

## **OCTET: The Oxford Community Treatment order Evaluation Trial**

### **Abstract**

On November 3<sup>rd</sup> 2008 Supervised Community Treatment Orders (CTOs) became available for the first time in England and Wales. These have been in discussion for nearly 20 years and are well established in Australia and New Zealand and were introduced in Scotland two years ago. They have been controversial for a range of reasons – legal, ethical and empirical. Many mental health professionals have criticized the introduction of CTOs without convincing scientific evidence of their effectiveness, in particular no convincing randomized controlled trial. The OCTET RCT is seeking to provide such evidence of CTO efficacy.

### **Background**

Under amendments made to the Mental Health Act 1983 (MHA) for England and Wales, Supervised Community Treatment Orders (CTOs) were introduced for severely ill, so-called 'revolving door' patients in November 2008. This new form of delivering involuntary outpatient treatment will supplement the existing leave regime under section 17 of the Act.

The introduction of compulsory treatment in the community has been intensely controversial and remains so, sustained in part by the absence of convincing scientific evidence for its effects (despite widespread international adoption). Such evidence is particularly necessary because of the complex ethical balance of personal autonomy against need for care and public safety, and because of strongly held conflicting opinions. The only methodology which will convincingly address these is a randomised controlled trial.

While several international studies have analysed outcomes of CTOs in different jurisdictions, the majority have been observational, non-randomised or explorative studies from which it is problematic to generalise. Randomised controlled trials (RCTs) are recognized as the most rigorous methodology and the 'gold standard' for testing new treatment forms. Only two RCTs have been conducted to date. Both are from the US and both have methodological weaknesses. A recent systematic review of current research concludes there is an 'urgent need' for a high quality RCT in this area.

The OCTET RCT is designed to fill the evidence gap. It will provide strong evidence of the efficacy or otherwise of CTOs compared to leave in the UK and should give a clear and early indication of the clinical groups which do and do not benefit from them. Without such a rigorous trial uptake of the new CTO regime by clinicians is likely to be slow, patchy and poorly focused.

The Helsinki guidelines for clinical trials advise that randomisation of treatment options is only ethical when the clinician is genuinely uncertain about which treatment is superior (clinical equipoise). There is now two main options for clinicians regarding patients who need ongoing supervision in the community: CTO or section 17 leave. However, since there is (i) no research evidence for which treatment option is better, and (ii) there is no clinical experience of the new CTOs to learn from, there is no **objective** way of knowing whether CTOs have better outcomes than current practice: we genuinely do not know. Given the lack of evidence, many clinicians will find themselves in clinical equipoise when considering whether their patients would benefit more from CTO or leave (which up till now has been standard care).

This lack of certainty about treatment efficacy is likely to be matched by uncertainty, in the minds of clinicians, concerning the application in individual cases of the new legal rules. The new legal

framework will present clinicians with two mechanisms for delivering compulsory community mental health care: the CTO and section 17 leave. The CTO regime is more structured and the leave regime more discretionary, but treatment under both mechanisms may be extended indefinitely, when the right procedures are followed, and similar powers may be exercised over the patient in the community, including rapid recall to hospital care. In practice, the CTO regime may tend to be used for longer, though that remains to be seen.

The same patient could readily be a candidate for both the leave and CTO regimes, particularly as applying the new legal standards will require clinicians to make predictions about the patient's likely progress, community stability, community supports, the prospects of relapse and readmission, and so on. Yet on these matters no certain knowledge will be available. It is likely, in these circumstances, that markedly different patterns of practice will emerge, between clinicians, and perhaps between services and regions, in the respective uses of leave and CTOs.

There will therefore be a window of opportunity soon after the change in the legislation to study the outcomes for patients of the varying clinical practices that are likely to emerge from the position of equipoise in which clinicians will find themselves due to genuine uncertainty about both treatment efficacy and proper application of the law. We wish to utilise this opportunity because it creates the conditions for the conduct of a lawful and ethical RCT that is designed to compare directly the two treatment options and establish which works best for different patient groups. In addition to the RCT, OCTET entails a qualitative component in which in-depth interviews will be conducted with a sub-sample of patients and focus group discussions will take place with carers and service providers. These interviews will capture participants' experiences broadly, including unintended effects (positive or negative) of CTOs and will relate findings to the wider context and should promote a more nuanced public discourse. A detailed economic analysis will model the national costs of introducing CTOs. Finally, a training resource for mental health professionals will be developed.

The overall hypothesis is that the use of CTOs in patients with psychosis and a history of compulsory admissions will result in a reduction in readmissions to hospital compared to treatment on leave. To test the hypothesis, the primary outcome measure is psychiatric hospitalisation in the 12-month follow-up period. The RCT will also explore whether the use of CTOs in these patients, compared to leave, will improve treatment adherence with a consequent reduction in relapse and readmission rates and improvement in social stability.

In sum, the overall aim of OCTET is to improve patient outcomes by informing mental health policy and practice. The study seeks to do this by:

- Providing rigorous and convincing evidence as to CTO effectiveness
- Demonstrating whether adding CTOs to high quality community care reduces readmission rates and affects a range of other patient outcomes
- Identifying patient characteristics and care patterns associated with good outcomes
- Informing an economic analysis to model the national cost of introducing CTOs
- Contributing to training for effective implementation.

### ***Who is eligible?***

Clinicians will identify patients and ask them if they will see the researchers. Our researchers will explain the study to your team and the patients and obtain written, informed consent and conduct interviews at baseline, 6 and 12 months.

Eligible patients are those currently detained in hospital on section 3 (or unrestricted, non-forensic, section 37) with a primary diagnosis of psychosis. Learning from the other studies we will restrict eligibility to those who need sustained supervision in the community (i.e. months not weeks) and to services that can offer to provide weekly contact. Patients are eligible for inclusion in the RCT when their clinicians, having carefully considered whether to use leave or a CTO in their case and the relevant considerations drawn from the Act and the Code of Practice, are still genuinely uncertain concerning the right approach to take. At baseline, after the first research assessment, consenting participants will then be allocated equally by RCs, who remain genuinely uncertain, to either the experimental group (CTO) or the control group (leave), on advice concerning random allocation provided by an independent statistician.

Thereafter, when RCs make decisions about patients allocated to either leave or a CTO, they should strictly adhere to the statutory process and criteria in every case, as the law requires, and should fully consider every option open to them within the legal regime and the relevant factors listed in the statute or the Code. Patients in both groups will retain all their usual legal rights, including their right of access to the Mental Health Review Tribunal (MHRT), which may discharge them from compulsory treatment. No attempt will be made to influence how clinicians subsequently manage these patients, including whether clinicians decide to renew a patient's treatment on leave or a CTO. When a patient is discharged from involuntary treatment by the Responsible Clinician or the MHRT, or transferred from leave to a CTO, for instance, as required by law, this will simply be counted as one outcome of the process for that patient.

We have explored the ethical and legal implications of our trial at great length and confirmed that it is both lawful and practical. The study has full ethical approval, and is adopted by the UNCRN and the Mental Health Research Network.

This is a vital study for UK psychiatry and may inform practice internationally. The window of opportunity to conduct it is narrow (the first 18 months after introduction). We have prepared detailed briefing for clinicians, MHRT members and legal representatives, which, along with various fact sheets, are available.

The trial is funded by a Programme Grant from the NIHR and is being conducted by the Social Psychiatry Unit at the Department of Psychiatry, University of Oxford. The research team includes experienced medical statisticians, economists, medical ethicists, psychiatrists as well as researchers with qualitative and quantitative expertise.

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