

Stratified physiotherapeutic (blended) care in neck and shoulder complaints

No registrations found.

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

Summary

ID

NL-OMON27269

Source

Nationaal Trial Register

Brief title

Meer op Maat

Health condition

Neck and/or shoulder complaints

Sponsors and support

Primary sponsor: HU University of Applied Sciences

Source(s) of monetary or material Support: Scientific College Physical Therapy (WCF) of the Royal Dutch Society for Physical Therapy (KNGF)

Intervention

Outcome measures

Primary outcome

The combined region-specific pain and disability score over 9 months follow-up (NPAD & SPADI)

Secondary outcome

- The combined region-specific pain and disability score over 3 months follow-up
- Reduction of neck and shoulder related costs
- Pain intensity
- Health-related quality of life
- Quality of life
- Illness perceptions
- Self-management skills
- Physical activity
- Exercise adherence
- Perceived effect
- Satisfaction with treatment
- Number of treatment sessions

Study description

Background summary

Rationale: Patients with neck and shoulder complaints experience pain and reduced physical functioning, resulting in high (in)direct societal costs. It is hypothesized that treatment can be improved by stratifying healthcare by matching the right treatment to the right patient. The two following tools can be used to stratify primary care physiotherapy.

- 1) The Keele STarT MSK Tool can be used to identify groups of patients depending on their risk of persistent disabling pain and disability (low, medium and high risk) in order to match them to appropriate treatments.
- 2) The Dutch Blended Physiotherapy Checklist determines whether a patient is suitable to receive a blended treatment and, if so, to what extent patients need more or less face-to-face contact alongside digital guidance. The tool will be used to select the most appropriate mode of delivery of the physiotherapy treatment, namely integrating an app or workbook within face-to-face sessions.

An example of evidence-based blended physiotherapy is e-Exercise, in which face-to-face physiotherapy sessions are integrated with a smartphone-application to support patients self-management skills. Recently, an e-Exercise application has been developed for patients with neck and/or shoulder complaints. For patients that are not suitable to receive a blended treatment, an information workbook with the same content as the smartphone-application was developed.

The two tools (Keele STarT MSK tool and the Dutch Blended Physiotherapy Checklist) will be integrated within the physiotherapeutic treatment process to match patients to the appropriate treatment. The prototype of this Stratified Blended Approach for treating patients with neck and/or shoulder complaints was developed in co-creation with patients, physiotherapists and relevant stakeholders. Feasibility of the Stratified Blended Approach was recently tested in a single group, non-randomized study. Based on patients' and

physiotherapists' experiences improvements were made. For the development, evaluation and implementation of the Stratified Blended Approach we use a theoretical framework, the CeHRes Framework.

Objective: To assess the (cost-)effectiveness of the Stratified Blended Care approach versus usual physiotherapy in primary care patients with neck and/or shoulder complaints.

Study design: A pragmatic multicentre cluster randomized controlled trial (cRCT) will be conducted. Physiotherapy practices will be randomized to either the usual physiotherapy arm or the 'Stratified Blended Approach' arm.

Main study outcomes: Primary outcome is the combined region-specific pain and disability score on the long term (9 months). Secondary outcomes are the combined region-specific pain and disability score on the short term (3 months), reduction of neck and shoulder related costs, pain intensity, health-related quality of life, quality of life, illness perceptions, self-management skills, physical activity, exercise adherence, perceived effect, satisfaction with treatment and number of treatment sessions.

Study objective

The Stratified Physiotherapeutic (Blended) Care approach is more (cost-)effective than usual physiotherapy in primary care patients with neck and/or shoulder complaints.

Study design

Four assessments will be performed, at baseline, 3, 6 and 9 months.

Intervention

Intervention:

According to the Stratified Blended approach, patients will be matched to an appropriate treatment based on their risk of persistent disabling pain (assessed with the Keele STarT MSK Tool – either low, medium or high risk) and their suitability for blended care (assessed with the Dutch Blended Physiotherapy Checklist – either suitable or unsuitable for blended care). Based on patients risk profile, the physiotherapy treatment will be targeted to patients' individual needs. If considered suitable for blended care, the patient will receive a digital and face-to-face blend of physiotherapy treatment (e-Exercise) in which an app with personalized information, exercises and physical activity modules is integrated with face-to-face physiotherapy care. If patients are considered unsuitable for blended care, they will receive an information workbook with similar content as the app will be integrated with face-to-face physiotherapy. The app and the information workbook aims to support adherence to physical activity and exercise recommendations. Content of care was based on the Dutch KNGF Clinical Practice Guidelines for Physiotherapy Neck pain, Complaints of Arm, Neck and Shoulder (CANS) and Subacromial complaints.

Control group:

Usual physiotherapy. Content of care was based on the Dutch KNGF Clinical Practice

Contacts

Public

Utrecht University of Applied Sciences
Cindy Veenhof

(+31) 652783000

Scientific

Utrecht University of Applied Sciences
Cindy Veenhof

(+31) 652783000

Eligibility criteria

Inclusion criteria

Patients with neck and/or shoulder complaints will be recruited within participating physiotherapy practices. In order to be eligible to participate in the data collection for the trial, a patient must meet all of the following criteria:

- consulting for physiotherapy for neck and/or shoulder complaints;
- one of the following physiotherapeutic diagnoses: subacromial complaints, biceps tendinosis, shoulder instability or non-specific musculoskeletal complaints of the neck and/or shoulder (not caused by acute trauma (fracture or rupture) or by any systemic disease);
- 18 years or older;
- sufficient mastery of the Dutch language.

Exclusion criteria

A patient who meets any of the following criteria will not be suitable to take part in the data collection for the trial:

- neck and/or shoulder complaints caused by specific pathology (e.g. shoulder pain with loss of active and passive range of motion (frozen shoulder), vertebral fracture, tendon rupture, Parkinson's disease, hernia nucleus pulposus, cervical stenosis), except for subacromial impingement, biceps tendinosis and shoulder instability.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-10-2019
Enrollment:	238
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description

N/A

Ethics review

Positive opinion	
Date:	21-12-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52723
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8249
CCMO	NL69963.041.19
OMON	NL-OMON52723

Study results

Summary results

N/A