Transmural Collaborative Care: Integrated antidepressant and psychotherapeutic treatment of concomitant pain and depressive disorder.

Gepubliceerd: 15-10-2007 Laatst bijgewerkt: 18-08-2022

Combined treatment (collaborative care + duloxetine) is more effective than mono-treatment (duloxetine or collaborative care + placebo) in depressive symptom reduction on the PHQ as main outcome for patients with MDD and (sub)chronic pain.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26763

Bron
Nationaal Trial Register

Verkorte titel
TCC:PAINDIP

Aandoening

1. Depressive disorder;

2. pain;

3. collaborative care;

4. primary care;

5. cost effectiveness;

6. RCT.

Ondersteuning

Primaire sponsor: Trimbos Instituut / NIMHA, Utrecht, the Netherlands.
Overige ondersteuning: Eli Lilly

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To establish effectiveness on severity of depression (measured by PHQ-9), of a closely monitored integrated intervention (TCCCL + duloxetine) for concomitant (sub)chronic pain and depression compared to TCCCL + placebo and compared to Duloxetine alone.

Toelichting onderzoek

Achtergrond van het onderzoek

The burden of pain and depression is high for patients in terms of disability, wellbeing, and use of medical care. Patients with major and minor depression often present themselves with pain to a general practitioner and recognition of depression is low. Also, physical symptoms, including pain, in major depressive disorder, predict a poorer response to treatment. A multi-faceted, patient-tailored treatment programme, such as collaborative care, is needed. However, treatment of chronic pain conditions in depressive patients has, so far, not received much attention. Also, cost effectiveness of an integrated approach of pain in depressed patients has not been studied yet.

This article describes the aims and design of a study that is currently underway. The aim of this study is to evaluate effects and costs of collaborative care with Duloxetine for patients with pain symptoms and a depressive disorder, compared to mono-treatment (collaborative care with placebo, Duloxetine alone).

This study is a placebo controlled double blind, three armed randomized Multi Centre trial with a factorial design. Patients with (sub) chronic pain and a depressive disorder will be included. They will be randomized to either collaborative care with Duloxetine, collaborative care with placebo, or Duloxetine alone. In the collaborative care conditions, the care-manager will provide Problem Solving Treatment and guidance with a self-help manual. The care-manager is also responsible for monitoring of depressive and pain symptoms. Also, patients are referred to a physiotherapist. Here, they will receive treatment according to a 'Graded Activity' protocol. The psychiatrist is responsible for the medication. According to an

antidepressant algorithm, the psychiatrist prescribes an antidepressant (Duloxetine or placebo). For the pain medication, a pain medication algorithm will be followed. The psychiatrist will also monitor progress of pain and depressive symptoms. After 12 weeks, the patient will be referred back to the general practitioner with a Consultation Letter. This letter contains information for further treatment of the patient. 189 completers are needed to attain sufficient power to show a clinically significant effect of 0.6 SD on the primary outcome measures. Data on depression, anxiety, mental and physical health, medication adherence, quality of life, patient-doctor relationship, coping, health resource use and productivity will be collected at baseline and after three, six, nine and twelve months.

Doel van het onderzoek

Combined treatment (collaborative care + duloxetine) is more effective than mono-treatment (duloxetine or collaborative care + placebo) in depressive symptom reduction on the PHQ as main outcome for patients with MDD and (sub)chronic pain.

Onderzoeksopzet

Assessments: T0 at baseline; T1 at 3 months, T2 at 6 months, T3 at 9 months and T4 at 12 months.

Onderzoeksproduct en/of interventie

Experimental intervention will be integrated care including psychoeducation with DVD developed specifically on depression and pain; a self-help manual with psycho education and exercises (i.e. relaxation techniques); a pain medication protocol; an antidepressant protocol, consisting of an algorithm for Duloxetine; Problem Solving Treatment; Graded Activity, provided by a physiotherapist; a Consultation Letter to the PCP. The control group will be treated with Duloxetine according to the antidepressant protocol with Duloxetine algorithm. The third group will receive a placebo plus integrated care as mentioned above.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

The patients are referred to a mental health centre and at this point they have the possibility to participate in this study. At the mental health centre, the patients will be screened with the PHQ for depressive disorder and with the BPI measuring for pain. In case of a cut-off score of >10 on the PHQ-9 and a numerical score of more than 3 on the 'average pain' item and after informed consent, the patient will be included in the study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients with pain for which by diagnostic medical assessment a structural and continuing physical cause has been found in terms of tissue damage, illness or otherwise, that requires treatment, such as pain due to cancer or recent post traumatic pain, are excluded from the study and advised to seek such treatment Other exclusion criteria are:

1. Alcohol use >3 units a day or drug abuse or dependence in the last 6 months, defined as current use of any hard drugs or cannabis;

2. Psychotic symptoms or use of antipsychotic medication that may influence perception of pain;

3. Use of St. Johns worth (Hypericum Perforatum);

4. Pregnancy and breastfeeding;

5. Inability to participate in case of too severe language barrier, dementia;

6. Somatization disorder without depressive symptoms;

7. All contra-indications for Duloxetine;

8. Lastly, suicidal ideation is an exclusion criterion if this constitutes immediate danger and the need for crisis management according to the consulted psychiatrist. For this purpose, a suicide protocol is used in the study, defining degrees of suicide risk and prescribing necessary steps to be taken to advert such risk.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2007
Aantal proefpersonen:	219
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-10-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1056
NTR-old	NTR1089
Ander register	: WC 2007-069
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
Facts on depression. DVD. Trimbos Instituut 2006.