A stratified approach integrated with eHealth in primary care physiotherapy for patients with neck and/or shoulder complaints: a cluster randomized controlled trial

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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52723

Source
ToetsingOnline

Brief title
Stratified physiotherapy in neck and shoulder complaints

Condition

- Other condition

Synonym
Neck and/or shoulder complaints

Health condition

Musculoskeletale klachten van de nek en de schouder

Research involving
Human

Sponsors and support

Primary sponsor: Hogeschool Utrecht
Source(s) of monetary or material Support: Wetenschappelijk College Fysiotherapie;onderdeel van het Koninklijk Nederlands Genootschap Fysiotherapie

Intervention

Keyword: Blended care, Personalized care, Physiotherapy, Stratified care

Outcome measures

Primary outcome

Primary outcome: neck and shoulder-specific pain and disability on the long

term (9 months).

Secondary outcome

Secondary outcomes are: neck and shoulder-specific pain and disability on the

short term (3 months), long-term reduction of neck and shoulder related costs,

pain intensity, quality of life, illness perceptions, self-management skills,

physical activity, exercise adherence, perceived effect, satisfaction with

treatment and number of treatment sessions.

Study description

Background summary

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 physiotherapy sessions alongside a digital application. The tool will be used to select the most appropriate mode of delivery of the physiotherapy treatment, namely integrating an app or workbook within physiotherapy sessions.

An example of evidence-based blended physiotherapy is e-Exercise, in which 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 Physiotherapeutic (Blended) Care (SPBC) approach for treating patients with neck and/or shoulder complaints was developed in co-creation with patients, physiotherapists and relevant stakeholders. Feasibility of the SPBC 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 SPBC we use a theoretical framework, the CeHRes Framework.

Study objective

To assess the (cost-)effectiveness of the Stratified Physiotherapeutic (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 SPBC intervention.

Intervention

According to the SPBC approach, patients will be matched to an appropriate treatment (six groups) 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 blend of physiotherapy treatment sessions (e-Exercise) and an app with personalized information, exercises and physical activity modules that will be integrated within 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 physiotherapy sessions. The app and the information workbook aim 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.

Study burden and risks

The risks for participants are expected to be negligible, because of the low burden of the SPBC approach. The content of the intervention is based on current literature, guidelines and focus groups. Therefore, risks for participating patients in the intervention arm are expected to be similar to usual physiotherapy care. The burden of the data collection consists of filling out questionnaires at baseline, 3 and 12 months. Cost questionnaires will be sent at 3, 6 and 9 months and used for the cost-effectiveness and cost-utility analysis. Additionally patients are asked to wear an accelerometer on their waist for 5 consecutive days at baseline, 3 and 9 months.

Contacts

Public
Hogeschool Utrecht

Heidelberglaan 7
Utrecht 3584CS
NL
Scientific
Hogeschool Utrecht

Heidelberglaan 7
Utrecht 3584CS
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion 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

- neck and/or shoulder complaints caused by specific pathology, except for subacromial impingement, biceps tendinosis and shoulder instability (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)

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:	Recruitment stopped
Start date (anticipated):	13-01-2020
Enrollment:	238
Type:	Actual

Ethics review

Approved WMO Date:	09-10-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	25-11-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	02-01-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	04-03-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	17-09-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	03-12-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	

Date:	02-07-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	06-04-2022
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27269
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL69963.041.19
OMON	NL-OMON27269

Study results

Date completed:	02-10-2023
Actual enrolment:	139