Proeftuin Integrative Medicine

No registrations found.

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

Summary

ID

NL-OMON27322

Source
NTR

Health condition

Patients with chronic musculoskeletal pain, (Osteo)arthritis, rheumatoid arthritis, fibromyalgia, low back pain, neck pain, tennis elbow or golfers arm, non-specific joint complaints, reuma, artrose, fibromyalgie, klachten bewegingsapparaat

Sponsors and support

Source(s) of monetary or material Support: "PGO fund of the Dutch Ministry of Health, Welfare and Sports."

Intervention

Outcome measures

Primary outcome

Quality of life: will be measured using a 36-item health survey (SF-36).

Secondary outcome

• Patient-rated pain: Patients are asked to rate their typical musculoskeletal pain on an ordinal 11-box scale rating (PRP) from no pain (0) to worst pain possible (10).

• Fatigue: Mean fatigue symptoms will be measured using the 20-item Multidimensional

Fatigue Inventory (MFI), including questions on physical and mental fatigue.

• Self efficacy is measured by the Pain Self-Efficacy Questionnaire (PSEQ), a 10-item scale used to assess the level of self-confidence in performing functional and social activities despite the presence of pain.

• Self-reported changes in main concern and well being by the Measure Yourself Concerns and Well-being (MYCaW).

• Changes in use of (pain) medication for musculoskeletal pain.

• Sense of Coherence: will be measured using the 29-item Dutch Sense of Coherence questionnaire (SOC).

• Patients' satisfaction with treatment and health care provider using the Participants' Satisfaction questionnaire (PS).

• Patients' Expectations about the treatment they will receive will be documented by short questionnaires (PE).

• GPs' opinion on SPC and IPC of chronic musculoskeletal pain, using a GP questionnaire (GPQ).

• Disease Related Costs: Data with respect to direct healthcare costs, direct non-healthcare costs and indirect costs will be collected in a questionnaire (DRC), including questions on medication use, use of complementary therapies, numbers of days absent from work and hospital visits.

Study description

Background summary

The use of Complementary and Alternative Medicine (CAM) among patients with chronic musculoskeletal pain has become increasingly popular in different countries. During the past two years in the Netherlands, 71% of the patients with chronic musculoskeletal pain visited a CAM practitioner. Manual therapists, acupuncturists and homeopaths were most frequently visited. CAM practitioners work mostly outside the world of conventional medicine. The majority of patients do not disclose these CAM visits to their General Physician (GP). However, previous studies have shown that the majority of patients would like to discuss CAM use and prefer a GP that refers them to CAM. To meet needs of patients, primary care disease management may thus benefit from an active involvement of GPs concerning CAM communication/referral. In the current study we would like to investigate the outcome of such an integrative primary care approach, in which the GP can refer patients to additional CAM therapies. The goal of this prospective study is to compare the outcome of an

integrative primary care (IPC) approach with standard primary care (SPC) management of patients with chronic musculoskeletal pain. A randomized intervention study is conducted to assess comparative effectiveness among patients of 18 year and older with chronic musculoskeletal pain for the duration of > 3 months who are visiting a GP. The primary outcome measure will be the change in quality of life. In addition, we anticipate to gain more insights in other factors related to chronic musculoskeletal pain such as pain, fatigue and general well-being.

Study objective

An integrative primary care approach, including communicating about and referring to CAM, may enhance quality of life of chronically ill patients

Study design

Individual duration:

12 months in total under the study

• T=0: Inclusion, baseline measurements

• T=3: Three months observation

• T=6: Six months observation

• T=12: Twelve months observation, study end point

Total duration of the study:

2,5 year: One year for inclusion of all patients, one year follow/up and half a year for including data analysis and reporting.

Intervention

Standard Primary Care Management (SPC): SPC will be according to the NHG guidelines and depends on the diagnosis and severity of complaints. SPC can include: Rest, physical exercise, physiotherapy, behavioural therapy and pharmacological treatment such as NSAID’s, systemic corticosteroids, DMARD’s such as methotrexaat, cyclosporine, hydroxychloroquine, sulfasalazine and azathioprine.
Integrative Primary Care Approach (IPC): In IPC, GPs can refer patients to five CAM therapies: Acupuncture, Tai-Chi, Osteopathy, Homeopathy and Naturopathy. Referral to a CAM therapy is in addition to SPC. The GP and the patient together will make the selection which CAM therapy is most suitable for the patient and his/her specific complaints.

Contacts

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Eligibility criteria

Inclusion criteria

• Patients visiting a GP

• With chronic musculoskeletal pain for a duration of ≥ 3 months due to: (Osteo)arthritis, rheumatoid arthritis, fibromyalgia, low back pain, neck pain, tennis elbow or golfers arm, non-specific joint complaints,

• Written informed consent

• >18 years

• Ability to understand and speak the Dutch language

• Accessible by phone and internet.

Exclusion criteria

• Patients with malignant diseases

• Patients with vertebral fractures

• Patients with severe of progressive neurological symptoms

• Patients with psychiatric complaints

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):	01-05-2013
Enrollment:	268
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-07-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 36897
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3897
NTR-old	NTR4059
CCMO	NL41527.028.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36897

Study results

Summary results
N/A