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A pilot randomized controlled trial of the Occupational Goal Intervention method for the improvement of executive functioning in patients with treatment-resistant schizophrenia



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ABSTRACT

Schizophrenia is a chronic disabling mental disorder that involves impairments in several cognitive domains, especially in executive functions (EF), as well as impairments in functional performance. This is particularly true in patients with Treatment-Resistant Schizophrenia (TRS). The aim of this study was to test the efficacy of the Occupational Goal Intervention (OGI) method for the improvement of EF in patients with TRS. In this randomized, controlled, single-blind pilot study, 25 TRS patients were randomly assigned to attend 30 sessions of either OGI or craft activities (control) over a 15-week period and evaluated by the Behavioural Assessment of the Dysexecutive Syndrome (BADS) as the primary outcome and the Direct Assessment of Functional Status (DAFS-BR) as well as the Independent Living Skills Survey (ILSS-BR) as secondary outcomes, all adapted for the Brazilian population. The Positive and Negative Syndrome Scale (PANSS) was used for monitoring symptom severity. Results showed significant statistical differences, favoring the OGI group in terms of improvement on the BADS, both in subtests (Action Program and Key Search) and the total score. Improvements in EFs were observed by families in various dimensions as measured by different subtests of the ILSS-BR inventory. The OGI group showed no significant results in secondary outcomes (DAFS-BR) except in terms of improvement of communication skills. Although preliminary, our results indicate that the OGI method is efficacious and effective for patients with TRS.

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1. Introduction

Schizophrenia is a severe mental disorder associated with personal, social and family burden (Haro et al., 2015). This disorder involves a range of cognitive, behavioural and emotional dysfunctions, which are commonly defined in terms of dimensions of symptomatology, such as psychotic (delusions and hallucinations), disorganization (thought disorders), and negative symptoms (blunted affect, lack of motivation and social withdrawal) as well as cognitive impairments (abstraction, attention, memory and executive functions) (American Psychiatric Association, 2013; Haro et al., 2015). Cognitive impairments are a central feature of schizophrenia that are present before the emergence of psychotic

symptoms and even in first episode patients who have never been treated with antipsychotics (Saykin et al., 1994; Bowie and Harvey, 2006; Fioravanti et al., 2012).

Various studies have found a relationship between cognitive impairment and functional disability in patients with schizophrenia (Green, 1996; Green et al., 2000) manifested by a compromised ability to learn, achieve employment, develop interpersonal relationships and take part in leisure activities (Mueser and McGurk, 2004; Bowie and Harvey, 2006; Shamsi et al., 2011).

Antipsychotics are the mainstay of schizophrenia treatment and are particularly effective for the improvement of psychotic symptoms (Keefe et al., 1999; Werneck et al., 2011). Patients who do not respond to at least two or more treatments with antipsychotics and have persistent psychotic symptoms are classified as having Treatment-Resistant Schizophrenia (TRS) (Elkis, 2007; Elkis and Meltzer, 2007; Englisch and Zink, 2012). These patients account for 30% of all cases of schizophrenia and are eligible to receive treatment with clozapine, which is the gold-standard

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antipsychotic therapy for this condition (Elkis, 2007). Patients with TRS are considered the most severe cases of schizophrenia, having high levels of psychotic symptoms and cognitive impairment (Elkis, 2007; Elkis and Meltzer, 2007).

In addition to the use of antipsychotics, psychosocial interventions are essential for the recovery of patients with schizophrenia. Cognitive remediation, combined with vocational rehabilitation, has proven to be effective for the recovery of patients with schizophrenia (Wykes et al., 2011; Fioravanti et al., 2012).

One of the main targets of such programs is the improvement of EFs, which play a major role in cognition. EF refers to an individual's ability to engage successfully in independent, purposive, self-serving behavior (Lezak, 1995; Stuss, 2011). Executive functioning involves processes that are severely compromised in schizophrenia and is considered the strongest predictor of long-term functional impairment in areas such as the performance of basic and instrumental activities of daily living (ADLs and IADLs, respectively), as well as participation in social and professional activities, even outweighing positive and negative symptoms in prognostic value for functional impairment (Velligan et al., 2000; Addington et al., 2010). The rehabilitation of executive functioning is associated with functional improvements as measured by the ability to perform ADLs and IADLs, which require a combination of different cognitive skills (Green, 1996; Green et al., 2000).

Programs targeting executive impairments in schizophrenia typically involve strategies such as planning, problem solving, and self-correction. In these programs, patients are encouraged to think before initiating a task and to develop their abilities for planning, subsequently becoming able to examine their performances and adapt them to the task at hand. The task performance process typically develops in the following sequence: planning; task performance; time management; performance monitoring; and metacognitive strategies, which are defined as the ability to recognize one's own successful cognitive processing (Fleming and Lau, 2014).

The OGI method is a rehabilitation program which targets EF using learning strategies to improve everyday functioning. It is based on the Goal Management Training (GMT) method developed by Levine et al. (2000), originally designed to improve EF in patients with traumatic brain injury. The OGI was adapted as a form of Occupational Therapy (OT) for patients with schizophrenia who have EF deficits that affect daily activities and participation in the community (Katz and Keren, 2011).

The stages of the OGI are displayed in Table 1.

Katz and Keren initially demonstrated the efficacy of the OGI method in schizophrenia in a small randomized controlled trial, in which 18 patients with schizophrenia were allocated to one of three possible interventions: OGI, the frontal executive program (a remedial approach), or an activity training approach aimed at developing specific skills without focusing on EF. Participants engaged in 18 treatment sessions over a period of 6–8 weeks until the end of the intervention. The authors found that the OGI method showed improvements in EF, with medium-to-large effect sizes that persisted for 6 months after the intervention (Katz and Keren, 2011).

Despite the fact that the OGI method has been shown to be effective in patients with schizophrenia, it has never been tested in patients with TRS, who account for one third of all cases of schizophrenia and, as previously mentioned, are considered to be the most severe cases (Elkis and Meltzer, 2007). Therefore, the aim of the present study was to evaluate the efficacy of the OGI method for the improvement of EF in patients with TRS. The secondary objectives were to quantify improvements in functional aspects of independent living (performance of ADLs and IADLs) and in other cognitive functions.

Table 1 Stages of the OGI method.

Stage Steps of the method

1 Stop and think!

- · Orienting and alerting to task.
- Initial discussion of interests and tasks the individual wants to work on; raises awareness of individual meaningful activities that will direct the choice of task.

2 Defining the main task.

- Define the specific goal. This stage includes choice, definition, and goal setting.
- Listing and partition goal into sub-goals.
 - Setting the steps to achieve the goal.
 - Recording the process, steps, and required material.
 - Estimating duration of performance.
- Learning the steps.
 - Encoding and retention, say the process by heart (sub-goals).
 - Perform the task.

Monitoring.

- Check and evaluate the outcome and the process.
- Compare the outcome with the goal definition.
- What kind of problems and difficulties did you meet?
- What factors promoted or interrupted the task completion?
- Are there alternative ways to carry out the task?

2. Methods

2.1. Study design

This was a randomized, controlled, single blind pilot study comparing the OGI method with craft activities. Participants were outpatients of the Schizophrenia Research Program of the Institute of Psychiatry of the University of São Paulo School of Medicine, in São Paulo, Brazil. The study was approved by the Institutional Review Board of the University of São Paulo General Hospital (Protocol no. 0781/10), and all participating patients gave written informed consent. The trial was registered in the ClinicalTrials.gov site (NCT01879956).

2.2. Selection of patients

Patients diagnosed with schizophrenia according to the DSM-IV-TR (American Psychiatric Association, 2000), aged between 18 and 55 years were selected for the study. Patients were defined as having TRS based on the Kane et al. (1988) historical criteria i.e., persistence of psychotic symptoms after at least two adequate trials with two different antipsychotics and were receiving clozapine. Daily doses of clozapine ranged from 230 to 350 mg and remained stable during the intervention period. Patients had to have a minimum of five years of schooling, and were excluded if they had been hospitalized in the last three months, had a diagnosis of substance abuse or dependence or had a history of traumatic brain injury or intellectual disability.

Thirty five patients were eligible for inclusion in the study but five of them declined to participate. The remaining 30 patients were randomized to attend sessions in the OGI group (n=16) or the craft activities group (n=14). They were randomized using the randomly permuted blocks method (available at: http://www.randomization.com). The person responsible for the randomization had no contact with the patients. Over the course of the study there were five dropouts, two from the OGI group and three from the control group. Therefore, the final sample comprised 25 patients: 14 in the OGI group and 11 in the control group. Fig. 1 shows the CONSORT diagram of the study (Schulz et al., 2011). Patients were evaluated at baseline and at the endpoint.

Based on Katz and Keren (2011).

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