Influence of social support and treatment of illness perceptions on patient's adherence to a physical activity advice

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The primary objective of this study is to investigate whether social support by a partner or friend and treatment of patients' illness perceptions influences the rate of adherence to an activity advice compared to treatment of patients'…

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

Summary

ID

NL-OMON55780

Source
ToetsingOnline

Brief title
Patient's Adherence to an Activity Advice (PAPA)

Condition

- Other condition

Synonym
low back ache, low back pain

Health condition

aspecifieke lagerugpijn

Research involving
Human

Sponsors and support

Primary sponsor: PMC RijKo
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: activity advice, adherence, illness perceptions, social support

Outcome measures

Primary outcome

The primary outcome measure will be walking and/or cycling according to the

NNGB and social support.

Secondary outcome

Other outcomes will be

1. measures of illness perceptions.

2. measures of comorbidity, BMI, number of recurrences of non-specific low back

pain, measures of attitude and intention to physical activity

3. measures of refusal of the study.

Study description

Background summary

The global burden of low back pain is enormous. Results of the latest Global Burden of Disease, Injuries and Risk Factors study confirms low back pain as the greatest contributor to disability worldwide with a lifetime prevalence of 39.9% (SD±24.3%) and estimates of recurrence at 1 year range from 24% to 80% (Hoy et al., 2010, Hoy et al., 2012, Buchbinder et al., 2013, Manchikanti et al., 2014). Causes of low back pain are mostly unknown, in 90% pain is not attributed to a recognisable pathology, which is defined as non-specific low back pain (Staal et al., 2013). Factors associated with the recurrence of non-specific low back pain are age, low levels of physical activity, smoking, overall poor health, comorbidity, obesity and not having a paid job (Hestbaek et al., 2003, Shiri et al., 2010, Nilsen et al., 2011, van Oostrom et al.,

2012, Hartvigsen et al., 2013, Shiri et al., 2013). In most circumstances, it seems that non-specific low back pain, particularly with a persistent course, cannot be successfully treated with individual interventions of any kind (Friedly et al., 2010).
The recurrence rate and the number of recurrences of non-specific low back pain could be reduced and time to a next episode could be prolonged by advising an active lifestyle (Staal et al., 2013). Additionally there is a positive effect of active lifestyle including physical activities on outcomes of pain and disability (Ooijendijk et al., 2007, Wai et al., 2008, Smith et al., 2010, Choi et al., 2010, van Middelkoop et al., 2010, Dahm et al., 2010, van Middelkoop et al., 2011, Hendrick et al., 2011, Staal et al., 2013).
This proposal addresses physical therapy in the management of non-specific low back pain in the clinical setting in which an additional advice to assume regular physical activity is given.
Advising regular physical activity to patients suffering from non-specific low back pain includes an appeal to patients to adhere to this advice. Many non-specific back pain sufferers do not seem to adhere to physiotherapist's advice (Kolt et al., 2003, Beinart et al., 2013). In our previous study only 8% of non-specific low back pain sufferers adhered to an activity advice and self-report was inaccurate (Zandwijk et al., 2015, van Koppen et al., 2016).
There is strong evidence that poor treatment adherence in patients typically managed in musculoskeletal physiotherapy outpatient settings is associated with low levels of physical activity at baseline or in previous weeks, low in-treatment adherence with exercise, low self-efficacy, perceived illness beliefs, depression, anxiety, helplessness, poor social support for activity, greater perceived number of barriers to exercise and increased pain levels during exercise (Medina-Mirapeix et al., 2009, Medina-Mirapeix et al., 2009, Jack et al., 2010,). Influencing these factors may improve adherence behaviour (Goulding et al., 2010, Olander et al., 2013).
After executing an Intervention Mapping procedure, two important interventions to positively change adherence behaviour to an activity advice remained and consisted of *treatment of illness perceptions* and *organizing social support* (Appendix 1). Leventhal's self-regulation model shows that maladaptive Illness perceptions predict maladaptive health behaviour and activity limitations in a variety of illnesses and conditions, including low back pain. These illness perceptions are recognised as target for treatment and can be positively influenced (Siemonsma et al., 2013).
In this study influence of patients* illness perceptions and social support on adherence behaviour to an activity advice will be investigated.

Study objective

The primary objective of this study is to investigate whether social support by a partner or friend and treatment of patients' illness perceptions influences the rate of adherence to an activity advice compared to treatment of patients' illness perceptions alone in patients suffering non-specific low back pain.

Secondary objectives are;
1) Whether *treatment of illness perceptions* changes patients* maladaptive illness perceptions into realistic ones,
2) Whether maladaptive illness perceptions, comorbidity and/or obesity and/or rate of recurrences of non-specific low back pain and/or attitude and intention to physical activity influences patient*s adherence to an activity advice.

Study design

This study is a multicentre randomized two arm, controlled clinical trial. During a twelve-week intervention period, one group of patients will receive an activity advice added to usual treatment including *treatment of illness perceptions* (C-group). The other group will receive an activity advice and the intervention addressing social support by a partner or friend added to usual treatment including *treatment of illness perceptions* (SoSup-group). Patients will be assessed at baseline, and after one, 6 and 12 weeks. Recruitment is scheduled from October 2016 to July 2017. The study will be performed in 12 centres for physiotherapy in the province Zuid-Holland, the Netherlands.

Intervention

In both the C- and SoSup-group an activity advice will be added to usual treatment. The advised activities will be walking and/or cycling outdoors, meeting the Dutch Standard Healthy Physical Activity (NNGB) (Hildebrandt et al., 2007). In both groups cognitive treatment on illness perceptions according to the common sense model to the patient in the presence of the partner or friend will be given. During a maximum of two half-hour contacts in a standardised dialogue on maladaptive beliefs and feelings about identity, time-line, causes, controllability, and curability of low back pain are mapped, maladaptive perceptions are challenged, alternative perceptions are formulated (Siemonsma et al., 2013).
The intervention in the SoSup-group (intervention group), organizing social support by a partner or friend depending on patient*s preferences, will be added. During a maximum of two half-hour contacts (one for explanation and one for evaluation), in a standardised discussion the partner or friend will be stimulated to support the patient in executing the activity advice.
During 12 weeks the social support by a partner or friend will be executed for at least 5 times a week.

Study burden and risks

The social support described in this study is designed for better outcomes of physical activity levels patients suffering low back pain, and has no proven advantage on better outcomes on pain and disability in non-specific low back pain sufferers. Therefore we consider there is no disadvantage in the SoSup-group versus the C-group because patients in both groups receive

concomitant best evidence healthcare according to the Dutch guideline for low back pain (Staal et al., 2013).
No adverse effects of the interventions are expected. There are no ethical implications to be expected as a result of this study, treatment of all patients during the intervention period will be according to the Dutch guideline for low back pain.

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

patients >=18 years presenting with at least a second episode of non-specific low back pain are recruited for the study

Exclusion criteria

Patients are excluded when presenting red flags as mentioned in the low back pain guideline (Henschke et al., 2009, Staal et al., 2013), patients physical active in accordance with the Dutch standart healthy physical activity (NNGB) (Hildebrandt et al., 2007) and patients with a medical history of cancer, osteoporosis, rheumatoid arthritis, tuberculosis, trauma and fractures in the lumbar spine as well as recent infections in the musculoskeletal system. Patients unable to read, write or speak the Dutch language will also be excluded

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-02-2017
Enrollment:	360
Type:	Actual

Ethics review

Approved WMO Date:	26-09-2016
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	11-10-2017

Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	28-01-2020
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	27-05-2021
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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
ClinicalTrials.gov	NCT02996955
CCMO	NL58005.096.16