Psychiatric morbidity in prisoners with intellectual disabilities

Hassiotis *et al*[1] describe an excess of probable psychosis in prisoners with intellectual disabilities (11.3% *v.* 5.7%, $P<0.01$). We tried to replicate this finding in a large database of 21 857 pre-trial reports of Dutch defendants.[2,3] A diagnosis of intellectual disability (IQ < 70) was made in 609 defendants (2.8%). However, these individuals had fewer psychotic disorders than defendants without intellectual disability (5.9% *v.* 12.7%, $P<0.001$). Furthermore, fewer defendants with intellectual disabilities reported misuse of hard drugs (13.4% *v.* 24.6%, $P<0.001$) and alcohol (16.6% *v.* 23.1%, $P=0.002$) and their rate of cannabis misuse was similar to that of defendants with a normal IQ (12.9% *v.* 14.2%, $P=0.51$). This again contradicts the findings of Hassiotis *et al*, who found more cannabis misuse and similar misuse of hard drugs and alcohol in individuals with intellectual disability.

What could explain these opposite findings? The diagnosis of probable psychosis in the Hassiotis *et al* study was, in 80% of the cases, based on a lay interview, and intellectual disability was defined as a low score on the Quick Test. Diagnosis in Dutch pre-trial reports is based on: (a) multiple examinations of the defendant by a psychiatrist and/or psychologist; (b) the defendant's judicial and psychiatric history, including previous examinations; (c) information from relatives; and (d) IQ tests in 88% of defendants with intellectual disabilities. As Hassiotis *et al* themselves suggest, their method may have led to an over-estimation of the prevalence of intellectual disability (4%). Indeed, a systematic review in 2008 showed that the prevalence of intellectual disability in prisoners ranged from 0.0 to 2.8%.[4] Moreover, low scores on the Quick Test are significantly related to the prevalence of psychosis.[5] Confounding of the relationship between probable psychosis and intellectual disability is therefore probable. The conclusion reached by Hassiotis *et al* is premature and more studies on this topic are needed.

1 Hassiotis A, Gazizova D, Akinlonu L, Bebbington P, Meltzer H, Strydom A. Psychiatric morbidity in prisoners with intellectual disabilities: analysis of prison survey data for England and Wales. *Br J Psychiatry* 2011; **199**: 156–7.

2 Vinkers D, Barendregt M, de Beurs E. Homicide due to mental disorder. *Br J Psychiatry* 2009; **194**: 185.

3 Vinkers DJ, de Beurs E, Barendregt M, Rinne T, Hoek HW. Pretrial psychiatric evaluations and ethnicity in the Netherlands. *Int J Law Psychiatry* 2010; **33**: 192–6.

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5 Marjoram D, Gardner C, Burns J, Miller P, Lawrie SM, Johnstone EC. Symptomatology and social inference: a theory of mind study of schizophrenia and psychotic affective disorder. *Cogn Neuropsychiatry* 2005; **10**: 347–59.

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Authors' reply: Vinkers *et al* have reported discrepant findings between their study and ours. First, their analysis is based on pre-trial reports, albeit detailed, whereas our study is based on a cross-sectional survey of current prisoners. Furthermore, additional variations that predetermine ascertainment and pathways through the criminal justice system must be taken into consideration in such comparisons. Our explanation of the higher rates of psychosis, one among a number of mental disorders we considered, is a combination of possible pre-existing morbidity and the impact of the environment on a vulnerable population. This relationship was mediated by current (defined as use while in prison) cannabis misuse. Second, our data on substance misuse are significant in terms of current use, as defined; lifelong use was similar between prisoners with and without intellectual disabilities. Third, the Quick Test may have led to over- or underestimation of the prevalence of intellectual disability, as we noted. There are additional arguments on this point, as the Quick Test has significant limitations: (a) we were quite conservative in the definition of intellectual disability, using not only a stringent cut-off for intellectual functioning but also poor educational attainment, and we excluded those not born in the UK, to avoid possible confounding by language-related problems; (b) according to Fazel *et al*,[1] the pooled prevalence based on screening was 6.1% (95% CI 5.3–7.0%),[2] therefore our calculations suggest that we have more or less identified the appropriate sample of prisoners; (c) the paper by Marjoram *et al*[3] is, in our view, erroneously cited, as its authors discuss specifically the impact of lower IQ on participant performance in theory of mind (hinting) tasks rather than psychopathology. It should be noted that all IQ tests would be compromised if administered to acutely ill individuals. Finally, the literature suggests a common pathway between psychosis and intellectual disability, particularly in early-onset cases[4] and this may be, to an extent, an underlying cause for the increased rates of psychosis. However, the cross-sectional nature of our study does not allow for further speculation on causality. In summary, prisoners with intellectual disabilities are vulnerable and may not receive adequate tailored input for their significant mental health needs. We agree that there should be further studies investigating these issues and we would like to thank Vinkers *et al* for their interest in pursuing this topic.

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Refurbishing the masked RCT design for psychological interventions

We would like to share some important statistical pitfalls of the randomised design in masked trials of music therapy such as that conducted by Erkkilä *et al*.[1] The randomised controlled trial (RCT) is generally considered to be the optimal design for estimating treatment efficacy in medical interventions. In a double-blind RCT, the placebo effect is equally distributed

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between treatment groups. In Erkkilä *et al*'s trial,[1] 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.[2] 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.[3] However, it may 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.[4]

Last, it is worth mentioning the doubly randomised preference trial.[5] 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.

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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.[1] 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,[2] 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[3] and partly randomised designs[4] 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.

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