

between treatment groups. In Erkkilä *et al's* trial,<sup>1</sup> in the music therapy arm both the patient and the therapist became aware of the treatment that the patient was receiving well before total data had been collected. Thus, masking was jeopardised. Moreover, the authors did not allow for the patients' treatment preferences. Patients who receive their preferred treatment may experience greater improvements in the outcome because of added motivation to follow the treatment protocol than patients who do not receive their preferred treatment.

Alternatives to the RCT design could have been used in the study. One option is the randomised consent design. In this, participants are randomised to treatment groups before the informed consent stage, and informed consent is then sought only for those allocated to the experimental treatment.<sup>2</sup> Any sense of deprivation is less in the treatment as usual (TAU) group, as its members are unaware that they might have received a new treatment.

A second option is the partially randomised preference trial, in which participants without a treatment preference are randomised and those with a treatment preference are allocated to the treatment of their choice. This design has recently been used in some studies of psychological interventions for depression. The design has been recommended as it may improve both the internal and the external validity of clinical trials.<sup>3</sup> However, it may be subject to the biases of an observational study and may not provide an unbiased measure of treatment effect. To improve both internal and external validity, Erkkilä *et al's* RCT could have included a measure of preferences and detailed characteristics of those who refused to take part in the study because of the random allocation to treatment. This would have allowed the authors to measure preference effects at the analysis stage and to estimate the external validity of the trial.

A third option addresses the higher drop-out rate in the control group (11 *v.* 4) of the trial, which suggests the probably more demanding and careful follow-up in the experimental (music therapy) group. Here, instrumental variable methods have the advantage of allowing adjustment for non-adherence and loss to follow-up. Instrumental variables are associated with treatment choice (e.g. proximity to the music therapy clinic) but not with outcome. Had the patients' treatment preferences been taken into account in this study, at least some of the eligible individuals would have refused to participate, especially those who lived further from the clinic. Instrumental variables provide an estimate of treatment effect that is adjusted for some of the bias associated with the patient preference design.<sup>4</sup>

Last, it is worth mentioning the doubly randomised preference trial.<sup>5</sup> This is the most recently proposed method of estimating causal and preference effects. Patients are initially randomised to a randomisation arm, in which treatments are randomised, or to a preference arm, in which patients choose which treatment they receive.

These alternatives to the RCT, which are particularly appropriate for studies in which participants express a treatment preference or masking is less easy, are not free from biases. Nevertheless, they can ameliorate the external and internal validity of trials.

1 Erkkilä J, Punkanen M, Fachner J, Ala-Ruona E, Pöntiö I, Tervaniemi M, et al. Individual music therapy for depression: randomised controlled trial. *Br J Psychiatry* 2011; **199**: 132–9.

2 Zelen M. A new design for randomized clinical trials. *N Engl J Med* 1979; **300**: 1242–5.

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4 Greenland S. An introduction to instrumental variables for epidemiologists. *Int J Epidemiol* 2000; **29**: 722–9.

5 Long Q, Little R, Lin X. Causal inference in hybrid intervention trials involving treatment choice. *J Am Stat Assoc* 2008; **103**: 474–84.

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**Authors' reply:** It is interesting that a methodological debate is emerging around our randomised controlled trial (RCT) of music therapy for depression.<sup>1</sup> Sen and colleagues could have used any RCT of a psychosocial intervention to discuss their ideas of alternative designs. In relation to our specific study, they raise the following three main points: (a) that our study was not double-blind; (b) that patients may have had a preference for music therapy; (c) that the experimental group may have been followed up more carefully than the control group. We will respond to these points in that order.

First, studies of psychosocial interventions such as music therapy can never be double-blind. Both the therapist and the patient are aware of the therapy they are providing or receiving, and active participation of the patient is necessary. Therefore, demanding a double-blind study shows a limited understanding of the nature of these therapies. We do not always agree with the opinions of Seligman,<sup>2</sup> but he has put this point very aptly: 'Whenever you hear someone demanding the double-blind study of psychotherapy, hold onto your wallet.' Single-blind RCTs are the most rigorous evaluation method that is possible in this field.

Second, the advertisement through which potential participants were recruited to our study did not mention music therapy. Therefore, we believe that a strong preference for music therapy was unlikely in our sample, although we are not able to completely rule out the possibility. Extensions of RCTs such as Zelen's design<sup>3</sup> and partly randomised designs<sup>4</sup> are not new. They provide interesting options for evaluating many kinds of intervention, including music therapy. However, there are also some good reasons why they are not used more frequently. For one thing, as Sen *et al* note, hybrid designs may be difficult to interpret. For another, the questionable additional merits of these trials may not justify their much higher costs. Our trial was the first of its kind, and a simple randomised design therefore seemed most appropriate to us. For future trials of psychosocial interventions it may be relevant to explore the potential use of hybrid designs.

Third, in our study, the person who did the assessments, and who also scheduled the assessment interviews on their own, was masked to treatment assignment, and only very few instances of broken masking occurred. We can therefore exclude the possibility that the experimental group might have been followed up with greater care than the control group. Our conclusion remains that the differences in drop-out rates were an effect of the treatment, not an artefact of the study design.

Overall, Sen *et al* present interesting general thoughts for the evaluation of psychosocial interventions. Of the various suggestions made for improving study designs, we believe that assessing treatment preference and incorporating it in either the design or the analysis is the most practicable one. Hybrid designs including both randomised and non-randomised elements may be useful in certain circumstances, but because of their high costs and unclear interpretation we would not recommend them for general use.

1 Erkkilä J, Punkanen M, Fachner J, Ala-Ruona E, Pöntiö I, Tervaniemi M, et al. Individual music therapy for depression: randomised controlled trial. *Br J Psychiatry* 2011; **199**: 132–9.

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### Praying with patients: belief, faith and boundary conditions

The debate between Professors Poole and Cook<sup>1</sup> focuses on what might be termed an epiphenomenon of faith. Poole in particular avoids any interpretation of the values he espouses for psychiatry as a belief system. In my view, this is fundamentally erroneous. The set of principles avowed by Poole find their origin in both Greek philosophy and in the Judaeo-Christian system of ethics. These are essentially systems of beliefs and in that sense, particularly for the secularist, are no different from a religious doctrine. In considering this issue it is impossible to start from a position that does not invoke shared belief, and that personal position of belief that is termed faith. I would assume that Poole would take the position that psychiatrists should practise using ‘evidence-based’ techniques and therapies. If one is to take cognitive therapies as an example of this, problems of belief immediately arise, as a primary aim is to change patients’ erroneous and maladaptive belief systems. I would ask to what belief system should one change them? Should it reflect the psychiatrist’s beliefs, the patient’s community and cultural beliefs or something else?

A common example of the integral involvement of belief with therapy is the Alcoholics Anonymous programme. Would Poole refer a patient to this as part of his treatment or would he regard it as the unethical imposition of a belief in a ‘higher power’? More broadly, in psychotherapy there exist a number of theoretical belief systems which have some level of evidence in their favour, particularly in the belief of their proponents. Having observed successful psychotherapists with a variety of backgrounds, I am tempted to say that their theories support their therapies by providing a belief structure that supports their faith that treatment can be of benefit when progress is slow, and that this faith in the future is a key element in their success. If the argument that faith is a fundamental part of the treatment process is accepted, and I would argue that, while this is particularly so for psychiatry it also applies in other areas of medicine, then the major question is the degree to which it is synonymous with belief. If faith provides strength and purpose to both psychiatrist and patient and can be asserted a positive asset without much criticism, belief can be considered as being more problematic and potentially dangerous. In a broad sense, depressive disorders may be considered to reflect a deficit of faith, whereas mania and psychoses reflect an excess of belief. This may apply to therapists as much as patients. Doctors with a high level of belief in particular therapeutic modalities have a history of causing harm as well as good. An uncritical belief in materialism and biological determinism can cause as many, if not more, problems than a Cartesian view.

It seems that the divergence of opinion between Professors Poole and Cook arises not from the potential for good but the potential for harm. Both are men of belief and even if their beliefs are considered existentially ‘good’, assertion that an atheistic belief

system is the only basis for treatment is potentially treacherous if imposed on a patient. Even our present evidence-based structure is predicated on a belief about an organised and regular universe. Speaking as a slightly irreverent theist, I would argue that the question posed in their debate does not have a single correct answer. In judging the most appropriate manner of dealing with a particular situation, the important thing is to consider the principles to be applied. There are some behaviours that would be generally agreed to be inappropriate and damaging without recourse to argument, but others may be appropriate only in certain situations. My recommendation would be that there should not be an overall statement or conclusion that the use of prayer in therapy is either right or wrong. It would have to be considered as an uncommon and unusual part of a therapeutic programme which can only be justified in very particular circumstances. It should be accepted that there are occasions when its use is appropriate and therapeutic. Nonetheless, because of its controversial nature, and the possibility of abuse by both therapist and patient, prayer should be considered an unusual therapeutic modality. The therapist should therefore be prepared to justify its use on a case-by-case basis and be able to demonstrate that no harm was likely to arise.

- 1 Poole R/Cook CCH. Praying with a patient constitutes a breach of professional boundaries in psychiatric practice (debate). *Br J Psychiatry* 2011; **199**: 94–8.

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I read with interest the debate between Professors Poole and Cook in this month’s journal.<sup>1</sup> I have been following the exchanges on these two highly polarised positions in the College for quite a while. Not wishing to take a position on the acceptability of praying with patients, I find myself astounded by the inability in some quarters to accept or even recognise the fact that praying with a patient may be as serious as preaching to a patient. Boundaries are set in professional practice to protect both the patient and the doctor. Would a physician feel easy taking stock market tips from their Wall Street banker patient? Or accepting racing tips from their very informed bookmaker patient? How about setting up a business venture with a venture capitalist patient with significant ‘daddy issues’?

Would it be appropriate for a doctor to tell his patient that his Church offers the best chance of redemption, or that she should divorce her cheating husband because this is what is perpetuating her depression? These are all hypothetical examples of boundary violations and are rightly proscribed in all codes of ethics worldwide. In deciding harm in a doctor–patient interaction, surely it is for the doctor to decide where the boundary lies and then to maintain it. The sexual boundary is not the only boundary we should be taught not to cross, although arguably it ought to be the first.

The fact the College has given so many column inches to the issue means that, even if there are no cogent arguments, this matter is something that has immense political clout. Matters are not being helped by letting this issue simmer. We need decisive action. Why can’t the College commission a working group representing all sides of this debate and issue a consensus statement to help believers and non-believers equally to navigate what appears not so much a moral conundrum as political posturing? When I am hauled before the GMC by a patient for inviting him (and encouraging with his ‘consent’) to give up his