Back2Action

No registrations found.

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

Summary

ID

NL-OMON28027

Source
NTR

Brief title
Back2Action

Health condition

nonspecifick neck pain, nonspecific low back pain, depressive symptoms, anxiety symptoms, kinesiophobia, pain catastrophizing

Sponsors and support

Primary sponsor: Vrije Universiteit Amsterdam, faculteit der Gedrags- en Bewegingswetenschappen
Source(s) of monetary or material Support: Vrije Universiteit Amsterdam, faculteit der Gedrags- en Bewegingswetenschappen

Intervention

Outcome measures

Primary outcome

Disability (Neck Disability Index or Oswestrey Low Back Pain Disability Questionnaire) and Perceived Recovery (Global perceived effect, a one-item 7-point Likert scale ranging from ‘worse than ever’ to ‘completely recovered’).

Secondary outcome

Pain intensity, Depressive symptoms, Anxiety symptoms, Fear of movement, Pain catastrophizing, Quality of life, Self-efficacy

Study description

Background summary

Being the first- and fourth greatest contributor to disability, lower back pain and neck pain respectively have a large societal and personal impact. Psychosocial factors, such as anxiety and depression, predict poor recovery and the development of persistent pain in patients with low back pain and neck pain better than physical or biological factors. Although these patients are typically treated with physiotherapy, physiotherapists indicate that they do not feel competent to appropriately identify and treat these psychosocial risk factors, nor do they have the appropriate tools, and focus mainly on the biological aspects of the disorder. There is evidence available that psychological interventions for low back pain are effective. However, there is currently no research available that specifically investigates the management of this population (patients with low back pain and/or neck pain, and psychosocial risk factors) in primary care practices with a multidimensional approach in the form of an added eHealth intervention. The overall aim of this project is to contribute to the optimization of treatment outcomes for patients at risk of developing persistent pain. In this study, we will conduct a randomized clinical trial to determine the (cost)effectiveness of physiotherapy plus an eHealth psychological intervention targeted at psychosocial risk factors versus physiotherapy only, for patients at risk of developing persistent low back – and/or neck pain.

Study objective

Adding an eHealth psychological intervention to physiotherapy in patients with low back pain and/or neck pain with psychosocial risk factors to develop persistent pain is (cost-) effective in reducing disability, psychological complaints (like distress, fear of movement, depression and anxiety), catastrophizing and pain and improving quality of life, coping and self-efficacy.

Study design

Baseline, post-treatment (8 weeks), intermediate follow-up (26 weeks) and long-term follow-up (52 weeks)

Intervention

Experimental intervention: eHealth in addition to physiotherapy (see Care as Usual). The eHealth psychological intervention will consist of a maximum of six online modules and is

targeted on; fear of movement, coping, pain catastrophizing, somatization, depression, anxiety and self-efficacy. Patients will be advised to do one or two online lessons per week. Control intervention: Care-as-Usual. Physiotherapy conducted according to the Dutch Clinical Practice Guidelines (KNGF) 'Physiotherapy for patients with neck pain' or 'Physiotherapy for patients with low back pain'. There will be a maximum of 9 multimodal physiotherapy sessions over a 6-week period (manual therapy, exercises).

Contacts

Public
Clinical Psychology, faculty of Behavioral- and Movement Sciences of the Free University of Amsterdam.
Lisette Bijker
van der Boechorststraat 1
Amsterdam 1081 BT
The Netherlands
+31 205985957
Scientific
Clinical Psychology, faculty of Behavioral- and Movement Sciences of the Free University of Amsterdam.
Lisette Bijker
van der Boechorststraat 1
Amsterdam 1081 BT
The Netherlands
+31 205985957

Eligibility criteria

Inclusion criteria

Participants 18 years or older, with non-specific low back pain and/or neck pain for at least six weeks with psychosocial risk factors to develop persistent pain, and proficient in Dutch

Exclusion criteria

1. Serious neck or lower back pathology, e.g. cancer or infection

2. Neck – or back fracture or cervical radiculopathy

3. Systematic diseases, e.g. rheumatoid 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- or anxiety symtpoms will be excluded

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2018
Enrollment:	202
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
Data will be made available upon request

Ethics review

Positive opinion

Date:	15-09-2016
Application type:	First submission

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
NTR-new	NL5941
NTR-old	NTR6122
Other	METC VUmc : 2017.286

Study results

Summary results
Not applicable