Title: Effectiveness of a cognitive behavioural therapy based rehabilitation programme (the Progressive Goal Attainment Programme) for patients who are work-disabled due to back pain: Study protocol for a multi centre randomised controlled trial.

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Author's response to reviews: see over
Effectiveness of a CBT-based rehabilitation programme (Progressive Goal Attainment Programme) for patients who are work-disabled due to back pain: Study protocol for a multi-centre randomised controlled trial.

Dear Editor,

Please find enclosed a revised edition of the above manuscript for your consideration. Below we have addressed each of the comments made by the reviewer:

1. The description of the trial methodology would benefit from additional description of the exclusion criteria.
   
   Additional detail on the exclusion criteria is now included on page 9 of the manuscript.

2. The authors need to describe what constitutes ‘serious cognitive or psychiatric disorder’ and how will these conditions be measured?
   
   We will exclude patients with serious cognitive and psychiatric co-morbidity. This will include patients who have a diagnosis of an axis 1 or axis 2 mental health disorder according to the Diagnostic and Statistical Manual of Mental disorders, fourth edition (DSM-IV). Patients will also be excluded if they have a diagnosis of a cognitive disorder that may affect their ability to engage in the programme (e.g. Alzheimer’s disease, aphasia, stroke etc.). The presence of these conditions will be confirmed by the patient’s GP. See additional information in the exclusion criteria section on page 9 of the manuscript.

3. What if a patient in MTAI-only condition enrolls in a psychological treatment for pain during the time they are in the trial? Are they told they cannot do so? More information would be helpful.
   
   Patients who are randomised to the control condition will not be precluded from enrolling in a psychological pain management programme for the duration of their participation in this trial. However if this happens, their data will be excluded from analysis. Clarification of this has now been added to the manuscript. See page 15.

4. It appears medication use is measured throughout the trial. This should be made more explicit.
5. Does the exclusion criteria of ‘serious psychiatric disorder’ include substance abuse and/or alcohol abuse/misuse?

No, the exclusion criteria will not include substance abuse/misuse. However, if there is significant cognitive impairment as a result of substance abuse the patient may be excluded. The extent of cognitive impairment and ability to engage in the programme will be based on the GP’s clinical judgement.

6. Are instructions given to the GP prior to either treatment to maintain the patient on stable medication dosage or not to prescribe a new dose or new medication?

No, GP’s are not given explicit instructions to maintain the patient on current medication. As such, this may mean that a change of medication or introduction of a new medication may occur for a patient during the trial. The trial will gather this information on all medication use pre and post treatment to examine its influence on outcome.

7. Patients are prescribed a wide variety of medications with dual usage e.g. psychiatric medication prescribed for pain not for mental health problems. Are there any medications whose use by the patient would cause exclusion from the trial?

Patients will not be excluded from the trial on the basis of any type of medication use. In this way we hope not to inadvertently exclude patients who may otherwise be suitable. In cases of potential dual-use medication being used by a patient, we will, with patient consent, confirm with the prescribing GP if the medication was prescribed for pain or otherwise. See page 11.

8. Why did the authors choose not to stratify on any other variables?

The decision to stratify on trial centre only was primarily for pragmatic reasons. As each treating psychologist was seeing the trial patients in addition to their usual caseload, a limit was agreed with the clinicians on the number of patients clinicians would be asked to see, thus limiting the sample size. Stratifying on additional variable, although useful, would have called for a larger sample. See additional information on page 12.

Track changes have been made in the main manuscript which also address these comments.

We look forward to hearing from you in due course.

Yours Sincerely,

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