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Original article

Effects on cognitive and clinical insight with the use of Guided Self-Determination in outpatients with schizophrenia: A randomized open trial

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ABSTRACT

Poor insight has a negative impact on the outcome in schizophrenia; consequently, poor insight is a logical target for treatment. However, neither medication nor psychosocial interventions have been demonstrated to improve poor insight. A method originally designed for diabetes patients to improve their illness management, Guided Self-Determination (GSD), has been adapted for use in patients with schizophrenia (GSD-SZ). The purpose of this study was to investigate the effect on insight of GSD-SZ as a supplement to treatment as usual (TAU) as compared to TAU alone in outpatients diagnosed with schizophrenia. The design was an open randomized trial. The primary hypothesis was cognitive insight would improve in those patients who received GSD-SZ + TAU as assessed by the BCIS. We additionally explored whether the intervention led to changes in clinical insight, self-perceived recovery, self-esteem, social functioning and symptom severity. Assessments were conducted at baseline, and at 3-, 6- and 12-month follow-up. Analysis was based on the principles of intention to treat and potential confounders were taken into account through applying a multivariate approach. A total of 101 participants were randomized to GSD-SZ + TAU ($n = 50$) or to TAU alone ($n = 51$). No statistically significant differences were found on the cognitive insight. However, at 12-month follow-up, clinical insight (measured by G12 from the Positive and Negative Syndrome Scale), symptom severity, and social functioning had statistically significantly improved in the intervention group as compared to the control group. "Improving insight in patients diagnosed with schizophrenia", NCT01282307, http://clinicaltrials.gov/.

1. Introduction

Poor insight or lack of awareness of illness has been commonly observed among one half to three fourths of persons with schizophrenia spectrum disorders [1,25]. These findings have been replicated cross-culturally [40,45] and found among both persons in early and later phases of illness [6]. Poor insight is of clinical interest as it is considered to be a barrier to treatment adherence [18] and a risk factor for poorer outcome [10,12,13,23,32,41].

Conceptually, poor insight in schizophrenia can reflect an unawareness of a number of different independent aspects of the illness, and is referred to as poor clinical insight. This can include a failure to acknowledge present or past symptoms, the consequences of the disorder, or the potential need for treatment. It is a particular form of unawareness that persists in the midst of other relatively intact forms of awareness [27]. Independent of their lack of awareness of illness they may respond in a fully adaptive manner to other life demands, meaningfully appraise their own physical health [24] and/or plainly recognize the symptoms of others who are mentally ill [42]. More recently, interest has arisen

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in an additional dimension of insight referred to as cognitive insight. Those with higher levels of cognitive insight are more aware of alterations in their reasoning processes [30]. Specifically, among persons with schizophrenia, lack of cognitive insight can be evidenced as holding excessive certainty about the accuracy of one's beliefs or being less reflective about one's thoughts and feelings [38].

Unfortunately, different treatment modalities, such as psychoeducation, cognitive behavioral therapy, and antipsychotic medication, have not been effective in improving insight in schizophrenia [15,34]. For the most part, while these approaches may increase knowledge about the illness, an increase in such knowledge has not corresponded with patients developing a more complex or coherent understanding of their personal experiences of psychiatric challenges [37,43]. This suggests that improving insight is not a matter of educating individuals about the right kind of behavior or inclining them to agree with the mental health care professionals (MHCP) regarding their understanding of illness and treatment.

To improve insight, an extensive time for self-reflection or exploration is required. Lysaker et al. [26,28] suggest that providing opportunities which support reflection may help patients develop a more coherent and consensually valid account of their psychiatric challenges and so feel sufficiently empowered to master a greater range of challenges and shape a meaningful life for themselves.

In order to meet the need for supporting patients' reflection and focus on assisting them to evolve narratives about their lives and what it means to them to live with schizophrenia, we have adopted a method called Guided Self-Determination (GSD), originally developed and proven effective in diabetes care [46,51] to address insight in schizophrenia.

The GSD method is not solely designed to improve insight, but life skills [46]. However, gaining insight is a consistent component in the method, as insight serves as a precondition for change and self-management. Focused communication, mutual reflection and self-reflection, facilitated through completion of semi-structured reflection sheets, help patients gain insight into their own attitudes towards illness as a necessary step to change it [47]. Considering that GSD may be a good candidate for addressing the current need for improving insight prompted us to transfer the GSD method from diabetes care to the care of individuals with schizophrenia (GSD-SZ). First three grounded theories that explained barriers to empowerment in difficult diabetes care [47–49] and underpin the GSD method [48,50] were tested qualitatively within a mental health context. Here we found that barriers and conflicts within the relationship between MHCPs and individuals with schizophrenia were similar to the relationship between health care professionals and individuals with diabetes. Second, the reflection sheets were modified, and finally a qualitative evaluation of the GSD-SZ methods was conducted. The results suggested that individuals with schizophrenia gained insight into their life when using the GSD-SZ method. Among other things, insight helped them to make sense of their daily challenges, understand their illness, make decisions and manage challenges involved in living with schizophrenia [19]. Further a single case study with data from the qualitative evaluation was conducted illustrating how an individual with schizophrenia gained insight into his illness, and particularly his own delusions and started to change his delusional thinking [20]. The studies all supported that the GSD-SZ method may improve insight in individuals with schizophrenia.

The aim of this study was to test, in a randomized trial, the effect of the GSD-SZ method supplemented to treatment as usual (TAU) compared to TAU alone. We hypothesized that persons randomized to the experimental treatment would show improvements in both cognitive and clinical insight. We additionally hypothesized that these persons would achieve higher levels of subjective recovery, self-esteem, social functioning and a significant reduction in symptoms relative to the controls.

2. Methods

2.1. Study design

This was an open randomized parallel group trial of outpatients recruited from six outpatient teams, three Assertive Outreach Teams (AOT) and three District Teams (DT) in Region North in Denmark. Patients meeting the selection criteria described below were randomly assigned to immediate receipt of individual training of approximately 10 sessions with GSD-SZ provided over 6 months in addition to TAU (intervention group) or to TAU alone (control group). Patients in the control group were put on a waiting list to receive delayed individual GSD-SZ training after the completion of the 12-month follow-up period. In the intervention group, participants were treated for six months with GSD-SZ. All participants were assessed at baseline, at three months (mid-treatment), at six months (end of treatment) and at 12 months (six-month post-treatment) on measures of cognitive insight, clinical insight, self-perceived recovery, self-esteem, symptoms and social functioning as explained below. Demographic information and information about the illness, medication and substance abuse were collected at baseline through a clinical interview. The first author administered all clinician-administered assessments, but was blind to participants' self-ratings. The trial was conducted as part of ordinary daily practice and the AOTs or DTs were had no extra financial incentives or extra MHCPs. The intervention group did not receive extra visits compared to the control group. The recruitment started February 2008 and ended July 2011. Data collection ended July 2012.

The trial was approved by the Danish Data Protection Agency and The Danish National Committee on Biomedical Research Ethics under number VN-20070070. The trial was registered at http://clinicaltrials.gov/ with identifier: NCT01282307.

2.2. Participants

Individuals were referred to the study by their MHCP. The recruitment of participants is described elsewhere [21]. All patients receiving treatment in an AOT were potentially eligible for the trial. Admission criteria for patients in the three AOTs were having frequent and/or long admissions without any or poor improvement in psychopathology and illness management, frequently discontinuing treatment, frequent relapse, or not demonstrating improvement. Also, patients in the three DTs meeting the criteria for patients in an AOT were potentially eligible for the trial. Participants needed to meet the following formal selection criteria: meeting the criteria for schizophrenia ICD-10 F.20.0-9 or schizoaffective disorder F.25.0-9 according to participants' hospital record, age 18–70 years, able to understand, speak and write Danish (if the person needed an interpreter, they were excluded), no previous GSD-SZ training, no evidence of dementia according to participants' hospital record, organic brain disease or intellectual handicap, and a signed informed written consent.

2.3. Randomization

A statistician with no connection to the trial established randomization. An external person packed opaque sealed sequentially numbered envelopes with the assigned treatment. The randomization list was then sealed in an opaque envelope that was not opened until the trial was completed. Participants were randomized 1:1 in blocks of 6 persons. After written informed