surgeon. Surgeons can use any proven surgical technique for decompression of the carpal tunnel. Surgical treatment will be a decompression of the median nerve at the carpal tunnel. As we aim to compare two intervention strategies, we choose to stay as close to daily practice as possible. This implicates that any proven surgical technique for decompression of the carpal tunnel can be used. In The Netherlands however, most surgeons use the standard open carpal tunnel release. This operation is performed in the ambulatory setting with field sterility and local anesthesia and without the need for an anesthesia provider. A tourniquet can be used. Open carpal tunnel release is performed by making a 2-3 cm long incision in the palm of the hand. The structures overlying the median nerve are divided and the transverse carpal ligament is cut under direct vision. Another, but less commonly used technique is the endoscopic carpal tunnel release. It is performed with one or two small incisions (portals) proximal and/or distal to the carpal tunnel. With aid of a camera, the surgeon obtains indirect access to the bottom surface of the transverse ligament. The ligament is cut from its lower surface with a knife, thus preserving the subcutaneous tissue and the overlying skin.

Injection group — The technique used for injections is as follows: injections will be given with a 3 cm long 0.7 mm needle as described by Dammers.[4] The site of injection will be at the volar side of the forearm 3-4 cm proximal to the wrist crease between the tendons of the radial flexor muscle and the long palmar muscle. In participants with a thin wrist the median nerve is close to the skin. In these participants the angle will be 10°. The angle will be larger, about 20°, in those with a thick wrist. In participants with well-developed muscles, the pronator quadratus muscle may push up the median nerve, so in a thick muscular arm the angle of introduction will also be flat, between 10° and 20°. The needle

is introduced slowly, and the participant will be instructed to say stop if he or she feels pins and needles or pain in the fingers. If a resistance is felt the needle will be withdrawn a few millimeters and then repositioned. The injection can be given without much pressure. After injection, the fluid bolus will be gently massaged towards the carpal tunnel.
The injection contains steroids. Each participating center is free in using their choice of brand and dosage of steroids, with or without local anesthetic.

5.2 Escape medication

The use of analgesics is allowed.

6. NON-INVESTIGATIONAL PRODUCT

6.1 Name and description of non-investigational product(s)

Steroid injections are widely used as treatment in patients with CTS. There are however a wide range of different brands and dosages used. Sometimes, the steroids are combined with a local anesthetic: usually lidocaine. The participating hospitals are not restricted in their choice of brands when using steroid injections. The following are some of the most commonly used steroids: methylprednisolone, betamethasone, hydrocortisone, dexamethasone, prednisolone, triamcinolone acetonide. Please see the Summery of Product Characteristics (SPC) for additional information (appendix 13.2).

6.2 Dosages, dosage modifications and method of administration

Participating centers are free to choose their own brand and dosage of steroids and use of local anesthetic provided. The method of administration is described in chapter 5.1.

6.3 Preparation and labeling of Non Investigational Medicinal Product

Each participating center will be responsible for providing and preparing their own steroid injections. As steroid injections are widely used as treatment for CTS, they are available in all participating clinics.

7. METHODS

7.1 Study parameters/endpoints

7.1.1 Main study parameter/endpoint

There is one main study parameter: number of patients recovered at 18 months after randomization.

Recovery is defined as having no or mild CTS symptoms as measured with the 6-item carpal tunnel symptoms scale (CTS-6).[18] The CTS-6 is a self-report disease-specific questionnaire referring to symptoms for a typical 24-hour period during the past two weeks. The CTS-6 is an abbreviated and validated questionnaire derived from the Boston Carpal Tunnel Syndrome Questionnaire (BCTQ) and highly responsive to change of symptoms.[19] It contains 6 questions about symptoms that patients may experience. Each item is scored 1 (no symptoms) to 5 (most severe symptoms). The summated score ranges from 6 to 30 points. The validated Dutch translation of the BCTQ[20] has been used to compose a Dutch version of the CTS-6 (appendix 13.3).

Recovery at 18 months is defined as scoring less than 8 points on the CTS-6.

Time to recovery is defined as the first time point after the last intervention (*e.g.*, splinting, steroid injection or surgical treatment) with a score of less than 8 points if this time point is followed by a score of less than 8 points at the next time point or if this is the last time point at 18 months. Recovery during follow-up is repeatedly determined at 6 weeks and 3, 6, 9,12, and 15 months after randomization.

7.1.2 Secondary study parameters/endpoints

Secondary outcomes are:

A) time to recovery. Time to recovery is defined as the first time point after the last intervention (*e.g.*, splinting, steroid injection or surgical treatment) with a score of less than 8 points if this time point is followed by a score of less than 8 points at the next time point or if this is the last time point at 18 months. Recovery during follow-up is repeatedly determined at 6 weeks and 3, 6, 9,12, and 15 months after randomization.

B) number of patients recovered at 6 weeks and 3, 6, 9,12, and 15 months after randomization;

C) level of symptoms severity at 6 weeks and 3, 6, 9,12, 15, and 18 months after randomization;

D) hand functioning at 18 months follow-up. The functional status is measured using the QuickDASH (appendix 13.4).[21] The scale measures upper extremity related disability on 11 items. Each item is scored 1 (no disability) to 5 (most severe disability). The summated score ranges from 11 to 55 points. The QuickDASH has been used in patients with CTS; [21]

E) pain scar or palm during 18 months follow-up. A Dutch translation of the palmar pain scale is used to measure the severity of experienced pain and the degree of limitation of activity after surgery or injection.[19] The palmar pain scale is a two-item pain scale adapted from the short form 36 questionnaire bodily pain scale. The severity of the pain ranges from 1 (none) to 6 (very severe). The degree of activity limitation ranges from 1 (not at all) to 5 (Extremely), appendix 13.5;

F) patient's global perception of recovery at 18 months compared to baseline measured with a 7 point Likert-type item ranging from 1 (substantially deteriorated) to 7 (substantially recovered) (appendix 13.6);

G) patient satisfaction at 18 months measured with a 7 point Likert-type item ranging from 1 (very dissatisfied) to 7 (very satisfied) (appendix 13.6);

H) quality of life at 18 months as assessed with the EuroQol (EQ-5D-5L)(appendix 13.7).[22] The EuroQol consists of 5 items on mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, and all rated on a 5-point scale. Overall health is measured with a 20 cm vertical VAS (with endpoints labeled 'the best health you can imagine' and 'the worst health you can imagine');

I) number of additional treatments defined as every treatment initiated by the treating physician after initial treatment, such as but not limited to steroid injections, (re)surgery and splints (appendix 13.8) . Additional undergone treatments are determined at 6 weeks and 3, 6, 9,12,15, and 18 months;

J) adverse events defined as the number, nature, severity, duration and frequency of any adverse event throughout the course of the study (appendix 13.9) . Adverse events are determined at 6 weeks and 3, 6, 9,12,15, and 18 months;

K) use of care and health-related costs during follow-up, as assessed with the adapted Medical Consumption Questionnaire and the Productivity Cost Questionnaire (appendix 13.10). Data will be collected at 3, 6, 12 and 18 months.

7.2 Randomization, blinding and treatment allocation

Patients will be randomized by the local clinician using a centralized web-based application (ALEA) in a 1:1 ratio and stratified by type of CTS symptoms (uni- or bilateral), secondary CTS due to a known underlying cause (yes/no) and a history of previous CTS injections (yes/no), using variable permuted blocks.

13.7 EuroQol (EQ-5D-5L)

Zet bij iedere groep in de lijst hieronder een kruisje in het hokje dat het best past bij uw gezondheid VANDAAG.

MOBILITEIT

Ik heb geen problemen met lopen ❑
Ik heb een beetje problemen met lopen ❑
Ik heb matige problemen met lopen ❑
Ik heb ernstige problemen met lopen ❑
Ik ben niet in staat om te lopen ❑

ZELFZORG

Ik heb geen problemen met mijzelf wassen of aankleden ❑
Ik heb een beetje problemen met mijzelf wassen of aankleden ❑
Ik heb matige problemen met mijzelf wassen of aankleden ❑
Ik heb ernstige problemen met mijzelf wassen of aankleden ❑
Ik ben niet in staat mijzelf te wassen of aan te kleden ❑

DAGELIJKSE ACTIVITEITEN *(bijv. werk, studie, huishouden, gezins- en vrijetijdsactiviteiten)*

Ik heb geen problemen met mijn dagelijkse activiteiten ❑
Ik heb een beetje problemen met mijn dagelijkse activiteiten ❑
Ik heb matige problemen met mijn dagelijkse activiteiten ❑
Ik heb ernstige problemen met mijn dagelijkse activiteiten ❑
Ik ben niet in staat mijn dagelijkse activiteiten uit te voeren ❑

PIJN/ONGEMAK

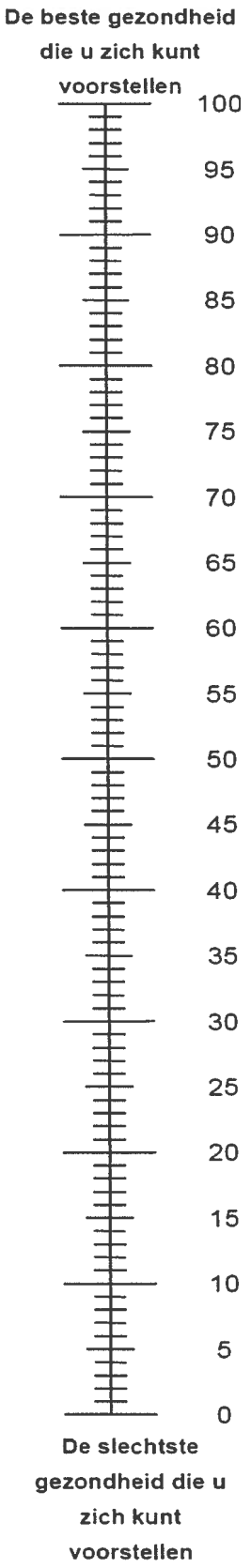
Ik heb geen pijn of ongemak ❑
Ik heb een beetje pijn of ongemak ❑
Ik heb matige pijn of ongemak ❑
Ik heb ernstige pijn of ongemak ❑
Ik heb extreme pijn of ongemak ❑

ANGST/SOMBERHEID

Ik ben niet angstig of somber ❑
Ik ben een beetje angstig of somber ❑
Ik ben matig angstig of somber ❑
Ik ben erg angstig of somber ❑
Ik ben extreem angstig of somber ❑

- We willen weten hoe goed of slecht uw gezondheid VANDAAG is.
- Deze meetschaal loopt van 0 tot 100.
- 100 staat voor de beste gezondheid die u zich kunt voorstellen.
  0 staat voor de slechtste gezondheid die u zich kunt voorstellen.
- Markeer een X op de meetschaal om aan te geven hoe uw gezondheid VANDAAG is.
- Noteer het getal waarbij u de X heeft geplaatst in onderstaand vakje.

UW GEZONDHEID VANDAAG = ☐



13.8 Additional treatments questionnaire

Heeft u sinds het vorige meet moment nog nieuwe behandelingen gehad voor uw hand/pols klachten?
(De injectie of operatie aan het begin van het onderzoek telt niet mee)
(Meerdere opties mogen aangekruist worden. Indien u meerdere dezelfde behandelingen heeft gehad, graag het aantal keer achter de behandeling zetten)

☐ geen nieuwe behandeling

☐ injectie ..... keer

☐ operatie ..... keer

☐ handspalk ..... keer

☐ fysio/ergotherapie ..... keer

☐ overige, welke? .... keer

Heeft u sinds het vorige meet moment nog nieuwe onderzoeken gehad voor uw hand/pols klachten?
(Meerdere opties mogen aangekruist worden. Indien u meerdere dezelfde onderzoeken heeft gehad, graag het aantal keer achter de behandeling zetten)

☐ geen nieuw onderzoek

☐ zenuwgeleidings- en/of spieronderzoek (EMG) ..... keer

☐ onderzoek met geluidsgolven (echografie) ..... keer

☐ beeldvorming (MRI of CT scan) ..... keer

☐ wel nieuw onderzoek, onbekend welke ..... keer

☐ overige, welke? .... keer

13.9 Adverse events questionnaire

Heeft u sinds het vorige meet moment nog nieuwe behandelingen gehad voor uw hand/pols klachten?
(De injectie of operatie aan het begin van het onderzoek telt niet mee)
(Meerdere opties mogen aangekruist worden. Indien u meerdere dezelfde behandelingen heeft gehad, graag het aantal keer achter de behandeling zetten)

☐ geen nieuwe behandeling

☐ injectie ..... keer

☐ operatie ..... keer

☐ handspalk ..... keer

☐ fysio/ergotherapie ..... keer

☐ overige, welke? .... keer

Heeft u in de afgelopen 3 maanden weleens in het ziekenhuis gelegen vanwege gezondheidsklachten als gevolg van het carpaletunnelsyndroom?
(U moest dus blijven slapen. Bijvoorbeeld omdat u geopereerd was en niet direct naar huis kon)

☐ Nee

☐ Ja, in totaal |__|__| verpleegdagen

1. In welk ziekenhuis?.....
2. In welk ziekenhuis?.....
3. In welk ziekenhuis?.....

Met de onderstaande vragen willen we te weten komen of er <u>sinds het vorige meetmoment</u> nieuwe gezondheidsklachten zijn ontstaan.
(Het gaat om klachten aan de hand/pols waarmee u meedoet aan het onderzoek)
*(het gaat hierbij **niet** om de bekende klachten die bij uw carpaletunnelsyndroom horen)*

Heeft u:	Ja	Nee
nieuwe pijnklachten hand/pols/litteken	☐	☐
nieuw veranderd gevoel in hand	☐	☐
nieuwe verminderde kracht in hand	☐	☐
nieuwe verminderde vaardigheid hand	☐	☐
wond/huid probleem waarvoor extra behandeling nodig was	☐	☐

<u>De volgende vragen gaan over klachten van de algemene gezondheid:</u>

Heeft er in de afgelopen 3 maanden een nadelige gebeurtenis ten aanzien van uw algemene gezondheid plaatsgevonden?

☐ Nee

☐ Ja, namelijk

Nadelige gebeurtenis 1: .....
Nadelige gebeurtenis 2: .....
Nadelige gebeurtenis 3: .....

Heeft u in de afgelopen 3 maanden een arts geraadpleegd vanwege een nadelige gebeurtenis ten aanzien van uw algemene gezondheid?

☐ Nee

☐ Ja, namelijk *(noteer naam en specialisme)*

Arts 1: .....
Arts 2: .....
Arts 3: .....

Heeft u een behandeling moeten ondergaan vanwege deze nadelige gebeurtenis ten aanzien van uw algehele gezondheid?

☐ Niet van toepassing

☐ Nee

☐ Ja, namelijk

Behandeling 1: ..... |__|__| keer
Behandeling 2: ..... |__|__| keer
Behandeling 3: ..... |__|__| keer

Bent u hersteld van de nadelige gebeurtenis ten aanzien van uw algemene gezondheid?

☐ Niet van toepassing

☐ Nee

☐ Gedeeltelijk

☐ Ja

Bent u opgenomen geweest in het ziekenhuis vanwege de nadelige gebeurtenis ten aanzien van uw algemene gezondheid?
(indien het een spoedopname betreft graag dit aankruisen)

☐ Niet van toepassing

☐ Nee

☐ Ja, in totaal |__|__| verpleegdagen

In welk ziekenhuis?.....□ spoedopname

In welk ziekenhuis?.....□ spoedopname

In welk ziekenhuis?.....□ spoedopname

Is er volgens u een verband tussen de doorgemaakte nadelige gebeurtenis ten aanzien van uw algemene gezondheid en de behandeling die u heeft gehad in verband met uw hand/pols klachten?

☐ Niet van toepassing

☐ Nee

☐ Mogelijk

☐ Ja

13.10 Care Use

Vraag 14: Wat doet u in het dagelijkse leven?
(Kruis aan wat u de meeste tijd doet.)
□ Ik zit op school, ik studeer

□ Ik werk in loondienst

□ Ik ben zelfstandig ondernemer

□ Ik ben huisvrouw, huisman

□ Ik ben werkloos

□ Ik ben arbeidsongeschikt voor |__|__|__| %

□ Ik ben met pensioen of prepensioen

□ Ik doe iets anders, namelijk.....

Vraag 15: Hebt u nu betaald werk?
(in de ziektewet zijn geldt ook als betaald werk)
□ Nee (*Ga verder met vraag 25*)

□ Ja, we vragen naar uw eigen netto inkomen uit betaald werk.

LET OP: het gaan alleen om uw eigen inkomen, dus zonder dat van uw eventuele partner. U hoeft dus maar een van de volgende mogelijkheden in te vullen. Ga daarna door naar vraag 16.

☐ Mijn eigen netto inkomen uit betaald werk is ongeveer:
..... Euro per week
..... Euro per 4 weken
..... Euro per maand
..... Euro per jaar
☐ Ik weet mijn inkomen niet of wil het liever niet zeggen.

Vraag 16. Wat is uw beroep?
.....

Vraag 17: Hoeveel uur per week werkt u? |__|__| uren per week
(Tel alleen de uren waarvoor u betaald wordt)

Vraag 18: Op hoeveel dagen in de week werkt u? Op |__|__| dagen per week

Vraag 19: Bent u in de afgelopen 4 weken afwezig geweest van uw werk vanwege gezondheidsklachten door het carpaletunnelsyndroom?
□ Nee (*ga verder met vraag 22*)

□ Ja, ik ben |__|__| dagen afwezig geweest
(Tel alleen de werkdagen in de afgelopen 4 weken)

Vraag 20: Was u langer dan de gehele periode van 4 weken afwezig van uw werk ten gevolge van gezondheidsklachten door het carpaletunnelsyndroom?
(Het gaat om een aaneengesloten periode van werkverzuim)
□ Nee *(ga verder met vraag 22)*

□ Ja *(ga verder met vraag 21)*

Vraag 21. Wanneer heeft u zich ziek gemeld?
|__|__| |__|__| |__|__|__|__|
d d m m j j j j

Vraag 22: Waren er in de afgelopen 4 weken dagen waarop u wel gewerkt heeft, maar tijdens uw werk last had van gezondheidsklachten door het carpaletunnelsyndroom?
□ Nee *(ga verder met vraag 25)*

□ Ja *(ga verder met vraag 23 en 24)*

Vraag 23: Op hoeveel dagen had u tijdens uw werk last van gezondheidsklachten door het carpaletunnelsyndroom?
(Tel alleen de werkdagen in de afgelopen 4 weken)
|__|__| werkdagen

Vraag 24: Op de dagen dat u last had kon u misschien niet zoveel werk doen als normaal. Hoeveel werk kon u op deze dagen gemiddeld doen?
(Kijk naar de cijfers hieronder. Een 10 betekent dat u op deze dagen net zoveel kon doen als normaal. Een 0 betekent dat u op deze dagen niets kon doen. Zet een cirkel om het goede cijfer)

Ik kon op deze dagen niets doen				Ik kon ongeveer de helft doen					Ik kon net zoveel doen als normaal
0	1	2	3	4	5	6	7	8	9	10

Vraag 25: Waren er dagen waarop u minder onbetaald werk kon doen vanwege gezondheidsklachten door het carpaletunnelsyndroom?
(Het gaat om dagen in de afgelopen 4 weken)
□ Nee *(ga verder met vraag 28)*

□ Ja *(ga verder met vraag 26 en 27)*

Vraag 26: Op hoeveel dagen was dit zo?
(Tel alleen de dagen in de afgelopen 4 weken)
|__|__| dagen

Vraag 27: Stel dat iemand, bijvoorbeeld uw partner, familielid of een bekende, u op deze dagen had geholpen. En al het onbetaalde werk wat u niet kon doen, voor u had gedaan. Hoeveel uur was die persoon hier op deze dagen dan gemiddeld mee bezig geweest?

Gemiddeld |__|__| uur op deze dagen

Vraag 28: Heeft u in de afgelopen 3 maanden één of meer van de volgende artsen of therapeuten bezocht als gevolg van het carpaletunnelsyndroom?

Huisarts	□	nee	□	ja,	|__|__| afspraken
Chirurg	□	nee	□	ja,	|__|__| afspraken
Neuroloog	□	nee	□	ja,	|__|__| afspraken
Fysiotherapeut	□	nee	□	ja,	|__|__| afspraken
Ergotherapeut	□	nee	□	ja,	|__|__| afspraken
Bedrijfsarts	□	nee	□	ja,	|__|__| afspraken
Anders, namelijk .....□		nee	□	ja,	|__|__| afspraken

Vraag 29: Heeft u de afgelopen 3 maanden vanwege klachten als gevolg van het carpaletunnelsyndroom gebruik gemaakt van betaalde thuiszorg of van onbetaalde hulp van familie, vrienden, buren of vrijwilligers?

(meer dan 1 antwoord mogelijk)

(Tel alle weken in de afgelopen 3 maanden bij elkaar op. Let op: een periode van 3 maanden telt 13 weken)

□ Nee

□Thuiszorg, hulp in de huishouding |__|__| weken |__|__| uren per week

□Thuiszorg, hulp bij persoonlijke verzorging |__|__| weken |__|__| uren per week

□Thuiszorg, verpleegkundige hulp |__|__| weken |__|__| uren per week

□Onbetaalde hulp van familie / vrienden / buren / vrijwilliger
|__|__| weken |__|__| uren per week

Vraag 30: Heeft u in de afgelopen 3 maanden vanwege gezondheidsklachten als gevolg van het carpaletunnelsyndroom medicijnen voorgeschreven gekregen?

□Nee

□Ja, de volgende medicatie heb ik voorgeschreven gekregen:

☐ .....

Aantal |__|__| per dag
Aantal mg |__|__||__|__| per tablet
Hoe lang gebruikt |__|__| dagen

☐ .....

Aantal |__|__| per dag
Aantal mg |__|__||__|__| per tablet
Hoe lang gebruikt |__|__| dagen

☐ .....

Aantal |__|__| per dag
Aantal mg |__|__||__|__| per tablet
Hoe lang gebruikt |__|__| dagen

Vraag 31: Heeft u na de behandeling in de afgelopen 3 maanden vanwege gezondheidsklachten aan de handen zelf nog extra kosten gemaakt zonder dat daar een vergoeding tegenover stond?
(meer dan 1 antwoord mogelijk).
□ Nee

□ Ja, namelijk .....

☐ Voor extra medicatie zoals pijnstillers ±|__|__|__| euro per maand

☐ Extra huishoudelijke hulp ±|__|__|__| euro per maand

☐ Reiskosten ±|__|__|__| euro per maand

☐ Anders, namelijk..... ±|__|__|__| euro per maand

Vraag 32: Welke wijze van vervoer heeft u gebruikt om van uw huis naar het ziekenhuis te gaan?
□ Auto
□ Openbaar Vervoer
□ Taxi
□Anders, namelijk.....

Vraag 33: Wat was de enkele reisafstand tussen uw huis en het ziekenhuis?

Deze afstand bedroeg |__|__|__| kilometer.

13.11 Assessment schedule

	inclusion	baseline	6 weeks	3 months	6 months	9 months	12 months	15 months	18 months
In- and exclusioncriteria	x								
Baseline characteristics		x							
Symptom severity (CTS-6)		x	x	x	x	x	x	x	x
Hand functioning (QuickDash)		x							x
Palmar pain			x	x	x	x	x	x	x
Perceived recovery (Likert-type)									x
Patient satisfaction (Likert-type)									x
Quality of life (EuroQol)		x							x
Additional treatment			x	x	x	x	x	x	x
Adverse events			x	x	x	x	x	x	x
Care use				x	x		x		x

x = assessment, blank = no assessment

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