The influence of musculoskeletal physiotherapy on the immune response in patients with neck pain.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24888

Source
Nationaal Trial Register

Brief title
project MoTION

Health condition

Non-specific neck pain
Patients with cervical radiculopathy
Immune system
Cytokine
Chronic pain
Microglia
Physiotherapy
Manual Therapy

Sponsors and support

Primary sponsor: Ducht Society for Manual Therapy; VU Amsterdam; MSG Science Network
Source(s) of monetary or material Support: This study is funded by the Dutch Association for Manual Therapy and by the Faculty of Behavioural and Movement Sciences Lab Fund 2019 of Vrije Universiteit Amsterdam. The MSG Science Network (https://www.msg-sciencenetwerk.nl/) will support participant recruitment. The funding sources have no role in the study design and will not have any roles in data collection,

analysis and interpretation of the data, nor in the reporting of the results.

Intervention

Outcome measures

Primary outcome

The primary outcomes are the short-term (i.e., immediately and two-hours following the intervention) differences in interleukin-1β (IL-1β) and tumor necrosis factor-α (TNF-α) following in-vitro stimulation of whole blood cells.

Secondary outcome

Several additional neuroimmune responses will be quantified as secondary outcomes at various time points:
- Ex-vivo inflammatory markers
- In-vitro inflammatory markers
- PBMC phenotyping
- Overall inflammatory index, pro-inflammatory index, anti-inflammatory index and ratio pro/anti inflammatory index

Study description

Background summary

Neck pain is a major public health problem alleged in its high prevalence, substantial impact on daily life and huge societal costs. Musculoskeletal Physiotherapy (MP) is an effective treatment for patients with persistent non-specific neck pain and cervical radiculopathy for reducing pain intensity. The effects of MP are often immediately noticeable after treatment. However, it is currently unknown which working mechanism might cause these effects. In persistent neck pain patients, the immune response - cytokines concentration - identified through whole blood lipopolysaccharide stimulation is elevated compared to healthy control. MP is able to attenuate the in vitro immune response in healthy volunteers. Thereby, a potential mechanism of MP might be attenuation of the immune response.

Study objective

Background of the study: Neck pain is a major public health problem alleged in its high prevalence, substantial impact on daily life and huge societal costs. Musculoskeletal Physiotherapy (MP) is an effective treatment for patients with persistent non-specific neck pain and cervical radiculopathy for reducing pain intensity. The effects of MP are often immediately noticeable after treatment. However, it is currently unknown which working

mechanism might cause these effects. In persistent neck pain patients, the immune response - cytokines concentration - identified through whole blood lipopolysaccharide stimulation is elevated compared to healthy control. MP is able to attenuate the in vitro immune response in healthy volunteers. Thereby, a potential mechanism of MP might be attenuation of the immune response. Therefore, the overall aim of this study is to gain insight into the immune response in patients with neck pain and the influence of MP on this immune response in neck pain patients.

Study design

Three time moments: baseline, immediate post-treatment, 120 minutes post-treatment

Intervention

Patients with non-specific neck pain in study 2 who are allocated to the intervention group will receive a single highvelocity low-amplitude distraction manipulation at the cervico-thoracic region (C7-T4) and a low-velocity low-amplitude cervical mobilization at all of the restricted/painfull cervical segments (C0-C7).

The sham treated patients receive the same treatment position but without the thrust.

Contacts

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Eligibility criteria

Inclusion criteria

Persistent non-specific neck pain

Inclusion:

• Age between 18-65 years.

• Minimal score of 40 on the Visual Pain Anaolgue Scale.

• Persistent pain is defined as pain complaints longer than 6 weeks.

• Can be classified as grade 1 or 2 non-specific neck pain.

• Written informed consent of the subject.

Exclusion criteria

Persistent non-specific neck pain

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

• Pregnancy or postpartum for 9 months • Contra-indications for phlebotomy (e.g. phlebitis) • Underwent treatment for current complaints for the last 6 weeks (e.g. physiotherapy, manual therapy, GP etc.) • Having diagnosed mental health disorders (e.g. depression) • Taken one of the following medication for the last 6 weeks: corticosteroids (e.g. prednisone), immunomodulatory medication (e.g. methotrexate, infliximab etc.) and the use of botox for the last 3 months. • Taken one of the following medication: NSAID's (e.g. diclofenac, ibuprofen, naproxen etc.), Aspirin, Simvastatin (58) for the last two weeks. • Long distance flight (within 7 days), ongoing shift work and hippocampal damage. • Having one of the following medical diseases o Neurological disorders (e.g. MS, myelopathie, cervical stenosis etc.) o Traumatic disorders (e.g. cervical fracture, surgery in the neck area etc.) o Having a history of malignity o Rheumatic or inflammatory disorders (e.g. Spondylitis Ankylpoetica, Crohn disease, sarcoidosis, colitis ulcerous, rheumatic arthritis, COPD, spastic colon, psoriasis etc.) o Cardiac diseases (e.g. history of myocardial infarction, abnormal heart rhythms) o Allergic reaction or auto immune diseases (e.g. type 1 diabetic, hay fever) o Metabolic disorders (e.g. type 2 diabetic) o Endocrinology disorders (e.g. Cushing Syndrome) o Haematological disorders (e.g. clothing problem) o Psychological/psychiatric disorders (e.g. depression, current high stress, Alzheimer disease) o Physical trauma for the last six weeks o Having the flue

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-01-2019
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
Individual deidentified participant data that underlie the results will be shared. Investigators whose proposed use of the data had been approved by an independent review committee identified for this purpose can access the data for individual participant data meta-analysis. Data will be available beginning 9 months and ending 36 months following article publication. Proposals may be submitted up to 36 months following article publication. After 36 months the data will be available in our University’s data ware house but without investigator support other than deposited metadata. Information regarding submitting proposals and accessing data may be found at https://research.vu.nl.

Ethics review

Positive opinion

Date:	18-01-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48587
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6575
NTR-old	NTR6961
CCMO	NL61404.029.18
OMON	NL-OMON48587

Study results