Duloxetine plus collaborative care treatment versus Duloxetine alone in the treatment of concomitant pain and depressive disorder. A randomized clinical trial in primary care.

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The primary objective of the study is to establish the effects of an integrated intervention for depression and pain in primary care.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON31476

Source
ToetsingOnline

Brief title
CC:PAINDIP (collaborative care: pain depression in primary healthcare)

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym
Depression, Major Depressive Dissorder

Health condition

pijnklachten

Research involving
Human

Sponsors and support

Primary sponsor: Trimbos instituut
Source(s) of monetary or material Support: Eli Lilly

Intervention

Keyword: collaborative care, duloxetine, major depressive disorder, pain

Outcome measures

Primary outcome

Primary parameter used to substantiate the primary study objective will be severity of pain measured by the *average pain* item of the BPI, this is a 0-10 numeric rating scale.

Secondary outcome

Secondary parameters will be severity of depression (PHQ-9, IDS-SR), QALY as measured by EQ-D5 and SF-36 and costs measured by TIC-P. Also other health symptoms (e.g. anxiety) will be taken into account (PHQ), and another secondary parameter will be the severity of somatoform symptoms (WI). Changes in pain catastrophizing will be evaluated with the Pain Catastrophizing Scale (PCS).
The LKV (Lichamelijke Klachten Vragenlijst) will be used to see which physical complaints are reported by the subjects.
The duration of the pain symptoms and pain catastrophizing behavior will be taken into account as effect modifiers.
Process measures will be compliance and adherence to treatment, the patient-doctor relationship as measured by the PDRQ-9, as well as assessment of the care provided in both experimental conditions (*Contacten met dokters en

andere behandelaars*).

Study description

Background summary

Patients with depression often present with pain. The positive predictive value for depressive disorder is 43 % for joints ache and 39% for backache (Gerber et al., 1992). Pain is one of the associated symptoms of depressive disorder (American Psychiatric Association, 1980). The percentage of chronic pain rises from a non-depressed general population sample from minor depressed patients to up to 70% in MDD patients (Ohayon & Schatzberg, 2003). Up to 85% of patients with pain symptoms experience a depression (Bair, Robinson, Katon, & Kroenke, 2003;Kroenke, Spitzer, & Williams, 2001). An increased risk for depression in patients with pain symptoms is found in groups without and with a somatic disorder. Furthermore, the presence of a major depressive episode results in a 2-fold increase in painful physical symptoms, both in medically unexplained and in medically explained conditions (Demyttenaere et al., 2006). Subjects with pain symptoms have at least a 2-fold increased risk for depression compared to subjects without pain (Bair et al., 2003) and the prevalence of depression increases when the number of pain symptoms increases (Gureje et al., 2007). The burden of pain and depression is high for patients (and doctors) in terms of disability, wellbeing and use of medical care (Bair et al., 2003).

Study objective

The primary objective of the study is to establish the effects of an integrated intervention for depression and pain in primary care.

Study design

A two-armed cluster randomized trial with randomization between PCPs. Randomization across PCPs will be used because the PCPs have a potential influence on the outcome of the intervention. If subjects are randomly assigned, there would be a possibility that transfer effects would influence the outcome of the intervention (Van der Feltz-Cornelis & Ader, 2000). Practices will be matched according to their location and size. It is an open label study, single blinded that is the outcome assessment will be performed by a blinded research assistant and the participants will not be aware if they are in the experimental or control condition. Differences in the outcome measures between the two conditions will be analyzed with Multi Level Analysis (MLA) to correct for the clustered design. To control for possible skewness in the randomized groups as far as distribution of confounders is concerned, propensity scores will be calculated. Propensity scores are used to correct for

a possible randomization bias, they balance the observed covariates (Joffe & Rosenbaum, 1999;Van der Feltz-Cornelis et al., 2006a). Possible confounders such as age, gender, immigrant status, level of education, history of treatment and life events will be taken as variables in the analysis. To assess the cost effectiveness, we will apply a cost-utility analysis (CUA). The results will be expressed as cost per Quality Adjusted Life Year (QALY). The economic evaluation will be undertaken from a societal perspective. Hence, all relevant effects and costs due to resource utilization within the healthcare (direct medical costs) and costs due to production losses (productivity costs) will be included. The study will take four years. Planned start of the study: 01.11.2007.

Intervention

In the experimental arm, treatment with the antidepressant duloxetine will be combined with psycho education in the form of a DVD provided by the PCP, a self help manual containing a short (approximately 6-12 weeks) behavioral intervention with focus on both pain symptoms and depression and including relaxation techniques and exercise techniques, handed out by the care manager (nurse practitioner) to the patient, and PST provided by the care manager. The participating PCP and CM apply this integrated treatment of an antidepressant, psycho-education, a self help manual and PST in a collaborative care model. The patients progress will be monitored during the intervention by use of a numeric rating scale for pain (NRS) and the PHQ9.
In the control condition, patients will only receive duloxetine.

Study burden and risks

The patients have to fill in a questionnaire at 4 different times. The patients in both conditions will receive duloxetine daily. Furthermore, patients in the intervention condition will receive a no-risc integrated treatment for pain and depression.

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 will be selected that have presented themselves with pain at their primary care physician. They will be approached for the study and asked informed consent. If they consent, they will be screened with the PHQ for depressive disorder and the BPI (brief pain inventory). In case of a cut-off score of >10 on the PHQ and a score of >= 3 on the 'average pain' item of the BPI, they will be included in the study.

Exclusion criteria

Exclusion criteria will be: cancer; recent post traumatic pain; alcohol or drug abuse; suicidal ideation; psychotic symptoms; dementia; somatization disorder; or already being under psychiatric treatment. Also, all contraindications known by the PCP for Duloxetine will be exclusion criteria as well.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-04-2008
Enrollment:	116
Type:	Anticipated

Ethics review

Approved WMO

Date:	08-07-2008
Application type:	First submission
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	NL20346.029.08