Cost-effectiveness of a primary care multidisciplinary treatment of patients with chronic pain

No registrations found.

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

Summary

ID

NL-OMON28304

Source
NTR

Brief title
COSMIC

Health condition

Chronic pain, multidisciplinary treatment, cost-effectiveness
Chronische pijn, multidisciplinaire behandeling, kosteneffectiviteit

Sponsors and support

Primary sponsor: Transcare Groningen, Vrije Universiteit Amsterdam, Vrije Universiteit Brussel
Source(s) of monetary or material Support: de Friesland Zorgverzekeraar

Intervention

Outcome measures

Primary outcome

Within the current study, the following outcomes will be measured in both groups

(intervention and control) after patients' have signed the informed consent.

Effect study:

• Health-related quality of life
Health-related Quality of life (HRQoL) will be measured using the RAND-36. The RAND-36 exists of 9 subscales: i.e. physical functioning, social functioning, role limitations (physical problems), role limitations (emotional problems), mental health, pain, general health perception. One item is added to measure health change (Hays, Sherbourne, & Mazel, 2016). The score on the RAND-36 will also be used to determine quality adjusted life years (QALY's), by applying a scoring algorithm developed by Brazier et al. (2002). This algorithm results in a meaningful health state classification measure, in which respondents can be classified in levels of functioning or limitations. The resulting index, scored from 0.0 to 1.0, can be used in the assessment of the QALY's.

• Intensity and extensiveness of pain

Pain intensity will be determined using a Visual Analogue Scale (VAS) ranging from 1 (no pain) to 10 (severe pain) and the extensiveness of the pain will be measured by the Widespread Pain Index (WPI) on which participants can indicate where the pain is located using an illustration of a human body.

Economic evaluation

Costs will be measured from a societal perspective, including medical costs, absenteeism- and presenteeism costs, unpaid productivity costs and informal healthcare costs using cost questionnaires at baseline and at 3, 6, 9 and 12 months after the intake (intervention group) or registration at a GP (control group).

• Medical costs: Health care utilization will be measured using retrospective questionnaires. Using these questionnaires, primary care (e.g. care by a GP, physical therapist), secondary care (e.g. care by an Orthopedic surgeon) as well as drug use will be measured. Health care utilization will be valued using 'the Dutch Manual of costing'(Hakkaart-van Roijen, van der Linden, Bouwmans, Kanters, & Swan Tan, 2015). Intervention costs (i.e. cost of the Transcare method) will be valued using a bottom-up micro-costing approach.

• Absenteeism costs: The number of sickness absence days will be measured using a modified version of the Short Form - Health and Labour Questionnaire(Hakkaart- van Roijen & Bouwmans, 2010) . Subsequently, absenteeism will be valued using the average price of production losses in the Netherlands and by making use of the 'Friction-Cost-Approach' (FCA (Hakkaart-van Roijen et al., 2015). This method argues that production losses only occur during the time needed to replace the vacancy caused by long-term absenteeism (the friction period; ±12 weeks). After a period of absenteeism longer than ±12 weeks, no more than ±12

weeks will be accounted to production losses (Hakkaart-van Roijen et al., 2015; Koopmanschap, Rutten, van Ineveld, & van Roijen, 1995).

• Presenteeism costs: Reduced productivity while at work (i.e. presenteeism) will be measured using the WHO-HPQ, in which participants will be asked to judge their own work performance on a scale from 0 (worst performance) to 10 (best performance; (Kessler et al., 2004). Subsequently, presenteeism will be valued using the average price of production losses in the Netherlands (Hakkaart-van Roijen et al., 2015).

• Unpaid productivity costs: Using retrospective questionnaires, production loss in unpaid work (for instance; housekeeping, home schooling and volunteering) will be measured. These costs will be valued using a recommended Dutch shadow price of €14,00 per hour (Euro's 2014; (Hakkaart-van Roijen et al., 2015).

• Informal care costs: Using retrospective questionnaires, Informal care (help from friends, neighbors, family, etc.) will be measured. Informal care will be valued using the aforementioned recommended Dutch shadow price (Hakkaart-van Roijen et al., 2015).

Secondary outcome

• Pain catastrophizing
Catastrophizing thoughts about the pain will be measured using the Pain Catastrophizing Scale (PCS). The PCS is a self-report scale to measure pain catastrophizing, divided into three subscales; magnification, rumination and helplessness(Sullivan, 2003).

• Central sensitization
The amount of central sensitization will be measured with the Central Sensitization Index (CSI; validated Dutch version (Kregel et al., 2015). The CSI is a self-report screening questionnaire to identify central sensitivity syndromes (e.g. fibromyalgia (Neblett et al., 2013).

Satisfaction
Satisfaction with the received treatment will be measured using a shortened version of the CQ-Index Module Pain (Krol, de Boer, Pass, & Rademakers, 2013).

Study description

Background summary

Introduction: In the Netherlands, about 20% of the population is suffering from chronic pain, with an average duration of 6.5 years. Quality of life among chronic pain patients is extremely poor and the Dutch societal cost of chronic pain is estimated to be between 12 and 59 billion Euros each year. Studies suggest that multidisciplinary treatment for chronic pain leads to improvements in pain and functioning and a reduction of chronic pain-related costs.

The current study therefore aims to evaluate the cost-effectiveness of multidisciplinary treatment for chronic pain implemented in primary care.

Methods: The cost-effectiveness of the multidisciplinary treatment program will be investigated by an economic evaluation alongside a non-randomized controlled study with a 12-month follow-up. The sample consists of an intervention group of chronic pain patients (pain >6 months, n=40) who receive multidisciplinary treatment and a control group (pain >6 months, n=40) who receive treatment as usual provided by their GP. Patients in both groups will fill out digital questionnaires before treatment (intervention)/shortly after their registration (control) and at 3 months, 6 months, 9 months and 12 months after the intake/registration. Within the current study, the following outcomes will be measured in both groups. Effect study (at baseline, 6 months and 12 months after the intake): health-related quality of life, the intensity and extensiveness of pain, pain catastrophizing, and signs of central sensitization. Economic evaluation (at baseline and at 3, 6, 9, and 12 months after the intake): health care costs, absenteeism and presenteeism costs, unpaid productivity costs and informal care costs.

Discussion: To our knowledge, this study is the first to investigate this issue this way: an economic evaluation alongside an effect study with a 12-month follow-up. The data consists of self-reported data, which could be a possible limitation of this study. The data can, inter alias, be subject to recall bias. To avoid this, the costs-questionnaires will be filled out every 3 months to optimize recall.

Study objective

In the Netherlands, about 20% of the population is suffering from chronic pain, with an average duration of 6.5 years. Quality of life among chronic pain patients is extremely poor and the Dutch societal cost of chronic pain is estimated to be between 12 and 59 billion Euros each year. Studies suggest that multidisciplinary treatment for chronic pain leads to improvements in pain and functioning and a reduction of chronic pain-related costs.
The current study therefore aims to evaluate the cost-effectiveness of multidisciplinary treatment for chronic pain implemented in primary care. It is expected that the multidisciplinary treatment program, compared to treatment as usual, will lead to a reduction in pain intensity and extensiveness, signs of central sensitization and pain catastrophizing, with at least an equal quality of life.

Moreover, we expect that the multidisciplinary treatment program will be cost-effective both from a societal as well as an insurance policy perspective.

Study design

Effect study:
The following outcomes will be measured at baseline (T0), at 6 months (T2) and at 12 months after the intake (T4):
• Health-related quality of life
• The intensity and extensiveness of pain

• Pain catastrophizing
• Central sensitization

In addition, participants in the intervention group will also fill out effect-questionnaires the moment they finish their treatment (T5).

Economic evaluation:
At baseline (T0) and at 3 (T1), 6 (T2), 9 (T3) and 12 (T4) months after the intake:
• Health care costs
• Absenteeism- and presenteeism costs
• Unpaid productivity costs
• Informal care costs.

Participants in both the intervention group as the control group will fill out a questionnaire measuring satisfaction with the received treatment after 12 months (T4).

Intervention

Intervention group:

The GP's participating in the multidisciplinary treatment program screen their patients for suitability for this study using the inclusion/exclusion criteria. If a patient is deemed suitable, he/she will be asked to participate in a cost-effectiveness study. If a patient is interested, the researcher will contact the patient and provide him/her with both verbal and written information about the study. The written information comprises the goal, the content and the duration of the study as well as information about risks and inconveniences, the possibility to withdraw and contact information of the research team. The patient will be asked two questions:

1) Do you object to the anonymous processing of your data for research purposes?

2) Do you object to filling out questionnaires every three months up to 12 months from now?

If a patient does not object to these two questions, he/she will be asked to sign an informed consent form.

Control group:

General practitioners providing TAU have been selected on account of the similarity of their patient population compared to the patient population in the intervention group (both situated in small villages in Friesland, the Netherlands).

GP's providing treatment as usual will be instructed about the inclusion/exclusion criteria. Using these criteria, they will screen and recruit suitable patients. If a patient is deemed suitable and agrees to participate in the study, the researcher will contact the patient.

Information about the study will be provided and the same questions as noted above will be asked. If the patient does not object to these two questions, he/she will be asked to sign an informed consent form.

Intervention group:

The intervention group will receive a multidisciplinary treatment. This treatment is already implemented in the general practices for a few years. The treatment comprises the following steps:

1. Pre-intake: After patients have registered for the multidisciplinary treatment, they will receive an invititation to fill out digital intake-questionnaires (see 'Methods' for an overview of the effect-questionnaires that are filled out at baseline). When they have filled out these questionnaires, they will be called in for an intake.

2. Intake: Prior to the intake, patients' will be asked whether they are interested in participating in a cost-effectiveness study. If they agree, an informed consent will be signed and their name will be noted.

During a three-hour intake, patients will be examined by the GP for one hour, by a physical therapist for one hour and they will speak with a psychologist for one hour. The GP and the physical therapist will examine the physical state of the patient and will discuss his medical history and medication. The psychologist will investigate the psychological state of the patient. After the intake, all clinicians will participate in a multidisciplinary consultation in which they decide on the diagnosis and the most appropriate treatment.

3. Treatment: The first step in the treatment program for the patient is receiving education about their pain. First, the patient will have an appointment with the GP in which they discuss the medical aspects of their pain. Then the patient receives education from the physical therapist and psychologist about their findings, the cause of the pain (often central sensitization) and what they can do for the patient. After the education, the patient will have weekly or bi-weekly appointments with the psychologist and/or the physiotherapist, for as long as necessary. Appointments with the GP can be made if necessary (for a medication consult for example).

Control group:

The control group will receive treatment as usual for chronic pain. General practitioners work according to the NHG-Standaard Pijn, a guideline for GP's in managing pain. This usually consists of advice to stay active and eat healthy, medication, referral to a physiotherapist, etc. (De Jong et al., 2015).

Contacts

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Eligibility criteria

Inclusion criteria

- Chronic pain lasting longer than 6 months

- Age between 18 and 70 years

- No prior treatment with cognitive behavioral therapy aimed at treating chronic pain-related psychological issues

Exclusion criteria

- Neurological pathology in medical history

- Diagnosed with cognitive impairments

- Current severe psychiatric problems

- Not able to complete the questionnaires

- Not able to speak/understand Dutch

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	05-09-2016
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-08-2016
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	NL5437
NTR-old	NTR6014
Other	METC VUMC : 2016.348

Study results

Summary results
The results of this study will be published in the future.