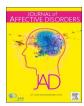
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#### Research paper

## A randomized controlled study of brief family-based intervention in obsessive compulsive disorder



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#### ABSTRACT

*Background:* Cognitive behaviour therapy (CBT) for Obsessive Compulsive Disorder (OCD) is therapist-intensive and prolonged making it less accessible to patients, particularly in resource-constrained situations. We examined the efficacy of a brief psychotherapeutic intervention as an adjunct to serotonin reuptake inhibitors (SRIs) in OCD.

*Method:* We randomized 64 adult OCD patients stabilized on SRIs to either the 6-session brief family-based intervention (BFBI; n=30) that included psychoeducation, exposure and response prevention and family intervention or to a control arm of relaxation exercises (RE). Assessments were conducted at baseline and at 1- and 3- months post-intervention. Primary outcome measure was response to treatment defined as  $\geq 35\%$  reduction in the Yale-Brown Obsessive Compulsive Scale total score relative to baseline score plus a Clinical Global Impression- Improvement rating of very much improved or much improved. Family accommodation and expressed emotions were also assessed.

*Results*: At 3- month follow-up, the BFBI group responded better than the RE group (53% vs. 12%, p < 0.001). Illness severity, family accommodation and expressed emotion declined significantly over time in the BFBI group compared to the RE group. The BFBI (OR = 13.17, p < 0.001) and baseline illness severity (OR = 0.746, p < 0.011) predicted treatment response.

*Limitations*: Sample size was small and follow-up duration was short. Control group had less time with the therapist although number of sessions was identical in both the groups.

Conclusion: Briefer intervention is effective in treating OCD. Briefer and inclusive format of intervention has important implications for clinical practice in resource-constrained circumstances.

#### 1. Introduction

Cognitive-behavioural therapy (CBT) involving exposure and response prevention (ERP) is an established treatment for obsessive compulsive disorder (OCD) (Abramowitz, 2006; Gava et al., 2007; Olatunji et al., 2013; Ponniah et al., 2013; Simpson et al., 2008; Wilhelm et al., 2009). Standard CBT for OCD involves at least 15–20 sessions of 90–120 min each over two to three months and at times, even longer (Abramowitz, 2006; Cottraux et al., 2001; Franklin et al., 2000; Tolin et al., 2011). However, administering CBT over such a

lengthy period is often not feasible in resource-constrained countries such as India where there is a severe scarcity of infrastructure and trained manpower. As a result, CBT is often not the first-line treatment for OCD and serotonin reuptake inhibitors (SRIs) become the obvious first-choice treatment options (Janardhan Reddy et al., 2017) despite convincing evidence that CBT may be offered as first-line treatment for OCD (American Psychiatric Association, 2007; National Institute for Care and Health Excellence, 2006). In such resource-constrained situations, it is imperative to test briefer psychotherapeutic approaches. If effective, such briefer approaches may address the issue of feasibility

Abbreviations: BFBI, Brief family based intervention; SRI, Serotonin reuptake inhibitors; DSM-IV-TR, Diagnostic and Statistical Manual of Mental Disorders-IV-TR; RE, Relaxation exercises; CTRI, Clinical Trials Registry- India; Y-BOCS, Yale-Brown Obsessive Compulsive Scale; MINI, Mini International Neuropsychiatry Interview; SCID=II, Structured Clinical Interview for DSM-IV Axis II –Personality Disorders; CGI, Clinical Global Impression scales for severity and improvement; FEICS, Family Emotional Involvement and Criticism Scale; FAS, Family Accommodation Scale, NIMHANS, National Institute of Mental Health and Neurosciences; ITT, Intent-to-treat

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and accessibility of psychosocial treatments for OCD (Maj et al., 2011; Subramaniam et al., 2012). One such alternative is to modify existing therapies so that they can be administered in time-limited period (Addis, 2002). Brief family-based and self-help treatments can be instrumental in reducing therapist time and in making the treatment more accessible (Mataix-Cols and Marks, 2006; Pearcy et al., 2016; Whiteside and Jacobsen, 2010).

This study was an attempt to develop and test the efficacy of a comprehensive and time-efficient psychosocial intervention in OCD that included all the effective elements that are integral to standard CBT. Standard family-based CBT includes structured baseline assessments, psychoeducation about OCD and behavioural principles, ERP (McKay et al., 2015), involvement of family to aid in therapy, to reduce accommodative behaviour and high expressed emotion and to help the family deal with burden related to caring for the person with OCD (Lebowitz et al., 2012; Steketee and Van Noppen, 2003). We developed a brief family-based intervention (BFBI) that included all these elements that are considered to be effective in treating OCD (details in the Section 2).

We employed family-based intervention because of the vital role of family in treating OCD. It is well known that family accommodation is common in families of patients with OCD. Family members often participate in patient's rituals and modify their routines in order to reduce distress associated with performance of rituals (Lebowitz et al., 2012). Family accommodation is associated with poorer treatment response (Garcia et al., 2010) and worse outcome (Cherian et al., 2014). Reduction in family accommodation is associated with improvement in symptom severity (Storch et al., 2010; Waters et al., 2001) and family functioning (Diefenbach et al., 2007). Because of family members' participation in patient's rituals and modification of family routines, there can be intense disagreements among family members concerning their response to patient's symptoms (Maina et al., 2006). This can lead to high expressed emotion (EE). Families of patients with OCD often display high levels of criticism and over-involvement (Hibbs et al., 1993; Shanmugiah et al., 2002; Steketee et al., 1998). High EE is also associated with relapse (Emmelkamp, 1992) and poorer treatment outcome in OCD (Chambless and Steketee, 1999).

Given the influence of family on the outcome of OCD, involvement of family in CBT has become particularly important (Albert et al., 2010; Maina et al., 2006; Nauta et al., 2012). Even though family-based CBT is effective, such interventions are not widely available (Storch et al., 2007; Valderhaug et al., 2004). Most approaches to family-based interventions have focused on the children and adolescent population where parents have been included as the participants (Freeman et al., 2008; Lewin et al., 2014; Piacentini et al., 2011). Family-based interventions in adult population have been tested mostly as adjuncts to CBT (Grunes et al., 2001; Thompson-Hollands et al., 2015) in the group format (Van Noppen et al., 1997) or in the context of solely adult romantic/intimate relationships as couple based CBT (Abramowitz et al., 2013a; Belus et al., 2014; Boeding et al., 2013).

Family-based psychotherapeutic interventions, however, are lengthy, time-intensive and often not feasible in most resource-constrained situations. A recent randomized controlled trial (RCT) (Thompson-Hollands et al., 2015) tested the efficacy of adjunctive brief family intervention of 2 sessions in reducing family accommodation. Patients received a course of standard ERP (a mean of 18 sessions) but their family members (n = 18) were randomized to either receive or not receive the adjunctive intervention, consisting of two sessions of psychoeducation and skills training in reducing accommodation. Patients whose family members received adjunctive treatment showed significant reduction in the Yale-Brown Obsessive Compulsive Scale (Y-BOCS) score at weeks 8 and 16 and a trend toward significance at week 25. The family accommodation scores declined significantly and accounted for a significant reduction in symptom severity at week 8. Another recent open-label study (Remmerswaal et al., 2016) added brief family intervention (5-sessions, 90 min each) to regular CBT and

found significant reduction in symptoms severity and family accommodation. A study by Peris and Piacentini examined efficacy of adding brief 6-sessions positive family interaction therapy to 12-week individual CBT in a randomized controlled trial involving 24 youths with OCD and found higher response rate (70%) compared to CBT alone (40%) (Peris and Piacentini, 2013). These preliminary studies support the need to test brief psychotherapeutic interventions in OCD.

This study was an attempt to develop and test the efficacy of a comprehensive and time-efficient family-based psychosocial intervention in OCD in the context of limited resources. The aim of the study was to examine whether a brief family-based intervention (BFBI) as an adjunct to SRIs, was more effective than SRI + relaxation exercises (RE), in improving the outcome of OCD. We hypothesized that the BFBI would result in a higher response rate compared to the RE. We also hypothesized that adjunctive BFBI would result in significant decline in severity of the illness and improvement in family measures over time compared to the adjunctive RE.

#### 2. Method

#### 2.1. Participants

Participants in the study were recruited from the specialty OCD clinic of the National Institute of Mental Health and Neurosciences (NIMHANS), Bangalore, India over a period of 20 months (1st May 2012 to 31st December 2013). The Institute Ethics Committee approved the trial for ethical aspects. It was registered under the Clinical Trials Registry- India (CTRI) (registration number: CTRI/2012/06/002740). All participants provided written informed consent to participate in the study. The study was carried out in accordance with the Declaration of Helsinki guidelines.

Eligible participants were aged between 18 and 45 years, had DSM-IV-TR (American Psychiatric Association, 2000) diagnosis of OCD of at least 1 year duration and of at least moderate severity (Y-BOCS score ≥ 20; Goodman et al., 1989b), and were on stable doses of SRIs for a minimum of 2 months prior to the study. We employed a Y-BOCS cutoff score of 20 since there is some evidence that those with less than that score may not be significantly impaired (Eisen et al., 2006). Participants were required to have a family member (related by blood or by marriage) who was primarily involved in care-giving and staying with them at least for previous one year. A stay of at least 1 year was decided arbitrarily to ensure that we were dealing with a family member who was involved in care-giving and was likely to continue offering care. If more than one member of a patient's family was involved in caregiving, the patient was asked to select one family member with whom he/she had most interaction. Although it is ideal to include multiple family members, we included only one family member because of practical difficulties in getting multiple family members to participate in the study. In our experience, it is often one family member who accompanies a patient because of many logistic and practical difficulties such as cost involved in travelling, distance, lack of time etc. Patients with comorbid schizophrenia, schizoaffective disorder, bipolar disorder, intellectual disability and serious concomitant medical disorders and those who were non-responders to 2 or more SRIs (Shetti et al., 2005) or had received or were receiving CBT were excluded. Family members were excluded if they had severe psychiatric or neurological disorders or were involved in the care of another family member suffering from serious physical or mental illness or had received similar psycho-social intervention earlier.

#### 2.2. Randomization

Patients who met the study criteria were randomized to either the BFBI or RE (allocated 1:1) using a computer-generated random sequence. Random allocation was concealed using sequentially numbered, sealed, opaque envelopes. Subjects were enrolled into the study

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