Mandatory Outpatient Treatment in England: An RCT

Do Community Treatment Orders (CTOs) reduce the readmission rate in psychosis patients discharged from inpatient care over the subsequent 12 months?

Tom Burns
Community treatment orders

- Legal regimes allowing compulsory community supervision exist in ~70 jurisdictions all over the World
- Legal regimes vary, but generally patients are obliged to adhere to treatment. Rapid recall
- Outpatient commitment, Mandated Outpatient Treatment, Community Treatment Orders, Supervised Community Treatment

Europe, e.g., Sweden, Scotland, England & Wales, Norway, Israel, some Swiss Cantons
What do we know about outpatient compulsion? 
Observational and Experimental studies

Rachel Churchill et al, 2007
Review of 72 empirical studies of CTOs

International experiences of using community treatment orders
Churchill conclusions

• 72 data-based empirical studies from six countries.
• Patient characteristics remarkably consistent
• A range of designs, conceptual, practical and methodological problems;
• Nine comparative studies, including only two RCTs.
• Quality of evidence is generally poor.
• No clear conclusion whether beneficial or harmful.
• Need for rigorous trials
Introduction of CTOs in E&W

• CTOs introduced in 2007/2008
  – 20 years of controversy
• Only from compulsory IP care
• Imposed by psychiatrist and social worker
  – Legal scrutiny after the event
• Conditions:
  – Regular contact with mental health team
  – Live at agreed address
  – Take medication
  – Recall if non-compliant (72 hrs)
  – **No force allowed outside hospital**
Current state of the evidence
Update on evidence 2006-2012
Daniel Maughan, Andrew Molodynski, Jorun Rugkasa, Tom Burns

• 17 further studies
• Mainly database studies (multiple analyses)
• before/after (BA) and controlled before after (CBA)
• 4 readmissions increased
  – Victoria database 8,879 CTO versus 16,094 non CTO
• 4 readmissions decreased
  – NY database 3,725 CTOs versus 2,025 non CTO
RCT evidence
When to conduct an RCT

- Persisting, important clinical question despite other studies
- Agreement on a clinically relevant and measureable outcome
- Ability to conduct a power calculation
- Primary outcome is decisive
- Secondary outcomes indicative
Multiple protocol violations, atypical, chaotic service, high drop out 142 -78
Can Involuntary Outpatient Commitment Reduce Hospital Recidivism?: Findings From a Randomized Trial With Severely Mentally Ill Individuals

Marvin S. Swartz, M.D., Jeffrey W. Swanson, Ph.D., H. Ryan Wagner, Ph.D., Barbara J. Burns, Ph.D., Virginia A. Hiday, Ph.D., and Randy Borum, Psy.D.

• Well conducted,
• 264 subjects, good follow up, few violations
• No difference in primary outcome (readmission)
• Emphasises positive outcomes in secondary analyses
• >6months< analyses taken up by advocacy movement
Do CTOs reduce the readmission rate in psychosis patients discharged from involuntary inpatient care over the subsequent 12 months?

Need to utilise the window of opportunity while clinical equipoise existed to conduct an RCT
Trial outline

• Multi-site trial, southern England
• 1:1 randomisation
  – (gender, diagnosis, duration of illness)
• CTO or voluntary Outpatient care
• 12 month follow-up

• Trial protocol published by Lancet 2010 (10PRT/0496)
Inclusion criteria

- Aged 18-65
- Psychosis diagnosis
- Involuntary inpatient (no restrictions)
- Ready for discharge
- Considered by team to be CTO candidate
- Able to give informed consent to research
How a CTO is imposed

- Patient must ‘need’ compulsory supervision to avoid rapid and severe relapse
- CTO imposed by Psychiatrist and Social worker. Not judge
- Must follow detailed and recorded discussion with family and nurses
- Takes several days/weeks
- Patient often ‘on leave’ during this process
Outcomes

• Primary outcome
  – Proportion readmitted within 12 months

• Secondary outcomes
  – Time to readmission
  – Duration of readmission
  – Number of readmissions
  – Clinical status at 12 months (BPRS)
  – Social functioning at 12 months (GAF)
Ethical and Legal barriers

• LREC rejected the study
  – required ‘legal guarantee’ that
    • nobody could be subject to legal action.

• UK signatory to European Convention on Human Rights
  – ‘If a patient warrants legal supervision they cannot be randomised to voluntary care’

• Randomisation must be to the least restrictive alternative
What to do?

• Staff already appointed!
• Teams being recruited
• Letters gone out
• Offices occupied

• Panic and run away?
Take a plane and get as far away from Oxford as possible
Fly to New Zealand
Go deep into the bush in search of rare creatures..
The shy, reclusive International Mental Health Lawyer
Section 17 leave

- Existing provision for section 3 patients
  - Permits patient to be outside hospital
- Clinical decision, no change in legal status
- Tests stability of recovery before discharge
- Hours, days, occasionally weeks
- No data on frequency or duration
Randomisation between S17 leave and CTO is lawful because

- The two treatment arms have similar legal criteria
- Neither can be determined *a priori* as more restrictive overall
- Genuine uncertainty exists
  - Evidence
  - UK practice
- At the exact moment of randomisation patients had to be on s17 but ongoing treatment was voluntary
LAWFULNESS OF A RANDOMISED TRIAL OF THE NEW COMMUNITY TREATMENT ORDER REGIME FOR ENGLAND AND WALES

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J. RUGKÅSA
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Community treatment orders for patients with psychosis (OCTET): a randomised controlled trial

Tom Burns, Joru Rügkäsa, Andrew Molodynski, John Dawson, Ksenija Yeeles, Maria Vazquez-Montes, Mervyn Voysey, Julia Sinclair, Stefan Priebe

Summary
Background Compulsory supervision outside hospital has been developed internationally for the treatment of mentally ill people following widespread deinstitutionalisation but its efficacy has not yet been proven. Community treatment orders (CTOs) for psychiatric patients became available in England and Wales in 2008. We tested whether CTOs reduce admissions compared with use of Section 17 leave when patients in both groups receive equivalent levels of clinical contact but different lengths of compulsory supervision.

Methods OCTET is a non-blinded, parallel-arm randomised controlled trial. We postulated that patients with a diagnosis of psychosis discharged from hospital on CTOs would have a lower rate of readmission over 12 months than those discharged on the pre-existing Section 17 leave of absence. Eligible patients were those involuntarily admitted to hospital with a diagnosis of psychosis, aged 18–65 years, who were deemed suitable for supervised outpatient care by their clinicians. Consenting patients were randomly assigned (1:1 ratio) to be discharged from hospital either on CTO or Section 17 leave. Randomisation used random permuted blocks with lengths of two, four, and six, and stratified for sex, schizophrenic diagnosis, and duration of illness. Research assistants, treating clinicians, and patients were aware of assignment to randomisation group. The primary outcome measure was whether or not the patient was admitted to hospital during the 12-month follow-up period, analysed with a log-binomial regression model adjusted for stratification factors. We did all analyses by intention to treat. This trial is registered, number ISRCTN73110773.
Results
Sample recruited 333
166 CTO, 167 Non-CTO

47 trusts engaged, 32 recruited
Interpreting the results

• Randomisation
  – Identical at baseline, no adjustments needed

• Treatments equivalent
  – Contacts CTO median 2.1 vs 2.2 per month

• Duration of CTO vs Section 17 leave
  – CTO median 183 days vs 8 days

• Any differences would be due to the different duration of coercion.
Outcomes at 12 months
Proportion readmitted: (primary outcome) 100% of data collected
Time to readmission median CTO 295 days vs 292 days

HR 1.00 (95% CI 0.70-1.43), p=0.983
Duration of admissions
CTO median 41.5 days vs 48 days
Clinical and social outcomes

• Only 75% of sample interviewed at 12/12

• Brief Psychiatric Rating Scale (BPRS)
  – CTO median 35 vs 34

• Global Assessment of Functioning (GAF)
  – CTO median 36 vs 35.5
Per protocol analysis

- No difference in results
- CTO minus 42
  – 7 not discharged, 35 no CTO
- Non CTO minus 46
  – 6 not discharged, 40 direct to CTO
- Duration of hospitalisation just makes $p<0.035$
Conclusions

In well functioning mental health services CTOs do not reduce the readmission rate, time to readmission or time in hospital for psychosis patients in the 12 months from discharge.
What now?
Just another study: needs replicating to address limitations:

- Cross overs
- Generalisability
## Controlled Before and After Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Dataset</th>
<th>Study Country</th>
<th>CTO group N</th>
<th>no CTO group N</th>
<th>Admission Rates (CTO vs. no CTO)</th>
<th>Reported Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Segal and Burgess (2006)</td>
<td>Victoria</td>
<td>Australia</td>
<td>8879</td>
<td>16094</td>
<td>Increased Admission Rate</td>
<td>CTO=4.7 (5.1); Control=2.1 (2.7)</td>
</tr>
<tr>
<td>Hunt et al (2007)</td>
<td>Toronto</td>
<td>Canada</td>
<td>224</td>
<td>92</td>
<td>Larger Reduction in Admission Rate</td>
<td>CTO=1.3 (0.96); Control=0.9 (1.71)  P&lt;0.009</td>
</tr>
<tr>
<td>Swartz et al. (2010)</td>
<td>New York</td>
<td>USA</td>
<td>3576</td>
<td>2025</td>
<td>Reduced Admission Rate</td>
<td>OR=0.77 95% CI 0.72-0.82</td>
</tr>
<tr>
<td>Zanni et al. (2007)</td>
<td>Washington</td>
<td>USA</td>
<td>115</td>
<td>78</td>
<td>Increased Admission Rate</td>
<td>CTO=4.25 (3.80); Control=1.64 (1.44)  p&lt;0.0001</td>
</tr>
</tbody>
</table>
Sample Sizes
Controlled Before and After Studies

Victoria CTO
8879

New York CTO
3576

Toronto CTO
224

Washington CTO
115

Victoria Non-CTO
16097

New York Non-CTO
2025

Toronto Non-CTO
92

Washington Non-CTO
78
• Are results of RCTs that much stronger than CBA studies?
  • When would they overlap?

• Could there be genuine US/UK treatment differences?

• What really works in Mental Health care?

• A positive therapeutic alliance?
The OCTET team

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Claire Visser
Merryn Voysey
Sue Woods-Ganz
Thank you for your attention