

Back2Action: Physiotherapy enriched with an eHealth psychological intervention for patients at risk of developing persistent low back pain or neck pain

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To study the effectiveness of physiotherapy plus an eHealth psychological intervention targeted at psychosocial risk factors compared to usual physiotherapy care on disability, for patients at risk of developing persistent low back pain and neck...

Ethical review	Approved WMO
Status	Completed
Health condition type	Muscle disorders
Study type	Interventional

Summary

ID

NL-OMON55492

Source

ToetsingOnline

Brief title

Back2Action

Condition

- Muscle disorders
- Mood disorders and disturbances NEC

Synonym

non-specific back pain, non-specific neck pain, Persistent low back pain, persistent neck pain

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: eHealth, low back pain, neck pain, Physiotherapy

Outcome measures

Primary outcome

Disability (measured by the Neck Disability Index for neck pain patients or the Oswestrey Low Back Pain Disability Questionnaire for low back pain patients) and Perceived Recovery measured with the Global Perceived Effect scale.

Secondary outcome

Pain intensity,

Depressive symptoms

Anxiety symptoms

Fear of movement

Pain catastrophizing

Self-efficacy

Study description

Background summary

Being the first- and fourth greatest contributor to disability, both low back pain and neck pain have a large societal and personal impact. Psychosocial factors, such as anxiety and depression, are stronger predictors for poor recovery and the development of persistent pain in patients with low back pain and neck pain than physical or biological factors. Patients should be approached according to the biopsychosocial model targeting both biological and psychological factors. However, physiotherapists indicate that they feel not

competent and equipped to appropriately identify and treat these psychosocial factors adequately, and focus mainly on the biological aspects of the disorder. To assist physiotherapists in treating these psychosocial factors, a new eHealth intervention is developed. This eHealth intervention will be added to usual physiotherapy care.

Study objective

To study the effectiveness of physiotherapy plus an eHealth psychological intervention targeted at psychosocial risk factors compared to usual physiotherapy care on disability, for patients at risk of developing persistent low back pain and neck pain.

Study design

A single blind multi-center randomized clinical trial with two arms will be conducted. This study is designed in accordance with the CONSORT statement.

Intervention

Intervention group: e-Health in addition to physiotherapy. The eHealth psychological intervention will consist of maximum 6 online modules and is targeted on psychosocial factors, namely; depression, anxiety, fear of movement, pain coping, pain catastrophizing and self-efficacy. Patients will be advised to perform one or two online modules per week. The e-Health intervention will be guided by trained physiotherapists supervised by a psychologist. Control group (usual care): Physiotherapy conducted according to the Dutch Clinical Practice Guidelines for low back pain or neck pain (in Dutch: KNGF). There will be a maximum of 9 multimodal physiotherapy sessions over a 6-week period

Study burden and risks

The main burden of participating in this trial will be adhering to the program, i.e. completing the physiotherapy sessions, the eHealth intervention and its assignments, and online questionnaires. There are no known risks associated with the investigational intervention.

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

1. Consulting a PT with low back pain- or neck pain complaints for at least 6 weeks
2. >18 years of age,
3. Satisfactory proficiency in Dutch
4. Access to a computer and the internet
5. Providing informed consent
6. A minimum of subclinical complaints of two psychosocial factors in the following domains: depression, anxiety, fear of movement

Exclusion criteria

1. Serious neck or lower back pathology (cancer, infection, trauma)
2. Lumbar or cervical radiculopathy
3. Systematic diseases (rheuma, arthritis)
4. Treated by a physiotherapist two months prior to inclusion
5. Currently treated by a mental health professional
6. Treated by a mental health professional two months prior to inclusion
7. Patients with severe depressive complaints (PHQ-9>20) or severe anxiety

complaints (GAD-7>15).

Study design

Design

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

Recruitment

NL	
Recruitment status:	Completed
Start date (anticipated):	28-06-2018
Enrollment:	260
Type:	Actual

Medical products/devices used

Generic name:	Back2Action;an eHealth psychological intervention
Registration:	No

Ethics review

Approved WMO	
Date:	25-10-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	18-01-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO
Date: 03-06-2021
Application type: Amendment
Review commission: METC Amsterdam UMC

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
CCMO	NL59545.029.16