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Protocol status: In development
We are still developing and optimizing this protocol

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Community Treatment Orders for Patients with Psychosis in a London Mental Health Service: A Target Trial Emulation

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ABSTRACT

Background:
Community Treatment Orders (CTOs) were introduced in the UK through the Mental Health Act 2007, allowing physicians to discharge patients with severe mental health disorders into the community under supervised and compulsory treatment. The Oxford Community Treatment Order Evaluation Trial (OCTET) in 2013 did not find CTOs effective in reducing overall hospital admissions compared to Section 17 leave. However, CTOs continue to be used in the UK. This study aims to employ a target trial emulation framework using observational data from electronic health records to estimate the causal effect of CTOs on rehospitalisation.

Methods:
Data will be sourced from the Camden & Islington NHS Foundation Trust (C&I) Clinical Record Interactive Search (CRIS) research database, serving the boroughs of Camden and Islington. The study will focus on patients detained for inpatient treatment, aged 18-65 years, diagnosed with a psychotic disorder. Exposures include patients discharged on CTO or Section 17 post-inpatient hospitalisation. Primary outcomes focus on hospital admissions during a 12-month follow-up after discharge. Secondary outcomes encompass time to first readmission, number of readmissions, overall hospital stay duration, and scores on the Brief Psychiatric Rating Scale (BPRS) and Global Assessment of Functioning (GAF). Confounders such as age, sex, ethnicity, living situation, and clinical history will be considered. Statistical analyses will be aligned with the OCTET study, using various regression models.

Discussion:
The use of electronic health records for research poses challenges due to data quality, as these records are not primarily collected for research purposes. The study will employ a complete case analysis for confounders, anticipating no issues with missing data for exposure and outcomes. Ethical considerations are covered under a blanket ethics approval, and data minimisation will be observed to ensure patient anonymity and data security.

PROTOCOL integer ID:
86505

Background

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Community treatment orders (CTOs), introduced in the United Kingdom through the Mental Health Act 2007, are a legal mechanism by which physicians may discharge patients with serious mental health disorders into the community while providing supervised and compulsory treatment. Evidence to support the effectiveness of CTOs in reducing rehospitalisation is mixed, and the major trial of CTOs in the UK in 2013 (The Oxford Community Treatment Order Evaluation Trial; OCTET) failed to find any reduction in overall hospital admission among patients on CTO compared to Section 17 leave. Notwithstanding, CTOs have been used in UK mental health services since they were first enacted and continue to be used. More recently, concerns about the disparate application of CTOs based on ethnicity and the perceived coercion of CTOs have been the subject of greater attention.
Real-world data, combined with a causal inference approach, may offer insights into whether CTOs are causally related to rates of rehospitalisation. A target trial emulation approach will allow the use of real-world, observational data.
This study aims to use the target trial emulation framework to use observational, routinely collected electronic health records to estimate the causal effect of CTOs on rehospitalisation.

CITATION

Burns T, Rugkåsa J, Molodynski A, Dawson J, Yeeles K, Vazquez-Montes M, Voysey M, Sinclair J, Priebe S (2013). Community treatment orders for patients with psychosis (OCTET): a randomised controlled trial..

LINK

https://doi.org/10.1016/S0140-6736(13)60107-5

Methods

2

Sample

Data from the Camden & Islington NHS Foundation Trust (C&I) Clinical Record Interactive Search (CRIS) research database will be used. C&I serves the two inner-city London boroughs of Camden and Islington with populations of approximately 260,000 and 240,000. CRIS contains the deidentified electronic health records of C&I patients from about mid-2008 onwards.
To ensure comparability with the OCTET study, the sample patient population will be selected using comparable or similar eligibility criteria, including patients detained for inpatient treatment, aged 18-65 years at the time of this detainment for treatment, and a diagnosis for a psychotic disorder. It is not possible to ascertain some eligibility criteria used in the OCTET study using CRIS, such as: not being subject to other legal restrictions, capability to give informed consent, and suitability for supervised outpatient care.

Exposures

Exposures will aim to match the OCTET study.

Patients discharged on CTO or Section 17 following inpatient hospitalisation, and the mechanism under which the patient is discharged will be the exposure.

Outcomes

Outcomes will aim to match the OCTET study.

The primary binary outcome will be whether a patient was admitted to hospital during the 12-month follow-up after discharge on CTO or Section 17.

Secondary outcomes during the 12-month follow-up will include: time to first readmission, number of readmissions, overall time in the hospital, and scores on the Brief Psychiatric Rating Scale (BPRS) and Global Assessment of Functioning (GAF).

Confounders

Confounders will aim to match the OCTET study.

Confounders will include age, sex, ethnicity, living situation, and clinical status/history.

Statistical Analysis

Statistical analysis will aim to match the OCTET study.

Statistical analysis is anticipated to be conducted using R statistical package.

The primary outcome will be analysed using a log-binomial regression model adjusted for sex, schizophrenic status, and duration of illness. For count outcomes, we will use adjusted negative-binomial regression or zero-inflated Poisson regression models, depending on data distribution. For time-to-event outcomes, we will use proportional hazards regression.

Software

R programming language	NAME
The R Foundation	DEVELOPER
Comprehensive R Archive Network	SOURCE LINK

Discussion

3 Use of routinely collected electronic health records for epidemiological study depends on the quality of the data. Because the data are not collected for a research purpose, missing data and recording of information may be a problem. To approximate the protocol of the OCTET study, we will use complete case analysis for the confounders. Problems with missing data with respect to the exposure and outcomes are not anticipated, as they are relevant eligibility criteria (i.e., we must have these data to conduct the analysis).

It will not be necessary to apply for a separate ethics approval as research using anonymised patient data from the research database is covered under a blanket ethics approval (REC reference 19/EE/0210). An application will be made to use the research database, which will be reviewed by a service user and clinician at C&I.

In accordance with best practice when using anonymised clinical data, data minimisation will be

observed when requesting and extracting data, and all outputs will be checked for risk of secondary data disclosure.