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Pilot study of exposure and response prevention for Japanese patients with obsessive-compulsive disorder

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ABSTRACT

This pilot study was conducted to evaluate the feasibility and efficacy of exposure and response prevention therapy in Japanese patients with obsessive-compulsive disorder. This study was the first to examine the effectiveness of exposure and response prevention therapy provided by Japanese clinical psychologists. The sample comprised 37 adults (male = 17, female = 20, mean age = 35.7 years, standard deviation [*SD*] = 10, mean Yale-Brown Obsessive Compulsive Scale score = 26.9, *SD* = 23.35) with a diagnosis of obsessive-compulsive disorder receiving treatment. Individually administrated exposure and response prevention was provided to the 37 patients with obsessive-compulsive disorder. We evaluated the feasibility and safety of the program using the dropout rate and adverse events. The primary outcome was the reduction of the Yale-Brown Obsessive Compulsive Scale score between the pre- and post-treatment periods. Secondary outcomes were depression, anxiety, and quality of life. Of the 37 patients, 5 (14%) dropped out and 32 (86%) completed the entire program. No severe adverse event was observed. The patients reported significant reductions in the Yale-Brown Obsessive Compulsive Scale score (obsession: Hedges' g = 2.11, 95% CI [1.57, 2.68]; compulsion: Hedges' g = 2.05, 95% CI [1.41, 2.56]). Some secondary outcomes (depression and quality of life) also showed significant change. The results suggest that the exposure and response prevention program provided by Japanese clinical psychologists is an efficacious and feasible treatment approach for Japanese patients with obsessive-compulsive disorder.

1. Introduction

Obsessive-compulsive disorder (OCD) is a psychiatric condition characterized by obsession (persistent unwanted images or thoughts) and compulsion (a repetitive or ritualized behavior; American Psychiatric Association, 2013). The lifetime prevalence rate of OCD is between 0.3% and 3.1% in the U.S. (Fontenelle, Mendlowicz, & Versiani, 2006). Although reliable epidemiologic data of Japanese OCD patients do not exist, previous hospital-based investigations have suggested that the lifetime prevalence rate of OCD in Japan is 0.51–3.82% (Matsunaga, Kiriike, & Oya, 2004).

Currently, exposure and response prevention (ERP) and selective serotonin reuptake inhibitors are widely perceived as the first-line treatment options for OCD (Foa, Franklin, & Moser, 2002). Treatment by ERP exposes patients to feelings of anxiety or disgust without engaging a ritualized or avoidant behavior and habituates patients to the stimulus (Foa, 2010). The results of a recent meta-analysis (Sanchez-Meca, Rosa-Alcazar, Iniesta-Sepulveda, & Rosa-Alcazar, 2014) showed large effect sizes for a combination of cognitive-behavioral therapy (CBT) and medication therapy (Cohen's d = 1.70), CBT alone (Cohen's d = 1.20), and clomipramine (Cohen's d = 0.74) at the post-treatment period.

In Japan, Nakatani et al. (2005) reported the effectiveness of ERP in the first randomized controlled trial (RCT), which was conducted on 31 OCD patients who met the DSM-III-R criteria. Twelve weeks of treatment were provided for the patients, who were divided into three groups (ERP with placebo, fluvoxamine with autogenic training, and autogenic training with placebo). The ERP was delivered by at least two experienced psychiatrists. The study reported a significant Y-BOCS score reduction in the ERP group as compared with the fluvoxamine group during the post-treatment period (between group effect size: Cohen's d = 0.97). After Nakatani's study, several studies related to ERP among Japanese people were reported. Okajima, Hashimoto, Noguchi, and Harai (2007) conducted a longitudinal study of improvement

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factors in Japanese OCD patients, and Yamanishi et al. (2009) investigated the brain images of treatment-resistant OCD patients after 12 weeks of ERP. Most other reports were case studies. In the two major clinical trials, Nakatani et al. and Yamanishi et al. utilized the same treatment manual (Iikura, 1999), and an updated treatment manual that is suitable for current Japanese clinical settings should be considered.

Although Nakatani's RCT and other studies proved the effectiveness of ERP, the accessibility of ERP for individuals with the potential for OCD is insufficient. One of the reasons for the difficulties of dissemination of ERP in Japan is the lack of well-trained therapists. Horikoshi (2015) investigated the implementation state of CBT in 617 governmental facilities and 3339 medical facilities. Of these facilities, 76.1% reported that they were not able to provide CBT to patients who seek it and the majority of the facilities reported a lack of well-trained therapists. Considering the increasing number of ERP therapists, it is necessary to expand treatment availability using co-medical staff (nurses, clinical psychologists, social workers, etc.); however, no RCT has been conducted of Japanese co-medical staff to examine the effectiveness of ERP.

In Nakatani's and Yamanishi's studies, treatment providers were experienced psychiatrists, and other medical staff were not included as therapists. Although these studies increased the visibility of ERP in Japanese society, effective ERP therapists remain scarce, as indicated by Horikoshi (2015). Moreover, the Japanese national insurance scheme announced that the coverage of ERP for OCD was limited to treatment by medical doctors and nurses (Ministry of Welfare and Health, 2016). It should also be noted that mastering western psychotherapy practices such as cognitive behavioral therapy and ERP have been hindered by language differences, leading to very few RCTs of psychotherapy in Japan (Ono et al., 2011). For this reason, we need to create a buy-in treatment workbook for both Japanese patients and therapists and increase the numbers of clinical trials led by Japanese clinical psychologists.

The present study examined the feasibility of an ERP program delivered by clinical psychologists. In the exploratory phase of our present study, many patients came to the session with their family members who needed support regarding interacting with the patient while he or she was engaging in his or her rituals. Therefore, we administered one family educational session that permitted optional family participation in the ERP, to educate the family members about family accommodation. Family accommodation, in which the patient's family members help the ritualistic behavior, is known to be a maintenance factor of OCD (Calvocoressi et al., 1995).

2. Method

2.1. Trial design

The present clinical trial was an open-label, single-site, single-arm study.

3. Participants and setting

Participants received the ERP treatment without cost. The treatment and assessment were conducted at the National Center fore Neurology and Psychiatry (NCNP). Thirty-seven participants were recruited from April 1, 2012 to April 15, 2016. All participants were recruited from outpatients who were receiving regular treatment at the NCNP hospital (Fig. 1). To recruit, we received referral from psychiatrists at the NCNP of potential participants who had OCD as a primary diagnosis and who had shown interest in CBT. Initially, the research coordinator gave participants a full explanation of the purposes and procedures of the study and received written informed consent from each participant. At the initial screening, the participants were asked to undergo a clinical interview using the Structured Clinical Interview for DSM-IV (First, Spitzer, Gibbon, & Williams, 2002), the Mini-International Neuropsychiatric Interview (MINI; Sheehan et al., 1998), and the Yale-Brown Obsessive Compulsive Scale (Y-BOCS; Goodman et al., 1989). Participants fulfilling the full diagnosis of OCD and the required Y-BOCS scoring (eight or higher, mild OCD) were invited to fill in the following screening questionnaires: the Beck Depression Inventory-II (BDI-II; Beck, Steer, & Brown, 1996), the Quick Inventory of Depressive Symptomatology (QIDS; Rush et al., 2003), the Overall Anxiety Severity and Impairment Scale (OASIS; Campbell-Sills et al., 2009), and the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36; McHorney, Ware, & Raczek, 1993).

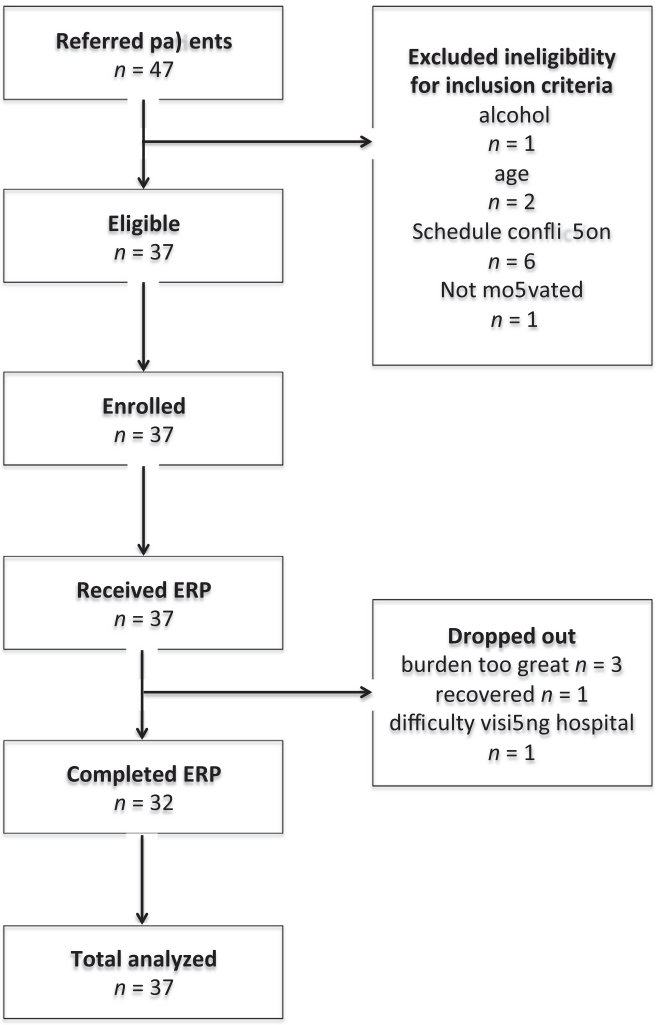

Fig. 1. Consort diagram.

The inclusion criteria were as follows: (1) aged 20–65 years at study entry, (2) outpatient receiving regular treatment at the NCNP, (3) primary diagnosis of OCD at screening, and (4) Y-BOCS score greater than or equal to eight at screening. The exclusion criteria were as follows: (1) any alcoholism or substance abuse in the past 6 months, as ascertained by the MINI; (2) history of structured CBT elsewhere; (3) other mental disorder, except OCD, as a primary diagnosis (AXIS-1 disorder); (4) dementia; and (5) unstable physical condition.

Regarding the sample size, we set that the least target number of *n* based upon Moore's suggestion that a pilot study should have *n* of at least 12 (Moore, Carter, Nietert, & Stewart, 2011). For the maximum number of *n*, we aimed to recruit as many patients as possible during the study period to estimate effect and sample size precisely for the future RCT. As a result, 37 participants were included. This sample size was sufficiently large for the primary outcome (Y-BOCS), since a large