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Compulsory outpatient treatment: a one-year follow-up study in Portugal

SOFIA BRISSOS*

GONÇALO SOBREIRA

JOÃO MIGUEL OLIVEIRA

ZITA GAMEIRO

FERNANDO VIEIRA

Lisbon's Psychiatric Hospital Centre

Abstract: Background: There is insufficient evidence regarding the impact of compulsory outpatient treatment (COT).

Aims: We evaluated the impact of COT over one year on symptoms, personal and social functioning, insight and cognition.

Methods: Naturalistic, longitudinal analysis, at baseline and one-year follow-up, of 15 patients followed in a specialized COT clinic. Patients underwent a standardized evaluation with the *Positive and Negative Syndrome Scale* (PANSS), *Personal and Social Performance Scale* (PSP), *Berrios-Markova insight scale* and *Scale to Assess Unawareness in Mental Disorder* (SUMD), *Trails A and B*, *Digit Span*, and the *Controlled Oral Word Association Test* (COWA).

Results: At follow-up there was significant improvement in personal and social functioning (baseline total PSP: mean=46.9; follow-up: mean=59.3), and specifically in *socially useful activities including work and study* ($p=0.012$), and *personal and social relationships* ($p=0.033$). Three patients (20%) scored ≥ 69 on the PSP, a good level of functioning. However, we found no significant improvements in symptoms (PANSS=56.8), subjective or objective insight (Berrios-Markova=10.0 and SUMD=11.0), or cognitive performance.

Conclusions: At one-year follow-up, patients on COT showed significant improvement in personal and social functioning, specifically in *socially useful activities including work and study* and in *personal and social relationships*, but no improvement in symptoms, insight and cognitive functioning.

Keywords: outpatient commitment; involuntary; psychosis; schizophrenia.

Introduction

Controversy remains as to whether compulsory outpatient treatment (COT) for people with severe mental illness (SMI) reduces health service use and/or improves clinical outcome and social functioning.

Supporters of COT argue that it is less restrictive to treat someone compulsorily in the community than to subject them to repeated hospital admissions¹, and that it brings stability to the lives of patients with severe mental illness². Opponents of COT fear treatment will be replaced by a greater emphasis on control, restraint and threat¹, contributing to a patient's sense of coercion³; they argue that intensive case management or assertive community treatment may be all that is needed⁴. It is also argued that COT has an adverse effect on the therapeutic alliance between healthcare professionals and patients, since more than half of patients subject to a COT order take a negative view of it⁵, driving patients away from services¹; however,

patients' relatives and their psychiatrists alike consider the legal procedure to be beneficial, finding a clinical improvement in the patient⁶⁻⁷. Indeed, some patients subject to COT consider it a positive step necessary to ensure treatment^{6,8-12}, suggesting that there is no single definitive experience or view of COT¹³.

Studies on the efficacy of COT show contradictory results; some have shown a decrease in the number of emergency department visits, admissions and days of hospital stay¹⁴⁻¹⁷, while others have reported an increase in readmission rates of around 70%¹⁸. As regards social functioning, studies have also shown negative results^{14, 19-20}. However, the majority of these studies have small sample sizes and they are often not controlled for selection bias, variations in treatment and differing criteria for COT²¹. Furthermore, in many states of the U.S.A. it is not possible to give medication forcibly in a community setting²⁰, whereas in Portugal it is.

Recent reviews of randomized controlled trials^{20,22} found no significant difference in service use, social function-

* Correspondence to: brissos.sofia@gmail.com

ing or quality of life in patients subject to COT as compared with standard voluntary care, even though patients on COT were less likely to be victims of violent or non-violent crime²⁰; however, this review focused on only three relatively small trials. Maughan et al.²² reviewed 18 studies and concluded that there remains a lack of evidence from randomized and non-randomized studies that COT is associated with or affected by admission rates, number of inpatient days or community service use. A more recent randomized controlled trial also showed no significant difference between the two arms in any of the reported outcomes at either 12 months¹⁹ or at 36-month follow-up²³. But the gold standard of randomized controlled trials may not be ideal for studying this specific population, since randomizing patients to a clinical trial involving a court mandate raises ethical questions. Of course in the case of non-randomized designs, a further difficulty lies in ensuring that the control group is as severely ill as the group placed on a community treatment order²⁴, which makes it difficult to know whether to attribute any improvement to COT or to the non-specific effects of increased contact with healthcare professionals^{4, 25-27}.

It is important therefore to study this population in a naturalistic, longitudinal fashion, but using standardized criteria in order to be able to compare results across the different services available locally, the community environment in which the trial takes place, funding and social insurance schemes and the sociodemographic characteristics of the participants²⁷⁻²⁸, not to mention the country's legal assumptions.

Objectives

To assess the impact of COT in patients followed at a specialized COT clinic in Portugal, immediately after discharge and after one year, specifically on symptoms, social and personal functioning, insight and cognitive performance.

Methods

Study design and setting

This study reports on a sub-analysis of an ongoing study of patients followed in a specialist COT clinic, who were evaluated immediately after compulsory admission and after one year of outpatient commitment²⁹.

The Portuguese Mental Health Law (36/98)³⁰ establishes that detention is replaced by COT whenever such treatment can be carried out under conditions of freedom; if the stipulated conditions are not met by the patient, this is reported to the court and compulsory hospitalization is resumed. A review of the patient's situation, by two psychiatrists, is mandatory every two months while COT is maintained.

The specialist COT clinic is run shoulder-to-shoulder by a psychiatrist (SB) and a resident (JMO, GS or ZG), and

is responsible for a geodemographic area of 815,580 inhabitants. Patients undergo a clinical evaluation at least bimonthly, and are subject to a standardized protocol designed specifically for this clinic, for the purpose of drawing up the mandatory report for the court stating whether the patients has to be kept in COT, or whether he/she can be transitioned to voluntary treatment.

Material and Procedures

The protocol has been described elsewhere²⁹, but briefly, it consists of:

- a) *Positive and Negative Syndrome Scale* (PANNS) to assess symptom severity³¹;
- b) Portuguese version of *Personal and Social Performance* (PSP) Scale to assess personal and social functioning³²⁻³³. The PSP assesses four domains of functioning: 1) *socially useful activities including work and study*; 2) *personal and social relationships*; 3) *self-care*; and 4) *disturbing and aggressive behaviors*. These are rated on a six-point severity scale (absent to very severe), and based on these the interviewer assigns a global score on a 100-point scale, higher scores representing better functioning. The total score is usually divided into three levels: 71-100 (*mild or no functioning difficulties*); 31-70 (*varying degrees of difficulty*); and 0-30 (*functioning so poor that the patient needs intensive support and supervision*);
- c) *Scale to Assess Unawareness of Disorder* (SUMD) – shortened version – to evaluate illness insight objectively³⁴;
- d) Portuguese version of the *Markova and Berrios Insight Scale*, to evaluate subjective illness insight³⁵⁻³⁶;
- e) *Trail-A, Trail-B, Digit Span* (total score) and *Controlled Oral Word Association Test* (COWAT) to briefly assess cognitive functioning³⁷.

Since the present evaluation is part of a standardized protocol applied to all patients, informed consent was not obtained; however, some patients refused to participate in some tests.

Patients were diagnosed according to DSM-IV criteria³⁸ American Psychiatric Association 1994, ascertained from personal interview and clinical file consultation, and resolution/remission state was assessed with the criteria of Andreasen et al.³⁹. Age at onset of symptoms and first psychiatric admission were retrospectively collected to estimate a proxy measure of duration of untreated psychosis (DUP).

Patients

This analysis relates to patients followed during a 1-year period (mean=348.5 days, min=296, max=440) from April 2014 onwards. During this period, 46 patients were referred for COT (26 to our specialized clinic and 20 to the previous attending psychiatrists). While at the COT

clinic, six patients were transitioned to a voluntary regime before 1-year follow-up and five were lost to follow-up (change of address, admission to long-term institutions); this analysis refers to the 15 patients who remained on the COT regime during that period.

As regards residential placement, of the 15 patients, the majority (73%) were discharged to independent living, i.e. alone or with family. Two patients were placed in the rehabilitation service of our hospital, one was placed in single-room occupancy housing, and one was placed in a community structure for people with co-occurring mental health and substance use disorders, or homelessness.

Under Portugal's Mental Health Law ³⁰, patients can be forced to take medication during COT. In line with that provision, and in order to be able to confirm before the court that patients are adhering to treatment, they are all medicated with long-acting injectable (LAI) antipsychotics, either in monotherapy or in association.

Statistical analysis

Statistical analyses were conducted using version 22.0 of the SPSS[®] statistical software package. Descriptive statistics were produced (mean, median, standard deviation and range) and normality distribution of continuous measures was checked with the Kolmogorov-Smirnov test. Differences between baseline and follow-up evaluations were tested using paired t-test or Wilcoxon signed rank sum test for interval and ordinal variables, respectively.

Results

Patients were predominantly male (80%), single (86.7%) and unemployed (73.4%), with a mean age of 42.0 years (range 26-59) and a mean educational level of 10.7 years. Patients had a mean illness duration of 16.8 years (range: 0-22) and an estimated DUP of 6.1 years (range: 0-45). They had previously been hospitalized on average 6.6 times (range: 2-31), of which 1.5 times (range: 0-6) on an involuntary basis. Total duration of hospitalization was 153.7 days (SD=181.3; range: 22-662) and the hospitalization that led to COT had a mean duration of 34.7 days (SD=21.0; range: 3-87).

During the follow-up period, six patients were compulsorily readmitted, but only once, with a mean duration of 39.0 days (SD=20.7; range: 20-76).

The majority of patients had a diagnosis of schizophrenia (11 patients; 73%), followed by schizoaffective disorder (four patients; 27%).

Symptoms at baseline and 1-year follow-up

At baseline patients showed moderate symptoms (PANSS total=58.4) and 46.7% were not in resolution ³⁹ (Table 1). At follow-up there was only a slight improvement in PANSS scores, but 20% were in symptomatic resolution and 46.7% in symptomatic remission ³⁹.

Personal and social functioning at baseline and 1-year follow-up

At baseline patients presented low levels of personal and social functioning (total PSP =46.9), but there was a significant improvement at 1-year follow-up (total PSP =59.3) (Table 1). Moreover, at baseline there were no patients with a total PSP score > 70, considered the ideal level of functioning ³², but at follow-up three patients scored ≥ 69 . As regards specific domains, we found significant improvement in patients' functioning in *socially useful activities including work and study*, and in *personal and social relationships*, but they did not improve significantly in the domains of *self-care* and *disturbing and aggressive behaviors* (Figure 1).

Insight at baseline and 1-year follow-up

At baseline patients presented low levels of insight on heteroevaluation (SUMD=11.0) and self-report (Berrios-Markova=11.9), which did not improve over the year of follow-up (SUMD=11.6; Berrios-Markova=12.8) (Table 1).

Cognitive performance at baseline and 1-year follow-up

Performance in cognitive tests is presented in Table 1, showing that there was a slight improvement over the 1-year follow-up period in tests that measure processing speed, executive functions and verbal fluency, but this improvement was not statistically significant.

Discussion

After 1-year follow-up on COT, patients showed statistically significant improvements in personal and social functioning, specifically in *socially useful activities including work and study* and in *personal and social relationships*, but not in other variables, namely symptoms, insight and cognitive functioning.

These results may reflect the more severe prognosis of a subset of patients who have to remain in COT for longer periods. In fact, we have previously shown that patients followed in this clinic and transitioned to voluntary treatment have a better profile than those it is decided, at their last evaluation, to keep in COT (Brissos et al, 2015 personal communication). This is why "*lack of the necessary discernment to evaluate the meaning and implications of consent*" is one of the legal principles for initiating and maintaining compulsory treatment in Portugal. Thus patients with low insight levels who do not improve with treatment are more likely to be kept in COT. On the other hand, there were five patients lost to follow-up, and these patients could have an even worse prognosis than the sample who remained in follow-up. Four of these patients are homeless; it is difficult, even with a court order, to locate patients and bring them to resume compulsory hospitalization if they do not comply with treatment.

One of the objectives of COT is to reduce hospital recidivism, especially in non-affective psychosis, reducing hospital readmissions by as much as 70% and requiring 28 fewer hospital days⁴⁰; however, this happens only when combined with a higher intensity of outpatient treatment²⁷, averaging more than seven service provisions per month. In our sample, six patients (40%) were readmitted during the follow-up period, which is higher than the 28.7% reported by Patel et al.¹⁶, but lower than the proportion reported by Steadman et al.¹⁴. This could be due to the fact that our legislation allows patients to be forced to take medication during COT and is probably not attributable to specialized service provisions, since the majority of patients were at home, and only two had substantial support in a rehabilitation setting. Moreover, two patients (1/3) were readmitted for non-compliance with the treatment and not because of any worsening of symptoms.

One of the main objectives of COT is to reduce the duration of future episodes of inpatient care⁴⁰. Although COT has been associated with a mean decrease of five bed-days from before the order when compared to controls⁴¹, in our sample readmitted patients had a duration of admission similar to that of the admission that prompted COT.

As regards personal and social functioning, a recent review found little evidence that COT was effective in any of the main outcome indices²⁰; however, this relates to only two studies, where social functioning considered “trouble with police – at least one arrest” and “ever arrested/picked up by police for violence against a person”, as opposed to measurement of personal and social functioning using clinical scales, as was the case in our study. What was meant by social functioning in these studies is therefore not equivalent to what was measured in our study, which is a much more reliable measure of personal and social functioning.

In the New York City Involuntary Outpatient Commitment Program¹⁴ a group of 78 COT patients was compared with a control group (n=64); no differences in social functioning, as measured by the GAF (Global Assessment of Functioning), were found between the groups at 12-month follow-up. However in the experimental group 50% were committed with a medication order, while the rest had no medication order. This might explain the better results in our sample, where all patients had to take medication as prescribed and this was mainly guaranteed by administering LAI antipsychotics.

More recently, the OCTET trial¹⁹ also showed no differences in patients' social functioning as measured by the GAF and the SIX (Objective Social Outcomes Index). Again, only 51% of patients were medicated with LAI antipsychotics. In fact, our proportion of patients treated with LAI antipsychotics is 100%, which is higher than that reported in other studies, where rates vary from 60-80%^{16, 42-44}. This underlines the importance of using LAI

antipsychotics to ensure treatment, especially in countries where a higher intensity of outpatient treatment is scarce due to economic constraints, as is the case in Portugal.

Modern mental health care is highly successful in maintaining contact with psychotic patients, and this may explain why compulsion seems to add so little in countries like England²³; however, in countries with less organized community teams and/or assertive outpatient treatment, such as Portugal, COT might prove a useful resource to keep patients engaged with services.

Besides showing significant improvement in global personal and social function, we found these improvements were significant in *socially useful activities including work and study* and in *personal and social relationships*, but not in the domains of *self-care* and *disturbing and aggressive behaviors*. This is probably because patients already had low impairment in *self-care* and *disturbing and aggressive behavior*; and although there was a slight improvement, it did not reach statistical significance due to ceiling effects and the sample size. Nevertheless, those domains that are critical to patients' recovery and that are most impaired in schizophrenia (*socially useful activities including work and study* and *personal and social relationships*) did show significant improvement after 1-year under COT.

Since patients in this specialized clinic have overlapping characteristics with those in the majority of studies²⁹, improvement in social functioning is not explained by patients' better profile at baseline.

The fact that patients have several previous psychiatric admissions before being referred to COT, and an illness duration of 16.8 years on average, could explain why it becomes more difficult to achieve symptomatic improvement with treatment, and remission in particular. Moreover, patients with longer DUP have more relapses, less symptom improvement and a lesser likelihood of remission, as well as poor social functioning and global outcome⁴⁵⁻⁴⁶. This leads us to think that COT is probably being delayed and used when its efficacy is probably lower, which might explain some negative results. Longitudinal studies of COT in early-onset patients are needed in the future to evaluate for this effect.

Even though we did not have a control group, the scores obtained by our patients in cognitive tests are below the population norms³⁷, and although there was a slight improvement in performance across all tests at follow-up, this was not statistically significant. It is unlikely that the slight improvement could have been due to practice effects, since these tests are not very prone to those. The fact that improvement in tests of processing speed, executive functions and verbal fluency was only very slight could be due to long illness duration and the occurrence of several relapses in the past. Cognitive deficits in schizophrenia are important predictors of impairment in most functional domains; they appear at or before the onset of illness and are

stable over time in most patients⁴⁷. Since there seems to be a decline in cognition at around the time of the first psychotic episode, this may be an important period when an aggressive intervention, specifically by way of COT, may have the greatest impact⁴⁷.

Cognitive functioning has been shown to be associated with personal and social functioning⁴⁸, and good cognition is thought to be necessary for adequate functioning, in particular academically and at the professional level. Nevertheless, improvements in functioning may be obtained without a corresponding improvement in cognition, as was the case in our sample. This lends some support to the hypothesis that cognitive deficits in schizophrenia remain relatively static with time⁴⁷ and are probably less amenable to treatment than other symptoms⁴⁹. In that sense, COT treatment may be effective, even if it does not bring about significant improvement in cognitive performance.

Because of the naturalistic nature of the study, we cannot evaluate the effect of antipsychotic treatment on variables such as insight and cognition. Nevertheless, the treatment compliance guaranteed by LAI antipsychotics may explain some of the better results in our sample as compared to other studies.

Since there is a lack of reports on this population in Portugal, we compared our results with those in other countries, which have different laws on COT. Variations in legislation, health service structures and funding clearly influence practice⁵⁰. Portugal's Mental Health Law is probably closer to "conditional release", an alternative in both the UK and the USA that has been shown to be as effective as COT in reducing hospitalization and promoting community engagement⁵¹: clinicians are allowed to treat pharmacologically and decide when patients can be released to community treatment on an outpatient basis, avoiding a court order for outpatient treatment. Therefore, although remarkable consistency has been noted in the characteristics of patients on COT across jurisdictions in very different cultural and geographic settings^{29,52}, results of COT may differ due to the degree of "freedom" that the clinician is permitted in each legal system.

Conflicts of interest

Dr. Sofia Brissos has received honoraria for lectures from Janssen Portugal. The other authors declare no potential conflicts of interest.

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Unfortunately we did not collect systematic information on substance use, aggression and/or detentions or convictions to be able to compare the results of our sample with those of other studies.

Although our sample is small and from a single center, it represents the majority of patients at our hospital, which is responsible for the psychiatric treatment of almost 10% of the country's adult population, who transitioned to COT and remained on that regimen for at least one year.

Lack of a control group is an acknowledged limitation of our study. However, since the study of COT involves legal and ethical constraints, quasi-experimental designs comparing people from jurisdictions with similar health systems, where one allows compulsory community treatment and the other does not, may be an answer²⁰, but this may also apply between countries, if the legal criteria and the services available are taken into consideration.

Lastly, the psychiatrists who administered the scales and tests were not blinded to the symptomatic and functional status of the patients. However, our study is innovative in that it presents results on several variables (symptoms, functioning and insight), some of which are rarely studied, namely personal and social functioning in several domains, as well as cognition, in a sample of naturalistically treated patients.

Conclusions

Patients who continued to meet the legal criteria for COT after one-year of follow-up showed significant improvements in personal and social functioning, specifically in *socially useful activities including work and study* and in *personal and social relationships*, albeit without accompanying significant improvements in symptoms, insight and cognitive functioning.

Naturalistic but systematized data on patients followed on this regimen is of crucial importance, as psychiatrists cannot disregard the law just because the results of randomized controlled trials (which pose ethical questions) show no effectiveness of COT.

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Table 1. Symptoms, personal and social functioning, insight, and neurocognitive performance of patients in COT at baseline and 1-year follow-up.

Variable	Baseline evaluation (n=15)		One-year follow-up evaluation (n=15)		t-Test	p
	mean	SD	mean	SD		
PANSS positive	13.5	3.34	12.3	2.97	0.993	0.339
PANSS negative	17.4	4.91	18.1	4.82	0.535	0.602
PANSS general	26.1	3.33	28.0	3.31	1.722	0.109
PANSS total	58.4	9.16	56.8	7.93	0.457	0.655
PSP	46.9	10.29	59.3	12.09	3.787	0.002
Berrios-Markova	11.9	3.07	10.0	4.09	0.975	0.349
SUMD	11.0	2.04	11.6	2.77	1.000	0.334
Trail-A (n=10)	52.8	29.54	49.7	29.33	0.812	0.438
Trail-B (n=10)	189.7	178.24	151.1	122.65	1.115	0.294
Digit Span (total) (n=4)	10.0	2.45	11.8	6.80	0.711	0.529
COWA (n=3)	13.0	2.65	18.0	6.08	2.500	0.130

SD Standard Deviation, COT Compulsory Outpatient Treatment, COWA Controlled Oral Word Association, PANSS Positive and Negative Syndrome Scale, PSP Personal and Social Performance scale, SUMD Scale to Assess Unawareness of Disorder

Fig. 1. Domains of personal and social functioning of patients at baseline and 1-year follow-up.

