Author's response to reviews

Title: Effectiveness and Cost-effectiveness of Transmural Collaborative care with Consultation Letter (TCCCL) and Duloxetine for major depressive disorder (MDD) and (sub)chronic pain in collaboration with primary care: a randomized placebo-controlled Multi-Centre trial. TCC:PAINDIP.

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Author's response to reviews: see over
Dear Editor,

Hereby I submit to you:

**Effectiveness and Cost-effectiveness of Transmural Collaborative care with Consultation Letter (TCCCL) and Duloxetine for major depressive disorder (MDD) and (sub)chronic pain in collaboration with primary care: study protocol of a randomized placebo-controlled Multi-Centre trial. TCC:PAINDIP.**


This article was not published and is not under review elsewhere. The abovementioned authors declare that they have no competing interests.

This study researches the effectiveness of psychotherapy and antidepressant medication treatment for co morbid depression and pain symptoms, which may result in a useful contribution to the field. Therefore, it will be of high interest to your journal. This study will be conducted according to the guidelines of 'Good Clinical Practice' (CPMP/ICH/135/95).

This is the design of a RCT that we will conduct. The design has been approved by the Medical ethical board of VUmc. I have enclosed the letters of this approval. The sentence 'Het oordeel over de methodologische kwaliteit was positief' in the letter 'Approval medical ethical committee VuMC (TCCPAINDIP)' means that the medical ethical committee has a positive judgment on the methodological quality. In the letter 'Approval medical ethical committee VuMC – adding 3rd mental health centre amendment (TCCPAINDIP)' the sentence 'Het ingediende amendement….eerder werd verleend' means that the medical ethical committee does not change their approval of conducting this trial after receiving this amendment for adding a 3rd mental health centre.

Furthermore, this study is approved by the commission of scientific research (CWO) of each participating mental health centre. I have enclosed the letters of approval. The sentence 'Op basis hiervan adviseert de CWO akkoord te gaan met het onderzoeksvoorstel,' in both the letters of the CWO of GGZ inGeest and Arkin means that the CWO approves of the research proposal in their mental health centers. The sentence 'Bij deze adviseert de CWO….de toegewezen subsidie' in the letter of the CWO of GGz Breburg means that the CWO of GGz Breburg approves of the study protocol in their mental health centre.

Next to the approval of the CWO's, the board of directors of each mental health centre approved with conducting this trial in their centre ('Lokale uitvoerbaarheid'). I have enclosed these letters. The sentence 'Hierbij laat ik u weten....in haar instelling' means that the board of directors of that specific mental health centre approves with conducting this trial in their centre.

The study is funded by Eli Lilly. I have enclosed the funding letter of Eli Lilly. Furthermore, this study is co-funded by GGz Breburg, GGz inGeest and Arkin by means of personnel and accommodations for treatment. These letters are also enclosed.

We do hope that you will consider to publish this study protocol without peer review, according to your policy.
Yours sincerely, also on behalf of the co-authors,

Eric W. de Heer