

implementation of the intervention. A definitive RCT should take place only after the first two stages have been completed. Our experience in Bradford is that advance statements are complex interventions that require lengthy developmental work if they are to stand a chance of success. Papageorgiou *et al* make no reference to what, if any, developmental work took place before the introduction and evaluation of advance statements, making it difficult to draw conclusions about their effectiveness or otherwise.

Declaration of interest

P.T. is a grant co-holder with the Mental Health Foundation in the Advance Statement Project in Bradford, funded through section 64 funding by the Department of Health.

Medical Research Council (2000) *A Framework for Development and Evaluation of RCTs for Complex Interventions to Improve Health*. London: MRC Health Services and Public Health Research Board.

Papageorgiou, A., King, M., Janmohamed, A., et al (2002) Advance directives for patients compulsorily admitted to hospital with serious mental illness. Randomised controlled trial. *British Journal of Psychiatry*, **181**, 513–519.

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Authors' reply: Dr Thomas is right to point up the difficulties of evaluating advance directives in mental health care. To answer their specific queries: (a) Who recruited patients? A psychologist (A.P.) and a psychiatrist (Anis Janmohamed) recruited the patients. (b) How did recruitment take place? The ward managers, responsible psychiatric nurses, junior doctors or consultants (depending on who was available at the time) were approached on a weekly basis and a list was drawn up of all patients who were near discharge from section. A.P. and A.J. introduced eligible patients to the trial and gave them a written summary of our aims and procedures. Patients were given time to read the summary and decide whether they wanted to participate in the study. Those who agreed undertook a baseline assessment and were randomised into the experimental and control group. (c) What steps were taken to inform the service users about the pros and cons of

advance statements? The participants were seen individually by A.P. and A.J., who informed them about the advantages and disadvantages of advance directives. Participants were also informed about accessibility of their local service users' groups for further advice on any related issues. (d) How were service users, professionals and structures of care such as the Care Programme Approach process prepared for advance statements? The lead academic (M.K.) had extensive discussions with managers, consultant psychiatrists and nurse managers about the study to ensure they were fully informed and prepared for the trial. Although it would have been useful to incorporate the directives into the formal Care Programme Approach process, clinicians did not think that this was warranted at that stage. Local service users' groups were informed about the study, and A.P. and M.K. talked to the groups regularly throughout and after the trial. M.K. leads a collaborative group in north London between service users and academics to promote user-led research. We considered it a strength of our trial that participants prepared their directives with someone who was *not* involved in their care, as this made the whole process less open to duress. (e) Do professionals really consider advance statements to be useful and take their implementation seriously? Professionals certainly took the intervention seriously at meetings and presentations where the study was discussed and readily agreed to the trial. However, by the end of the trial they were unsure about the value of the directives, a finding that we discuss in a further paper that has been submitted for publication (further details available upon request). (f) Was there developmental work before the introduction and evaluation of advance statements? Considerable work with users and professionals was carried out before the trial commenced to develop the format of the advance directive. However, as Dr Thomas will know, obtaining funds for this valuable work is extremely difficult, and thus it was limited. During our developmental work, we became more aware of the legal complexities of advance directives and the possibility that they could be considered binding on clinicians. Because their worth was at this stage unproven, we took the step of including a clause stating that users' wishes could be overridden. We concur with Dr Thomas's views on the Medical Research Council's framework for the evaluation of complex

interventions. However, when our study was conceived in 1996 these recommendations were not available. The pre-clinical justification for the study was increasing use of advance directives in this country and in the USA. Given the mood of the time, our study was justified.

We made it clear in our paper that we did not consider our study definitive. We would welcome further research on the additional matters raised and hope our study stimulates such work. We acknowledge that our study does not evaluate the effectiveness of advance directives under optimum conditions – in fact, that was not our aim. Ours was a pragmatic trial in which we sought to assess whether such directives were useful in a real, inner-city clinical setting. We used rates of compulsory readmission as our main outcome measure to test one bold claim made for them, namely that they may reduce the need for patients to be civilly committed at a later time. If substantiated, this is a very important matter.

Advance directives may be a useful expression of patient autonomy and self-direction. We look forward to reading the results of further research.

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Rivastigmine and QT interval prolongation

Walsh & Dourish (2002) reported that a 78-year-old man, receiving a number of medications and with a history of myocardial infarction and hypokalaemia, developed an abnormal QTc interval a week after starting rivastigmine treatment. I have performed an extensive review of the tolerability and safety of cholinesterase inhibitors (Inglis, 2002), in which I described the favourable cardiac safety profile of rivastigmine. Therefore, I contacted Novartis for more information. This case, which was initially submitted to the authorities in June 2001, included further clinically relevant information.

Primarily, the patient's pre-rivastigmine QTc (3 weeks before starting treatment) was 431 ms rather than 397 ms as suggested by Walsh & Dourish (C. Videbaek (Novartis), personal communication, 2002). The reported QTc of 397 ms was obtained a week after starting rivastigmine