(Cost)effectiveness of a personalized multimodal physical therapy program compared to surgery in patients with cervical radiculopathy: a randomized non-inferiority trial

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To investigate if a personalized multimodal physical therapy program compared to ACDF surgical treatment is non-inferior over a 12-month period and cost-effective in patients with painful cervical radiculopathy who have an indication for...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON56220

Source
ToetsingOnline

Brief title
MOVE-IT:

Condition

- Spinal cord and nerve root disorders

Synonym
Cervical radiculopathy, neck herniation

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: (cost)effectiveness, Cervical radiculopathy, Personalized multimodal physical therapy, Surgery

Outcome measures

Primary outcome

Primary outcome for non-inferiority is disability over a 12-month period.

Secondary outcome

Secondary outcomes are arm and neck pain intensity, self-perceived recovery, fear of movement, treatment adherence, health-related quality of life, patient-specific activities, patient-acceptable symptom state, return-to-work, pressure, heat, cold tests (QST measurements), medication use, costs, percentages cross-overs, (re)surgeries, and complications. Additionally, transcriptomics of peripheral immune cells will be performed at baseline and 6 months follow up to compare gene expression profiles between patients who recover and those who do not.

Study description

Background summary

A neck hernia is a highly painful condition that can lead to significant limitations in functioning and work. Surgery is the standard treatment when pain and loss of feeling or strength in the arm persist. However, such surgery also carries risks of complications and comes with high costs. An intensive physiotherapy program tailored to the signs and symptoms of each individual patient appears to have comparable effects as surgery after a year. If this is

the case, it provides patients with a good alternative treatment option and may help prevent surgeries. We expect that personalized physiotherapy is equally effective and more cost-effective than surgery. This is beneficial for patients and society, as patients deserve safe and effective care. Multiple hospitals are participating in the study. Patients are randomly assigned to either surgery or physiotherapy treatment, and the effects are measured at 3, 6, 12, 24 and 60 months.

Study objective

To investigate if a personalized multimodal physical therapy program compared to ACDF surgical treatment is non-inferior over a 12-month period and cost-effective in patients with painful cervical radiculopathy who have an indication for surgery

Hypothesis: A personalized multimodal physical therapy program is less expensive and non-inferior in effectiveness compared to surgery.

Study design

A multicenter (11 clinics), randomized non-inferiority trial, with economic and process evaluation.

Intervention

Intervention: A personalized multimodal physical therapy program consisting of neuromobilizations, cervical mobilizations, exercise, pain education, behavioral therapy depending on the clinical findings. The number of sessions is 12 to 18 over a period of ~12 weeks. Only physical therapists who hold a master's degree and have completed the training are allowed to participate in the study. They are required to execute the intervention properly and consult the researchers in case of any issues. Additionally, the researchers maintain regular communication to monitor progress and assist in resolving any problems encountered by the physical therapist.

Control (Usual care): Surgery (Anterior Cervical Discectomy with Fusion) with usual post-operative care.

Study burden and risks

In order to reduce the burden of physical examination, blood withdrawal and questionnaire completion, we have carefully selected physical tests and questions, limiting their number as much as possible while still allowing for effective research (Table 1). Venous blood samples will be taken to asses immune parameters. The maximum amount of venous blood taken during the study is 14 ml (7 ml each).

The questionnaires will be administered at baseline and at 3-6-12-24-60 month follow-up. The physical tests will only be conducted at baseline and at 12 month follow-up (except for the QST Measurements) (Tabel 1, C1 protocol), and blood samples will be collected at baseline and 6 months follow-up.

The patients assigned to the personalized multimodal physical therapy will be treated by a specialized physical therapist near their residential area. The researchers will train and invite participating physical therapists to join the study. Patients assigned to the personalized multimodal physical therapy will receive 12-18 sessions of half an hour each. Patients assigned to the surgery will receive usual care.

Participation in this study may be of benefit to patients as both interventions reduce pain intensity and improve quality of life. Recent studies show that multimodal physical therapy treatments are effective in reducing pain intensity, neck mobility, daily functioning and quality of life. Additionally, a systematic review shows that manual therapy leads to clinical improvements in neck pain and disability at the short term. Exercise therapy is also considered an effective treatment strategy for cervical radiculopathy. Surgery is an effective treatment for pain relief and improvement in daily functioning. Although surgical treatment provides a faster pain reduction compared to conservative care, the effectiveness at the long term is comparable. The overall complication rate for ACDF ranges from 13.2% to 19.3%. These include in descending order; dysphagia (1.7%-9.5%), postoperative hematoma (0.4%-5.6% (surgery required in 2.4% of 5.6%), with epidural hematoma 0.9%), symptomatic recurrent laryngeal nerve palsy (0.9%-3.1%), cerebrospinal fluid leak (0.5%-1.7%), wound infection (0.1-0.9%-1.6%), increased radiculopathy (1.3%), Horner*s syndrome (0.06%-1.1%), respiratory insufficiency (1.1%), esophageal perforation (0.3%-0.9%, with a mortality rate of 0.1%), and instrument failure (0.1%-0.9%). No serious adverse effects are reported for multimodal physical therapy rehabilitation. The addition of QST measurements (Pressure, heat and cold tests) was discussed with our patient panel. They acknowledged that the development of a prediction model provides valuable benefits for personalizing care. It was also noted that incorporating QST does not exceed the time limits of a comprehensive physiotherapeutic consultation for the patient.

Under the basic insurance, physical therapy treatment is reimbursed for CR with motor deficits, starting from the 21st treatment, for a maximum of 3 months. For this project, an Innovation Policy rule will be requested from the NZA (Nederlandse Zorg Autoriteit), with a preferred health insurance company.

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 with CR with an indication for surgery and no contra-indication for conservative management are eligible to participate. CR is diagnosed when the patient*s clinical presentation corresponds to relevant Magnetic Resonance Imaging (MRI) findings. An e-consult between the patients and the neurosurgeon will take place to verify the indication for surgery. Further inclusion criteria: Age >=18, at least 8 weeks of unilateral arm pain and/or paraesthesia, with arm pain intensity and/or paraesthesia intensity Numeric Pain Rating Scale (NPRS) >=4/10, sensory deficits, motor deficits and/or reduced reflexes.

Exclusion criteria

Exclusion criteria: myelopathy, motor deficits measured by Medical Research Council (MRC) scale for muscle strength<=3, previous neck surgery, psychiatric disorders, systemic disease (e.g. rheumatoid arthritis), malignancies or

pregnancy. In case of myelopathy or MRC strength<=3, surgery will immediately be preferred instead of a conservative policy due to the risk of permanent disability.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-05-2024
Enrollment:	126
Type:	Actual

Ethics review

Approved WMO Date:	13-11-2023
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	21-03-2024
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	19-12-2024
Application type:	Amendment

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
Other	https://doi.org/10.17605/OSF.IO/S7HWA
CCMO	NL84177.028.23