Reviewer's report

**Title:** The COPE LBP trial: Cognitive Patient Education for Low Back Pain - a cluster randomized controlled trial in primary care

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**Reviewer:** Nadine Foster

**Reviewer's report:**

This protocol summarises a large trial comparing an educational intervention (cognitive based education following the Explain Pain courses of Moseley) plus usual care versus usual care alone, for patients with nonspecific low back pain.

Overall, the paper is reasonably well written although it needs a careful check for spelling and language errors.

The design will adequately test the hypothesis - it uses a cluster trial, randomising at the level of clinicians (GPs and physiotherapists). What is not clear is whether only those randomised to provide the new educational intervention received the 2 day training course on the intervention. Can the authors address this?

More detail could be provided on a) the new intervention and b) usual care. In particular, page 7 states 'patients will be given lessons between the sessions in addition to registrations on function, pain and work absence'. This is not clear - do the authors mean homework (lessions) and what are registrations? Page 8 mentions two control groups but is this an error? What is usual care, and in particular why have the authors decided to control for time/interaction by ensuring that all control participants also receive 4 treatment sessions? This is likely to serve to reduce the differences between the two groups, and make it very difficult to show significant differences between the new education arm and usual care (which presumably also includes patient education and advice)?

The sample size section could be more detailed. In particular, a previous study is quoted (ref 27) that showed a significant difference but no mention is made of the size of the effect seen in that previous study. Education is known to be a rather 'weak' intervention and this trial is comparing a new type of education plus usual care with usual care alone (which is very likely to also involve patient education). Thus, there is likely, at best, to be a very small difference between the interventions. Can the authors justify their sample size given this likely small effect? They quote a SD on the RMDQ of 3, could they provide reference support for this, as primary care samples in the UK tend to have SDs of 5 and 6. This would mean needing to increase the sample size.

**Level of interest:** An article whose findings are important to those with closely related research interests
Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I have no competing interests