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Correspondence

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Psychiatry does need more randomised controlled trials

In their editorial, Duncan *et al* claim that 'Conventional approaches to evidence that prioritise randomised controlled trials appear increasingly inadequate for the evaluation of complex mental health interventions'.[1] Nothing could be further from the truth. The exaggerated distinctions presented between research in psychiatry and that in the rest of medicine are in a long tradition of special pleading that does our discipline no favours.

Randomised controlled trials (RCTs) seek to identify what works for whom – careful identification of the target population and appropriate outcome measures are key to all successful trials. Their findings do, indeed, 'apply to groups …not equally to everyone' – clinicians are still needed to interpret and apply their findings. RCTs do not seek to substitute for the exploration of mechanisms, nor the creative development of alternative approaches to treatment. Their purpose is to reduce persisting doubts about the effectiveness or otherwise of an intervention. If there are no doubts they are not needed. But where there is doubt about treatment effects (highly likely in the long-term relapsing–remitting disorders in psychiatry with their probabilistic outcomes over extended periods) their superiority has proved itself time and time again. One simply needs to observe the staggering improvements in evidence-based medicine over the past 50 years.

The authors' implication that in general medicine trials are so much simpler, interventions less complex, or treatments less 'personalised' would receive a dusty response from our colleagues in oncology or cardiology. Where interventions are complex they need to be carefully dissected to determine what is potentially effective and what is potentially redundant. Such hard-nosed examination is sorely needed in psychiatry and it can be highly productive in its own right, even without RCTs to test core components.

Psychiatry is not handicapped by the dominance of 'positivistic' research favouring RCTs and systematic reviews. On the contrary it is handicapped by there not being anywhere near enough of them, and not enough weight being given to their results. In their contrast between 'realist' and 'positivist' research the authors omit to acknowledge what Karl Popper considered scientific method's cardinal virtue – its ability to falsify hypotheses.[2]

Rigorously designed and conducted RCTs have an almost unique power to reverse strongly held clinical convictions. It was Acker *et al*'s 1957 RCT that ended insulin coma's two decades of dominance in schizophrenia treatment.[3] Twice I have been forced, painfully, to abandon cherished beliefs when confronted by RCT evidence. Assertive community treatment teams did not, despite my enthusiasm and commitment to it, deliver superior care to community mental health teams,[4,5] nor do community treatment orders stabilise severe psychosis in the community.[6,7] Would the proposed realist studies have anything like the power of RCTs to achieve this?

Our current demand is for parity of esteem. We are more likely to get equal respect and funding if our practice matches that of our medical colleagues. Holding psychiatry's practice to the same rigorous standards in research will go a long way to establishing society's trust and, through that, genuine parity of esteem for our profession and patients.

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Authors' reply

We would like to thank Professor Burns for his thoughtful reply to our recent editorial and we are grateful for this opportunity to respond. To clarify: we would be happy to see more RCTs in psychiatry, but only as one form of evidence among others. Interestingly, the same work of Karl Popper referred to in the reply is drawn on by a leading proponent of realism to support such a position.[1]

Professor Burns gives two examples of RCTs of complex interventions to demonstrate their value. Our view of the implications of these trials is, unsurprisingly, different. We find it hard to believe that assertive community treatment teams and community treatment orders are not effective for anyone, anywhere, or in any way. And although we agree with Professor Burns that the scarcity of trials evidence is problematic – in the case of community treatment orders, there have only been three RCTs with a total sample size of 749 patients[2] – we also believe that RCTs alone will never be the whole answer.

Rather than privileging a method designed to estimate singular 'average treatment effects' and whether a treatment does or does not 'work', we would argue that a more sensible way to proceed is to develop approaches intrinsically attuned to detecting variation and difference and, most importantly, understanding what gives rise to it.[3] Where RCTs design out the effects of context, realist approaches see this as key.

We agree that other medical and healthcare specialities rely on evidence for the effectiveness of complex interventions. But what distinguishes mental health is the preponderance of interventions that require human agency, and factors such as therapeutic alliance, empathic communication and motivation:

the relationship between community treatment orders and readmission rates is of a different complexity than that between chemotherapy and cancer remission, or between digitalis and cardiac function.

We acknowledge, and celebrate, the contribution of RCTs to evidence-based healthcare. But there remains a need for a plurality of methods. However astute and research-literate the clinician, RCTs select participants in ways that can make generalisation to real-world settings difficult. Realist approaches that help bridge the gap between the 'what' and the 'how' of clinical outcomes can only be a good thing. And the more complex the intervention – and the more context dependent – the more important this is. For us, RCTs alone are unlikely to be sufficient.

Parity of esteem for psychiatry is undoubtedly worthwhile, but this does not mean we have to imitate other specialities; as so often in the past, we can lead the way instead. *Primus inter pares*.

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Does pharmacotherapy really have as enduring effects as psychotherapy in anxiety disorders? Some doubts

Bandelow *et al* recently presented a meta-analysis testing the assumption that the effects of psychotherapy in anxiety disorders are more endurable than those of pharmacotherapy.[1] From non-significant differences between psychotherapy and pharmacotherapy in pre-follow-up effect sizes the authors concluded that '… patients who stopped taking a drug showed the same durable improvement as patients who stopped psychotherapy'.[1]

Besides the severe (and properly discussed) limitation that an unclear percentage of patients may have started new psychological treatment or taken medications in the follow-up period, this meta-analysis raises further serious concerns.

First, the authors did not clearly specify their inclusion criteria. Apparently, they did not require head-to head comparisons of psychotherapy and pharmacotherapy as an inclusion criterion. Second, as a consequence, Bandelow *et al* compared pre–post and pre-follow-up effect sizes of psychotherapy, medication and placebo obtained from different randomised controlled trials. Thus, the studies being compared may differ with regard to important treatment moderators such as characteristics of patient populations and setting conditions. For these and other reasons analyses of pre–post and pre-follow-up effect sizes should be avoided in meta-analyses.[2]

Third, Bandelow *et al* did not adhere to the logic of equivalence testing that includes the definition of a margin compatible with equivalence and performing two one-sided tests (TOST).[3] They apparently applied the more usual two-sided superiority test. However, concluding from a non-significant two-sided superiority test that two treatments (i.e. pharmacotherapy and psychotherapy) are equally efficacious (in the long-term) is questionable.[3] The traditional two-sided test and TOST often yield inconsistent results.[4] Fourth, furthermore, Bandelow *et al* seem to have not controlled for researcher allegiance.[5] Thus, a bias in favour of pharmacotherapy cannot be excluded given that the first and last authors disclose multifold collaboration with pharmaceutical companies.

Finally and of note, the authors avoid discussing potential long-term negative effects that any type of psychotropic drug treatment, particularly after long-term use, may have, for example by increasing the risk of experiencing additional psychopathological problems that do not necessarily subside with discontinuation of the drug or of modifying responsiveness to subsequent treatments.[6]

The data presented by Bandelow *et al* suggest that pharmacotherapy may have endurable effects in anxiety disorders as well. However, the authors' conclusion that in the long-term term psychotherapy and pharmacotherapy are equally efficacious in anxiety disorders is questionable for the reasons given above.

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Authors' reply

We found that gains with psychotherapy were maintained for up to 24 months. We also showed that patients who stopped medication remained stable. This is good news for the affected patients. However, as patients in the placebo groups also did not show deterioration we concluded that enduring effects observed in follow-up studies might be superimposed by spontaneous remission or effects of concurrent treatments.

For detailed inclusion criteria, we had referred to our previous meta-analysis.[1] As there are only a few head-to-head follow-up comparisons of psychotherapy and pharmacotherapy, we decided to calculate pre–post effects. Thus, we were able to include as many as 93 follow-up studies, which also comprised all head-to-head comparisons.

Pre–post effect sizes do not only measure 'true' treatment effects, but also natural course and placebo effects. However, when conditions are the same in psychotherapy and pharmacotherapy studies, this comparison is fair. Patients are mainly