Interventions with similar efficacy to placebo: a useless randomised controlled trial

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Re: Interventions with similar efficacy to placebo: a useless randomised controlled trial

A non-inferiority randomised controlled trial (RCT) in patients with neck pain1 concludes that a brief physiotherapy intervention based on cognitive behavioural principles,--which is not a true cognitive behavioural therapy--, provided by a physiotherapist should be available for patients who prefer this modality rather than usual physiotherapy. Some aspects of the study should be commented on.

The same 12 physiotherapists delivered both types of care, and their preferences were not assessed. An observational study of eight participating physiotherapists carried out by an independent researcher indicated that there was treatment fidelity. However, the authors recognise that there could have been a "contamination" effect, whereby usual physiotherapy patients benefited from some of the cognitive behaviour treatments used in the brief intervention. Why not a "contamination effect" in the opposite direction? Physiotherapists agreed to take part in a non-inferiority trial and they accepted to be trained in the "new" approach. It seems logical to assume that they were probably convinced of the advantages of the "new" brief intervention and confident of its usefulness. Therefore, their enthusiasm may have been greater than with usual physiotherapy, favouring the brief physiotherapy intervention.

Most procedures used in the "usual physiotherapy" group (electrotherapy, traction, acupuncture) have not proven to be more effective than placebo.2-4 Because results in the brief intervention group were clinically and statistically worse for pain, disability or quality of life, this may be interpreted as the experimental treatment being worse than placebo. On the other hand, the findings cannot be used to claim the efficacy of treatments used in the "usual physiotherapy" group. Since there was no sham or control group, slight improvements might be explained by the higher amount of time devoted to each patient, or by the non- specific (placebo) effect triggered by the procedures used. If the experimental treatment worsened patients' evolution, the potential influence of the Hawthorne effect and the natural course of the condition in the "usual physiotherapy" group should also have been taken into account.

Actual results in the experimental group may have been worse than reported. Twenty patients (17%) in the brief intervention group crossed over to usual physiotherapy. No patient in the usual physiotherapy group crossed over to the experimental group. The effect of the patients' flow should be analysed in the per-protocol data set, since the intention to treat approach may have artificially improved the results in the brief intervention group.

The sample size was calculated to reach a "non-inferiority" conclusion but, in spite of the actual study population being approximately 30% lower than planned, there was sufficient statistical power to demonstrate the inferiority of the brief

physiotherapy intervention. Having led to these results, the possibility that the experimental treatment was simply useless or even worsening the patients' evolution should have been at least discussed, although it was not.

Accordingly, 1) the conclusion that these results do not "show clearly that the brief intervention based on cognitive behaviour principles was as effective as usual physiotherapy" may be seen as misleading since, in fact, the brief intervention was worse than the usual physiotherapy; 2) the conclusion that "physiotherapy as usual (five sessions) can result in small benefits" could be seen as misleading, since it should be mentioned that this is true "when compared to an experimental treatment on which evidence on efficacy or effectiveness is (also) lacking"; 3) the conclusion that "for some patients a brief intervention (two sessions) can be as beneficial if this is their treatment preference and costs less" may be also misleading, since results do not prove that any one of those treatments is much better than doing nothing, and no cost assessment was included in this study; and 4) the conclusion that "in a clinical setting, patients should be given a choice of treatment approaches to include a brief intervention encouraging self management" and the statement that "some may argue that there is a role for the brief intervention for all patients" are not supported by the results obtained.

Evidence based medicine states that clinical management should be based, as far as possible, on proofs of efficacy and effectiveness. Therefore, the conclusion that the brief intervention "should in any case be available for those who prefer it" seems contrary to that principle. This study further confirms that it makes no sense to compare the effectiveness of two procedures when neither one has previously shown its efficacy versus placebo.

References:

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