Official Title:

Dealing With Intrusive Thoughts in OCD - a Comparison of Detached Mindfulness and Cognitive Restructuring

Date of Document:

July 12th, 2018

NCT number:

NCT03002753

Methods

Study Design

The study protocol was reviewed and approved of by the ethics committee of the Department of Psychology at the University of Münster, Germany. Additionally, the study protocol was registered at ClinicalTrials.gov under the ID NCT03002753. All participants provided written informed consent after the study procedure had been fully explained. The study was conducted between January 2017 and June 2018. The study employed a randomized, controlled, waitlist control group design (WLCG). Participants randomized to the non-waitlist (NWL) group started their treatment at the beginning of the week following Pre1 assessment whereas participants randomized to the waitlist control group (WL) started treatment with a delay of two weeks.

Procedure

Participants were recruited via postings in social media including OCD-related German online platforms as well as via posters in university buildings and flyers that were distributed in surrounding psychiatric, neurologic and dermatologic practices and outpatient departments as well as in local physicians' practices. Recruitment also involved repeated advertisements in local newspapers and emails to local psychotherapists. Additionally, some patients were recruited via the psychotherapeutic outpatient department of the University of Münster.

Participants received € 30 each for the completion of both pre- and post-assessment as well as € 40 for completing follow-up assessment. Moreover, participants in the WL were paid additional € 20 for their participation in the second pre-assessment (Pre2). Beyond that, participants received an additional amount of € 80 to € 100 for filling in questionnaires of a smartphone-based ecological momentary assessment (EMA) study that was run prior to the

first treatment session and directly after the last treatment session. Results of the EMA study will be reported elsewhere.

Assessment

A two-step assessment was conducted to check inclusion/exclusion criteria. The first step involved a phone screening that was conducted by a graduate student research assistant. Second, participants meeting the criteria of the phone screening were invited to an assessment session (Pre1) which was conducted by one of six study evaluators. All evaluators were Master level psychologists currently participating in an advanced training to become a cognitive behavioral psychotherapist. They received special training in diagnosing OCD by the investigators. The evaluators were blind with regard to the treatment condition of the patient (MCT vs. CT) but could not be blinded in terms of whether the patient was in the WL or the NWL condition due to aspects concerning the organization of the study process. Pre1 assessment comprised about three hours and included, among others, the administration of the German versions of the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I, Wittchen, Zaudig, & Fydrich, 1997) as well as the German version of Y-BOCS (Hand & Büttner-Westphal, 1991). The level of premorbid intelligence was assessed by the Multiple-choice vocabulary intelligence tes*t* (MWT, Lehrl, 2015). Information about demographic variables as well as previous pharmacological or psychotherapeutic treatments was collected. At the end of the Pre 1 assessment, participants filled in a number of questionnaires (described in detail below) - most of which they additionally filled in prior to each treatment session to obtain process measures.

The primary outcome measure was the Y-BOCS total score, followed by several process measures described below. The primary outcome measure was assessed at three (NWL) or four (WL) time points. Baseline measures were collected during Pre1 assessment and, in the WL group, additionally during Pre2 assessment. Post-assessment was conducted

directly after the last treatment session. A follow-up assessment (FU) was conducted 4 weeks after the end of the treatment. During the follow-up period no additional treatment was provided, but participants were told and encouraged to further practice the techniques they had learned in therapy.

Inclusion and exclusion criteria

Inclusion criteria comprised a current primary diagnosis of OCD based on the SCID-I, a minimum total score of 16 in the Y-BOCS, a minimum age of 18 years, fluent German language skills and a minimum IQ of 80. Exclusion criteria included current suicidality or suicidal behavior during the last six months, a current or past diagnosis of bipolar or psychotic disorder, a current addictive disorder or a current borderline personality disorder. Also, participants were excluded if they were currently undergoing a cognitive-behavioral psychotherapeutic treatment focusing on OCD or if they had undergone such a treatment in the past 12 months. For patients under medication, it was required that the dose was stable for at least eight weeks prior to Pre1 assessment. Patients not meeting these criteria were told to contact the investigators when their medication had been stable for at least eight weeks. Similarly, patients withdrawing from medication had to be at least eight weeks off their prior medication before they entered the study.

Randomization

Based on the total Y-BOCS score and the total BDI-II score at baseline (Pre1) as well as age and gender, participants were randomized by minimization conducted with *MinimPy program 0.3* (Mahmoud Saghaei, 2010-2011) with default settings to either the WL or NWL. Either following Pre1 (NWL) or following Pre2 assessment (WL), participants were once more randomly allocated to the treatment group (MCT/CT) using the same minimization procedure as described above. Whereas for NWL, this second randomization was based on

the Pre1 scores of Y-BOCS and BDI-II, the Pre2 scores were used for the WL. The participants were randomly assigned to one of the two therapists, which were the first two authors. Both therapists were Master level psychologists at an advanced stage of their clinical training to become cognitive behavioral psychotherapist and were supervised by the fourth author.

Treatment

Treatment in both conditions (MCT/CT) comprised four sessions delivered within two weeks. Each session lasted 100 min. It was specified that there had to be two sessions per week, with a minimum of one day in between the two weekly sessions. The two treatment protocols were manualized by the first two authors following the guidelines of Wilhelm and Steketee (2006) for the CT group and of Wells (2011) for the MCT group, respectively. Based on the suggestions of the OCCWG, the cognitive therapy proposed by Wilhelm and Steketee (2006) focuses on six cognitive domains, which are *overimportance of thoughts, control of thoughts, overestimation of danger, desire for certainty, responsibility,* and *perfectionism*. As *overimportance of thoughts* refers to thought action fusion and *control of thoughts* contains beliefs about the need to control thoughts - which both are parts of metacognitive models of OCD - these domains were explicitly excluded from the CT manual in order to avoid an overlap with metacognitive aspects and strategies. Similarly, the MCT manual did not feature any references to a conceptual way of dealing with cognitions.

Adherence and competence ratings

All treatment sessions were videotaped. For adherence and competence ratings, four complete treatments from each therapist (two MCT and two CT, each) were randomly selected and then rated by another Master level psychologist on a 5-point Likert scale. The rater was at an advanced stage of his training to become a cognitive behavioral psychotherapist and was not otherwise involved in the study.

Cognitive Therapy (CT)

The first session of the CT condition consisted of psychoeducation about characteristics of OCD (e. g. the fact that obsessive thoughts are ubiquitous and therefore not the actual problem) and comprised the development of an individual cognitive model based on the model of (Salkovskis, 1985b, 1999). Focusing on the patient's individual obsessive-compulsive symptoms, the model was designed to explain the disorders' maintenance via the distorted appraisals of intrusions, which should therefore be questioned and altered. During the second session typical cognitive distortions occurring in OCD were explained (overestimation of danger, desire for certainty, responsibility and perfectionism) and strategies to question and modify these appraisals were provided and trained, drawing from Socratic questioning and logical and hedonistic strategies of disputation. Depending on the appraisal at hand, this would for instance include techniques such as multiplication of probabilities, distribution of responsibility, cost-benefit analysis, etc., whereas the whole process of questioning was recorded in writing. Prior to and after each questioning phase, the patient was asked to rate his/her level of conviction concerning the original appraisal. Additionally, s/he was encouraged to develop an alternative cognition and to practice this new cognition in everyday life. During the third session and the first part of the fourth session, these strategies were further trained. The last part of the fourth session consisted of summarizing the new knowledge and the techniques the patient had acquired during therapy. Homework during therapeutic sessions comprised monitoring and documenting obsessive thoughts and dysfunctional appraisals as well as engaging in the active questioning of the latter and practicing alternative cognitions in everyday life.

Metacognitive Therapy (MCT)

The first session of the metacognitive treatment condition comprised the same psychoeducation as in the CT treatment. Afterwards, therapist and patient developed an

individual metacognitive model of the patient's obsessive-compulsive symptoms (based on Wells, 2011), explaining the maintenance of the disorder via the mechanism of assigning obsessive thoughts too much importance and meaning. That is, in contrast to the CT condition, patients were taught that it is about their general attitude towards their obsessions, not about any specific appraisals in response to their obsessions. During the second session, therapist and patient developed a list of the most prominent obsessions, rating each obsession's frequency and its level of distress. This was followed by introducing the strategy of DM using different examples and metaphors and finally by training DM applying the suggestions by (Wells, 2011). Training DM usually involved the patients closing their eyes and following the therapist's standardized instructions to visualize an obsession, to dissociate oneself from the obsession and to switch to a mode of passive observing instead of active interaction. The third session and the first part of the fourth session were made up by further DM training. The last part of the fourth session was identical to the CT condition. Homework between therapeutic sessions comprised monitoring and documenting obsessive thoughts (only between sessions 1 and 2) and exercising DM several times per day.

Process Measures

Prior to each treatment session, participants completed the following questionnaires: German equivalent of the self-rating version of the Y-BOCS (Baer, 1993), German version (Gönner, Leonhart, & Ecker, 2007) of the Obsessive-Compulsive Inventory-Revised (Foa et al., 2002), German version (Ertle et al., 2008) of the Obsessive-Beliefs Questionnaire (Obsessive Compulsive Cognitions Working Group, 2005), German translation of the Thought-Fusion Instrument (Wells, Gwilliam, & Cartwright-Hatton, 2002), German translation of Beliefs About Rituals Inventory (Wells & McNicol, 2004), German translation of Stop Signals Questionnaire (Myers, Fisher, & Wells, 2009) and the German version of Beck Depression Inventory Revised (Hautzinger, Keller, & Kühner, 2006). German version

of Personality Inventory for DSM-5 (Krueger, Derringer, Markon, Watson, & Skodol, 2013) was assessed at Pre1. Study measures showed good to very good psychometric properties. The questionnaires were presented on a tablet computer using a web-based online-survey software (www.unipark.de). Results of the process measures will be reported elsewhere.

Homework Rating. During each session, homework compliance was rated by the therapist on a 7-point rating scale ranging from 0 (no homework implemented) to 7 (homework done exactly as the patient was told). These results will be reported elsewhere.