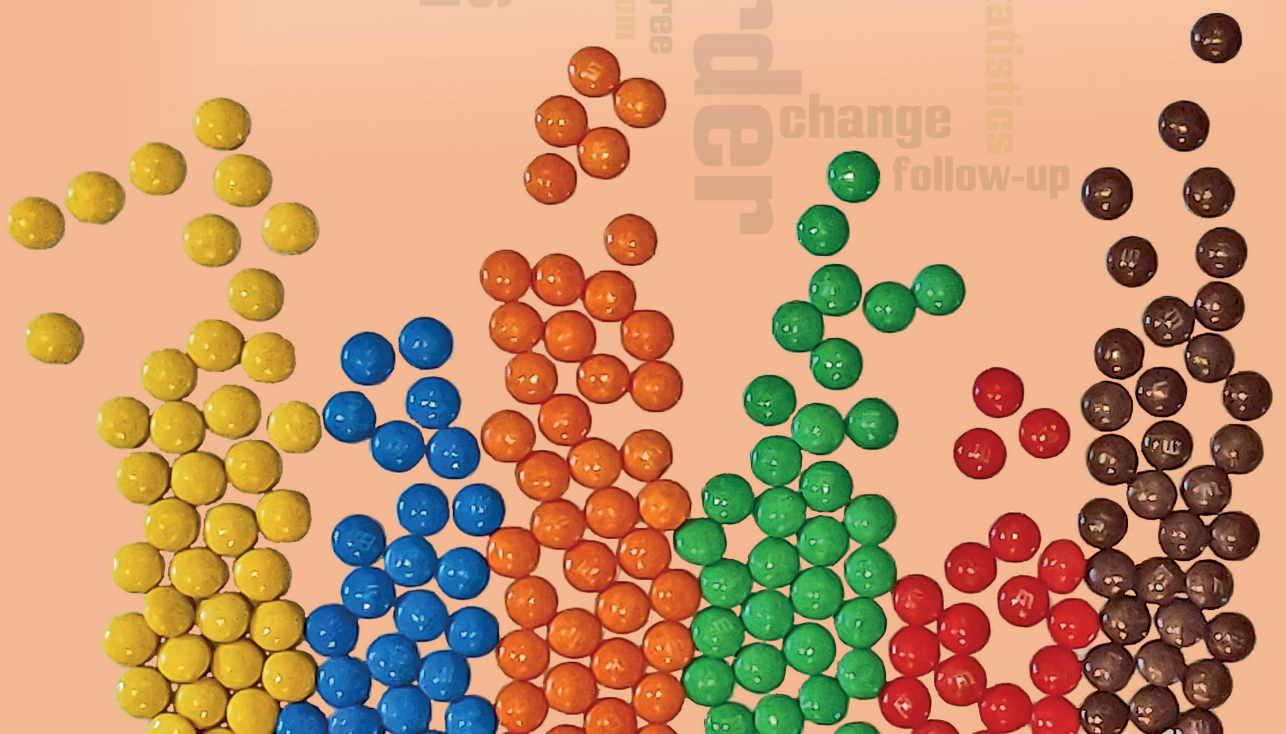
Metacognitive Therapy for Obsessive Compulsive Disorder

Kim Melchior



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Lay-out by: Proefschrift All in One (AIO) – Guus Gijben
Printed by: Proefschrift All in One (AIO)
Cover: Lucien de Konink, RowOne IT Services

Rotterdam, Parnassia Groep, 2021

Publication of this dissertation was supported by the Parnassia Groep and the Erasmus University Rotterdam.

Metacognitieve therapie voor obsessieve-compulsieve stoornis

Metacognitive Therapy for Obsessive Compulsive Disorder

Proefschrift

ter verkrijging van de graad van doctor aan de
Erasmus Universiteit Rotterdam
op gezag van de
rector magnificus

Prof.dr. A.L. Bredenoord

en volgens besluit van het College voor Promoties.
De openbare verdediging zal plaatsvinden op

donderdag 3 februari 2022 om 15.30 uur

door

Kim Melchior
geboren te Alkmaar

Erasmus University Rotterdam

Promotiecommissie

Promotor: prof.dr. I.H.A. Franken

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Chapter 1
General Introduction

Doing nothing is better than being busy doing nothing

Background

Clinical presentation and diagnostic features of obsessive-compulsive disorder

Obsessive-compulsive disorder (OCD) is a severe mental disorder. The main characteristic symptoms of OCD are obsessions and compulsions. Obsessions are repetitive thoughts (e.g., about contamination), images (e.g., violent or horrific scenes), or urges (e.g., to slap someone). Obsessions are experienced as intrusive and unwanted and cause marked distress and anxiety in the affected individual. A typical OCD patient attempts to avoid (e.g., by avoiding triggers), suppress (e.g., by using thought suppression) or neutralize the obsessions by performing compulsions. Compulsions are repetitive behaviors like washing or checking, or mental acts like praying or counting. In the majority of cases, the OCD patient has both obsessions and compulsions and the individual feels driven to perform compulsions in response to an obsession. Typically, the aim is to reduce the distress triggered by the obsession or to prevent a feared event. The most common themes in OCD include those of checking, washing, hoarding, symmetry, forbidden or taboo thoughts, and harm (Williams, Mugno, Franklin, & Faber, 2013).

The lifetime prevalence of OCD worldwide is estimated to be 2 to 3%, the 12-month prevalence 1.1% to 1.8%. In adulthood, females are affected in a slightly higher rate than males. The onset of symptoms is mostly gradually and the mean age of onset is 20 years. OCD is a long term disorder with a chronic course when untreated in 80% of cases. OCD is associated with significant functional impairment such as social isolation or inability to work. The comorbidity rate in OCD patients is high, especially with anxiety disorders (76%) and major depressive disorder (63%) and the course of OCD is negatively affected by the co-occurrence of these comorbid disorders (American Psychiatric Association, 2013).

Until 2013, OCD was classified under the category 'Anxiety disorders' in the Diagnostic and Statistical Manual of Mental Disorders-4th edition (DSM-IV). Based on the statement that obsessions and compulsions are the core symptoms of OCD, rather than anxiety, and the increasing evidence that OCD had more substantial similarities with other DSM disorders, a separate category was created in the DSM-5. In the DSM-5, OCD is now listed under the heading of 'Obsessive-Compulsive and Related Disorders', together with

Body Dysmorphic Disorder (BDD), Hoarding Disorder, Trichotillomania and Excoriation Skin Picking Disorder (American Psychiatric Association, 2013). The DSM-5 lists the following diagnostic criteria for OCD:

Diagnostic Criteria of Obsessive-Compulsive Disorder according to the DSM-5.

A. Presence of obsessions, compulsions, or both:

Obsessions are defined by (1) and (2):

1) Recurrent and persistent thoughts, urges, or images that are experienced, at some time during the disturbance, as intrusive and unwanted, and that in most individuals cause marked anxiety or distress.
2) The individual attempts to ignore or suppress such thoughts, urges, or images, or to neutralize them with some other thought or action (i.e., by performing a compulsion).

Compulsions are defined by (1) and (2):

1) Repetitive behaviors (e.g., hand washing, ordering, checking) or mental acts (e.g., praying, counting, repeating words silently) that the individual feels driven to perform in response to an obsession or according to rules that must be applied rigidly.
2) The behaviors or mental acts are aimed at preventing or reducing anxiety or distress, or preventing some dreaded event or situation; however, these behaviors or mental acts are not connected in a realistic way with what they are designed to neutralize or prevent, ore are clearly excessive.

B. The obsessions or compulsions are time-consuming (e.g., take more than 1 hour per day) or cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.
C. The obsessive-compulsive symptoms are not attributable to the physiological effects of a substance (e.g., a drug of abuse, a medication) or another medical condition.
D. The disturbance is not better explained by the symptoms of another mental disorder.

In the DSM-5, disorders listed under 'Obsessive-Compulsive and related Disorders', can be specified according to insight ranges. For OCD the following specifiers can be applied:

1) With good or fair insight: The individual recognizes that obsessive-compulsive disorder beliefs are definitely or probably not true or that they may or may not be true.
2) With poor insight: The individual thinks obsessive-compulsive disorder beliefs are probably true.
3) With absent insight/delusional beliefs: The individual is completely convinced that obsessive-compulsive disorder beliefs are true.

The mean time from OCD symptom onset to initial treatment is nearly 8 years (Altamura, Buoli, Albano, & Dell'Osso, 2010; Dell'Osso, Camuri, Benatti, Buoli, & Altamura, 2013). This is partly due to the fact that a majority of the OCD patients has poor or even no insight in the experienced symptomatology and only seek help until comorbid problems arise or when relatives encourage them to do so (American Psychiatric Association, 2013). Also, symptoms are often not reported to general practitioners or counsellors because the patient feels embarrassed about their thoughts and behaviors. Yet, OCD often deteriorates and becomes chronic while untreated so adequate treatment is crucial.

Current guidelines in clinical practice

For decades, OCD was seen as an untreatable disorder. Fortunately, we now know that specific forms of psychotherapy and pharmacotherapy with Selective Serotonin Reuptake Inhibitors (SSRI'S) are effective in treating this disorder (Skapinakis et al., 2016). The prognosis of OCD is especially substantially improved since the introduction of exposure and response prevention (ERP) in 1966 by Myer. The core principle of ERP is to expose patients to anxiety-provoking stimuli (e.g., objects, situations, or thoughts) while encouraging them to refrain from performing ritual behavior (Meyer, 1966). Our understanding of the underlying mechanisms responsible for the effects of ERP treatment has evolved over the years. Nowadays, the most accepted vision is that of the "expectancy violation model" which emphasize exposure exercises as a form of behavioral testing to disconfirm beliefs (Craske et al., 2016). More specifically, by encouraging the OCD patient to minimalize their checking behavior (e.g., checking the water tap), they can experience the feared event (e.g., flooding into the house) is not going to happen.

Meanwhile, also Cognitive Therapy (CT), in which cognitive belief domains like catastrophizing, inflated responsibility and intolerance of uncertainty are addressed with specific cognitive techniques (e.g., 'questioning the evidence' or 'pie chart method'), has been found to be effective in treating this disorder (Skapinakis et al., 2016). A summary of the clinical guideline for OCD in the Netherlands in which both ERP and CT are contained, is shown in Figure 2. It must be mentioned however that this clinical guideline is outdated, since the differentiation between exposure therapy and cognitive therapy is trivial with our enhanced understanding of "belief confirmation" as underlying mechanism responsible for change during exposure exercises. Nowadays, both ERP and CT are seen as specific forms of Cognitive Behavioral Therapy (CBT) and it would be expected that a differentiation between both treatment forms is no longer made in a future revision of the clinical guideline for OCD.

Many studies and meta-analyses have established the effectiveness of ERP and CT for OCD (Olatunji et al., 2010; Öst et al., 2015; Rosa- Alcázar et al., 2008; Skapinakis et al., 2016). For both ERP and CT, large effect sizes between pre-treatment en post-treatment scores on primary OCD symptoms measures are found. Also, both treatments are more effective in comparison with control conditions. Olatunji et al. (2013) found some evidence suggesting ERP may be more effective than cognitive therapy in treating OCD. Since there is also a larger amount of effectiveness studies for ERP in comparison to CT, especially into the effectiveness on long term follow-up, ERP is regarded as the psychological treatment of first choice for OCD (Trimbos-institute, Multidisciplinary Guideline Anxiety Disorders, 2013). Meta-analysis also suggests pharmacotherapy with a SSRI as an effective treatment, but psychotherapeutic interventions had a larger effect for OCD patient without comorbid depression (Skapinakis et al., 2016). Combination therapies are only recommended if patients had a comorbid depression or for them who show no or only partly response to cognitive behavioral therapy.

Aim of the current thesis: why a metacognitive model and therapy?

Although the prognosis of OCD improved substantially since the introduction of ERP in 1966, treatment outcomes are suboptimal for the majority of patients. Despite many meta-analyses supporting the statistically significant results of exposure therapy, there is a large discrepancy regarding these results and the clinically relevant change for patients. There are two main problems with ERP in clinical practice. First, of all patients which are offered ERP, approximately 25% refuse treatment and another 25% drop-out from

therapy prematurely (Olatunji, Cisler, & Deacon, 2010). A study of Franklin and Foa (2007) revealed that the main reason for patients to refuse treatment was the belief that ERP is difficult, whereas the main reason for dropping-out prematurely was the demanding requirements of treatment interventions, which were too hard to tolerate. These negative beliefs about the demanding nature of exposure interventions are not only found in patients, but also in therapists. Specifically, research has shown that many therapists believe that patients' anxiety will increase in such a way during exposure, that patients might decompensate during exposure tasks (Cook, Schnurr, & Foa, 2004; Deacon, Lickel, Farrell,Kemp, & Hipol, 2013). Overall it appears that engaging and maintaining in ERP treatment is challenged by negative beliefs about ERP by both patients and therapists. A second main problem with ERP is that the majority of OCD patients treated with ERP continue to experience disturbing OCD symptoms after treatment. Fisher and Wells (2005) developed standardized criteria to classify patients as not recovered, recovered (but still disturbing

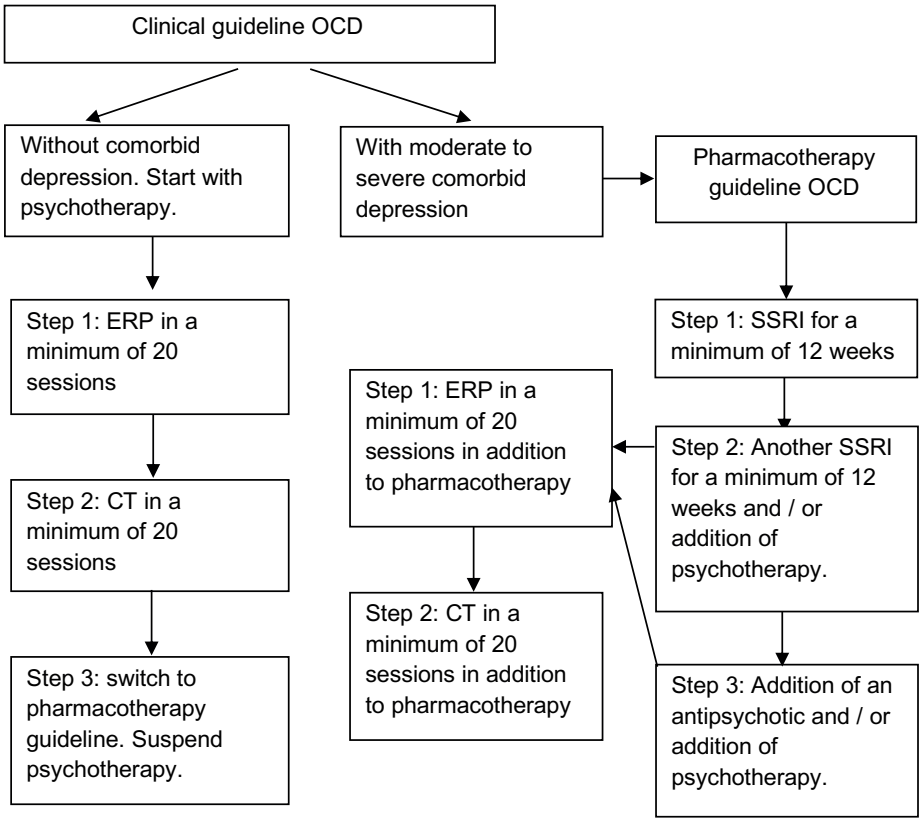

Figure 1. Summary of clinical guideline for OCD, version 2013.

symptoms), or asymptomatic (no disturbing symptoms). Although about 60% of treatment completers achieve recovery after ERP, only approximately 25% of patients is asymptomatic following treatment (see figure 3).

In sum, approximately 25% OCD patients refuse ERP treatment, another 25% drop-out prematurely during treatment, and of the treatment completers only 60% meets criteria for recovery. Most of them, however, still experience disturbing symptoms afterwards, as only 25% can be classified as 'symptom-free' after treatment. As such, it seems crucial to further improve treatment efficacy to overcome these problems. It has been suggested that progress might be made by basing treatment on key cognitive processes involved in the development and maintenance of OCD. One promising novel approach is the metacognitive model and treatment for OCD, which states that metacognitive beliefs about obsessions and compulsions are such sustaining cognitive processes.

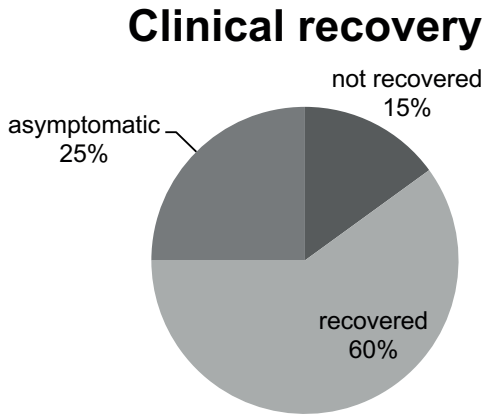

Figure 2. Percentages clinical recovery after ERP treatment in OCD according to standard criteria of Fisher and Wells (2005).

The metacognitive model of psychopathology

The metacognitive model of psychopathology was first described by Wells and Matthews (1994, 1996). The core principle of the metacognitive model is that psychopathology evolves and persists because of a particularly perseverative cognitive style, called the Cognitive Attentional Syndrome (CAS). The CAS consists of dysfunctional cognitive strategies in reaction to distressing thoughts or feelings, like worrying, threat monitoring and thought suppression. The model states that distressing thoughts and

feelings are normal occurring phenomena, but when a person responds to these with CAS activity, psychological distress extends. The CAS arises from dysfunctional beliefs about inner experiences, called the metacognitive beliefs, such as 'worrying helps me to be prepared', and 'feelings like this means, I'm losing my mind'. Such metacognitive beliefs drive people to employ coping strategies as an attempt to manage stressful thoughts and feelings, the CAS. However, on the long term, these coping strategies turn out to be dysfunctional in a way psychological distress extends. The core principle of the metacognitive model is illustrated graphically in figure 4.

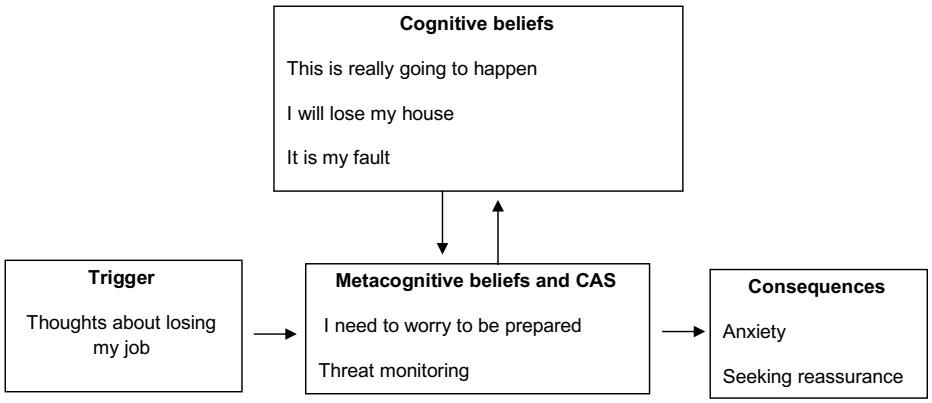

Figure 3. Metacognitive case conceptualization of a person experiencing distressing thoughts.

There are specific metacognitive models for different psychological disorders, for example for generalized anxiety disorder, posttraumatic stress disorder, major depressive disorder, and also for obsessive-compulsive disorder (Wells, 2009). The appointing of metacognitive beliefs implies that it is possible to develop alternative ways of experiencing normal occurring internal events like distressing thoughts. In metacognitive therapy (MCT), the metacognitive beliefs and the dysfunctional cognitive strategies of the CAS are identified and modified during treatment, instead of questioning the cognitive beliefs itself. CAS activities like threat monitoring and thought suppression are for the most part transdiagnostic strategies. Metacognitive beliefs on the other hand, are disorder specific.

For OCD it is proposed that two domains of metacognitive beliefs are fundamental in the development and maintenance of OCD: metacognitive beliefs about obsessions and metacognitive beliefs about the necessity of performing ritual behaviors. The first domain contains metacognitive beliefs about the significance and consequences of intrusive thoughts, also called fusion beliefs. Wells (2009; 2017) states that obsessions are misinterpreted because of these fusion beliefs and distinguish three categories: (1) Thought Action Fusion (TAF; Rachman, 1993) refers to the belief that obsessional thoughts can lead to the commission of an action (e.g., "If I think about stabbing my husband I will probably stab them"). Next, (2) Thought Event Fusion (TEF; Wells, 1997) refers to the belief that obsessional thoughts can make certain events happen (e.g., "thinking of a car crash means I will be involved in a car crash") or mean that an event has already occurred (e.g., "If I think I ran into someone with my car, I probably did it"). Finally, (3) Thought Object Fusion (TOF; Wells, 2000) refers to the belief that thoughts or negative feelings can be passed into objects (e.g., "my thoughts and feelings can contaminate objects"). The fusion beliefs can be activated by multiple intrusive experiences (e.g., situations, images, doubts) and give significance to them. This lead to cognitive processes like worrying about the thoughts and threat monitoring, and consequently leads to feelings of anxiety. This primes the second domain of metacognitive beliefs: The beliefs about the necessity of performing ritual behavior in order to reduce the anxiety and/or the perceived threat (e.g., "I must wash my hands, otherwise I will be unable to relax"). As a result, patients with OCD engage in both overt and covert ritual behavior, the compulsions. A key problem with these ritual behaviors is that they prevent the individual from learning that their metacognitive beliefs about the intrusive thoughts and ritual behaviors are inaccurate.

Several clinical trials evaluated the efficacy of MCT for different psychological disorders. A meta-analysis of Norman and Morina (2018) revealed that MCT is very effective in 25 trials, of which 15 were randomized controlled trials, in several populations of patients with anxiety, OCD and depression. They concluded that MCT is an effective treatment for a wide range of psychological disorders including OCD, and even may be superior to other psychotherapies like cognitive therapy. In order to draw firm conclusions about the relative effectiveness of MCT for specific psychological disorders, more randomized controlled trials in specific populations and larger numbers of participants are needed. In the current thesis, we focus on detailed description of the metacognitive model of OCD, on the assessment of the two metacognitive

belief domains which are considered as key cognitive processes in OCD, and on the evaluation of the effectiveness of MCT in comparison with the current treatment of choice for this difficult disorder to treat: ERP.

Outline of the current thesis

The first aim of this thesis is to provide an outline of the metacognitive model and the metacognitive therapy for OCD. To improve the understanding of the model and therapy, in chapter 2, OCD case Thomas is introduced to illustrate the model and the different treatment phases in the metacognitive therapy for OCD **(Chapter 2)**.

The second aim of this thesis is to provide an overview of the empirical evidence for the importance of the two proposed domains of metacognitive beliefs in OCD: metacognitive beliefs about obsessions and metacognitive beliefs about the necessity of performing ritual behaviors. Also, we introduce two self-report questionnaires to assess these belief-domains. The Thought Fusion Instrument (TFI: Wells, Gwilliam, & Cartwright-Hatton, 2001) measures metacognitive beliefs about the significance and consequences of intrusive thoughts and the Beliefs About Ritual Inventory (BARI: McNicol & Wells, 2012) assess metacognitive beliefs about the necessity of performing ritual behaviors. Finally, data about the validity and reliability of both measures is provided **(Chapter 3)**.

The third and most important aim of current thesis is to evaluate the effectiveness of metacognitive therapy for OCD. First, an open trial is described in which we examined the effectiveness of MCT among 25 OCD patients **(Chapter 4).** Next, we present a study protocol for a randomized controlled trial (RCT) to evaluate the relative effectiveness of MCT to ERP in an outpatient clinical sample of 90 OCD patients **(Chapter 5).** Finally, in chapter 6 the results of this RCT are presented **(Chapter 6).**

In the final chapter the conclusions and implications for clinical practice are discussed. Also, we provide implications and directions for future research **(Chapter 7)**.

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Chapter 2

Metacognitive Therapy for obsessive-compulsive disorder: A case report

Published as: Melchior, K., Franken, I. H.A., Heiden, C. van der (2018). Metacognitive Therapy for obsessive-compulsive disorder: A case report. *Menninger Bulletin, 82 (4), 375-389.*

Big Journeys begin with small steps

Abstract

Obsessive compulsive disorder (OCD) is a common and disabling disorder. The most effective psychological treatment for obsessive compulsive disorder is currently exposure with response prevention (ERP). Although ERP is an effective therapy, recovery rates are relatively modest, so there is room for improvement. Metacognitive therapy (MCT) for OCD focusses primarily on modifying metacognitive beliefs about obsessions and compulsions, instead of their actual content. Based on a few small preliminary studies there are some indications for the effectiveness of MCT for OCD. In the present paper the metacognitive model and treatment are discussed, as well as empirical support for its efficacy. As detailed descriptions of the application of this treatment modality in patients with OCD are scarce, we report a case study to illustrate the content of this form of therapy.

Background

Phenomenology and treatment literature. Obsessive-compulsive disorder (OCD) is characterized by obsessions and/or compulsions that cause significant interference with daily functioning. The lifetime prevalence of this disorder has been estimated to 2% (American Psychiatric Association, 2013). Both pharmacological treatment with antidepressant drugs and specific forms of psychological treatment are effective forms of treatment for OCD (Blanco et al., 2006). Meta-analytic reviews indicate that the psychological treatment of choice for OCD is exposure and response prevention (ERP; see Rosa-Alcazar, Sanchez-Meca, Gomez-Conesa, & Martin-Martinez, 2008; Ost, Havnen, Hansen, & Kvale, 2015; Skapinakis et al., 2016). In ERP treatment, a specific type of cognitive behavioural therapy (CBT), patients are exposed to anxiety-provoking stimuli (situations, objects, thoughts) that are avoided and/or trigger obsessive thoughts, with the instruction to refrain from engaging in compulsive behaviour (Meyer, 1966). This procedure is based on learning theory, in which classical conditioning is considered to be responsible for the development of obsessions, and operant conditioning processes maintain compulsive behaviours (Mowrer, 1951).

Although numerous studies have found statistical significant change and large symptomatic improvements, the majority of patients still experience distressing OCD-symptoms after ERP. More specifically, although about 60% of treatment completers achieve recovery, only approximately 25% of

patients are asymptomatic following treatment (Fisher & Wells, 2005). In addition, approximately 30% of patients with OCD refuse ERP or withdraw from treatment (Olatunji, Cisler, & Deacon, 2010). So it can be concluded that ERP is efficacious, but that there is room for improvement. One promising novel approach is metacognitive therapy (MCT; Wells, 1997, 2000). In the present paper, the metacognitive model and treatment of OCD are discussed, using a case example.

The metacognitive model of OCD

Theoretical model. Metacognition refers to thinking about one's own mental processes, beliefs about thinking and strategies used to regulate and control thinking processes, such as thought monitoring (Flavell, 1979). The metacognitive model of OCD concerns two subcategories of metacognitive beliefs that are supposed to be fundamental in the maintenance of the disorder. First, metacognitive beliefs about the significance and consequences of intrusive thoughts and feelings, the so-called fusion beliefs, and second, beliefs about the necessity of performing rituals. Three classes of fusion beliefs are specified: a) thought action fusion (TAF; Rachman, 1993) refers to the belief that obsessional thoughts can make someone do things he or she doesn't want (e.g., "thinking about jumping of the bridge will make me do it"), b) thought event fusion (TEF; Wells, 1997) refers to the belief that obsessional thought can make events happen or mean an event has happened (e.g., "thinking about a car accident means I will be involved in such an accident"), and c) thought object fusion (TOF; Wells, 2000) refers to the belief that thoughts or negative feelings can be transferred into objects (e.g., "my feeling of disgust could be passed into objects and from objects to other people"). Once activated by a trigger (intrusive thought or image, an urge or doubt), fusion beliefs give significance to obsessional thoughts which provokes worrying and anxiety. Consequently, patients with OCD engage in ritual behaviours based on a second class of metacognitive beliefs, beliefs about the necessity of performing rituals in response to obsessive thoughts (e.g., "I must wash my hands, otherwise I will never have peace of mind again"). These rituals are carried out until specific internal rules (instead of external observation) and stop signals are met (e.g., 'I must wash my hands until 'it feels right'). A key problem with these ritual behaviours is that they prevent patients from learning that their metacognitive beliefs about both intrusions and ritual behaviours are inaccurate and even backfire by increasing the awareness for intrusive experiences, as depicted in Figure 1.

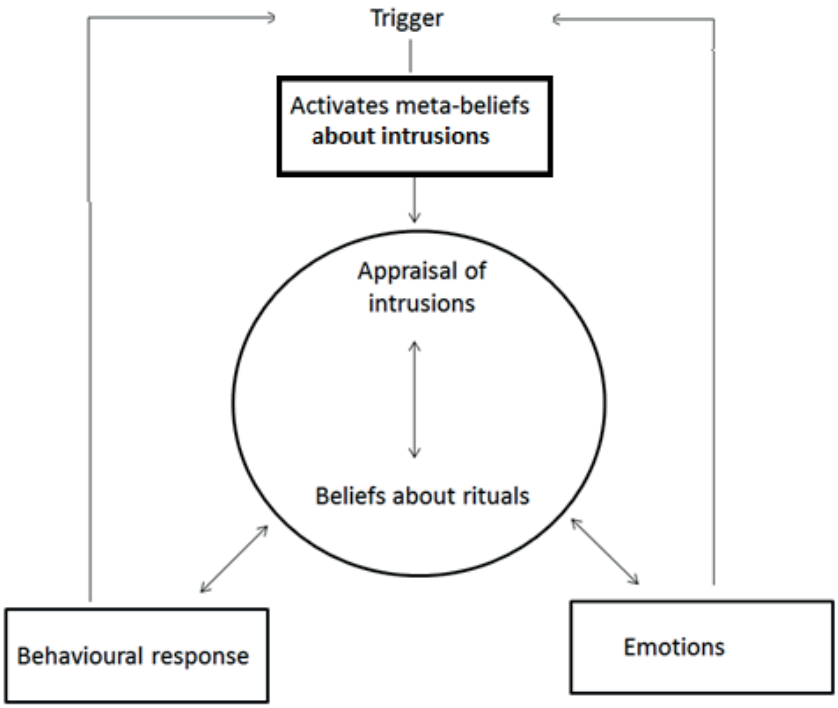

Figure 1. Metacognitive model of OCD (Wells, 1997)

There is a growing body of evidence that both thought fusion beliefs and beliefs about rituals contribute to OCD (see Wells, 2009). For instance, a high correlation has been found between metacognitive beliefs and OCD symptoms (Myers, Fisher, & Wells, 2009) and metacognitive beliefs have a predictive value for OCD symptoms (Wells & Papageorgiou, 1998).

Metacognitive therapy for OCD. Resulting from the metacognitive model, treatment should focus on modifying patients' beliefs about the importance of intrusive thoughts and the necessity of performing rituals (Fisher & Wells, 2008). Typically, metacognitive therapy for OCD consists of 10-15 treatment sessions, divided into 4 treatment phases as described in Table 1.

Table 1. Metacognitive treatment manual (Van der Heiden et al., 2016; based on Wells, 1997)

Phase	Session Topic	Techniques
1	Case conceptualization and identifying metacognitive beliefs	-Administration of the Thought Fusion Instrument (TFI) and the Beliefs About Rituals Inventory (BARI) -Guided questioning to identify metacognitive beliefs -Experiments to illustrate effect of coping behaviour -Detached mindfulness
2	Modifying metacognitive beliefs about obsessive thoughts	-Questioning the evidence of fusion beliefs -Behavioural experiment to test fusion beliefs (exposure with response commission, exposure with response prevention or ritual postponement and adaptive checking)
3	Modifying metacognitive beliefs about ritual behaviours	-Questioning the evidence of beliefs about rituals -Advantage-disadvantage analysis of ritual behaviour -Questioning the advantages of ritual behaviour -Ritual modulating experiments -Response prevention to test beliefs about rituals
4	Relapse prevention	-Relapse prevention -Development of a new plan for dealing with obsessions

Phase 1: Case conceptualization and identifying metacognitive beliefs. In the first sessions, an idiosyncratic metacognitive case formulation is generated, to increase patient awareness of metacognitive factors maintaining OCD. Metacognitive beliefs are identified using the OCD case formulation interview (Wells, 2009), in which all components of the model (trigger/intrusion, fusion beliefs, appraisal of the intrusion, beliefs about rituals, emotions and behavioural responses) are discussed based on the recent occurrence of an obsessive thought or image. After the case formulation has been derived, patients are socialized to the model. This can be achieved by explaining that obsessions are normally occurring phenomena, by behavioural experiments to illustrate the counterproductive effect of thought suppression (e.g. the thought suppression experiment in which the patient is asked to suppress the thought of a white rabbit which is rarely completely successful), or by questioning the consequences of coping behaviours (e.g., "If your ritual behaviours are helping, why do you still have a problem with OCD?"). Also, detached mindfulness (DM) is introduced as an alternative way to engage with obsessions. In DM patients are asked to observe their intrusive thouhts and notice them as "just mental events in the mind" instead of engaging with them. This can be achieved by using metaphors, such as a passenger train metaphor, in which patients are asked to deal with intrusions in the same way they deal with a train passing through a station as just a bystander (Wells, 2009).

Phase 2: Modifying metacognitive beliefs about obsessive thoughts. In the second treatment phase, fusion beliefs are modified using verbal cognitive restructuring techniques, such as questioning the evidence and searching for counterevidence, as well as behavioural experiments. In MCT for OCD, three specific behavioural experiments are used to test fusion beliefs. In exposure and response commission (ERC), patients are asked to continue with rituals while holding their intrusions in mind throughout. In this way patients can obtain distance from their intrusions and discover that they are only unimportant events in their mind instead of subjective realities that must be controlled. Metacognitively delivered exposure and response prevention or ritual postponement experiments are goal-oriented and used as a way of testing fusion beliefs. Finally, adaptive checking can be used to collect data, instead of getting reassurance, in order to modify a fusion belief. For instance, in case of a TAF belief "Thinking I've killed someone in a car accident means that I did" checking can be used to collect data unambiguously showing that the event has not occurred and the thought is only an irrelevant event in the mind.

Phase 3: Modifying metacognitive beliefs about ritual behaviours. In the next phase metacognitive beliefs about rituals are challenged, again by using verbal interventions (e.g., questioning the evidence and making an advantages-disadvantages analysis) and behavioural experiments, such as a ritual modulation experiment. In this experiment patients are asked to alternate between more and less ritual behaviour with the aim of assessing its impact on daily life and to test metacognitive beliefs about the necessity of performing rituals (e.g. "I must perform my rituals or else I will never find peace again").

Phase 4: Relapse prevention. In the fourth and final phase, a new plan for processing in response to intrusive thoughts is developed. This plan consists of attentional strategies and coping behaviours opposite to the strategies and behaviours of the old plan, e.g., applying detached mindfulness instead of worrying about intrusions. In addition, a relapse prevention plan is developed, consisting of a summary of the therapy, the case conceptualisation, a list of metacognitive beliefs and an overview of evidence challenging them.

Gap between current treatment protocols and MCT. The key theoretical insight underpinning MCT is that disordered higher order metacognitive processes such as beliefs about the importance and power of thoughts are responsible for the development and maintenance of OCD. As a result, MCT focuses on

the process rather than the content of thinking. Indeed, it focuses exclusively on challenging metacognitive beliefs about obsessions or compulsions, and makes no attempt to modify lower order appraisals such as inflated responsibility or perfectionism, as these belief domains are thought to be products of metacognitive beliefs (Gwilliam, Wells, & Cartwright-Hatton, 2004; Myers & Wells, 2005). The goal is to help patients bring thinking under flexible control and discover that it is possible to respond to negative thoughts in more adaptive ways, instead of replacing obsessive thoughts by reality-testing as in CBT. In addition to standard reattribution techniques such as socratic questioning and behavioural experiments (aimed at metacognitive beliefs!), MCT uses detached mindfulness as a specific technique to enhance flexible control and choice over reactions to intrusions. MCT also differs from CBT, and more specifically from ERP, in that it does not include exposure exercises aimed at habituation. Instead, behavioural experiments are used to modify metacognitive processes. One distinct behavioural experiment is ERC, aimed at enabling patients to shift to a 'metacognitive mode' of experiencing thoughts with the goal to illustrate that their intrusions do not hold any special significance or meaning (Fisher, 2009).

Metacognitive treatment for OCD: case conceptualization

Unique manifestation of OCD symptomatology. Thomas is a 57-year-old man referred by his GP for treatment of his long-lasting fear of contaminating himself or other people with asbestos. His intrusive thoughts and images about asbestos contamination are sometimes triggered by concrete stimuli, such as walking by an old house, but can also come without an obvious trigger. Thomas believes that having these obsessive thoughts means he actually is contaminated (an example of thought event fusion), resulting in strong feelings of anxiety. Thomas performs ritual behaviours to remain safe, such as washing his hands a couple of times when coming home, in order to reduce the risk of asbestos contamination. Not performing his rituals seems impossible to Thomas, as he believes he then "will never have peace of mind again" (a metacognitive belief about the necessity of performing rituals). To prevent intrusive thoughts from occurring, Thomas tries to avoid situations that might trigger his obsessions and displays daily routines, such as taking a one-hour shower every evening. As he earlier received ERP twice, with only modest and short-term results, MCT was offered as a new and promising treatment to Thomas.

Treatment

Assessment. At pre-treatment assessment, Thomas's total score on the Yale-Brown Obsessive Compulsive Scale (Y-BOCS; Goodman et al., 1989), a clinician-rated semi-structured interview for measuring OCD symptoms was 21, which can be classified as "moderate" in comparison with other OCD-patients. On the Padua-Inventory Revised (Padua-IR; Burns, Keortge, Formea, & Sternberger, 1996), a self-report scale for measuring OCD symptoms, Thomas's pre-treatment score was 53, which is "below-average" in comparison with OCD-patients (Van Oppen, Emmelkamp, Balkom, & van Dijck, 1995).

Interventions. Treatment started with the administration of the OCD case formulation interview. A verbatim fragment from this interview is shown below.

Therapist: "*Do you believe your thoughts about being contaminated with asbestos mean something*?" (identifying fusion beliefs)

Thomas: "*Yes, especially when a specific thought keeps coming, I become anxious*"

Therapist: "*What does it mean to you when a thought keeps coming back?*

Thomas: "*When I cannot get rid of a thought, I start to believe that the thought will warn me*"

Therapist: "*Warn you for what?*"

Thomas: "*That what I am thinking has actually happened. That I really am contaminated with asbestos. That's what frightens me*"

Therapist: "*How much do you believe that having these thoughts about being contaminated mean you actually are contaminated?*"

Thomas*: "At the moment of occurrence, 100%*"

Therapist: "*Did you do anything to prevent contamination with asbestos?*" (identifying behavioural responses)

Thomas: "*Yes. By washing my hands over and over again*".

Therapist: *"What is the worst that could happen if you shouldn't do those things?"*(identifying beliefs about rituals)

Thomas: "*Then I can't relax ever again*"

Therapist: *"How do you know when the contamination is over and you can stop washing?"* (identifying stop signals)

Thomas: *"I have no idea, I stop when I feel that it is okay to stop".*

The resulting case conceptualization is displayed in figure 2.

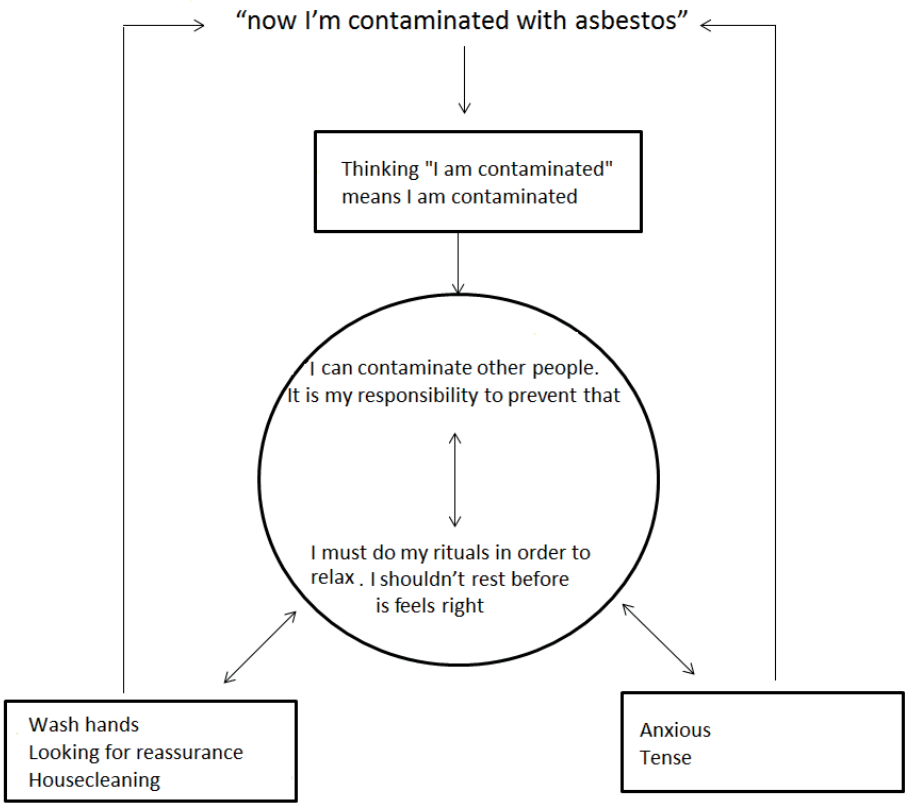

Figure 2. Case conceptualization of Thomas's fear of asbestos

After the case formulation was derived, psychoeducation about the metacognitive model and intrusions was given. The fact that approximately 80% of people experience intrusive thoughts occasionally (Rachman & de Silva, 1978) made Thomas realise that obsessions might not be the main problem since this percentage is much higher than the actual number of patients suffering from OCD. Next, detached mindfulness was introduced. After two weeks of practicing detached mindfulness with the passenger train metaphor every day for at least 15 minutes, Thomas noticed that both the duration and frequency of his obsessive thoughts had reduced.

The second treatment phase turned out to be the most helpful part of the therapy for Thomas. This seemed mainly due to the behavioural experiments for modifying fusion beliefs, which are described below.

Experiment 1: Adaptive Checking experiment. Thomas was asked to go home when having intrusive images of his house on fire to check if his house was actually on fire. The purpose of this experiment was to test his TEF belief "Thinking my house is on fire, means my house is on fire". As he repeatedly discovered that his house was not on fire, he concluded that these images only are events in his mind without actual meaning or power to cause an event to occur.

Experiment 2: Exposure with response commission experiment. Thomas practiced with washing his hands repeatedly while holding the obsessive thought "I am contaminated" in mind throughout his ritual. After a while, Thomas felt silly doing this and experienced a meta-level of the intrusion as 'just a disturbing but meaningless event in my mind'.

Experiment 3: Metacognitively delivered exposure with response prevention experiment. Thomas was asked to contaminate water with his own old mercury thermometer and then spray this "contaminated" water everywhere in the therapist's office without performing any ritual behaviour. At first, intrusive thoughts about contamination emerged, meaning that the office actually was contaminated (TEF) However, after a while Thomas realized that there were no actual signs of contamination, which he considered to be evidence for the alternative thought "the problem is only thoughts about contamination, not contamination itself". Again, Thomas concluded that intrusive thoughts about contamination are only meaningless events in his mind.

Although his metacognitive beliefs about rituals were not targeted at this point of treatment, both Thomas's ritual behaviours in reaction to obsessive thoughts and his avoidance behaviour were reduced after the second phase of therapy. In the third phase, an advantage – disadvantage analysis of his daily rituals without a clear relation to obsessive thoughts, such as showering for more than one hour every day, revealed that the amount of time spend on rituals was most important to Thomas, and outweighed the advantages. When the therapist asked Thomas why he still had problems with OCD if his rituals make him feel comfortable, Thomas realized that his rituals did not help him overcome his OCD. This notion was reinforced by carrying out a ritual modulating experiment, which is described below.

In a ritual modulating experiment, Thomas was asked not to take a shower for one evening (day 1), whereas he was allowed to perform his ritual the next day (day 2), in order to test his believe that not performing his rituals will cause him terrible distress and a sleepless night. On both days he monitored his degree of distress and his ability to sleep. Thomas reported being distressed at both nights; the first night because of not being allowed to take a shower and the second night because of the amount of time spent on his ritual behaviour. At both nights, he slept through the night, leading Thomas to the conclusion that he does not need his rituals in order to sleep. He further noticed that at day 1, he spend his free time by watching a movie which make him feel happy whereas he did not have time for relaxing activities at day 2 due to his time consuming ritual. The credibility of his belief "I need to perform my rituals, otherwise I will never have peace of mind" lowered to zero.

Finally, the therapist and Thomas worked on a relapse prevention plan. The most important element in his old plan for dealing with obsessions for Thomas was 'trying to get rid of the thought', which was driven by his fusion belief: "If I cannot get rid of a thought, then it will happen". Adaptive checking while holding the obsessive thought in mind was the most helpful strategy for Thomas, because this convinced him that obsessive thoughts by itself had no meaning or power. Other strategies in his new plan were applying detached mindfullness and reading his advantage-disadvantage analysis to remember that performing rituals are not necessary in order to relax.

Treatment outcomes. After treatment, Thomas no longer fulfilled the DSM-IV diagnostic criteria for OCD as assessed by the SCID-I. Scores on the OCD self report measures decreased from 21 (= moderate) to 1 (= very low) on the Y-BOCS and from 53 (below average) to 20 (very low) on the Padua-IR. In terms of clinical significant change, Thomas was classified as asymptomatic on the Y-BOCS (the most stringent criterion for defining recovery; Jacobson & Truax, 1991) because his posttreatment score on this measure met criteria for reliable change (a minimal reduction of 10 points on the Y-BOCS) and is below the cut-off score of 7, which indicates an absence of OCD symptoms (Fisher & Wells, 2005). Interestingly, scores on two questionnaires measuring OCD-specific types of metacognitions also decreased substantially. On the Thought Fusion Instrument (TFI, Wells, Gwilliam, & Cartwright-Hatton, 2001), a self-report questionnaire measuring fusion beliefs, Thomas score decreased from 590 at start to 130 after treatment. On the Beliefs About Rituals Inventory (BARI; McNicol & Wells, 2012), Thomas score decreased from 44 to 19. Together, these results suggest that the correction of metacognitive beliefs is the specific vehicle that is responsible for the treatment gains. Treatment gains were maintained at 3 months follow-up.

Conclusions

Results and impact on field. In case of Thomas, MCT appeared to be an efficacious treatment for OCD. This is in line with preliminary evidence from pilot studies supporting the efficacy of MCT for OCD, showing significant and large decreases on both OCD-specific as general outcome measures, and high recovery rates (Fisher & Wells, 2008; Rees & Van Koesveld, 2008; Van der Heiden, Melchior, Dekker, Damstra & Deen, 2016). However, further research comparing MCT to other active treatments for OCD is necessary to study the relative effectiveness of this innovative treatment. Therefore, we recently set up a randomized controlled trial (RCT) with a pretest-posttest-6-month-30-month-follow-up-design to compare MCT with ERP, the current golden standard for OCD patients.

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Chapter 3

The assessment of thought fusion beliefs and beliefs about rituals in clinical and non-clinical populations

Published as: Melchior, K., Franken, I. H.A., Vuijk, R., Peerbooms, V., Heiden, C. van der (2021). The assessment of thought fusion beliefs and beliefs about rituals in clinical and non-clinical populations: psychometric properties of the Thought Fusion Instrument (TFI) and Beliefs About Rituals Inventory (BARI). *Psychological Test Adapation and Development, July 2 2021, pp 1-12.*

Most important thing in life is learning how to fall

Abstract

Background. According to the metacognitive model, two domains of metacognitive beliefs play a role in the development and maintenance of obsessive-compulsive disorder (OCD). The Thought Fusion Instrument (TFI) has been developed to measure metacognitive beliefs about the significance of intrusive thoughts. The Beliefs About Ritual Inventory (BARI) assesses metacognitive beliefs about the necessity of performing ritual behaviors. Studies assessing the psychometric properties of the TFI and BARI are scarce. There are no studies assessing the factor structure of the TFI and the BARI.

Methods. In this study we assessed the psychometric properties of the TFI and the BARI in non-clinical (*n*=141) and clinical populations (OCD [*n*=60], anxiety disorder [*n*=30] and autism spectrum disorder [*n*=50]). In the non-clinical population, the factor structure is also explored.

Results. For both the TFI and the BARI, an explorative factor analysis revealed a one-factor solution, which now needs further exploration using confirmative approaches. The internal consistency appeared good and they had a moderate test-retest reliability. Convergent and divergent validity of the instruments appeared sufficient, but more research is required to draw firm conclusions. The criterion validity turned out to be moderate for the BARI but low for the TFI in measuring OCD-specific metacognitions.

Conclusions. Based on the explorative factor analysis, we hypothesize the TFI and the BARI to measure a single-factor construct. The current study shows that the TFI and the BARI are potentially suitable questionnaires to asses metacognitions in clinical and non-clinical populations. More research is required before clear recommendations can be made for the utility and use in clinical practice.

Keywords: Obsessive-compulsive disorder; fusion beliefs; beliefs about rituals; validation; factor structure; TFI; BARI.

Introduction

Obsessive-compulsive disorder (OCD) is characterized by distressing and intrusive recurring thoughts or urges, the obsessions, that individuals try to neutralize by engaging in repetitive actions, called compulsions (American Psychiatric Association, 2013). Unwanted intrusions are considered almost universal and occur in healthy individuals just as they do in OCD patients (Muris et al., 1997). OCD however, occurs in only 1.6% of the general population (Kessler et al., 2005). The metacognitive model (Wells, 1997) suggests that metacognitive beliefs contribute to the development of normal occurring intrusions into OCD.

In the metacognitive model of OCD, two types of metacognitions are distinguished (Wells, 2009). The first type concerns beliefs about the meaning and power of intrusive thoughts, the fusion beliefs. This concept contains three different subdomains, Thought Action Fusion (TAF), Thought Event Fusion (TEF), and Thought Object Fusion (TOF). TAF refers to the belief that certain thoughts will lead irrevocably to carrying out an act (e.g. "If I think about harming myself, I will do so"). TEF, the second subdomain, implies that solely thinking about an event is responsible for causing it in the future, or is a sign that the event actually did happen or is happening (e.g. "If I think of an unpleasant event, then it will happen"). Finally, TOF refers to the belief that it is possible to transfer thoughts and feelings to objects (e.g. "My memories can be passed into objects"). According to the metacognitive model, thought fusion beliefs are activated by a trigger (a normally occurring intrusion, urge or doubt) and consequently cause OCD patients to negatively appraise these triggers as overly important or even potentially dangerous, leading to phenomena like worrying and thought monitoring. Consequently, OCD patients experience distress. In turn, beliefs about the necessity of performing rituals are activated (e.g., I have to perform my rituals, otherwise I will never have peace of mind again), the second class of metacognitive beliefs in OCD, leading to the performance of ritual behaviors in order to get rid of the intrusive thought and experienced distress. As a result, because of the feeling of safety and rest after performing ritual behaviors, the positive metacognitive beliefs about the usefulness and necessity of the neutralizing rituals are exacerbated (Fisher & Wells, 2005). The metacognitive model is depicted in Figure 1.

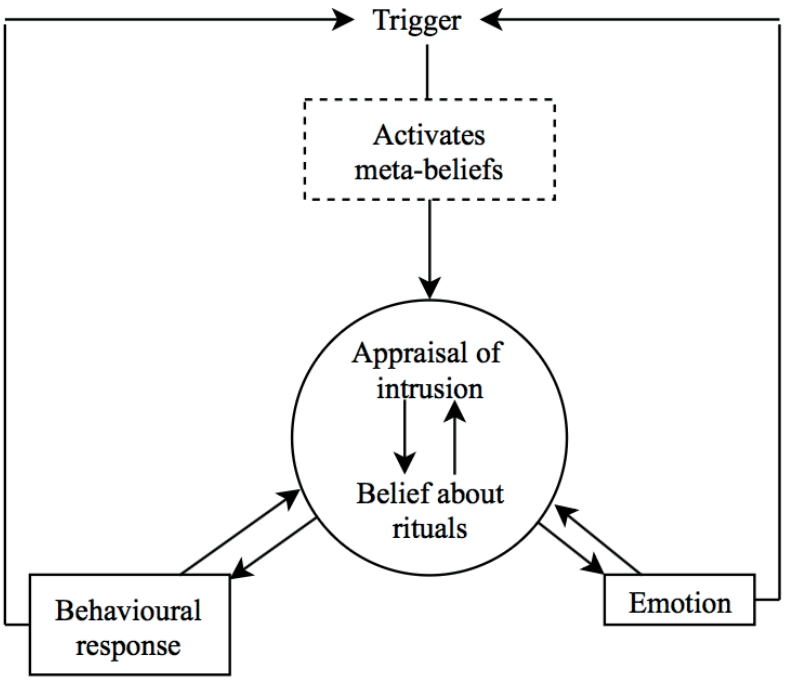

Figure 1. The metacognitive model of obsessive-compulsive symptoms (Wells, 1997)

It is assumed that all people experience some degree of fusion beliefs and beliefs about rituals, but there is empirical evidence that a high degree of these beliefs contribute to the development and maintenance of OCD (for an overview, see Fisher, 2009; Wells et al., 2017). Cross-sectional studies have shown that both fusion beliefs and beliefs about the necessity of performing rituals are significantly associated with symptoms of OCD (Gwilliam et al., 2004; Myers & Wells, 2005; McNicol & Wells, 2012). Moreover, support for a causal relationship between fusion beliefs and OCD symptomatology can be found in experimental research. Fisher and Wells (2005) manipulated thought-fusion in OCD patients, which led to changes in their obsessive-compulsive symptoms. Also, Myers and Wells (2013) found that experimental manipulation of fusion beliefs leads to an accretion of intrusive experiences. Myers et al. (2009) conducted a study to directly investigate the metacognitive model in a student sample and found that when they controlled for cognitive beliefs, worry, and threat, fusion beliefs and beliefs about rituals remained as independent predictors of obsessive-compulsive symptoms. In contrast, cognitive factors like responsibility and perfectionism that have been frequently associated with OCD (Frost & Steketee, 1997), did not turn out

to be independent predictors of the symptomatology of OCD. This finding was replicated by Hansmeier et al. (2016) in a large sample of patients with OCD and also in a clinical sample by Myers et al. (2017). Finally, support for the importance of metacognitive beliefs in OCD comes from therapy effect studies. Metacognitive therapy for OCD tailored to both fusion beliefs and beliefs about the necessity of performing rituals, leads to significant reductions in OCD symptoms (Fisher & Wells, 2008; Rees & Van Koesveld, 2008; Van der Heiden et al., 2016). To summarize, there is empirical evidence that a high degree of fusion beliefs and beliefs about rituals contribute to the development and maintenance of OCD.

Since there is empirical evidence for the importance of metacognitive beliefs in OCD, there is a demand for well-validated instruments that measure these constructs in both normal and clinical populations, for research purposes and for individual assessment. For the assessment of fusion beliefs, multiple scales have been developed containing only items about Thought Action Fusion (TAF), for example the Thought-action Fusion scale (Shafran et al., 1996), and as such, do not cover the full range of beliefs about thoughts across the three fusion domains that are considered relevant for OCD according to the metacognitive model. Also, in comparison studies, no differences between OCD and other clinical groups (e.g. anxiety disorders and depression) were found regarding fusion beliefs, as measured with the Thought-action Fusion scale (Rassin et al., 2001; Abramowitz et al., 2003; Solem et al., 2010; Hansmeier et al., 2016). This raises questions about the disorder-specificity of TAF as a single construct and underlines the need for instruments that measure the whole range of OCD specific metacognitive beliefs as disorder-specific parameter

The Thought Fusion Inventory (TFI; Wells et al., 2001) was designed in order to measure fusion beliefs across fusion domains that are considered relevant in the metacognitive formulation and treatment of OCD. The questionnaire consists of 14 items to assess beliefs about thoughts on a single scale, no separate subscales are formulated. Although it can be hypothesized that the three classes of fusion beliefs as described above, TEF, TAF and TOF, are represented in the TFI, this has not been investigated yet. There are some preliminary investigations addressing the psychometric properties of the TFI. Gwilliam et al. (2004) found a Cronbach's alpha for the overall scale of .89, suggesting a good internal consistency. Positive correlations between the TFI and theoretically related measurements, for example the Meta-Cognition Questionnaire (MCQ; Cartwright-Hatton & Wells, 1997), a

well-validated self-report scale for measuring metacognitive parameters in psychopathology in general, and positive correlations with obsessive-compulsive symptoms suggests a good convergent validity. However, these investigations were only carried out in a general population. Also, there are no studies available addressing the factor structure and the test-retest reliability of the TFI.

The Beliefs About Rituals Inventory (BARI; McNicol & Wells, 2012), is a 12-item unidimensional measurement to assess beliefs about the necessity of performing rituals. McNicol and Wells describe a Cronbach's alpha of .86 in their paper in which they introduce the BARI. They also reported preliminary evidence for the convergent and divergent validity since they found a higher correlation between the BARI score and the theoretically related Obsessive-Compulsive Inventory (OCI; Foa et al., 1998) than with a measure of worry (Penn State Worry Questionnaire, PSWQ; Meyer et al., 1990). No further studies have addressed the psychometric properties of the BARI so far, for example in clinical groups. There are also no studies available addressing the factor structure or the test-retest reliability of the BARI.

In sum, although there are some preliminary investigations into the psychometric properties of the TFI and the BARI, previous studies leave room for further research. Since the TFI and the BARI are of value for research purposes, for example for considering them as mechanisms of change in treatment studies, more research into the psychometric properties in both normal and clinical populations is necessary, especially into the factor structure and test-retest reliability. Secondly, since the questionnaires are also of value for clinicians, for example for individual assessment in psychological treatment for patients with OCD, investigation of the criterion validity of the measurements is also necessary.

The goal of the present study was to evaluate the psychometric properties of the Dutch versions of both the TFI and the BARI, (identical to the English versions). Three substudies were set up to accomplish this goal. In the first study, we used a non-clinical sample. First, we employed an explorative factor analysis on the data. We chose for an explorative factor analysis, rather than confirmative factor analysis since the factor structure of both the TFI and the BARI have not yet been investigated. Secondly, the reliability coefficients of the scales were determined, using both Cronbach's alpha and McDonald's omega coefficients. Finally, the convergent and divergent validity were assessed by studying the correlation coefficients between the

scales and other constructs. In order to investigate the convergent validity, we chose theoretically related constructs, to wit, obsessive compulsive symptoms (for which we use a measurement which assesses both obsessions and repetitive behaviors), a general measurement for metacognitive beliefs in psychopathology, and intolerance of uncertainty, which is also proposed as a disorder-specific cognitive domain involved in the development and maintenance of OCD (Freeston et al., 1994). The correlation between the TFI and the BARI is also an indicator of the convergent validity evidence. Next, the correlation coefficient with a divergent construct (depressive symptoms) is calculated. Although there is a high comorbidity between OCD and depression, there is no theoretical reason why OCD-specific metacognitive beliefs are directly associated with depressive symptoms. In a second study, a subpopulation of study one was asked to complete the questionnaires a second time after 4 to 6 weeks in order to determine the test-retest reliability coefficient of the scales. In the third study, we explore the validity and reliability coefficients of the TFI and BARI in an OCD sample. We also used two other clinical samples and a non-clinical control group to explore the criterion validity of the measurements by making a comparison between OCD and other anxiety disorders, and with patients with autism spectrum disorder (ASD). Since both OCD and ASD are characterized with repetitive thoughts and the urge to perform repetitive actions (McDougle et al., 1995), this offers a stringent test of the disorder-specific contribution of the factors.

Study 1

Reliability, validity and factor structure in a normal population

Participants and procedure

A group of 141 healthy subjects volunteered in this first study (28.8% male, 71.2% female). We used Shoukri et al. (2004; table 3) to determine the appropriate sample size needed in our studies, considering the number of questionnaires and measurement points in our study. Participants were recruited using snowball sampling (authors asked three relatives to complete the questionnaires and also asked these three participants to ask three relatives in their own lives to participate, and so on). The mean age of the participants was 46.7 (*SD* = 14.42, range 19-90 years). Eighty-nine percent of the sample had completed high school or a higher education level and 75.4% had a fulltime job. In the sample 43.9% was married and another 25.2% lived

together. A subsample of these participants (*n* = 55) were asked to complete the questionnaires twice, a second time after 4 to 6 weeks in order to assess the test-retest reliability (see study 2). There was no reward for participation.

Instruments

Thought Fusion Instrument (TFI, Wells et al., 2001)

The TFI was used for measuring metacognitive beliefs about the influence and meaning of thoughts. The TFI consists of 14 items (e.g., 'If I think about an unpleasant event, it will make it more likely to happen'), which have to be rated on an eleven-point scale from 0 (= 'I do not believe this at all') to 100 (= 'I am completely convinced this is true'). A total score is computed by summing up the scores on all 14 items. It is hypothesized that the three classes of fusion beliefs as described earlier, TEF, TAF and TOF, are represented in the TFI, but this has not been investigated yet. Also, there are no studies available addressing the factor structure of the TFI yet, so in our studies only the total score of the TFI is used.

The original English version of the TFI was translated into Dutch by one of the authors. This Dutch translation was also translated back into the original English language by a native speaker which showed that the meaning of the items stayed intact.

Beliefs about Rituals Inventory (BARI, McNicol & Wells, 2012)

The BARI was used as a self-report measure for assessing beliefs about the necessity to perform rituals. It consists of 12 items (e.g., 'I must perform my rituals, otherwise I will never find peace again') which are rated on a four-point scale from 1 ('disagree') to 4 ('agree'). A total score is computed by summing up the scores on all 12 items. Again, no information about the factor structure is available yet. The original English version of the BARI was translated into Dutch by one of the authors. Again, the Dutch translation was translated back into the original English language by a native speaker which showed that the meaning of the items stayed intact.

Padua Inventory-Revised (PI-R; Burns et al., 1996)

The PI-R was included as a self-report measure to assess obsessive and compulsive symptoms, and the degree to which these symptoms interfere with daily functioning (Dutch version: Van Oppen et al., 1995). The PI-R incorporates 41 items, which have to be rated on a five-point scale from 0 (= 'not at all') to 4 (= 'very much'). Both the original PI-R and the Dutch

translation were found to have satisfactory reliability, as well as good convergent and divergent validity (Van Oppen et al., 1995; Sternberger & Burns, 1990). The Cronbach's alpha in the present study was .93.

The Beck Depression Inventory, 2nd version (BDI-II; Beck et al., 1996)
The BDI-II is a widely used self-report instrument for measuring depressive symptoms. The BDI-II consists of 21 items which have to be rated on a scale from 1 to 4, describing the severity of depressive feelings in the past week. The BDI-II has adequate psychometric properties (Beck et al., 1996), which is also true for the Dutch version of the BDI-II (Van der Does, 2002). The Cronbach's alpha in the present study was .91.

Intolerance of Uncertainty Scale (IUS; Freeston et al., 1994)
The IUS is a 27-item self-report measure to assess emotional, cognitive and behavioral reactions to uncertain or ambiguous situations. Each item is scored on a scale from 1 to 5. A higher score indicates a higher amount of intolerance towards ambiguous situations. The Dutch version of this questionnaire demonstrated good psychometric properties (De Bruin et al., 2006). The Cronbach's alpha in the present study was .96.

Meta-Cognition questionnaire (MCQ-30; Wells & Cartwright-Hatton, 2004)
The MCQ-30 measures five domains of metacognition which are central in metacognitive models of psychological disorders. The MCQ-30 is the shortened and refined version of the original MCQ-65. The five subscales, which have been identified with explorative factor analysis and which have been verified by confirmatory factor analysis in multiple studies, are: positive beliefs about worry, negative beliefs about worry, low cognitive confidence, need to control thoughts, and cognitive self-consciousness (Cartwright-Hatton & Wells, 1997). Cronbach's alphas for the subscales range from .72 to .93. For our study, only the total score was used. This total score showed adequate psychometric properties in terms of test-retest correlation (.75) and a positive correlation was found between the MCQ-30 and other theoretically appropriate measures (Wells & Cartwright-Hatton, 2004). Although the psychometric properties of the Dutch version of the MCQ-30 are unknown, the Cronbach's alpha in the present study was good (.92).

Statistical analysis

Data were obtained using Qualtrics, an online self-report program for surveys. After reading the participant information and providing informed consent, the online survey was e-mailed to the participants. All statistical analyses were performed using SPSS, version 25.

As a first investigation of the factor structure of the questionnaires, we perform an explorative factor analysis using the principal axis factoring (PAF) method and using an oblique rotation to allow for correlations among potential factors. The item-total score correlations for the TFI ranged from .49 to .91 and all appeared significant. For the BARI the item-total score correlations ranged from .47 to .85, also all significant. Also, prior to conducting the factor analyses, the distribution of all items was inspected. None of the items were excessively skewed or kurtotic, so no items were dropped from the further analysis. All items were submitted to two separate PAF analyses. Since multiple researchers have shown that the Kaiser criterion (Kaiser, 1960) can misidentify the number of factors (Gaskin & Happell, 2014), and the scree plot can also be subjective in case of a more gradual slope, we used Parallel Analysis (PA; Horn, 1965) based on Monte Carlo simulations on randomly generated data. We used 5000 Monte Carlo simulations to generate a 95th percentile cut-off line which was displayed in a scree plot together with the eigenvalues from our data. Factors above this cut-off line were considered as meaningful and were used in a subsequent explorative factor analysis. The PA for our current study was run in SPSS, by using the SPSS code rawpar.spss developed by O'Connor (2000).

To evaluate the reliability of the scales, we used both Cronbach's alpha and McDonald's omega coefficients. We chose to use both of these since the Cronbach's alpha is the most widely used method for the evaluation of reliability, which makes comparison with earlier studies possible, however, Cronbach's alpha has been criticized recently since it is susceptible to problems with inflation and attenuation. Dunn et al. (2014) propose McDonald's omega as a more accurate estimation of reliability. For the calculation of McDonald's omega, the macro for SPSS by Prof. Andrew F. Hayes was used.

To explore the construct validity of the TFI and the BARI, Pearson's correlation coefficients were calculated with both convergent constructs (obsessive compulsive symptoms [PI-R], a general measurement for metacognitive beliefs [MCQ30] and intolerance of uncertainty [IUS]) and a

divergent construct (depressive symptoms [BDI-II]). We hypothesize that the correlation coefficients between the TFI, the BARI and the related convergent constructs will be substantially larger than the correlation with depressive symptoms (divergent construct).

Results

Factor structure

TFI:

First, a parallel analysis (PA) was performed to identify the number of factors to extract for our Principal Axis Factoring (PAF). In this procedure, eigenvalues from the raw data were produced, next to eigenvalues of a 95th percentile based on Monte Carlo Simulations. A scree plot of this 95th percentile cut-off line overlaid onto the eigenvalues of the raw data is presented in Figure 2. Our PA indicates three factors from the raw data which are above the 95th percentile cut-off line. However, the slope of the scree plot for this three-factor solution dramatically shifts after the first factor. Based on suggestions by Cattell (1966), who states that a dramatic change in the raw data eigenvalues indicates the cut-off for the amount of factors to extract, a one-factor solution can also be justified. This is also in line with the assumption that PA tends to indicate more factors than warranted and that additional procedures should be used to trim trivial factors (Buja & Eyuboglu, 1992). Neverthless, based on the PA combined with the assumption that there is a theoretical reason for a three-factor structure, a first inspection of this three-factor solution needs further investigation.

We conducted a principal axis factoring (PAF) with an oblique rotation on the 14 items of the TFI specifying a three-factor solution. The Kaiser-Meyer-Olkin measure verified the sampling adequacy for the analysis, KMO = .80. Bartlett's test of sphericity also indicated that the correlations between items were sufficiently large for PAF (χ^2 = 894.238, $p < .001$). In our first analysis based on the PA results, a three-factor solution accounts for 58.9% of the variance. Table 1 shows the factor loadings of the 14 items into this three-factor solution. When this three-factor solution was analyzed, multiple observations made the solution difficult to interpret. First of all, only two items loaded on the first factor and another two items loaded on the second factor. This can hardly be seen as sufficient to measure a meaningful construct. Also, multiple items loaded on more than one factor. Lastly, inspection of the three factors gives no theoretically reason for meaningful factors since the factors did not, for example, correspond with the three classes of fusion beliefs.

Based on the scree plot inspection which shows only one inflection, we also performed a second PAF for a one-solution structure. This one-solution structure appeared to explain 39.23% of the variance. Table 2 shows the factor loadings for each item for this one-factor solution. Applying Stevens' (2002) guidelines for substantive importance of factor loadings, a loading of .4 can be considered as significant. Based on this criterion, 2 items can be considered as less meaningful for the total score.

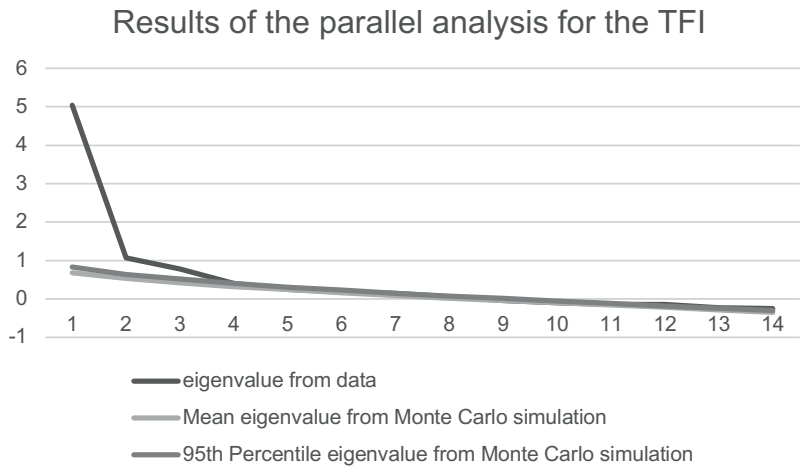

Figure 2. Scree plot of the results of the parallel analysis for the TFI

Table 1. Pattern matrix of the Exploratory Factor Analysis of the TFI for a three-factor solution.

Item	Factor 1	Factor 2	Factor 3
1	.037	.907	.002
2	.225	.261	.384
3	-.131	.316	.301
4	-.046	.368	.566
5	-.019	-.045	.472
6	-.014	-.072	.813
7	.122	.113	.473
8	.169	.230	.295
9	.165	.222	.005
10	.020	.037	.556
11	.812	.256	-.097
12	.408	-.087	.475
13	.339	.331	.177
14	.987	-.149	.135

Table 2. Summary of the Exploratory Factor Analysis of the TFI for a one-factor solution

Item	Factor loadings
1	.645
2	.666
3	.442
4	.688
5	.393
6	.601
7	.605
8	.595
9	.339
10	.543
11	.644
12	.620
13	.685
14	.656

BARI: For the BARI, a parallel analysis (PA) was also performed first to explore the number of factors to extract for our Principal Axis Factoring (PAF). A scree plot of the results from this PA can be found in Figure 3. Our PA indicates five factors from the raw data which are above the 95th percentile cut-off line. However, just as with the TFI, the slope of the scree plot for this five-factor solution dramatically shift after the first factor. Based on suggestions by Cattell (1966), and the assumption that PA tends to indicate more factors than warranted, a five-factor solution can hardly be meaningful in a twelve item questionnaire and additional procedures should be used to trim trivial factors (Buja & Eyuboglu, 1992), in the subsequent analysis we explore a one-factor structure. We conducted a PAF on the 12 items of the TFI. The Kaiser-Meyer-Olkin measure verified the sampling adequacy for the analysis, KMO = .81. Also, Bartlett's test of sphericity indicated that the correlations between items was sufficiently large for PAF (χ^2 = 962.35, p < .001). The one-solution structure appeared to explain 42.64% of the variance. Table 3 shows the factor loadings for each item for this one-factor solution. Applying Stevens' (2002) guidelines for substantive importance of factor loadings, all items can be considered as meaningful.

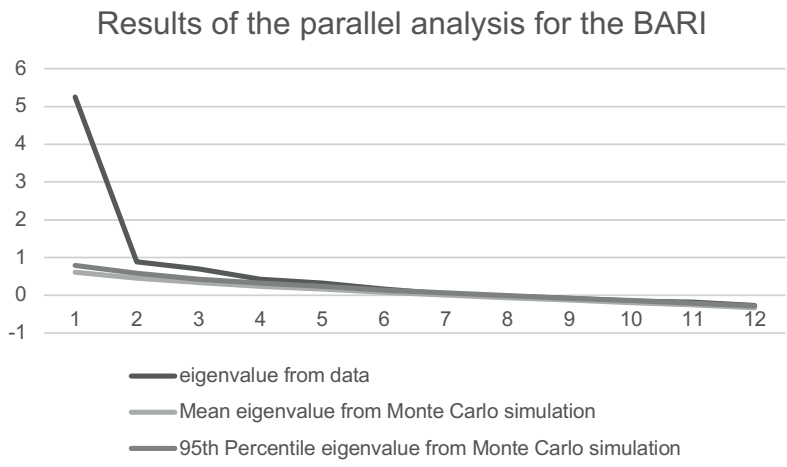

Figure 3. Scree plot of the results of the parallel analysis for the BARI

Table 3. Summary of the Exploratory Factor Analysis of the BARI for a one-factor solution

Item	Factor loadings
1	.792
2	.828
3	.694
4	.737
5	.449
6	.754
7	.833
8	.521
9	.487
10	.532
11	.570
12	.444

Reliability

The Cronbach's alpha for the TFI was .86, indicating a good internal consistency. The item-total score correlations were ranging from .49 to .91. The mean item-total score correlation turned out to be .80. The Cronbach's alpha for the BARI turned out to be . 89. The mean item-total score correlation was .67 with a range from .47 to .85. This result suggest a good internal consistency. In addition, McDonald's Omega showed similar results for both scales. McDonald's Omega for the TFI turned out to be .86, and for the BARI .90.

Construct validity

Table 4 shows the correlations between the TFI, the BARI and various other related scales to determine the construct validity. Pearson's correlations for the TFI ranged from .39 with the BDI-II to .53 with the MCQ-30. For the BARI Pearson's correlation ranged from .28 with the BDI-II to .62 with the PI-R. The correlations with the convergent constructs turned out to be moderate to strong and all appeared to be significant. The highest correlations were found between the TFI and the MCQ-30 and between the BARI and the Padua-IR, both convergent constructs. This suggests that the TFI and the BARI draw on strongly related constructs to the measurements chosen as convergent constructs. Correlations with the BDI-II turned out to be the lowest. For the BARI, the correlation with the BDI-II turned out to be .28. The correlation between the TFI and the BDI-II also turned out to be the lowest (r = .39).

Table 4. Pearson correlation coefficients between the TFI, BARI and various other scales in a normal population (n = 141)

	TFI	BARI	PI-R	BDI-II	MCQ-30	IUS
TFI		.44**	.44**	.39**	.53**	.50**
BARI	.		.62**	.28**	.48**	.42**
PI-R				.58**	.75**	.70**
BDI-II					.68**	.67**
MCQ-30						.77**

**p<.001.

TFI=Thought Fusion Instrument, BARI=Beliefs About Rituals Inventory, PI-R=Padua Inventory, BDI-II=Beck Depression Inventory, 2nd Version, MCQ-30=Metacognition Questionnaire, IUS=Intolerance of Uncertainty Scale.

Study 2

Test-retest reliability in a normal population

Participants and procedure

A subsample consisting of the first 55 participants who completed the questionnaires for study 1, was asked to complete the TFI and the BARI for a second time with an interval of 4 to 6 weeks to determine the test-retest reliability coefficients. Fifty-one participants completed this study (attrition rate of 7%). The mean age of these participants was 40.6 (SD = 16.7), 31% of the sample was male, 84% of the sample had a minimum education level of high school and was fully employed at time of administration.

Statistical analysis

In order to investigate the test-retest reliability, mean scores at the two measurement points were calculated for our questionnaires. A *t*-test was used to determine a possible significant difference between mean scores of the two measurement points. The intraclass correlation coefficient (ICC) was calculated to determine the test-retest reliability coefficients of the instruments. Based on the selection flowchart suggested by Koo and Li (2016), we chose an ICC estimate based on a single rating, absolute agreement, 2-way mixed effects model. ICC's will be interpreted as follows: values less than 0.5, between 0.5 and 0.75, between 0.75 and 0.9, and greater than 0.90 are indicative of poor, moderate, good, and excellent reliability, respectively (Koo & Li, 2016)

Results

The mean scores at the first measurement point were 214.6 (*SD* = 147.2) for the TFI and 15.1 for the BARI (*SD* = 4.4). On the second occasion this was 141.7 for the TFI (*SD* = 145.9) and 14.6 for the BARI (*SD* = 4.02). The mean scores at the two measurement points were significantly different for the TFI ($t[50] = 5.53$, $p < .001$). The mean scores at the two measurement points for the BARI were not different ($t[50] = .99$, $p = .324$). The ICC estimate and its 95% confidence interval based on a single rating, absolute agreement, 2-way mixed effects model for the TFI was .84 with a 95% confidence interval = 0.47-0.93 ($p < 0.001$) suggesting a good test-retest reliability. For the BARI this was .63 with a 95% confident interval = 0.43-0.77 ($p < .001$), suggesting moderately adequate test-retest reliability.

Study 3

Reliability and validity in clinical samples

Participants and procedure

To assess the reliability and validity of the TFI and the BARI in an OCD sample, data were collected in four groups, 3 clinical groups and a non-clinical control group. First, measurements were administered to 61 patients with a primary diagnosis of OCD. They were diagnosed with OCD based on the criteria of the fourth version of the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) by means of the structured clinical interview for DSM-IV axis-I disorders (SCID-I; First et al., 2001), which was administered by a trained psychologist. At the time of testing, they were on the waiting list

for psychological treatment at the therapeutic centre PsyQ in Rotterdam. Also, they did not receive any other form of psychological treatment for at least three months and there was no change in medication dose or type in the six weeks before testing.

To determine the criterion related validity of the TFI and the BARI, data were also collected in two other patient groups. Thirty patients with an anxiety disorder, also on the waiting list at the therapeutic centre PsyQ and not receiving any form of treatment at the time of testing, volunteered for this purpose. These group consisted of patients who had a primary diagnosis of panic disorder (n = 7), social phobia (n = 13), a generalised anxiety disorder (n = 5) or specific phobia (n = 5). Diagnoses were established using the SCID-I interview. Patients with a comorbid axis-I disorder next to the above-mentioned primary diagnoses were excluded from participation in this study. A third patient group consisted of 50 patients with an autism spectrum disorder (ASD), formerly classified as DSM-IV-TR autistic disorder (n = 24), Asperger syndrome (n = 15) and pervasive developmental disorder – not otherwise specified (n = 7). The diagnoses in this sample were based on the Dutch Interview for Diagnosing Autism Spectrum Disorder (Vuijk, 2016), a structured clinical interview including an evaluation of autism-specific behaviors by direct observation and a developmental history report provided by a parent or other caregiver. All diagnoses were verified by a registered psychologist or psychiatrist. Patients in the ASD group were selected based on the criteria of not having a comorbid diagnosis on axis-I, but this was not verified with a structured clinical interview before testing. Finally, a control group (n = 63) was collected in the general population, again using snowball sampling among relatives of the authors. In all groups, the TFI and the BARI and also the PI-R and the BDI-II were administered. Participant characteristics and outcome variables of the four groups are displayed in table 5.

Statistical analysis

To evaluate the reliability of the scales in clinical samples, we again used both Cronbach's alpha and McDonald's Omega coefficients. To explore the construct validity of the TFI and the BARI, Pearson's correlation coefficients were calculated between the TFI, the BARI and a theoretically related construct (obsessive compulsive symptoms [PI-R]) for the convergent validity and also with a divergent construct (depressive symptoms [BDI-II]). We hypothesize that the correlation coefficient between the TFI, the BARI and the convergent construct will be substantially larger than with the discriminant construct (depressive symptoms).

Table 5. Descriptives and differences in metacognitive beliefs among the samples

	OCD (*n* = 61)	ASD (*n* = 50)	Anxiety disorder (*n* = 30)	Controls (*n* = 63)
Variable	**Mean (*SD*)**	**Mean (*SD*)**	**Mean (*SD*)**	**Mean (*SD*)**
Age	30.87 (10.7)	41.73 (12.7)	27.63 (7.3)	45.52 (10.8)
Gender (% female)	64%	34%	80%	69%
TFI	368.56 (259.0)	386.40 (267.4)	386.33 (280.1)	272.54 (201.9)
BARI	26.25 (7.9)	23.18 (11.0)	18.97 (8.4)	14.56 (3.86)
PI-R	60.69 (24.9)	52.55 (32.9)	40.61 (27.3)	25.78 (17.6)
BDI-II	21.21 (11.0)	23.86 (14.7)	22.37 (13.6)	10.78 (9.3)

TFI=Thought Fusion Instrument, BARI=Beliefs About Rituals Inventory, PI-R=Padua Inventory-Revised, BDI-II=Beck Depression Inventory, 2nd Version

In order to explore the criterion validity of the tests, we compared the TFI and BARI scores among participants with OCD, anxiety disorders, autism spectrum disorder and a normal control condition. Differences in test scores among the groups were first examined by calculating the analysis of variance (ANOVA) with the TFI and the BARI as the dependent variables. Also, Bonferroni corrected post-hoc tests were performed to make separate comparisons between each of the groups. Significantly higher ratings on the TFI and the BARI were expected in the OCD group in comparison with the other groups. Secondly, the accuracy of the instruments will be explored with area under the curve (AUC) analysis of receiver operating characteristics (ROC) curves. In a first analysis, data of all four groups will be used. We assessed whether the instruments are capable of distinguishing those with OCD from those without OCD based on the total score on the TFI and the BARI. Based on Swets (1994), ROC analysis results were interpreted as follows: AUC <0.70, low accuracy; AUC in the range of 0.70–0.90, medium accuracy; and AUC ≥0.90, high accuracy.

Results

Reliability

For the total group of patients (*n* = 141) Cronbach's alpha of the TFI turned out to be .89. The mean item-total score correlation was 0.76 (ranging from .59 to .78). More interestingly, separate analyses were carried out for the three patient groups. Cronbach's alpha for the anxiety disorder group was .94 for the TFI, .90 for the group of patients with ASD and .88 for the group of OCD patients. Assessing reliability with McDonald's Omega, similar coefficients were found. For the total group of patients, McDonald's Omega turned

out to be .89. For the separate patient groups McDonald's Omega showed coefficients ranging from .86 to .91. In sum, the TFI seems to be a reliable measurement in both a general psychiatric sample and an OCD sample.

The same appears true for the BARI. For the total group of patients, the Cronbach's alpha was .96. The mean item – total score correlation was .87 with a range from .55 to .89. The Cronbach's alpha's for the separate patient groups were .95 for the anxiety disorder group, .96 for the group of patients with ASD and .89 for the OCD group. Additionally, McDonald's Omega for the total group turned out to be .96 and for the separate patient groups, coefficients ranged from .90 to .96.

Construct validity

Table 6 shows the correlations between the TFI, the BARI and two other scales in our OCD sample (PI-R as a convergent construct and BDI-II as a divergent construct). We found a moderate and significant correlation between the score on the TFI and the PI-R (r = .37, p = .001). On the other hand, as hypothesized, the correlation between the TFI and the BDI-II appeared not to be significant, and was smaller (r = .25, p = 0.052). The same pattern is found for the BARI. The Pearson's correlation between the BARI and the PI-R appeared substantially larger (r=.44, p < .001), than the correlation coefficient between the BARI and the BDI-II (r=.19, p = .149).

Table 6. Pearson correlation coefficients between the TFI, BARI and various other scales in an OCD sample (n = 61)

	TFI	BARI	PI-R	BDI-II
TFI		.28*	.37**	.25
BARI	.		.44**	.19
PI-R				.69**

*p<.05
**p<.001.
TFI=Thought Fusion Instrument, BARI=Beliefs About Rituals Inventory, PI-R=Padua Inventory, BDI-II=Beck Depression Inventory, 2nd Version.

Criterion validity

A one-way ANOVA showed a significant between-groups effect, F(3, 200) = 2.71, p = 0.046 for the TFI. However, Bonferroni corrected post-hoc tests revealed no significant differences between the four groups. A Bonferroni corrected post-hoc test between the healthy controls and the total group of patients appeared to be significant (p < 0.05).

The criterion validity of the BARI appeared moderate. Here, a one-way ANOVA also showed a significant between-groups effect, $F(3, 200) = 24.57$, $p < .001$ and post-hoc tests with the Bonferroni correction revealed significant differences between all three patient groups and the control group ($p < .001$). Also, the OCD group had higher BARI scores in comparison with the group with anxiety disorders ($p < .001$). The difference between the OCD group and the ASD group was not significant ($p = .266$).

In line with the ANOVA results, the AUC analysis of the ROC curves for the BARI appeared to be .78, showing medium accuracy of the BARI in identifying those with OCD from those without OCD in our sample. The AUC of the TFI turned out to be .54, which can be interpreted as low accuracy of the TFI in distinguishing those with OCD from those without OCD in our sample. In a second AUC analysis using the combined clinical group, the AUC turned out to be .71, suggesting a medium accuracy for the TFI in distinguishing those with psychopathology from those without.

Discussion

In this study, the psychometric properties of the TFI and the BARI, two short questionnaires for measuring metacognitive beliefs in both the general population and clinical populations, were assessed.

First of all, by using a general population, for both the TFI and the BARI, an explorative factor analysis using parallel analysis and subsequent principal axis factoring was carried out. Although the PA's at first revealed a three-factor solution for the TFI and a five-factor solution for the BARI, after inspection of the scree plots and pattern matrices, a one-factor solution seems to connect closer to the data for both questionnaires. Since explorative factor analysis only allows to construct a hypothesis regarding the factor structure, future research must strengthen this conclusion by performing confirmative approaches.

Secondly, we found excellent reliability in both clinical and non-clinical populations for both scales. Cronbach's Alpha's and McDonald's Omega correlations were high for both questionnaires in a sample of healthy controls and in an OCD sample. Next, we found meaningful correlations between the TFI and the BARI and other theoretically related constructs. There were statistically significant correlations between the two scales and

questionnaires for theoretically related concepts of obsessive-compulsive symptoms, intolerance of uncertainty and metacognitive parameters in psychopathology in general. Correlations were substantially large, suggesting that the scales measure related constructs, pointing towards convergent validity. The lowest correlations were found between the two scales and the measurement for depressive symptoms, which was chosen as a divergent construct. The correlation between the BARI and the BDI-II appeared the lowest in both the healthy control group and in the OCD group, which suggests that the scale measures a distinct construct from depression. For the TFI, the correlations with the BDI-II also appeared the lowest of all correlations in both the healthy control condition and in the OCD group, pointing to divergent validity. Although the results regarding the construct validity are in line with our hypothesis (larger correlation coefficients with convergent constructs than with divergent ones), it must be mentioned that caution is warranted. First of all, although the convergent correlations are indeed larger than the divergent one in study 1, the correlations with depressive symptoms are also moderate and significant. The same appears to be true in the OCD sample of study 3. Here too, some of the convergent correlations are only slightly larger than the divergent one. Second, when analysing the entire pattern of correlations, it must be acknowledged that some of the correlations between convergent and divergent constructs are also high, for example between the MCQ and the BDI. Although we state that there is no theoretical reason why OCD-specific metacognitive beliefs are directly associated with depressive symptoms, and therefore the BDI-II is suitable as a divergent construct, the MCQ is developed as a measurement for assessing metacognition over a broad range of psychological disorders (e.g., depressive disorder). This might explain the fact that the entire pattern of correlations is relatively high and of questionable utility to draw firm conclusions about the convergent and divergent validity of the measurements. In sum, although the results are in line with our hypothesis, more research is needed to draw more definitive conclusions, for example by adding more measurements which are meant to capture the same and similar constructs as the TFI and the BARI for the examination of the convergent validity (e.g. the Thought-action Fusion scale), and by using questionnaires distinguishing metacognitive beliefs from theoretically unrelated constructs for the examination of the divergent validity (e.g. measurements for distinct cognitive processes).

Third, we assessed the test-retest reliability over a period of 4 to 6 weeks. For the TFI, the test-retest reliability as determined with the intraclass correlation coefficient turned out to be good (ICC = .84), for the BARI it was less stable over time (ICC = .63), but still satisfactory (Koo & Li, 2016). For the TFI, there was however a significant difference between the mean score on the first and second occasion. Apparently, although the intraclass correlation was high, the stability of the item scores over time was low in our study, raising questions about whether the item scores on the TFI are affected by other variables (e.g., mood). Additional research is needed to test this hypothesis, and also warranted before clear recommendations for the use in clinical practice and research can be made.

Finally, the criterion validity of the TFI and the BARI was assessed by making a comparison of total scores on the TFI and the BARI between both a sample of healthy controls and various clinical groups. The BARI was able to discriminate between the healthy controls and the group of OCD patients, ASD patients and patients with an anxiety disorder. Only the difference between the OCD and ASD group was not significant. A possible explanation can be found in the fact that, although there is a clear difference between OCD and ASD, both are characterized by repetitive thoughts and the urge to perform repetitive actions (McDougle et al., 1995; Zandt et al., 2007). In summary, the criterion related validity of the BARI seems to be moderate. Differences in total scores on the TFI appeared not to be significant between patient groups. Only the difference between the healthy control group and the total group of patients appeared significant. Also, the AUC of the TFI turned out to be .54, which can be interpreted as low accuracy of the TFI in distinguishing those with OCD from those without OCD in our sample, suggesting a low criterion validity in this study. A second AUC analysis using the combined clinical group, turned out to be .71, suggesting a medium accuracy for the TFI in distinguishing those with psychopathology from those without.

Concerning the fusion beliefs of TAF, this is in line with earlier research which finds no differences between individuals with OCD versus other clinical samples (Rassin et al., 2001; Abramowitz et al., 2003; Solem et al., 2010; Hansmeier et al., 2016). However, as we assumed that the TFI assesses fusion beliefs across the three fusion domains that are considered relevant and specific for OCD, this finding is contradictory to our hypothesis. Although more research is needed at this point, our study indicates that the TFI did not differentiate individuals with OCD from individuals with other disorders, which implies restrictions for the use in clinical practice. The TFI might be

a useful instrument for setting up an individual case conceptualization or monitoring the treatment process, but not as a diagnostic instrument. Also, more research is needed before clear recommendations can be made about the use of both instruments as primary outcome measurement in treatment effect studies.

Our study is not without limitations. We chose an explorative factor analysis, rather than confirmative factor analysis since the factor structure of both the TFI and the BARI had not been investigated yet. Although explorative factor analysis is the most suitable method for a first investigation of the factor structure of the measurements at this point and corresponds to the purpose of the current study, explorative approaches are not without limitations. The analyses in our study are only a first investigation into the factor structure of the measurements, and do not provide a test of the unidimensionality of the scales. Since an explorative approach only allows to generate hypothesis about the underlying structure, confirmative approaches are now needed in order to draw more definitive conclusions about the factorial validity of the TFI and the BARI. Also, for the TFI, it can be hypothesized that there is a reason for a multi-dimensional scale, since the TFI is considered to assess fusion beliefs across three theoretically meaningful classes of fusion beliefs. Further research using confirmatory approaches should test whether a three-dimensional model would fit the data better. Also, since the Parallel Analysis also revealed solutions with multiple factors for the BARI, confirmative approaches should take a closer look into this. Finally, future studies in larger populations could test whether the scales behave similarly in clinical and non-clinical samples.

Related to the limitations of our factor analysis is the fact that we have used the total scores of the measurements in the subsequent correlational analysis on convergent and divergent validity. Since our explorative factor analysis only allows to make hypothesis about the underlying structure, this is an limitation of our subsequent analysis. Additional limitations are the lack of information about comorbidity in some of the clinical samples, while high rates of comorbidity might affect the outcome of our analysis, especially in the third study. Another limitation is that there were no data on mental health status of participants in the control conditions. Also, a limitation with the chosen sampling procedures is that they can generate a homogenous sample of individuals with specific demographic characteristics. For example, eighty-nine participants of study 1 had completed high school or a higher education level. Such specific demographic characteristics cause limitations to the

generalization of the results. Other limitations are the use of only self-report measures of metacognitive beliefs and the higher number of females in the samples.

To summarize, both short questionnaires seem to have promising potential for research purposes and for use in clinical settings. More research into the psychometric properties is however necessary. Since some critical observations are made about the criterion validity, and test-retest reliability of the TFI, conscientious use in clinical practice is required. Also, confirmative evidence regarding the factor structure of the measurements and additional research with regard to the concept of convergent and divergent validity is needed.

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Chapter 4

Metacognitive therapy for obsessive–compulsive disorder: A pilot study

Published as: Heiden, C. van der., Melchior, K., Dekker, A., Damstra, M., & Deen, M. (2016). Metacognitive therapy for obsessive-compulsive disorder: A pilot study. *Journal of obsessive-compulsive and related disorders*, 9, 24-29.

If you do not like the road you are walking, start paving another one

Abstract

The first-line psychological treatment for OCD, exposure and response prevention (ERP), has been shown to lead to statistically significant improvements in 75% of patients. However, as only about 60% of treatment completers achieve recovery, and 25% of patients is asymptomatic following treatment, there is room for improvement. One promising account is metacognitive therapy, which targets metacognition, a key cognitive process involved in the development and maintenance of OCD. This open trial examined the effectiveness of MCT among 25 consecutively referred outpatients with OCD. At posttreatment and follow-up, MCT produced significant and large reductions across all outcome variables, with high proportions of clinically significant change (patients recovered at posttreatment, 74%; at follow-up, 80%) on the Y-BOCS. In addition, the majority of patients (63% and 80% respectively) no longer fulfilled the diagnostic criteria for OCD. These encouraging results justify a controlled trial in which the effectiveness of MCT is evaluated against ERP.

Introduction

Obsessive-compulsive disorder (OCD) is characterized by recurrent obsessions and/or compulsions that cause marked distress and interfere with daily functioning (APA, 2013). In the absence of treatment the course of OCD can be chronic. Until the 1960s, this relatively common condition was considered unresponsive to psychological treatments. However, with the introduction of exposure and response prevention (ERP) the prognosis for OCD improved substantially (Meyer, 1966). The procedure is based on learning theory, which suggests that classical conditioning is responsible for the development of obsessions, whereas operant conditioning processes maintain anxiety and compulsive behaviors (Fisher & Wells, 2005). As a consequence, ERP consists of (a) exposure to anxiety provoking stimuli and (b) prevention of compulsive responses that reduce anxiety.

Although widely regarded as first-line psychological treatment for OCD (Olatunji, Cisler, & Deacon, 2010; Öst, Havnen, Hansen, Kvale, 2015), ERP is a good example of the discrepancy between statistically and clinically significant change. While several studies and meta-analyses have shown ERP to lead to statistically significant improvements in 75% of patients, only about 60% of treatment completers achieve recovery, whereas only approximately 25% of patients is asymptomatic following treatment (Fisher & Wells, 2005). As only treatment completers were included in these analysis, and approximately 30% of patients refuse ERP or dropout from treatment, overall recovery rates may be lower (Clark, 2004). Furthermore, there appears to be a clear dose-effect relationship for ERP, i.e., the greater the number of treatment hours, the greater the percentage of recovered and asymptomatic patients (Fisher & Wells, 2005). As such, optimal ERP requires considerable amounts of therapist time, with typically 15 to 20 treatment sessions of 90 min (Kozak & Foa, 1996). These data show that there is room for improvement in both the effectiveness and cost-effectiveness of OCD-treatment. It has been suggested that progress might be made by basing treatments on key cognitive processes involved in the development and maintenance of the disorder (Frost & Steketee, 2002), such as metacognition (Purdon & Clark, 1999; Wells, 1997).

Metacognition refers to knowledge or beliefs about thinking and strategies used to regulate and control thinking processes (Flavell, 1979). The metacognitive model of OCD specifies two subcategories of belief that are fundamental to the maintenance of the disorder; (a) metacognitive beliefs about the meaning and consequences of intrusive thoughts and

feelings, containing themes of thought action fusion (TAF), thought event fusion (TEF), and thought object fusion (TOF), and (b) beliefs about the necessity of performing rituals in response to obsessions. Resulting from the metacognitive model, treatment focuses on modifying patients' beliefs about the importance and power of thoughts and rituals using verbal reattribution and behavioural experiments, with the aim to alter the patients' relationship with their thoughts as opposed to challenging the actual content of intrusive thoughts (Fisher & Wells, 2008).

So far, two studies have provided support for the efficacy of MCT for OCD. Using single case methodology in four consecutively referred patients with OCD, Fisher and Wells (2008) found clinically significant improvements for all patients treated individually with MCT, whereas Rees and Van Koesveld (2008) found that all eight participants in an open trial of group metacognitive therapy for OCD demonstrated improvements on all outcome measures, with even recovery achieved for seven of the eight patients on the Y-BOCS. Together, these findings suggest that MCT might be an efficacious treatment for OCD. However, it should be acknowledged that the evidence is only preliminary given the small sample sizes in both studies and the lack of control groups. Given the promising potential for the treatment of OCD, the present study was conducted to further evaluate the efficacy of MCT in a larger sample of clinically referred patients with OCD. It was hypothesized that MCT would result in significant and large reductions in both symptoms of OCD and comorbid depression, and in metacognitive beliefs about intrusive thoughts. If effective, the next step will be to conduct a large study comparing MCT with ERP, the current treatment of choice for OCD, in an outpatient clinical sample of patients with OCD.

Method

Participants and design

Patients were recruited between January 2013 and March 2014 from consecutive referrals to PsyQ, an outpatient community mental health center in the Netherlands, for anxiety disorder treatment from clinical services. Diagnosis was established using the Dutch version of the Structured Clinical Interview for DSM-IV axis-I (SCID-I) (First, Spitzer, Gibbon, & Williams, 2001), which was administered by an independent trained assessor. Inclusion criteria are 1) primary diagnosis of OCD, and 2) age 18-65. To enhance the clinical representativeness of the sample, exclusion criteria were kept to

a minimum. Patients were only excluded if they currently 1) met DSM-IV-TR criteria for severe major depressive disorder that requires immediate treatment, psychotic disorder, or bipolar disorder, 2) had mental impairment or evidence of organic brain disorder, 3) had substance abuse requiring specialist treatment, 4) had a change in medication type or dose in the six weeks before assessment or during treatment, or 5) received a concurrent psychological treatment for any Axis I or II disorder. The presence of other comorbid disorders or the continued use of psychopharmaca patients already used longer than six weeks before assessment were not exclusion criteria. Eight of the 34 potentially eligible patients did not meet inclusion criteria, of which 3 refused to take part in the study. One patient met exclusion criteria (use of an SSRI for only 2 weeks at the pretreatment assessment), leaving 25 entering the treatment program.

At the end of the clinical screening eligible patients received extensive information about the design and procedures of the study. After they provided informed consent, patients were assigned to one of the MCT therapists. Each treatment consisted of up to 15 weekly sessions of 45 minutes. Treatment could be terminated earlier when patient and therapist agreed that recovery had occurred. A detailed manual was used, which was based on publications of the researchers who developed MCT for OCD (Wells, 1997; 2009).

Of the 25 patients entering the study, 6 (24%) dropped out in the active treatment phase, 3 for unknown reasons, the other 3 started using a SSRI. Another 3 patients (12%) were lost to follow-up, due to receiving additional treatment (for other problems) during the 3-month follow-up period. Demographic characteristics of the participants are displayed in Table 1.

Table 1. Demographic characteristics (N =25)

	M	***SD***
Age in years	32.3	11.4
	n	%
Gender (female): n (%)	17	68
Married/partnered	13	52
Living alone	12	48
Tertiary education	8	32
Current employment	21	84
Use of psychopharmaca	11	44
≥ 1 comorbid axis I disorder	13	52

Measures

Questionnaires were administered one week before treatment (pretest), after the last treatment session (posttest), and three months after treatment had ended (follow-up). No additional treatment was provided after posttest.

Treatment outcome was evaluated by means of the Dutch versions of both a standardized self-report scale (Padua Inventory; Burns, Keortge, Formea, & Sternberger, 1996) and a semi-structured interview (Y-BOCS; Goodman et al., 1989) conducted by an independent clinician (at all assessment points) for measuring the core symptoms of OCD (primary outcomes). In addition, the Beck Depression Inventory (BDI-II; Beck, Steer, & Brown, 1996) was administered to assess comorbid symptoms of depression (secondary outcome). To study changes in the cognitive process as targeted by MCT, the Thought Fusion Instrument (TFI; Wells, Gwilliam, & Cartwright-Hatton, 2001) was employed.

Therapist characteristics, recruitment and training

Seven staff psychologists (1 male, 6 female) of the participating mental health care center participated in the study. All of them were certified cognitive-behavioral therapists, who were familiar with the provision of cognitive-behavioral treatment protocols. The mean age of the therapists was 35.0 years (range 27-42), and they had on average 9.1 years of clinical experience (range 5-15). The participating therapists were trained in MCT in a three-day workshop by prof. Adrian Wells and dr. Peter Fisher, experts in the field of MCT. During the project, all therapists were supervised monthly by the first author (CH). At these group meetings all active cases and therapy notes were reviewed to ensure adherence to protocols and treatment quality.

Treatment

Following the rationale of the metacognitive model, MCT proceeds with increasing patients' awareness of the role that metacognition plays in maintaining their symptoms by developing an idiosyncratic case formulation, socialization strategies, and 'detached mindfulness', a strategy in which patients are asked not to engage with their obsessional thoughts in any way, but instead to simply notice them and choose to let the thoughts naturally decay (Wells, 2000). The goal is to enable patients to move from treating their thoughts about their obsessions and compulsions as facts to being able to objectively evaluate their obsessions as merely mental events not requiring further processing (Fisher & Wells, 2008). MCT then proceeds with further practice of detached mindfulness and the direct modification of

metacognitive beliefs by means of verbal cognitive restructuring strategies (e.g., questioning the evidence supporting these beliefs) and within session behavioral experiments designed to illustrate that intrusions do not hold any special significance or meaning. An example of such experiments are exposure and response commission exercises, in which patients are asked to perform their rituals (e.g., checking the door) but instead of attempting to remove an intrusive thought from consciousness, patients are asked to deliberately keep the intrusive thought in mind (e.g., their doubt about the door being unlocked). The modification of metacognitions follows a particular sequence: first thought fusion beliefs are targeted, and then both positive (e.g., my rituals prevent me from doing bad things to others) and negative (e.g., my compulsions are uncontrollable) beliefs about performing rituals in response to obsessions are addressed. During the last stage of MCT, a new plan for processing in response to unwanted thoughts, feelings, or events is developed, consisting of attentional strategies and coping behaviors opposite to the strategies and behaviors of the old plan (e.g., 'apply detached mindfulness to intrusions' [= new plan] instead of 'pay attention to intrusions' [= old plan]). Also, the therapist and patient work on writing out a therapy blueprint, consisting of the case conceptualization, a summary of evidence challenging the fusion beliefs, and a list of disadvantages of performing rituals. Together with the new plan for processing, this therapy blueprint functions as a relapse prevention strategy designed to reduce vulnerability to future episodes of prolonged emotional disturbance (Fisher & Wells, 2009). See table 2 for an overview of the treatment phases.

Module	Topic	Goals	Interventions	Sessions
1	Case conceptualization and identifying metacognitions	Engage patient in program Generate case conceptualisation Increase awareness of maintaining metacognitive factors Shift from object mode to metacognitive mode	Provide treatment overview Use guided questioning to elicit metacognitions Guided questioning and experiments to illustrate unhelpful effects of coping behaviours (e.g., thought suppression experiment) Practice detached mindfulness	3
2	Modifying metacognitions about intrusions	Help patients to challenge metacognitive fusion beliefs about intrusions, using verbal and behavioural interventions for cognitive restructuring	Questioning the evidence and searching for counterevidence In-session behavioural experiments Exposure with response commission, in which patients are asked to perform rituals while deliberately keeping the intrusive thought in mind Ritual postponement, in which patients postpone rituals until a set 10-minute period, and apply detached mindfulness instead Exposure with response prevention to test predictions based on metacognitions about intrusions	5
3	Modifying metacognitions about rituals	Help patients to challenge metacognitive beliefs about rituals, using verbal and behavioural interventions for cognitive restructuring	Questioning the evidence and searching for counterevidence Advantages-disadvantages analysis Reframing advantages using socratic questioning Ritual modulating experiments, in which rituals are increased and decreased with the aim of assessing its impact on daily outcomes Ban rituals to test predictions about the consequences of not engaging in rituals	4

4	Reinforcing new plans for processing, and relapse prevention	Develop alternative plan for attention, behaviour, and processing of intrusions or doubts Develop therapy blueprint	Devise and implement new plan for dealing with intrusions Devise therapy blueprint consisting of a) the case conceptualization. b) a list of metacognitions about intrusions and a summary of evidence challenging them, and c) a summary of statements concerning disadvantages of rituals	3

Statistical analyses

Data were analysed using linear mixed models (Singer & Willett, 2003; Verbeke & Molenberghs, 2000), with time (t = 0, 1, 2) as a predictor for each of the four treatment outcome variables. To detect a possible curvature in the time effect, a squared time effect was added as well. Within each of these analyses, a random intercept was included. Due to convergence problems, random slopes were left out of the models. Selection of the best suitable model was performed using the corrected AIC (AICC; Hurvich & Tsai, 1989). A model with a lower AICC has a better fit on the data, and has a better generalizability outside the data at hand. The predictors in this model are considered to be relevant for predicting the outcome variable. Using linear mixed models, data were analysed following the intention to treat principle. For each of the outcome variables, the difference between the first two measurements (pretest and posttest) and the differences between the last two measurements (posttest and follow-up) were both analyzed using Wilcoxon signed-rank test, followed by calculation of effect size *r* (Rosenthal, 1991). Due to non-normality in the outcome variables, nonparametric analyses were used here, and median values were calculated. To allow for comparison with other treatment studies, we also calculated effect sizes *d* (Cohen's *d*, 1992: M1-M2 / pooled SD) for all outcome measures, using the last-observation-carried-forward procedure for the intent-to-treat sample. In addition to statistical significance tests, the clinical significance of treatment effects were examined for both the intent-to-treat and the completers sample, using the standard criteria for the Y-BOCS developed by Fisher and Wells (2005), as per Jacobson and Truax (1991). Patients were classified as recovered, if they achieved a reduction of at least 10 points on the Y-BOCS (indicating a reliable change) and a posttreatment score of 14 or below (indicating a score which is likely to fall within the normal range).

Patients were classified as asymptomatic (a more stringent criterion for defining recovery) when they achieved a posttreatment score of 7 or less (indicating an almost total absence of OCD symptomatology), in addition to meeting the reliable change index. Further, diagnosis-free status was also used as an index of clinically significant change.

Results

Data were gathered from 25 outpatients (8 male, 17 female), with a mean age of 32.3 years (*SD* = 11.4; range 20-57 years). There were 19 treatment completers, from whom data are available for the first two measurement occasions. For the follow-up measurement, data on the Padua, BDI-II, and TFI were available from 16 patients. As for one patient data on the Y-BOCS at follow-up were missing, data on this specific measure were available for only 15 patients. The mean number of sessions for the treatment completers was 13.7 (*SD* = 2.98). Table 3 displays mean scores on various outcome measures at the pre- and posttreatment, and 3-month follow-up assessments.

General effect of time

For all four outcome measures, the model with a fixed and random intercept, as well as a linear and a squared time effect, were found to be the most appropriate models according to their AICCs. Parameter estimates for each of the analyses can be found in Table 4. The directions of the fixed effects indicate a similar effect for all the outcome measures: there is a negative linear time trend, indicating that the scores descend over time. The positive squared time effects indicate, again for all four outcome variables, that the amount by which the scores descend over time, diminishes eventually. This indicates that the descent is largest between the first two measurements (i.e., during treatment).

Effect between measurements

For each of the four outcome measures, the Wilcoxon signed rank test was performed on subsequent measurement occasions. In accordance with the linear mixed models, the same pattern is found for all outcome measures, again: there is a statistically significant decline between the first two measurement occasions (i.e., during treatment), but no statistically significant difference was found between the last two measurement occasions (i.e., the three months after treatment). For each outcome measure, effect sizes *r* were large (Cohen, 1988, p. 79-80) between the

first two measurements and, albeit not statistically significant, small to medium between the last two measurements. The effect sizes *d* for the completers sample were also large for each outcome measure for both pre- to posttreatment and pretreatment to follow-up changes, but in the intent-to-treat sample this was only true for the Y-BOCS. On the other outcome indices (i.e., Padua, BDI-II, and TFI) effect sizes *d* were indicating only a medium treatment result, at both posttreatment and follow-up. Median values for each outcome measure at each measurement occasion, as well as test statistics and effect sizes *r*, can be found in Table 5. Effect sizes *d* are given in Table 3, with $d > 0.80$ indicating a large effect, *d* between 0.20 and 0.80 indicating a moderate effect, and $d < 0.20$ indicating a small effect.

Table 3. Mean scores (standard deviations) and effect sizes (Cohen's *d* computed for pre- to posttreatment and pretreatment to follow-up changes) for outcome measures at pretreatment, posttreatment. and 3-month follow-up assessments.

Note: Y-BOCS = Yale-Brown Obsessive Compulsive Scale; Padua = Padua Inventory;

	Intent-to-treat sample (n = 25)		**Completers sample (n = 16)**	
Measure and Time	***M (SD)***	***d***	***M (SD)***	***d***
Y-BOCS				
Pretreatment	23.96 (5.96)		22.88 (5.16)	
Posttreatment	13.96 (11.33)	1.10	7.69 (6.69)	2.54
Follow-up	13.60 (11.46)	1.13	7.13 (6.47)	2.69
Padua				
Pretreatment	62.80 (25.21)		53.31 (18.82)	
Posttreatment	41.32 (32.41)	0.74	25.63 (18.21)	1.49
Follow-up	42.60 (31.87)	0.73	27.63 (18.48)	1.38
BDI-II				
Pretreatment	19.00 (11.31)		16.37 (10.85)	
Posttreatment	12.32 (11.85)	0.58	6.06 (5.20)	1.21
Follow-up	13.56 (12.18)	0.46	8.00 (8.00)	0.88
TFI				
Pretreatment	390.83 (293.54)		368.0 (300.34)	
Posttreatment	182.00 (245.14)	0.77	64.38 (68.11)	1.39
Follow-up	197.20 (238.02)	0.72	88.13 (69.88)	1.28

BDI-II = Beck Depression Inventory, 2nd edition; TFI = Thought Fusion Instrument.

Table 4. Parameter estimates for linear mixed models with outcome measures BDI, TFI, Padua and Y-BOCS.

	BDI-II			TFI			Padua			Y-BOCS		
	Estimate	***SE***	***p***	**Estimate**	***SE***	***p***	**Estimate**	***SE***	***p***	**Estimate**	***SE***	***p***
Fixed effects												
Intercept	18.82	1.98	<.01	389.94	39.80	<.01	62.80	5.03	<.01	23.96	1.51	<.01
Time	-12.36	3.91	.03	-397.75	92.81	<.01	-37.77	7.00	<.01	-16.24	2.99	<.01
Time^2	4.02	1.94	<.05	127.10	46.01	<.01	12.35	3.48	<.01	4.33	1.51	<.01
Variance components												
Within-person residual	50.70	12.52	-	29128.93	7274.91	-	164.04	39.04	-	31.35	7.28	-
Random intercept	44.63	22.08	-	9024.32	7732.81	-	468.53	163.96	-	25.69	11.70	-

Note: Y-BOCS = Yale-Brown Obsessive Compulsive Scale; Padua = Padua Inventory; BDI-II = Beck Depression Inventory, 2nd edition; TFI = Thought Fusion Instrument.

Clinical significance

As to the clinical significance, at posttreatment 14 (= 74% of the 19 completers, 56% of the 25 patients entering treatment) met criteria for recovery, whereas 9 (47% of the completers, 36% of the intent-to-treat sample) met the more stringent criteria for being classified as symptom-free. Also, 12 patients no longer met the diagnostic criteria for OCD (63% of the 19 patients who completed treatment, 48% of the intent-to-treat sample). At follow-up, 12 patients could be classified as recovered (= 80% of the 15 completers, 48% of the intent-to-treat sample) and 10 patients (= 67% of the completers, 42% of the intent-to-treat sample) could be classified as symptom-free. In addition, 13 patients no longer met the diagnostic criteria for OCD (81% of the 16 completers, 52% of the intent-to-treat sample).

Table 5. Median values for three measurements occasions and test statistics from Wilcoxon signed rank test.

				Wilcoxon signed rank test					
	Median			Pre-post			Post-f.u.		
	pre	post	f.u.	*Z*	*p*	*r*	*Z*	*p*	*r*
BDI-II	16.50	6.00	6.00	-2.40	.02	-.52	-1.54	.12	-.39
TFI	365.00	80.00	95.00	-3.11	<.01	-.68	-1.76	.08	-.44
Padua	53.00	26.00	28.50	-3.78	<.01	-.81	-0.50	.62	-.13
Y-BOCS	25.00	8.00	4.00	-3.67	<.01	-.77	-1.05	.29	-.27

Note: Y-BOCS = Yale-Brown Obsessive Compulsive Scale; Padua = Padua Inventory; BDI-II = Beck Depression Inventory, 2nd edition; TFI = Thought Fusion Instrument.

Discussion

The results of this pilot study provide further evidence for the effectiveness of MCT in the treatment of patients with OCD. As hypothesized, MCT produced large pre- to posttreatment decreases in obsessive thoughts and compulsive behavior among patients with OCD. The same was true for comorbid symptoms of depression. Significant changes were also found in metacognitive beliefs about obsessions, as indexed by the TFI. These encouraging results were maintained at 3 month follow-up assessment. As for the data's clinical significance, results point to good outcomes, with around three quarter of the patients who completed treatment meeting criteria for recovery at both posttreatment and follow-up assessment, and half respectively two-third of the patients meeting criteria for being symptom free. Recovery rates at both post-treatment and follow-up appeared at

least comparable to those obtained in each of the five studies analyzed by Fisher and Wells (2005), whereas the percentages of asymptomatic patients appeared even higher. These results were achieved within 15 sessions of 45 minutes, suggesting that MCT has the potential to lead to at least comparable results as ERP in considerably less time.

There are limitations with this study that must be borne in mind. Most importantly, the study does not include a comparison group, which limits its interpretability. Although without treatment remission rates are low (e.g., 20% for those reevaluated 40 years later; APA, 2013), spontaneous fluctuations in symptoms cannot be ruled out as a result of the lack of a no-treatment control group. Further, the absence of a treatment control group means that it cannot be concluded that the observed improvements were not due to other variables, such as nonspecific therapy factors. However, like Rees and Van Koesveld (2008) we observed changes in metacognitive beliefs about obsessions, which suggest some specificity of treatment. Another limitation is the 3-month follow-up period, which is rather short to draw reliable conclusions about the enduring effects of MCT for OCD. Finally, we did not include formal measures of therapists' competence and treatment adherence. Although all therapists were trained by experts in the field in the provision of MCT to patients with OCD, we cannot rule-out that therapist factors may have affected outcomes. Future studies would benefit from including active control groups and longer follow-up intervals. Further, future studies should use designs in which therapist factors are ruled out, e.g. by using a therapist cross-over design and by assessing therapists' adherence to and competence in carrying out the treatment.

Besides these limitations, the study also had a number of strengths: it was conducted within an routine outpatient community mental health center, and interventions were applied by therapists who worked within this routine setting; it included a sufficient amount of therapists; it involved independent assessors of clinical diagnosis (SCID-I) and symptom severity (Y-BOCS) at all assessment points; and it used a clinically representative sample of OCD patients, that was relatively unselected.

In conclusion, the results of this pilot study appear encouraging and justify a controlled trial in which the effectiveness of MCT is evaluated against the first line treatment for OCD, ERP, to explore whether one type of treatment produces better results than the other.

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Chapter 5

Metacognitive therapy versus exposure and response prevention for obsessive-compulsive disorder: study protocol for a randomized controlled trial

Published as: Melchior, K., Franken, I. H.A., Deen, M., & Heiden, C. van der (2019). Metacognitive therapy versus exposure and response prevention for obsessive-compulsive disorder: study protocol for a randomized controlled trial. *Trials, 20: 277.*

If your dreams don't scare you, they are to small

Abstract

Background: The recommended psychological treatment of choice for obsessive-compulsive disorder (OCD) is exposure with response prevention (ERP). However, recovery rates are relatively modest, so better treatments are needed. This superiority study aims to explore the relative efficacy of metacognitive therapy (MCT), a new form of cognitive therapy based on the metacognitive model of OCD.

Design and methods: In a randomised controlled trial we will compare MCT with ERP. Hundred patients diagnosed with OCD will be recruited in an outpatient mental health centre in Rotterdam (the Netherlands). The primary outcome measure is OCD-severity, measured by the Yale-Brown Obsessive Compulsive Scale (Y-BOCS). Data are assessed at baseline, posttreatment, and at 6 and 30 months follow-up.

Discussion: By comparing MCT with ERP we hope to provide an indication whether MCT is efficacious in the treatment of OCD, and if so, whether it has the potential to be more efficacious than the current 'gold standard' psychological treatment for OCD, ERP.

Trial registration: Dutch Trial Register, NTR4855.
Registered 21 October 2014,
http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=4855

Background

Phenomenology and treatment

Obsessive-compulsive disorder (OCD) is a severe mental condition which is characterized by intrusive thoughts (obsessions) and repetitive behaviors (compulsions) intended to neutralize anxiety induced by these thoughts (American Psychiatric Associations, 2013). OCD has been ranked among the ten most debilitating disorders by the World Health Organization and tends to be chronic without adequate treatment (WHO, 2004). Both studies into pharmacological treatment, primarily with selective serotonin reuptake inhibitors (SSRI's), and studies into specific forms of psychological treatment, supported the effectiveness of these treatment modalities in reducing symptoms of obsessive-compulsive disorder (Blanco et al., 2006). The first-choice psychological treatment for OCD is exposure and response prevention (ERP) (see Rosa-Alcazar, Sanchez-Meca, Gomez-Conesa, & Martin-Martinez, 2008; Ost, Havnen, Hansen, & Kvale, 2015; Skapinakis et al., 2016), a specific type of cognitive behavioural therapy (CBT) which is based on learning theory, which suggests that classical conditioning is responsible for the development of obsessions, whereas operant conditioning processes maintain anxiety and compulsive behaviors (Mowrer, 1951). In ERP treatment, patients are exposed to anxiety-provoking stimuli (situations, objects, thoughts) combined with the strict prevention of performing ritual behaviors (Meyer, 1966). Since its introduction in 1966, the prognosis for OCD improved substantially. However, OCD remains a difficult disorder to treat. Although numerous studies have found statistically significant change and large improvements in OCD-symptoms after ERP, the outcomes are sub-optimal for the majority of patients. More specifically: although about 60% of treatment completers achieve recovery, only approximately 25% of patients are asymptomatic following treatment (Fisher & Wells, 2005), which means that the majority of patients treated with ERP continue to experience distressing OCD symptoms. Furthermore, the overall effectiveness of ERP for OCD is attenuated by some limitations of the approach. As approximately 30% of patients with OCD refuse ERP or drop out from treatment prematurely, it is assumed that overall recovery rates are lower (Olatunji, Cisler, & Deacon, 2010). Moreover, these figures suggest that ERP might be hard to tolerate and is burdensome, which is supported by the finding that an important reason for not attempting ERP are the requirements of treatment (e.g. exposure to anxiety provoking stimuli; Whittal, Thordarson, & McLean, 2005). So, although it can be concluded that ERP is efficacious, there is clearly room for

improvement in the psychological treatment of OCD. It is assumed that this improvement could result from a better understanding in the mechanisms involved in the maintenance of the disorder.

The metacognitive model of OCD

A recently developed theoretical account explaining the maintenance of OCD symptoms is the metacognitive model by Adrian Wells (Wells, 1997, 2000). In this model of OCD two belief domains are assumed to be fundamental in the maintenance of the disorder. First, it is proposed that obsessions are misinterpreted because of metacognitive beliefs about the dangerousness, significance and consequences of intrusive thoughts and feelings, the so-called fusion beliefs. Three classes of fusion beliefs are highlighted: thought action fusion, thought event fusion and thought object fusion. Thought action fusion (TAF; Rachman, 1993) refers to the belief that obsessional thoughts can lead to the commission of an action (e.g., "thinking about killing someone will make me do it"). Thought event fusion (TEF; Wells, 1997) refers to the belief that obsessional thoughts can make events happen (e.g., "thinking about a car accident means I will be involved in such an accident") or mean an event has already occurred (e.g., "If I think I ran into someone with my car, I probably did it"). Finally, thought object fusion (TOF; (Wells, 2000)) refers to the belief that thoughts or negative feelings can be passed into objects (e.g., "my feeling of evil could be passed into objects and from these objects to other people"). Once the fusion beliefs are activated, they give significance to obsessional thoughts and lead to appraisal of, and worrying about the thoughts and consequently to feelings of anxiety and perceived threat. This anxiety primes a second domain of metacognitive beliefs; beliefs about the necessity of performing rituals in response to obsessive thoughts in order to reduce the perceived threat (e.g., "Counting to seven will restrain me from acting on my thoughts"). Consequently, patients with OCD engage in both overt and covert ritual behaviours and thereby, use specific internal rules (instead of external observation) and so-called 'stop signals' to determine how the ritual must be conducted and when it can be terminated. Such stop signals are often metacognitive experiences, such as a feeling of satisfaction (e.g., "I must wash my hands until 'it feels right'"). They also use other neutralizing coping strategies like monitoring for further intrusive experiences, which is seen as a counterproductive strategy as it increases the awareness and frequency of intrusive thoughts. The metacognitive model of OCD is illustrated in figure 1.

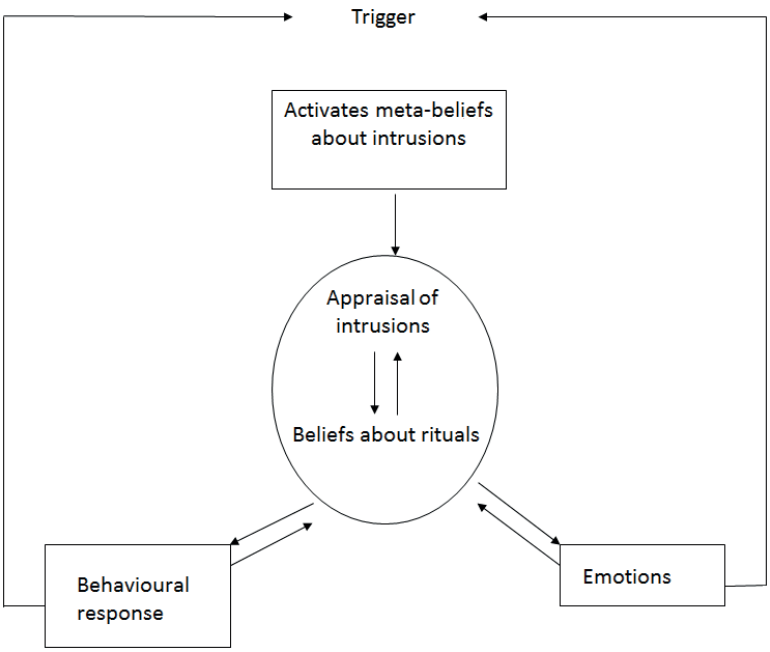

Figure 1. Metacognitive model for OCD (Wells, 1997)

Metacognitive treatment for OCD

Based on the metacognitive model, treatment should focus exclusively on modifying patients' beliefs about the importance and power of intrusive thoughts and the necessity of performing rituals, instead of challenging the actual content of the obsessions and compulsions (Fisher & Wells, 2008). Although metacognitive therapy (MCT) uses comparable techniques as cognitive therapy (CT) for this purpose, such as verbal reattribution and behavioral experiments, the two approaches are fundamentally different (Fisher, 2009). For example, patients with OCD can describe appraisals in the domain of inflated responsibility, perfectionism and intolerance of uncertainty. The metacognitive model proposes that such appraisals result from the activation of metacognitive beliefs about obsessions, and consequently it is not necessary to modify these lower order beliefs as is done in CT (e.g., by using the pie chart technique to compare the patient's original estimated probability with a more realistic estimate of probability ; Clark, 2004; Frost & Steketee, 2002). Targeting such lower order beliefs and automatic thoughts is seen as counterproductive as it just promotes further conceptual processing, such as worrying and rumination (Fisher & Wells, 2009). Instead, it is thought that modification of the metacognitive

beliefs about the meaning and power of obsessions, remove the need for further conceptual processing. So, interventions are explicitly aimed at the metacognitive processes which perpetuate the continued maladaptive processing instead of attempting to modify the content of perseverative thinking (i.e., apprasials) (Fisher, 2009).

So far, there is preliminary evidence supporting the efficacy of MCT for OCD. The clinical significance of treatment effects in the following mentioned studies is calculated using the standard criteria developed by Fisher & Wells (2005), based on the method of Jacobson en Truax (1991). Based on these criteria, patients are classified as recovered if they achieved a reduction of minimal 10 points on the Y-BOCS (Goodman et al., 1995; a semi-structured interview for OCS) and a posttreatment score below 14. When achieving a posttreatment score below 7, patients are classified as asymptomatic. Using single case methodology, Fisher and Wells (2008) found clinically significant improvements for four OCD patients with different clinical presentations who were treated individually with MCT. Two of the four participants were asymptomatic at both posttreatment and 3-month follow-up assessments. Furthermore, Rees and Van Koesveld (2008) found that seven out of eight participants in an open trial of group MCT for OCD reached criteria for a recovery status on the Y-BOCS at 3-month follow-up (87.5%). In an additional study, Fitt and Rees (2012) found similar clinically significant reductions among three patients treated with MCT using videoconference. In an open trial of individual metacognitive therapy among 25 patients with OCD, Van der Heiden et al. (2016) found statistically significant reductions on all outcome variables. Moreover, in terms of clinically significant results, 74% of the treatment completers (n = 19) were classified as recovered after treatment and 47% as asymptomatic. At follow-up, this increased to respectively 80% and 67%. Finally, Simons, Schneider, and Herpertz-Dahlmann (2006) found positive outcomes of MCT in comparison to ERP in the treatment of pediatric OCD in a case series design. Together, these findings suggest that MCT might be an efficacious treatment for OCD and deserves controlled evaluation. The present trial has been initiated to compare the relative efficacy of MCT with ERP, in an outpatient clinical sample of patients with OCD. Our main hypothesis is that MCT is more efficacious than ERP in the treatment of OCD in terms of both statistically and clinically significant improvements, both directly after treatment (primary outcome) and at follow-up.

Design and methods

Design

We will conduct a randomized controlled trial (RCT) with a pretest-posttest (primary outcome)-6-month-30-month-follow-up-design. Patients will be recruited from consecutive referrals to the Anxiety Disorders department of PsyQ, an outpatient community mental health center in the Netherlands. After screening for eligibility and informed consent, we will randomize the patients into two groups: metacognitive therapy and exposure and response prevention. The number of excluded patients and refusers and their reasons are registered. Participating patients will be assessed by self-report measures and semi-structured clinical interviews administered by a research assistant who is blind to group allocation at entry (pretreatment), after the last treatment session (posttreatment – primary outcome), six months (first follow-up) after treatment completion and 30 months (second follow-up) after treatment has ended. The latter assessment is included to answer a secondary research questions on the durability of both the ERP and MCT effect on the long term. Due to a lack of studies with follow-up periods of longer than one year (Eddy, Dutra, Bradeley, & Westen, 2004; Whittal, Robichaud, Thordarson, & McLean, 2008) the information on longer term effects are unknown. In case of drop-out, measurements and interviews are also administered directly after treatment had ended whenever this is possible. The study has received ethical approval from the Medical Ethical Committee of the Leiden University Medical Centre (LUMC) (protocol number NL50201.058.14) and is registered in the Dutch Trial Register (protocol number NTR4855). All data will be stored anonymously, and there is a data safety and monitoring board for the study. Figure 2 shows a flowchart of the study from patients enrollment up to data analysis and reporting. This study follows the "guidance of standard protocol items: recommendations of interventional study's (SPIRIT). The SPIRIT figure template is displayed in figure 3.

Participants are excluded if they:

1) meet DSM-IV criteria for major depressive disorder or substance use disorders (other than smoking) that needs immediately treatment
2) meet DSM-IV criteria for psychotic or bipolar disorder. have mental impairment or organic brain disorder.
3) have started medication or have a change in medication type or dose in the 6 weeks before treatment, or during treatment.

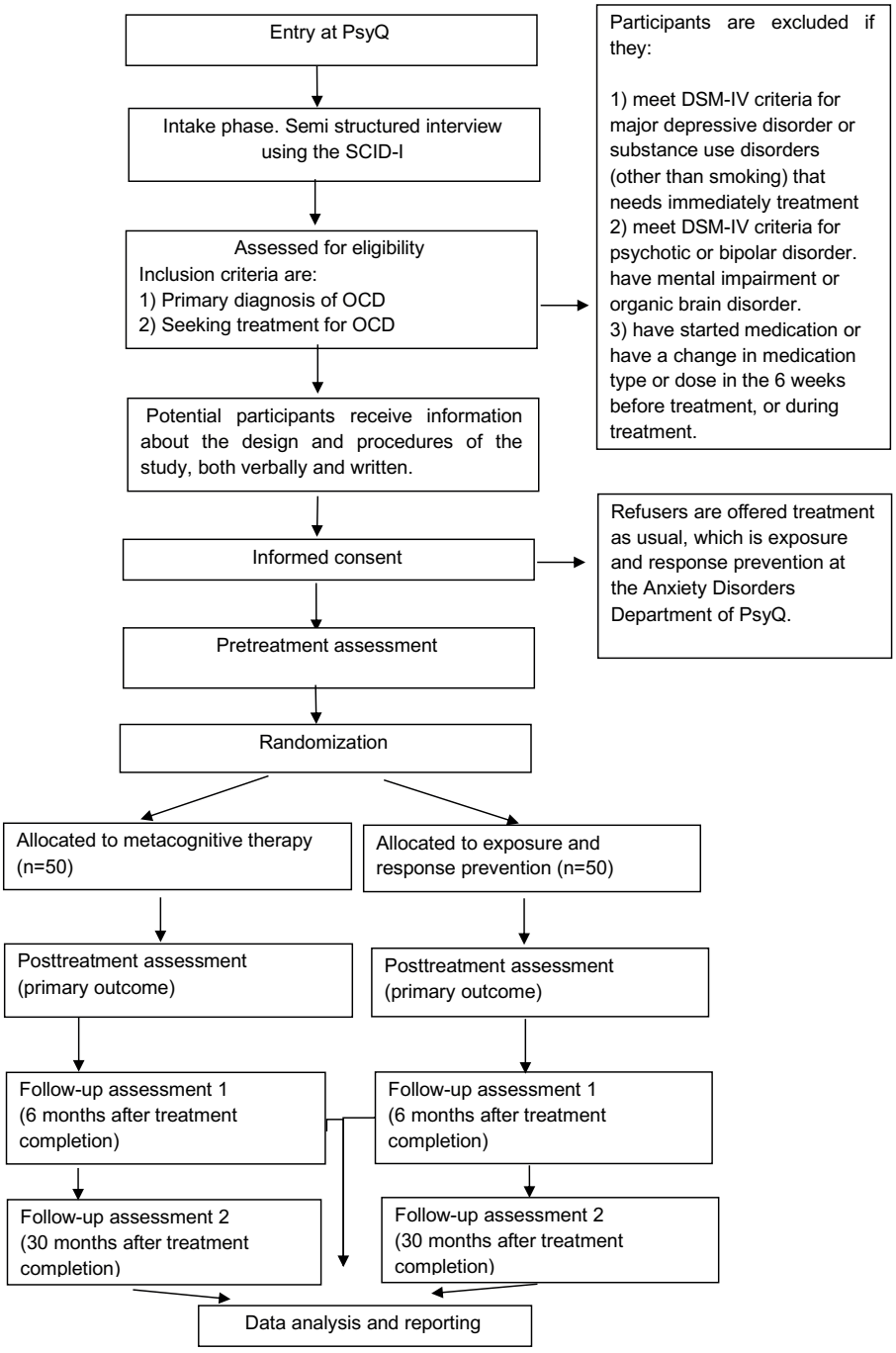

Figure 2. flowchart of the study

	STUDY PERIOD				
	Enrolment		Post-allocation		
TIMEPOINT	**$-t_1$**	**Pretest**	**Posttest**	**6-month follow-up**	**30-month follow-up**
ENROLMENT:					
Eligibility screen and SCID-I	x				
Informed consent	x				
Randomization	x				
INTERVENTIONS:					
MCT		⟷	⟷		
ERP		⟷	⟷		
ASSESSMENTS:					
Primary outcome Y-BOCS		x	x	x	x
Secondary outcomes*		x	x	x	x
Process measures**		x	x	x	x
SCID-I			x	x	x
Treatment Change Recording Form (TCRF)				x	x

Figure 3. Standard protocol Items: Recommendations for Interventional Trials (SPIRIT). Diagram of enrolment, interventions and assessments over time.

MCT Metacognitive Therapy, ERP Exposure and response prevention, SCID-I Structured Clinical Interview for DSM Axis I Disorders.

Primary outcome measure: Yale-Brown Obsessive Compulsive Scale (Y-BOCS). *Secondary outcomes: Padua Inventory-Revised (Padua IR), The symptom checklist (SCL-90), The Beck Depression Inventory, 2nd version (BDI-II), World Health Organization Quality of Life (WHOQOL-Bref), Obsessive Belief Questionnaire (OBQ-44).

**Process measures: Thought Fusion Instrument (TFI), Beliefs About Rituals Inventory (BARI).

Sample size

There are no studies available directly comparing ERP with MCT. We chose to design our study with enough statistical power to enable us to detect a medium between-group effect (Cohen's d = 0.5 (Cohen, 1992)) from baseline to posttreatment. We chose for this medium between-group effect because expecting a larger difference between the two treatment groups does seem unrealistic since numerous studies have found statistically significant change and large improvements in OCD-symptoms after ERP. On the other hand, designing our study to enable us to detect a small between-group effect is of less relevance for clinical practice. We used the statistical method presented by Liu and Liang (1997) for sample size calculations for studies with

correlated observations. To achieve a power of 0.80 with four measurement points with a correlation of 0.5 between repeated measures (standard value) and to detect a medium effect size (Cohen's *d* = .50) between the two treatment conditions over time on the primary outcome measure, severity of OCD symptoms and an expected drop-out rate of 20%, the minimal sample size necessary in each condition is 50.

Participants enrolment and randomization

Hundred adult patients (aged between 18 and 65) with a primary diagnosis of OCD will be recruited from consecutive referrals to the Anxiety Disorders department of PsyQ, an outpatient community mental health center in the Netherlands. Diagnosis of OCD will be established using the SCID-I (First, Spitzer, Gibbon, & Williams, 2001), a diagnostic interview based on the DSM-IV, because diagnostic instruments based on the DSM-5 (American Psychiatric Association, 2013) were not yet available at the development phase of this studyTo enhance the clinical representativeness of the sample, exclusion criteria are kept to a minimum. Patients are only excluded if they currently 1) meet DSM-IV-TR criteria for severe major depressive disorder or substance use disorder (other than smoking) that requires immediate treatment, psychotic disorder, or bipolar disorder, 2) have mental impairment or an organic brain disorder, or 3) had a change in medication type or dose in the six weeks before assessment or during treatment(see Figure 2). The presence of other comorbid diagnosis or previous treatment for OCD are not exclusion criteria. Potential participants will receive extensive information about the design and procedures of the study at the end of the clinical screening. Following informed consent, patients will be randomly assigned to the MCT or ERP condition. Randomization will be done by using www.randomization.com, an online generator which randomizes each subject to a treatment condition by using the method of randomly permuted blocks (McLeod, 1985). With randomly permuted blocks, subjects are assigned to a treatment condition in blocks to ensure that equal numbers of subjects have been assigned to each treatment, not only at the end of the study but also at various intermediate time points. The generator also randomizes the block sizes (range 1-4 per group), to ensure that it is unknown when a block is finished and it is not possible to guess the remaining treatment allocation. The process of allocation of cases to intervention conditions will be done by an independent employee of the participating mental health care center, using the generated randomization plan. Patients will be allocated to treatment conditions in order of entry. The investigators and therapists have no insight in the randomization plan.

To control for therapist effects all therapists will deliver both treatments in blocks but not in parallel. For this reason, in the first 2 years of the study half of the therapists from each site deliver MCT whilst the other half does ERP. Two years later, treatment conditions will be crossed over.

Outcome measures

On all assessment points, the Dutch versions of the measures described below are included. The administration of the SCID-I and the Y-BOCS during intake will be conducted face to face, later assessments are by telephone. Self report measures will be conducted on paper and are home-based.

Primary outcome: The primary outcome of interest for this MCT superiority study is OCD-severity at posttreatment, which will be measured with the Yale-Brown Obsessive Compulsive Scale (Y-BOCS (Goodman et al., 1995), a semi-structured interview and the 'gold standard' for measuring OCD symptoms. The Y-BOCS is a clinican-rated semi-structured interview which is designed to rate the severity of both obsessions and compulsion. The Y-BOCS consists of 10 items rated from 0 to 4 (range 0-40).. The Y-BOCS has been shown to have good psychometric properties and is sensitive for measuring treatment effects (van Oppen, Emmelkamp, van Balkom, & van Dijck, 1995). Further, good internal consistency for both the subscales (obsessions and compulsions) and for the total score of the Y-BOCS has been reported (Frost et al., 2010).

Secondary outcomes: The presence of OCD and comorbid Axis I diagnosis will be assessed with the Structured Clinical Interview for DSM Axis I Disorders (SCID-I (First, Spitzer, Gibbon, & Williams, 2001)). A recently conducted study with a large sample size (n=151) found adequate to good inter-rater reliability for all Axis I disorders (Lobbestael, Leurgans, & Arntz, 2010). Secondary outcomes include self-report questionnaires to assess OCD-symptoms, comorbid symptoms and degree of perceived well-being. The Padua-Inventory revised (Padua-IR; Burns et al., 1996) is a self-report measure for OCD severity which consists of 60 items scores on a 0-4 scale (range 0 – 240). The Padua-IR has reasonable psychometric properties (van Oppen, Emmelkamp, van Balkom, & van Dijck, 1995). The symptom checklist (SCL-90 (Derogatis, 1983)) is used as a measurement of general psychopathology. The SCL-90 consist of 90 items, all scores from 1 (not at all) to 5 (very much; range 90-450). This self-report measure has shown good psychometric properties. The Beck Depression Inventory, 2nd version (BDI-II (Beck, Steer, & Brown, 1996)) is included to assess the affective, behavioural,

somatic and motivational components of depression. This frequently used self-report consist of 21 items ranging from 1 to 4 and has good psychometric properties. Finally, World Health Organization Quality Of Life (WHOQOL-Bref (2004)) is included and assesses the individuals perception of quality of life with respect to physical health, psychological health, social relationships and environment. The WHOQOL consists of 26 items which are answered on a five-point scale. It is concluded that the psychometric properties of this questionnaire is good.

Process measures: Changes in both belief domains that have been proposed to be important in the etiology of OCD are assessed. To study changes in metacognitive beliefs about the meaning, significance, and danger of intrusive thoughts, the Thought Fusion Instrument (TFI (Wells, Gwilliam, & Cartwright-Hatton, 2001)) will be employed. To study changes in metacognitive beliefs about the necessity of performing rituals in response to obsessions, the Beliefs About Rituals Inventory (BARI (McNicol & Wells, 2012)) is used. The TFI consists of 14 items and the BARI of 12 items. All items are answered on a four-point scale ranging from 1 to 4.There is little data available about the psychometric properties of the TFI and the BARI. Gwilliam et al. (2004) found reasonable internal consistency, a moderate test-retest reliability, and some support for the convergent and divergent validity for the TFI. In the developmental phase of this study the psychometric properties of the TFI and the BARI will be further assessed by our research group.

The Obsessive Belief Questionnaire (OBQ-44 (Obsessive Compulsive Working Group, 2005)) is included as another measurement with the purpose of the assessment of beliefs considered to be important in the maintenance of OCD. Factor analysis of the scale reveals four factors: (1) perfectionism and intolerance of uncertainty, (2) importance and control of thoughts, (3) responsibility, and (4) overestimation of treat (Myers, Fisher, & Wells, 2008). OBQ-44 consists of 44 items answered on a scale from 1 to 4. The psychometric properties are good.

Additionally, on both follow-up assessments, participants will be called by a research assistant, who will ask them to provide responses for the Treatment Change Recording Form (TCRF (Tolin et al., 37)), which will be used to assess the initiation, termination, or change of any form of therapy, hospital services, support group, self-help program, or medication utilized by the participant since post-treatment.

Interventions

The interventions will be offered at the Anxiety Disorders Department of PsyQ, at which ERP is already delivered as treatment as usual for OCD. Both manual-driven treatments consist of up to 15 weekly sessions of 45 minutes duration. Treatment can be terminated earlier, when both patient and therapist agree that treatment goals are completed. A minimum of 8 sessions will be managed as criteria for each patient to can be classified as treatment completer in the statistical analysis. Interventions will be delivered by nine staff psychologists, who are trained in CBT and who are familiar with the provision of ERP for OCD. Four of the participating therapists were trained by dr. Adrian Wells and dr. Peter Fisher, experts in the field of MCT, preceding the start of a pilot study into the efficacy of MCT for OCD in which they participated as therapists (Heiden et al., 2016). The other five therapists will be trained in the provision of MCT for OCD by the fourth author (CH) preceding the start of this study. During the study, therapists will be supervised monthly by the fourth author (CH) in separate group sessions for ERP and MCT. In these one hour supervision meetings, all current cases and therapy notes will be reviewed to ensure treatment quality and adherence. Treatment integrity will also be evaluated by means of randomly assessing recordings of treatment sessions against a session-by-session intervention checklist.

For the purpose of this study we will use an ERP protocol based on the inhibitory learning model of extinction (Craske et al., 2016), which states that the original fear conditioning is not erased during exposure therapy but stays intact while a second conditioning is developed. Translated to clinical practice, this means that during exposure and response prevention exercises, attention is focused on the disconfirmation of fear cognitions. Before exposure exercises, the fear cognitions are recorded and the exposure is introduced as a way to collect evidence for or against these appraisals. The ERP manual consists of three phases. In the first phase, an explanation of the behavioural model of OCD and rationale is discussed and an anxiety hierarchy containing all of the anxiety provoking situations is developed. The second phase includes both within-session and between-session in vivo and imaginal exposure-exercises, with early exposure to moderately distressing situations with progression toward more anxiety evoking ones. This latter is done to minimalize dropout in the first exposure and response prevention sessions. Later on, the patient is asked to practice in many different situations, circumstances and even alternate between the more easy and difficult exercises. According to the inhibitory learning model, the more variability is added throughout exposure exercises, the better the new

information can be retrieved at a later point which minimize relapse (Craske et al., 2016). Ritual prevention includes instructions to refrain from all compulsive behaviours. In the final phase, a relapse prevention plan is developed.

MCT focuses exclusively on modifying metacognitive beliefs about intrusive thoughts and the necessity of performing rituals (Fisher & Wells, 2008). MCT consists four treatment phases. Phase 1 involves psycho-education about the metacognitive model, increasing patients' awareness of the role of metacognitions and generation of an idiosyncratic case conceptualisation. This is accomplished by eliciting metacognitive beliefs, e.g., by guided questioning. Experiments are used to illustrate maladaptive coping strategies, e.g., the thought suppression experiment in which the patient is asked to suppress the thought of a white rabbit which is rarely completely successful (Wegner et al., 1987) . Also, detached mindfullness (DM) is practiced. In DM, patients are asked to be aware of their intrusive thoughts and try to stop or disconnect any response to that thought, like engaging with their obsessional thoughts by worrying about consequences or the chance of occurrence (Wells, 2009). Instead, patients practice with evaluating their intrusions and notice them as "just mental events in the mind", e.g., by visualising the thought moving away from them. In the second phase, metacognitive beliefs about intrusions are targeted by verbal cognitive restructuring (e.g., questioning the evidence and searching for counterevidence) and behavioural experiments. An example of such an experiment is exposure and response commission (ERC), in which patients are asked to perform rituals and to keep their intrusive thought in mind at the same time, instead of trying to get rid of the intrusive thought. The main aim of ERC is to enable patients to experience obsessive thoughts on a meta-level by obtaining distance from them and discovering that they are unimportant events in the mind (Wells, 2009) In phase 3, metacognitive beliefs about rituals are challenged, again by means of both verbal methods (e.g., questioning the evidence and an advantages-disadvantages analysis) and behavioural experiments, such as ritual modulation experiments in which patients are asked to alternate between more and less ritual behaviour with the aim of assessing its impact on daily life. In the final phase, the therapist and patient work on a relapse prevention plan consisting of a new plan for reacting in response to intrusive experiences combined with a blueprint of the therapy. The old versus new plan consists of attentional strategies and coping behaviours opposite to the strategies and behaviours of the old plan (e.g., applying detached mindfulness [new plan] instead of worrying about intrusions [old plan]). Also a blueprint of the therapy is developed, consisting of a summary of the therapy, the case conceptualisation,

a list of metacognitive beliefs and an overview of evidence challenging them. An overview of the both treatments is provided in Table 1. The full manuals (in Dutch) are available from the corresponding author upon request.

Table 1. overview of metacognitive therapy (MCT; van der Heiden et al., 2016; based on Wells, 2009) and exposure and response prevention (ERP) for obsessive-compulsive disorder (OCD)

	MCT		**ERP**	
Phase	**Interventions**	**Sessions**	**Interventions**	**Sessions**
1	-Provide treatment overview -Psycho-education about the metacognitive model of OCD -Elicit metacognitions by guided questioning -Practicing of detached mindfullness	1-2	-Provide treatment overview -Psycho-education about the behavioural model of OCD -Generation of a hierarchy of anxiety-provoking situations and avoidance behaviours	1-3
2	-Modifying metacognitions about intrusions by verbal methods (e.g., questioning the evidence) and behavioural experiments (e.g., exposure with response commission, ritual postponement and exposure and response prevention experiments)	3-8	-Exposure and response prevention exercises, both within-session and between sessions	4-13
3	-Modifying metacognitions about the necessity of rituals by verbal methods (e.g., questioning the evidence, advantages-disadvantages analysis of performing rituals) and behavioural experiments (e.g., ritual modulation experiments)	9-12	-Generation of a treatment summary consisting of an overview of OCD complaints pretreatment, rest symptoms at posttreatment and a relapse prevention plan containing helpful interventions to maintain	14-15
4	Generation of a new plan for processing in response to unwanted thoughts, feelings, or events and a therapy blueprint consisting of the case conceptualisation, a list of metacognitive beliefs and an overview of evidence challenging them.	13-15		

Statistical analysis

Outcomes

Data will be analysed using SPSS for Windows version 25.

Because of the expected dropout and the uneven time intervals between measurements (posttest-6-month-30-month-follow-up), the use of mixed models is the most appropriate statistical method (Singer & Willett, 2003). This methodology is very suitable to analyse repeated measures by taking dependency between observation into account and the ability to handle missing data. In case of Missing At Random (MAR), we will use these variable(s) as covariate in our analysis. In case of Missing Not At Random (MNAR) we will use pattern mixture models. Mixed models will be adjusted by the baseline values of the repeated measures. Descriptives for means and proportions of baseline clinical and demopraphic variables between treatment conditions will be reported so potential magnitudes of imbalances can be be assessed. Model diagnostics will be assessed by exploring residual plots. In case they are not acceptable, we will apply bootstrapping procedures with the use of R (R core team, 2018).

Fixed effects in our model will be time, treatment and their interaction. In case of missingness, we will add these variable(s) also as fixed effects. The Benjamini-Hochberg procedure is applied to the significances of the time*treatment interaction p-values (two-sided $p<0.05$) of the different outcome measures. The time variable will be treated categorically, with the first post-baseline measurement as the reference category. To accommodate the modeling of correlation among repeated measurements, we impose a first order autoregressive (AR(1)) structure on the residuals. Next, the interaction effect between time and group will be explored by analyzing the estimated marginal means at different time points. We expect a significant interaction effect between time and group, which means that scores change differently over time in the two treatment conditions. More specifically, we expect a more negative time trend for MCT than for ERP, indicating that the measurement scores in the MCT condition decline more over time than in the ERP condition. To gain further insight into the statistical significance of the improvements achieved in the two treatment conditions, we will perform a least significant difference test with the estimated marginal means to compare changes between treatment conditions. In accordance with the linear mixed models, we expect a statistical significant decline in both treatment conditions between pretest and posttest, but no statistical differences between posttest and both follow-up measures. To allow for comparison with other studies

into the effectiveness of ERP and MCT for OCD, Cohen's *d* statistic (mean 1 – mean 2) / pooled SD) will be employed to calculate within-group effect sizes (ESs) for changes on outcome measures and to evaluate between-group differences. We will calculate Cohen's *d* statistics for both intent-to-treat samples by using multilevel analysis with all available data and completer samples (our primary analysis: minimum of 8 treatment sessions and no change in medication during treatment will be managed as criteria for each patient to can be classified as treatment completer). Based on previous research we expect a large within treatment effect-size for both treatment conditions (Cohen's $d > .8$). We expect a medium between-group effect size in the favour of MCT. In addition, the clinical significance of treatment effects and amount of drop-out will be examined also to gain further insight into the clinical value of the two treatment conditions.

Endpoints

The clinical significance of treatment effects will be examined using the procedures outlined by Jacobson and Truax (Jacobson & Truax, 1991). Patients will be classified as recovered, if they score within the normal range on the Y-BOCS after treatment (cut-off point = 14), and display statistically reliable improvement on that measure (reliable change index = 10) (Jacobson & Truax, 1991). Patients will be classified as improved but not recovered if they meet only one criterion. Patients will be classified as asymptomatic (a more stringent criterion for defining recovery) when they achieve a posttreatment score of 7 or less (indicating an almost total absence of OCD symptomatology), in addition to meeting the reliable change index. Further, diagnosis-free status will also be used as an index of clinically significant change.

Discussion

MCT is a relatively new treatment for OCD, based on a metacognitive model that states that rather than the intrusive thoughts and compulsive behaviors, it is in fact beliefs about the meaning and significance of obsessive thoughts on the one hand, and beliefs about the need to conduct rituals and neutralizing behaviors on the other hand that are crucial for the development of OCD As a result, interventions should be targeted at these metacognitive beliefs. Our hypothesis is that MCT is more efficacious in the treatment of OCD than the current 'gold standard' psychological treatment for OCD, ERP. Since there is a wide variation in symptomatology between OCD patients, and beliefs about

intrusions and compulsions are comparable for each subtype, it may be that MCT is particularly well suited in the treatment of this disorder. Moreover, it may be that MCT is less burdensome since it does not include prolonged exposure to anxiety provoking stimuli. So far, five relatively small studies suggest that MCT might be an efficacious treatment for OCD and may be even more efficacious than the current 'gold standard', ERP (Fisher & Wells, 2008; Rees & Van Koesveld, 2008; Fitt & Rees, 2012; Van der Heiden et al., 2016; Simons, Schneider, & Herpertz-Dahlmann, 2006). We presented the rationale and design of a RCT assessing the relative efficacy of ERP and MCT for OCD. To our knowledge this is the first long-term randomized controlled trial to explore whether MCT produces better results than ERP.

The study has several strengths, including randomization of patients to two active treatment conditions, use of an unselected, clinically representative sample of OCD patients, and long-term follow-up assessments.

However, the current study also has limitations. Treatment conditions might be contaminated as participating therapists will deliver both ERP and MCT. It might also be difficult to maintain treatment integrity as both treatments will be conducted by therapists who work within a routine outpatient community mental health center. We aim to minimize these limitations by means of reviewing all active cases in consultation meetings and careful checking of treatment integrity.

Trial Status

This study received ethical approval from the Medical Ethical Committee of the Leiden University Medical Centre (LUMC) on 21 October 2014. The first patient enrolled on 6 February 2015. Sixty-eight participants are randomized yet. We are still recruiting patients and have planned to close the inclusion at the end of 2019.

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Chapter 6

Effectiveness of Metacognitive Therapy and Exposure and Response Prevention for Obsessive-Compulsive Disorder: A randomized controlled trial

Melchior, K., Franken, I. H. A., Mayer, B, Deen, M., & Heiden, C. van der (2021). Effectiveness of Metacognitive Therapy and Exposure and Response Prevention for Obsessive-Compulsive Disorder: A randomized controlled trial. *Under review by Behaviour Research and Therapy*

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Abstract

Background. The recommended psychological treatment of choice for obsessive-compulsive disorder (OCD) is exposure with response prevention (ERP). Although this treatment is quite effective, recovery rates are modest and drop-out is relatively high. Also, ERP treatment requires amounts of therapist time. A possible way to improve OCD treatment is by taking into account key cognitive processes involved in the development and maintenance of the disorder. The metacognitive model is such an account and pilot findings suggest that the associated metacognitive therapy (MCT) might be an effective treatment for OCD and might be more effective than ERP.

Methods. In the present study, a randomized controlled trial (RCT) is used to assess the effectiveness of MCT in comparison to ERP in an outpatient clinical sample of patients with OCD. Besides statistical significant treatment results, the clinical significance of treatment effects and drop-out rates were examined to gain further insight into the clinical value of the two treatment conditions.

Results. Both MCT and ERP produced significant pre-treatment to post-treatment decreases in obsessive-compulsive, comorbid psychological symptoms and metacognitive beliefs, both with moderate to large within-group effect sizes and high proportions of significant clinical change. Drop-out rates were low and treatment gains were maintained at six-months follow-up. There were no differences in efficacy observed between MCT and ERP treatments.

Conclusions. MCT proves to be a promising effective alternative treatment to the well-established ERP in the treatment of OCD.

Introduction

Obsessive-compulsive disorder (OCD) is a severe mental condition which is characterized by intrusive thoughts (obsessions) and repetitive behaviors (compulsions) intended to neutralize anxiety or suffering induced by these thoughts (American Psychiatric Association, 2013). It is a relatively common condition with a lifetime prevalence rate of almost 1% and a one-year prevalence rate of 0.5%. OCD has been ranked among the most debilitating disorders by the World Health Organization and is associated with loss of performance and poor quality of life (WHO, 2004). Also, symptoms tend to increase or eventually can become chronic if left untreated (WHO, 2004). Yet, adequate treatment for OCD is crucial.

The first-line psychological treatment for OCD is exposure and response prevention (ERP), widely regarded as the "gold standard" (Öst, Havnen, Dansen, & Kvale, 2015; Skapinakis et al., 2016). ERP is a specific procedure within cognitive behavioral therapy (CBT) which is based on learning theory. This theory suggests that classical conditioning is responsible for the development of obsessions, whereas operant conditioning processes maintain anxiety and compulsive behavior (Mowrer, 1951). The core principle of ERP is to expose patients to anxiety-provoking stimuli (objects, situations, thoughts) combined with the strict prevention of performing ritual behavior (Meyer, 1966). Although the prognosis of OCD improved substantially since the introduction of ERP (Öst, et al., 2015; Skapinakis et al., 2016), there is a discrepancy between statistically and clinically significant change. While several studies and meta-analyses have shown ERP to lead to statistically significant improvements in 75% of patients, only about 60% of treatment completers achieve recovery, whereas only approximately 25% of patients is asymptomatic (a more stringent criterion for defining recovery) following treatment (Fisher & Wells, 2005). Overall recovery rates may be lower as only treatment completers were included in these analyses. Approximately 30% of patients refuses ERP or dropout from treatment prematurely (Olatunji, Cisler, & Deacon, 2010). These findings illustrate that ERP might be hard to tolerate (Olatunji et al., 2010) which might be due to the requirements of treatment (Whittal, Thordarson, & McLean, 2005). Furthermore, as most ERP protocols are based on the believe that fear reduction during an exposure trial is necessary to achieve long lasting cognitive changes in the perceived harm associated with the phobic stimulus (habituation model; Foa & Kozak, 1986; Foa & McNally, 1996), ERP is a time-consuming treatment method, with typically 15 to 20 sessions of 90 minutes duration (Foa & Kozak, 1996).

Clearly, there is room for improvement regarding the psychological treatment of OCD, both in terms of tolerance, effectiveness and cost-effectiveness. It has been suggested that progress might be made by taking into account key cognitive processes involved in the development and maintenance of OCD (Frost & Steketee, 2002), such as metacognition (Purdon & Clark 1999; Wells 1997).

Metacognition refers to knowledge and cognitive processes that are involved in the interpretation, monitoring and control of thinking processes (Flavell, 1979). Wells (1997, 2000) developed a theoretical model based on metacognition, in order to explain the maintenance of OCD symptoms (see Figure 1). In this so-called metacognitive model, it is proposed that two domains of metacognitive beliefs are fundamental in the development and maintenance of OCD. The first domain contains metacognitive beliefs about the significance and consequences of intrusive thoughts and feelings, also called fusion beliefs. Three classes of fusion beliefs are highlighted: (1) Thought action fusion (TAF; Rachman, 1993) refers to the belief that obsessional thoughts can lead to the commission of an action (e.g. "If I think about stabbing my children, I will probably stab them"), (2) Thought event fusion (TEF; Wells, 1997) refers to the belief that obsessional thoughts can make certain events happen (e.g. "Thinking of a plane crash means I will be involved in a plane crash") or mean that an event has already occurred (e.g. "If I think I ran into someone with my car, I probably did it") and (3) Thought object fusion (TOF; Wells, 2000) refers to the belief that thoughts or negative feelings can be passed into objects (e.g. "My thoughts and feelings can contaminate objects"). These misinterpretations of obsessive thought and images cause worrying and anxiety. This consequently primes the second domain of metacognitive beliefs: beliefs about the necessity of performing ritual behaviours in order to reduce the perceived threat (e.g. "Counting to seven will restrain me from acting on my thoughts"). As a result, patients with OCD engage in both overt and covert ritual behaviours (e.g., checking, washing, ordering, repeating particular words). These behaviours serve the function of reducing threat and controlling feelings of distress and anxiety. Since the importance and danger of intrusive thoughts is determined by metacognitions, there is no objective evidence that a situation is safe. Therefore, ritual behaviors are performed until specific internal rules, the so-called stop signals, are met. For example, an OCD patient with contamination fears might stop washing when she can wash her hands for 2 minutes without feeling anxious. A key problem with ritual behaviours is that they prevent the OCD patient from learning that their metacognitive beliefs about the intrusive

thoughts and ritual behaviours are inaccurate. Moreover, patients often fail to notice that their ritual behaviour backfires by causing an increase in the awareness and frequency of intrusive thoughts.

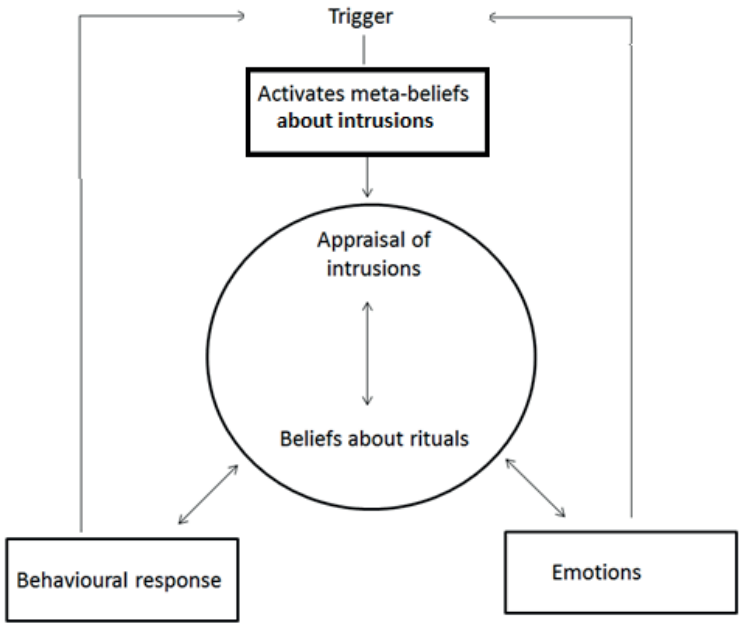

Figure 1. Metacognitive model for OCD (Wells, 1997).

Following from this metacognitive model, treatment should focus on modifying patients' beliefs about the importance and power of intrusive thoughts and the necessity of performing rituals, instead of challenging the actual content of the obsessions and compulsions (Fisher & Wells, 2008). Although MCT uses comparable techniques as CBT for this purpose, such as socratic questioning and exposure exercises, the two approaches are fundamentally different (Fisher, 2009). Firstly, within MCT it is assumed that disordered higher order metacognitive processes, such as beliefs about the importance and power of thoughts, are responsible for the development and maintenance of OCD. As a result, MCT focuses on the process (meta-level) rather than the content of thinking (object level), as is done in CBT. Instead of addressing obsessive thoughts by reality testing as is the case in CBT, MCT focuses solely on challenging metacognitive (high-order) beliefs about obsessions or compulsions and does not aim to modify lower order appraisals such as perfectionism or inflated responsibility, as these belief domains

are thought to be products of metacognitive beliefs (Gwilliam, Wells, & Cartwright-Hatton, 2004). As such, in CBT exposure exercises are used as a way to violate expectations regarding the possible occurrence of negative outcomes and the need to engage in ritual behaviors to prevent these outcomes from happening. In MCT, exposure exercises are used to challenge metacognitive beliefs. A second difference is that MCT uses a novel technique called *detached mindfulness*, to enhance flexible control over reactions to intrusive thoughts, instead of challenging them as is done in CBT. In detached mindfulness patients are asked to be aware of their intrusive thoughts and try not to respond to them, instead of engaging like they normally would do (e.g., by worrying about consequences; Wells, 2009). The main aim is for patients to be able to notice the intrusive thoughts as "just mental events in the mind".

Only a few studies have examined the effectiveness of MCT for OCD. Using single case methodology, Fisher and Wells (2008) found clinically significant improvements for 4 OCD patients with different clinical presentations who were treated individually with MCT. At post-treatment, all 4 participants met standardized recovery criteria. Two out of 4 participants were asymptomatic at both post-treatment and six-month follow-up assessments. In an open trial of group MCT for OCD, Rees and Van Koesveld (2008) found that 7 out of 8 participants (87.5%) achieved recovery on the Y-BOCS at three-month follow-up. Furthermore, a pilot study by Van der Heiden, Melchior, Dekker, Damstra, and Deen (2016) among 25 patients with OCD showed that after treatment, 74% of the treatment completers (n = 19) could be classified as recovered and 47% as asymptomatic. At three-month follow-up, these numbers were increased to 80% and 67% respectively. Finally, very recently Glombiewski et al., (2021) compared the efficacy of MCT with ERP in a pilot randomized trial among 37 patients with OCD. MCT and ERP appeared both effective with significant reductions in OCD symptoms and large effect-sizes. Both post-treatment and at three-month follow-up, 28.6% of the MCT treatment completers achieved clinically significant change. In the ERP condition, this was 50%. Noteworthy, there was a significant difference in the face-to-face time spent with a therapist between the treatment conditions, namely 22.9 hours within the ERP condition vs 13.1 in the MCT condition. More randomized controlled trials (RCTs) comparing MCT directly with ERP amongst larger groups of patients and with longer follow-up measurements are needed to reach more definitive conclusions regarding the relative efficacy of both treatments.

In the present paper, the design and results of an RCT comparing MCT and ERP in the treatment of OCD are described. We hypothesized statistically and clinically significant improvements in both treatment conditions, and we expected MCT to be more effective than ERP.

Method

The current RCT was carried out to assess the effectiveness of MCT as compared to ERP in a large outpatient clinical sample of patients with OCD. Assessments were carried out at pre-treatment, post-treatment, and six-month follow-up. Potential participants were screened for eligibility and received extensive information about the design and procedures of the study at the end of the intake phase. Following informed consent, patients were randomly allocated to either MCT or treatment as usual (ERP). Randomization was done by using *www.randomization.com*, an online generator which randomizes each subject to a treatment condition by using a method of randomly permuted blocks. The generator also randomizes the block sizes, to ensure that it is unknown when a block is finished and it is not possible to guess the remaining treatment allocation. Ethical approval was obtained from the Leiden University Medical Centre (NL50201.058.14). The trial was registered in the Netherlands Trial Register (NTR4855). A detailed description of the research design is also found in the published study protocol of Melchior, Franken, Deen, and Van der Heiden (2019). Figure 2 shows the patient flow through the trial.

Recruitment and eligibility criteria

Between June 2015 and February 2020, 133 patients were recruited from consecutive referrals to the Anxiety Disorders department of PsyQ, an outpatient community mental health center in the Netherlands. As structured diagnostic instruments based on the DSM-5 (American Psychiatric Association, 2013) were not yet available in the Dutch language at the development phase of the RCT, diagnosis was established using the Dutch version of the Structured Clinical Interview for DSM-IV (SCID-I; First, Spitzer, Gibbon, & Williams, 2002), which was administered by independent trained psychology master students. Lobbestael, Leurgans, and Arntz (2011) found adequate to good inter-rater reliability for the Dutch version of the SCID-I. The inclusion criteria were 1) primary diagnosis of OCD; and 2) age 18-65. Exclusion criteria were kept to a minimum to enhance the clinical representativeness of the sample. Patients were excluded if they currently

1) met DSM-IV criteria for severe major depressive disorder that requires immediate treatment, bipolar disorder, or psychotic disorder; 2) had substance abuse requiring specialized treatment; 3) had mental impairment or evidence of organic brain disorder; 4) were receiving a psychological treatment for any comorbid psychiatric disorder; or 5) had a change in medication type or dose in the six weeks before assessment or during treatment. The presence of other comorbid disorders or the continued use of psychopharmaca patients already used longer than six weeks before assessment were not exclusion criteria. No reward was offered for participating in the study.

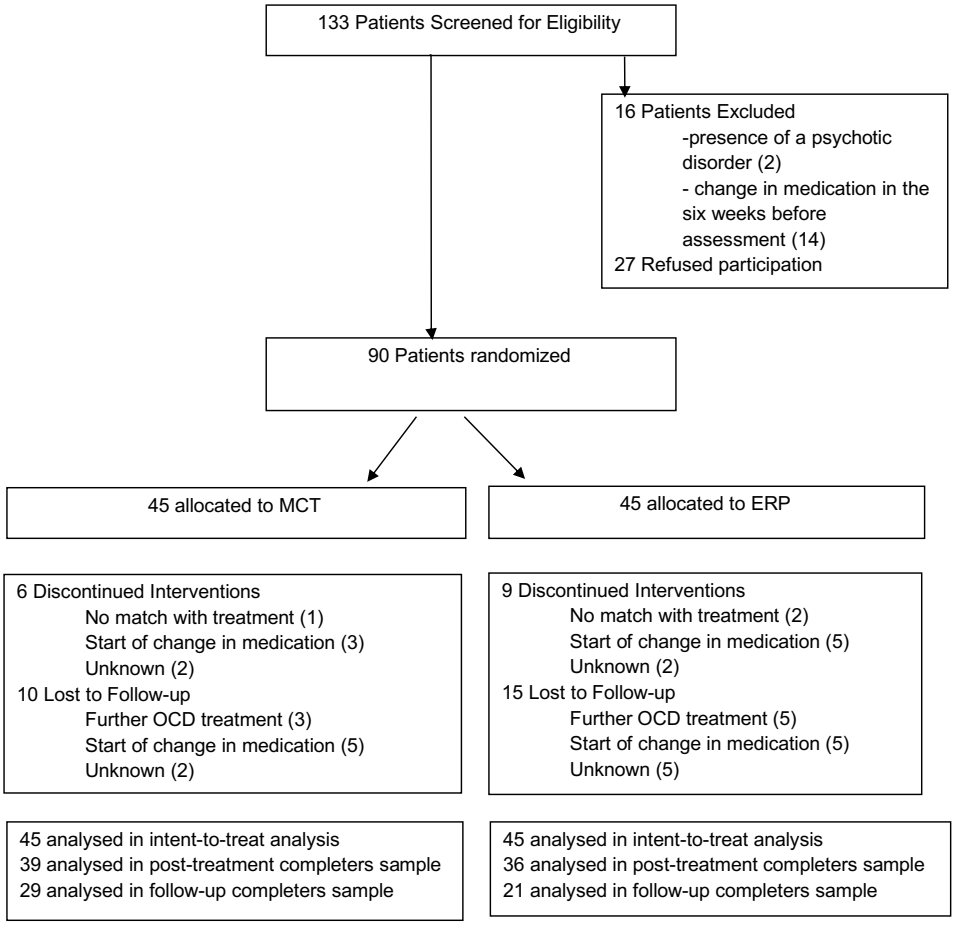

Figure 2. Flowchart of the study

Note. ERP = exposure and response prevention; MCT = metacognitive therapy.

Sixteen of the 133 potentially eligible patients were excluded based on the presence of a psychotic disorder (N = 2) or a change in medication in the six weeks before assessment (N = 14). Next, 27 patients refused randomization, leaving 90 patients entering the active treatment phase. Of these 90 patients, 15 (16.7%) dropped out from the active treatment phase, 9 in the ERP condition (19.9%), and 6 in the MCT condition (13.3%). At six month follow-up, the 75 treatment completers were approached. Seven patients appeared unreachable, 2 in the MCT condition and 5 in the ERP condition. For the remaining 68 patient, the Treatment Change Recording Form (TCRF; Tolin, Maltby, Diefenbach, Hannan, & Worhunsky, 2004) was administered to assess the initiation, termination, or change of any form of (psycho)therapy, hospital services, support group, self-help program, or medication used by the participant following completion of treatment. Based on the information obtained with the TCRF, 18 patients were excluded from the follow-up analyses. In the MCT condition, 3 patients had received additional treatment for OCD and 5 had a change in their medication. In the ERP condition, 5 patients had received additional treatment for OCD and 5 had a change in their medication. Overall, 50 participants completed follow-up assessments (55.6%), 29 participants in the MCT-condition (64.4%) and 21 participants (46.7%) in the ERP-condition.

Assessment

Participants were assessed by means of self-report measures and a semi-structured clinical interview (administered by independent and trained psychology students who were blind to treatment allocation) at entry (pre-treatment), after the last treatment session (post-treatment), and at six-month follow-up. In case of dropout, measurements and interviews were administered as soon as possible after treatment had ended.

Primary treatment outcome

Yale-Brown-Obsessive-Compulsive-Scale (Y-BOCS). The main outcome of interest for this study is the severity of the OCD symptoms, which was measured with the Y-BOCS (Goodman et al., 1989). The Y-BOCS is a clinician-rated semi-structured interview which is designed to rate the severity of OCD symptoms. It consists of 10 items, of which 5 items measure the severity of obsessions and 5 items measure the severity of compulsions. Each item is rated on a 5-point scale ranging from 0 (*none*) to 4 (*extreme*) leading up to a range from 0 to 40. The Y-BOCS is widely used in treatment outcome research in OCD, and proved to have reasonable psychometric properties (López-Pina et al., 2015; Van Oppen, Emmelkamp, van Balkom, & van Dyck, 1995). In the present trial, Cronbach's α at pretreatment was .76.

Secondary outcomes

Padua-Inventory Revised (Padua-IR). The severity of common obsessions and compulsions was measured with the Padua-IR (Burns, Keortge, Formea, & Sternberger, 1996), a self-report questionnaire consisting of 41 items. Each item is rated on a 5-point Likert scale from 0 (*not at all*) to 4 (*very much*) which makes up a range from 0 to 164. Previous research has found that the PADUA-IR has adequate psychometric properties (Van Oppen, 1992). In the present trial, Cronbach's α at pretreatment was .93.

Symptom Checklist (SCL-90). General psychopathology and common psychological complaints were measured with the SCL-90 (Derogatis, 1983). The SCL-90 consists of 90 items, all scored on a 5-point Likert scale ranging from 1 (*not at all*) to 5 (*very much)* (range 90-450). The SCL-90 has shown sound psychometric properties (Ettema & Arrindell, 2003). In the present trial, Cronbach's α at pretreatment was .97.

Beck Depression Inventory (BDI-II). To assess comorbid depressive symptoms the revised version of the Beck Depression Inventory (BDI-II; Beck, Steer, & Brown, 1996) was included. The questionnaire is based on self-report and consists of 21 items scored on a 4-point scale from 0 (*absence of symptoms*) to 3 (*intense symptoms*) (range 0-63). The BDI-II is a reliable and well-validated measure of depressive symptoms (Wang & Gorenstein, 2013). In the present trial, Cronbach's α at pretreatment was .92.

World Health Organization Quality of Life Questionnaire (WHOQoL-BREF). Finally, the WHOQoL-BREF was used, a 26 item self-report measurement developed for the assessment of well-being. Responses to questions are on a 1-5 Likert scale from 1 (*disagree*) to 5 (*completely agree*) (range 26-130). Analyses revealed the WHOQoL-BREF as a valid assessment of quality of life (Skevington, Lotfy, & O'Connell, 2004). In the present trial, Cronbach's α at pretreatment was .92.

Measures of treatment process

Thought Fusion Instrument (TFI). Changes in metacognitive beliefs about the significance and consequences of intrusive thoughts and feelings were measured with the TFI (Wells, Gwilliam, & Cartwright-Hatton, 2001), a 14-item self-report scale. Each item is rated on a 0 to 100 scale (range 0-1400). Melchior et al. (2021) found adequate psychometric properties. In the present trial, Cronbach's α at pretreatment was .89.

Beliefs About Rituals Inventory (BARI). Changes in metacognitive beliefs about the necessity of performing rituals in response to obsessions were assessed with the BARI (McNicol & Wells, 2012). This self-report questionnaire contains 12 items which can be rated on a 5-point Likert scale from 0 (*do not agree*) to 4 (*agree very much*), giving it a range from 0 to 48. Unfortunately, the Dutch version was not available at the beginning of this study, so the BARI was not administered in the first 11 patients that were included in this study. In the study of Melchior et al. (2021), the BARI appeared as a valid assessment with adequate reliability and validity coefficients. In the present trial, Cronbach's α = .87.

Obsessional Beliefs Questionnaire (OBQ). Finally, we included the OBQ (Obsessive Compulsive Cognitions Working Group [OCCWG], 2005). The OBQ is a 44-item instrument, specifically designed to measure dysfunctional beliefs assumed to contribute to the escalation of normal intrusive thoughts into clinical obsessions. Responses to questions are on a -3 to 3 Likert scale where -3 represents *'disagree very much'* and 3 represents *'agree very much'* (range -132 – 132). The instrument has shown good validity, internal consistency and reliability. In the present trial, Cronbach's α at pretreatment was .96.

Treatments, therapists and treatment integrity

An overview of both treatments is provided in Table 1. Both treatments consisted of up to 15 weekly sessions of 45 minutes duration and could be terminated earlier, in case both patient and therapist agreed that treatment goals were completed. However, to be classified as treatment completer in the statistical analyses, treatment should have encompassed at least 8 sessions. The interventions were delivered by 10 female certified cognitive behavioral therapists (mean age 39 year [range 27 – 57]), familiar with the provision of ERP for OCD and on average 13 years (range 5 – 24) of clinical experience. During monthly supervision meetings the second author (CH) supervised current cases in both treatment conditions to ensure treatment quality and adherence. Also, treatment integrity was evaluated by means of randomly assessing recordings of treatment sessions. In both conditions, treatment sessions 2, 5 and 9 were recorded. By using an intervention checklist, trained master students evaluated whether therapists used the interventions as described in the respective treatment sessions of both treatment manuals, and whether they did not use interventions outside the scope of the treatment they were offering. A 3-point Likert scale was used as an estimation for treatment adherence (complete adherence), slight deviation (e.g., forgotten

to reflect on homework), and large deviation (e.g., interventions were applied that were not described in the manual). Finally, a therapist cross-over design was used to control for therapist effects, meaning that therapists delivered both types of treatment in separate blocks. Two psychologists however delivered only one type of treatment due to the fact they left the organization during our trial and were replaced by other therapists.

Table 1. Overview of MCT and ERP for OCD.

Phase	MCT	Sessions	ERP	Sessions
1	- Provide treatment overview - Psycho-education about the metacognitive model of OCD - Elicit metacognitions through guided questioning - Practicing of detached mindfulness	1-2	- Provide treatment overview - Psycho-education about the behavioral model of OCD - Formulation of a hierarchy of anxiety-provoking situations and avoidance behaviors	1-3
2	- Modifying of metacognitions about intrusive thoughts by verbal methods and behavioral experiments, e.g., exposure and response commission	3-8	- Exposure and response prevention exercises (within-session and between sessions)	4-13
3	- Modifying of metacognitions about the necessity of rituals by verbal methods and behavioral experiments, e.g., ritual modulation experiments	9-12	- Development of a personal relapse prevention plan and treatment summary	14-15
4	- Formulation of a new plan for responding to intrusive thoughts, a therapy blueprint consisting of the case conceptualization, and a list of metacognitive beliefs including an overview of evidence challenging them	13-15		

Note. ERP = exposure and response prevention; MCT = metacognitive therapy.

MCT consists of four phases. In the first phase, the metacognitive model is explained to increase the patients' awareness of the role of metacognitions and to develop an idiosyncratic case conceptualization. Experiments are used to illustrate maladaptive coping strategies. For example, thought suppression experiments like the White Bear-experiment (Wegner et al., 1987) are used to illustrate that the suppression of thoughts will lead to an increase in the frequency and intensity of the suppressed thought. Also, detached mindfulness is introduced as a way to enable patients to move from treating their thoughts about their obsessions and compulsions as facts to being able to objectively evaluate their obsessions as merely mental events not requiring further processing (Fisher & Wells, 2008). In the second phase, verbal cognitive restructuring (e.g., questioning the evidence) and behavioral experiments are used to target metacognitive beliefs about intrusive thoughts. To illustrate, exposure and response commission is an experiment in which patients are asked to perform their rituals while maintaining the intrusive thought simultaneously, instead of trying to get rid of this thought. The goal is to enable patients to experience obsessive thoughts on a metacognitive level by obtaining distance from them and discovering that they are unimportant events in the mind (Wells, 2009). The third phase focuses on challenging metacognitive beliefs about rituals, also by verbal techniques and specific behavioral experiments. For instance, in ritual modulation experiments patients are asked to perform more and less ritual behavior alternately, in order to assess whether rituals are as functional as they state in their metacognitive beliefs (such as 'if I do not carry out my rituals, I will never find peace of mind again'). In the fourth and final phase, a personal relapse prevention plan is formulated for responding to intrusive experiences, in which 'the old plan' (e.g., worrying in response to obsessive thoughts) is replaced by 'a new plan' (e.g., practicing detached mindfulness) of attentional strategies and coping behaviors in reaction to intrusive thoughts. This phase is completed by developing a blueprint of the therapy, including the case conceptualization, a summary of the therapy, and a list of personalized metacognitive beliefs and overview of evidence challenging them.

As in the last 15 years a shift has taken place in our knowledge of proposed underlying working mechanism of ERP, we used an ERP protocol based on the inhibitory learning model of extinction (Baker, Mystkowski, Culver, Mortazavi, & Craske, 2010; Deacon et al., 2013). This theory states that fear reduction results from the learning of new non-threat (i.e., inhibitory) associations that compete with older threat associations (e.g. shaking hands and not

washing afterwards in order to learn not getting sick). Exposure therapy therefore should focus on the mismatch between expectancies and outcomes so that the inhibitory association becomes sufficiently strong and retrievable to compete with excitatory fear memories. As such, exposure exercises are only continued for the duration determined to be most effective to violate expectancies, rather than whether anxiety was declined. Our ERP protocol consists of three phases. During the first phase, the cognitive-behavioral model of OCD and the treatment rationale are discussed. Subsequently, anxiety provoking situations are registered. In the second phase, the patient is asked to perform in vivo and imaginary exposure exercises both within- and between-session. Prior to exposure exercises, fear expectancies are defined. Subsequently, exposure exercises are used to violate expectancies regarding the frequency or intensity of the aversive outcomes. In the third and final phase, a personal relapse prevention plan is developed.

Power and sample size

We chose to design our study with enough statistical power to enable us to detect a medium between-group effect (Cohen's d = 0.5; Cohen, 1992) from baseline to posttreatment. We chose for this medium between-group effect because expecting a larger difference between the two treatment groups did seem unrealistic since numerous studies have found statistically significant changes and large improvements in OCD-symptoms after ERP. We used the statistical method presented by Liu and Liang (1997) for sample size calculations for studies with correlated observations. To achieve a power of 0.8 with four measurement points with a correlation of 0.5 between repeated measures (standard value) and to detect a medium effect size (Cohen's d = 0.5 between the two treatment conditions over time on the primary outcome measure (severity of OCD symptoms as measured by the Y-BOCS) and an expected drop-out rate of 20%, the minimal sample size necessary in each condition is 45.

Statistical analyses

Data were analyzed using SPSS for windows 25. First of all, adequacy of randomization was assessed by studying pretreatment differences between treatment conditions on baseline clinical and demographic variables using t-tests and Pearson's chi-squared tests. Also pretreatment differences between participants who completed the treatment (with a minimum of 8 sessions) and those who did not were analyzed (intent-to-treat [ITT] sample).

Next, treatment outcome is examined. Because of the dropout and the uneven time intervals between measurements (posttest-six-month follow-up), the use of mixed models is the most appropriate statistical method (Singer & Willett, 2003). Model diagnostics were assessed by exploring residual plots. Fixed effects in our model are time, treatment and their interaction. The Benjamini-Hochberg procedure was applied to the *p* values of the time x treatment interactions (Cronbach's $\alpha = 0.05$) of the different outcome measures. The time variable was treated categorically, with the first post-baseline measurement as the reference category. To accommodate the modeling of correlation among repeated measurements, we impose a first order autoregressive (AR[1]) structure on the residuals. Next, the interaction effect between time and group was explored by analyzing the estimated marginal means at different time points. To gain further insight into the statistical significance of the improvements achieved in the two treatment conditions, we perform a least significant difference test with the estimated marginal means to compare changes between treatment conditions.

Further, to allow for comparison with other studies into the effectiveness of ERP and MCT for OCD, Cohen's *d* statistic ([mean 1 – mean 2] / pooled SD; Cohen, 1991) was employed to calculate within-group effect sizes (ESs) for changes on outcome measures. We calculated Cohen's *d* statistics by using the observed means and standard deviations. Based on previous research we expected a large within-treatment effect-size for both treatment conditions (Cohen's $d > 0.8$).

Finally, the clinical significance of treatment effects and amount of drop-out was examined also to gain further insight into the clinical value of the two treatment conditions. The clinical significance of treatment effects is examined using the standardized criteria developed by Fisher and Wells (2005) based on the procedures outlined by Jacobson and Truax (1991). Patients were classified as recovered, if they score within the normal range on the Y-BOCS after treatment (cut-off point = 14), and display statistically reliable improvement on that measure (reliable change index = 10). Patients were classified as asymptomatic (a more stringent criterion for defining recovery) when they achieve a posttreatment score of 7 or less (indicating an almost total absence of OCD symptomatology), in addition to meeting the reliable change index. Further, diagnosis-free status was also used as an index of clinically significant change. The clinical significance of treatment effects was examined for both the completers as well as the ITT sample.

Results

Descriptive and preliminary analysis

Demographic characteristics of the sample prior to the start of treatment are displayed in Table 2. On average, patients experienced OCD symptoms for more than eleven years. Moreover, more than two-third (72.2%) received treatment for their OCD symptoms at least one previous time, of which 31.1% even two or three times. Also, more than two-third (71.1%) met DSM-IV criteria for at least one co-morbid diagnosis, with personality disorder (in most of the casus cluster C personality disorder; 28.9%), depressive disorder (24.4%), panic disorder (13.3%), social phobia (11.1%), generalized anxiety disorder (7.8%) and posttraumatic stress disorder (3.3%) being the most common comorbid diagnoses.

T-tests and Pearson's chi-squared tests revealed no significant differences between treatment groups on demographic and clinical variables at baseline, except for psychopharmaca use. Specifically, 44.4% of the patients in the MCT condition and 22.2% in the ERP condition were using psychopharmaca on a stable dose for at least 6 weeks before entering the treatment program, a significant difference (χ^2 [1] = 5.000, p = 0.025).

Table 3 shows observed means on primary, secondary and process measures for the ITT sample. We found no significant differences between the two treatment conditions on any of the outcome or process measures at baseline (Fs[1,88] < 3.34, ps > .05).

In the MCT group, 6 patients (13.3%) did not complete treatment as intended. In the ERP group this involved 9 patients (19.9%), a substantial but non-significant difference in attrition rate (χ^2 = 0.95, p = .81). The 75 patients who completed the active treatment phase did not differ from the 15 drop-outs on any of the baseline outcome measurements. This also appeared true when analyzing differences in baseline characteristics between the 47 study completers (completing all assessment points up to follow-up) and drop-outs from active treatment phase (ps > .05). Finally, there was no significant difference in number of sessions between treatment conditions (MCT: M = 13.82, SD=2.32, range 8-15; ERP: M=12.51, SD=3.99, range 8-15; t(88) = 1.51, p = .14).

Treatment integrity

A sample of 66 randomly selected recordings of treatment sessions, equally divided between the two treatment conditions, were analyzed. Of the analyzed recordings, 85% was scored in the 'complete adherence'-category. In 15% of the cases a slight deviation was perceived. In only 4% of the analyzed recordings, therapeutic interventions were applied that were not described in the treatment manual, but no interventions derived from the other treatment condition were observed.

Table 2. Sample characteristics at pre-treatment

	Total sample (N=90)		**ERP (N=45)**		**MCT (N=45)**	
	M	***SD***	***M***	***SD***	***M***	***SD***
Age in years	31.22	9.9	31.6	9.8	30.8	10.2
Duration of OCD in years before start of treatment	11.24	9.8	10.4	8.7	12.11	10.7
	N	**%**	**N**	**%**	**N**	**%**
Gender (female)	55	61.1	26	57.8	29	64.4
Highly educated (Bachelor, Master, PhD)	45	50	21	46.6	24	53.4
Living alone	55	61	27	60	28	62.2
Currently unemployed	13	14.4	4	8.9	9	20
Use of psychopharmaca	30	33.3	10	22.2	20	44.4
≥ 1 comorbid disorder	64	71.1	35	77.8	29	64.4
1 previous treatment for OCD	37	41.1	16	35.6	21	46.7
2 previous treatments for OCD	19	21.1	8	17.8	11	24.4
≥ 3 previous treatments for OCD	9	10	3	6.6	6	13.4

Note. ERP = exposure and response prevention; MCT = metacognitive therapy.

Treatment outcome

The results of the multilevel analyses of treatment condition and time effects are shown in Table 4. Time proved to be the most important predictor on all outcome variables. On all outcome variables, the time-effect appeared significant for both groups, both posttreatment and at the time of follow-up, indicating significant improvements on all outcome variables for both groups over time. The time x condition models were all non-significant (YBOCS: $F[2,116] = 0.168$, $p = .85$, Padua: $F[2,117] = 1.228$, $p = .30$, BDI: $F[2,124] = 0.264$, $p = .77$, SCL-90: $F[2,86] = 1.180$, $p = .31$, WOHQoL: $F[2,140] = 1.411$, $p = .25$, TFI: $F[2,135] = 2.801$, $p = .07$, BARI: $F[2,89] = 1.175$, $p = .31$, OBQ: $F[2,127] = 0.092$, $p = .91$), which means that the effect of treatment over time did not differ between treatment condition on any of the outcome or process measures.

Table 3. *Observed means, (standard deviations) of all variables at Pre, Post and Follow-up and effect-sizes (cohen's d) of the dependent variables.*

	MCT					ERP				
	M (SD)			cohen's *d*		*M (SD)*			cohen's *d*	
	Pre	Post	Follow-up	Post	Follow-up	Pre	Post	Follow-up	Post	Follow-up
Primary outcome										
Y-BOCS	24.78 (6.01)	12.95 (8.32)	12.07 (8.25)	1.65	1.78	24.36 (5.21)	11.81 (7.18)	10.38 (6.98)	2.03	2.29
Secondary outcomes										
PADUA-IR	61.64 (27.53)	40.59 (25.29)	35.37 (27.49)	.80	.95	63.24 (27.39)	39.11 (27.11)	39.50 (18.10)	.89	1.04
BDI-II	19.67 (10.31)	13.49 (12.31)	8.89 (8.56)	.55	1.14	21.44 (12.14)	14.00 (12.13)	9.80 (9.49)	.61	1.08
SCL-90	192.09 (50.13)	164.03 (56.61)	148.52 (51.82)	.53	.85	198.50 (55.05)	151.69 (57.44)	145.85 (44.44)	.83	1.06
WOHQoL	87.16 (13.27)	92.31 (16.65)	100.11 (13.62)	.34	.96	86.47 (15.67)	95.75 (17.83)	100.15 (13.72)	.55	.93
Process measures										
TFI	425.91 (287.67)	258.46 (251.48)	194.07 (203.04)	.62	.94	357.56 (254.74)	252.22 (223.51)	230.50 (231.60)	.44	.52
BARI	26.65 (7.68)	19.86 (7.79)	17.59 (6.36)	.88	1.29	27.77 (8.95)	18.79 (7.79)	17.40 (5.45)	1.07	1.44
OBQ	9.67 (47.77)	-16.80 (52.33)	-39.70 (54.93)	.53	.96	1.62 (59.69)	-24.04 (59.54)	-51.20 (49.04)	.43	.97

Table 4. Parameter estimates for mixed models regarding baseline – posttreatment– follow-up

	Estimate	*SE*	*p*
Y-BOCS			
Intercept	24.78	0.89	<.01
Condition	-0.422	1.17	.72
Time-posttreatment	-11.67	1.00	<.01
Time-follow-up	-11.40	1.13	<.01
Time x condition posttreatment	-0.94	1.62	.56
Time x condition follow-up	-0.94	1.84	.72
Padua-IR			
Intercept	61.64	4.06	<.01
Condition	1.60	5.73	.78
Time-posttreatment	-21.33	2.19	<.01
Time-follow-up	-19.74	3.58	<.01
Time x condition posttreatment	-2.16	4.24	.61
Time x condition follow-up	6.09	4.97	.22
BDI-II			
Intercept	19.67	1.52	<.01
Condition	1.78	2.35	.45
Time-posttreatment	-5.84	1.36	<.01
Time-follow-up	-7.91	1.31	<.01
Time x condition posttreatment	-1.18	2.24	.60
Time x condition follow-up	0.07	2.65	.98
SCL-90			
Intercept	192.09	7.39	<.01
Condition	6.80	11.02	.54
Time-posttreatment	-28.09	5.72	<.01
Time-follow-up	-31.98	7.34	<.01
Time x condition posttreatment	-17.66	12.11	.15
Time x condition follow-up	-10.42	12.76	.42
WHOQoL			
Intercept	87.16	1.96	<.01
Condition	-0.69	3.03	.82
Time-posttreatment	4.45	1.69	.01
Time-follow-up	8.87	1.81	<.01
Time x condition posttreatment	3.92	2.55	.13
Time x condition follow-up	0.79	2.72	.77

TFI			
Intercept	425.91	42.87	<.01
Condition	-68.35	56.99	.23
Time-posttreatment	-179.57	32.72	<.01
Time-follow-up	-176.35	33.94	<.01
Time x condition posttreatment	87.00	42.79	.05
Time x condition follow-up	107.85	48.53	.03
BARI			
Intercept	26.41	1.17	<.01
Condition	1.34	1.82	.46
Time-posttreatment	-6.96	1.06	<.01
Time-follow-up	-6.96	1.08	<.01
Time x condition posttreatment	-2.76	1.92	.16
Time x condition follow-up	-2.85	1.94	.15
OBQ			
Intercept	11.63	7.16	.11
Condition	-10.15	11.44	.38
Time-posttreatment	-28.15	6.47	<.01
Time-follow-up	-42.27	8.61	<.01
Time x condition posttreatment	3.60	8.90	.69
Time x condition follow-up	4.47	12.54	.72

Both MCT and ERP were associated with large ESs on the primary outcome measure (Y-BOCS), at posttreatment (MCT: 1.65; ERP: 2.03) and at follow-up assessment (MCT: 1.78; ERP: 2.29). At posttreatment, ESs on both the secondary outcome measures and process measures appeared moderate to large for both the MCT condition (Padua-IR:0.80, BDI: 0.55, SCL-90: 0.53, WOHQoL: 0.34, TFI = 0.62, BARI: 0.88, OBQ: 0.53) and the ERP condition (Padua-IR: 0.89, BDI: 0.61, SCL-90: 0.83, WOHQoL: 0.55, TFI = .44; BARI: 1.07, OBQ: .43). For the follow-up assessment, ESs for the MCT condition were all large (Padua-IR: 0.95, BDI: 1.14, SCL-90: 0.85, WOHQoL: 0.96, TFI: 0.94, BARI: 1.29, OBQ: 0.96), for the ERP condition moderate (TFI: 0.52) to large (Padua-IR: 1.04, BDI: 1.08, SCL-90: 1.06, WOHQoL: 0.93, BARI: 1.44, OBQ: 0.97).

Clinical recovery

An overview of the recovery status of patients is presented in Table 5 (completers sample) and Table 6 (ITT-sample). Pearson's Chi square tests revealed no significant differences on both recovery and asymptomatic rates between treatment conditions (all *p*s > .05). Table 5 and 6 also show the

percentages of patients with a diagnosis-free status at post-treatment and at follow-up assessment. Again, no significant difference between the ERP and MCT groups were found (all ps > .05).

Table 5. The rate of clinical recovery at post-treatment and six-month follow-up for completers of the study.

		Recovered (%)	Asymptomatic (%)	Diagnosis-free
Post-treatment	ERP (N=36)	22 (61.1%)	12 (33.3%)	19 (52.7%)
	MCT (N=39)	28 (71.8%)	10 (25.6%)	24 (62.0%)
	Significance test	$\chi^2 = 0.96$, $p = .33$	$\chi^2 = 0.53$, $p = .47$	$\chi^2 = 0.59$, $p = .44$
Follow-up	ERP (N=21)	14 (66.7%)	7 (33.3%)	12 (57.1%)
	MCT (N=29)	21 (72.4%)	9 (31.0%)	20 (69.0%)
	Significance test	$\chi^2 = 0.19$, $p = .66$	$\chi^2 = 0.03$, $p = .86$	$\chi^2 = 0.74$, $p = .39$

Note. ERP = Exposure and Response Prevention; MCT = Metacognitive Therapy.

Table 6. The rate of clinical recovery at post-treatment and six-month follow-up for patients who entered treatment (intent-to-treat sample).

		Recovered (%)	Asymptomatic (%)	Diagnosis-free
Post-treatment	ERP (N=45)	22 (48.9%)	12 (26.7%)	19 (42.2%)
	MCT (N=45)	28 (62.2%)	10 (22.2%)	24 (53.3%)
	Significance test	$\chi^2 = 1.62$, $p = .20$	$\chi^2 = 0.24$, $p = .62$	$\chi^2 = 0.80$, $p = .37$
Follow-up	ERP (N=45)	14 (31.1%)	7 (15.6%)	12 (26.7%)
	MCT (N=45)	21 (46.7%)	9 (20.0%)	20 (44.4%)
	Significance test	$\chi^2 = 2.29$, $p = .13$	$\chi^2 = 0.30$, $p = .58$	$\chi^2 = 0.54$, $p = .47$

Note. ERP = Exposure and Response Prevention; MCT = Metacognitive Therapy.

Discussion

In the present study, an RCT was carried out to assess the effectiveness of MCT in comparison to ERP in an outpatient clinical sample of patients with OCD. Exclusion criteria were kept to a minimum in order to enhance the clinical representativeness of the sample. Results of the current RCT show that ERP and MCT are both effective treatment methods for OCD. Both treatments produced significant pre-treatment to post-treatment decreases in obsessive-compulsive symptoms, comorbid psychological symptoms (e.g., depressive symptoms) and dysfunctional (metacognitive) beliefs as

indexed by the process measures. Further, quality of life increased between pre- and post-treatment. We found large within-group effect sizes on the measurements for obsessive-compulsive symptoms and moderate to large within-group effect sizes for secondary and process measures. High percentages of clinically significant change were found in both treatment conditions. Also, drop-out rates were relatively low in both treatment conditions. Treatment gains were maintained at six-months follow-up. No significant differences were found between the two treatments on any outcome or process measure, nor in terms of clinically significant change or drop-out rate. As such, we did not find support for our main hypothesis that MCT is more effective than ERP in treating OCD.

One explanation for not finding significant differences might be that underlying mechanisms of change are shared between the two treatment conditions. This hypothesis is supported by the fact that we found statistically significant decreases in dysfunctional (metacognitive) beliefs as indexed by the process measures in both treatment conditions without significant between-group differences. It is possible that the implementation of the inhibitory learning model of extinction in our ERP condition has reduced the differences in treatment protocols between MCT and ERP, as both treatments focus on expectation violation by utilizing mainly behavioral experiments (e.g., exposure exercises). Although theoretically different expectations are targeted (metacognitive beliefs about obsessions/rituals and obsessive thoughts respectively), it cannot be ruled out that the exposure exercises address the same expectations in both conditions, or even target both kind of expectations at the same time. For instance, it might well be that a patient who is asked in MCT to stand by an open window and repeat his obsessive thought 'I will jump out of the window' in order to challenge his metacognitive belief that 'thinking of jumping means that I will jump' also learns that his obsessive thoughts on jumping out of windows are incorrect. In a similar way is it possible that patients who are asked to refrain from washing their hands after visiting the toilet in order to challenge their obsessive thoughts on becoming ill, also (unintentionally) learn that their thoughts on becoming ill does not have any meaning or power and/or that their compulsive washing is in fact not necessary. It can be argued that specific behavioral experiments as formulated in MCT (e.g. exposure and response commission) may be added to the current, more classical behavioral experiments, in ERP treatments. This will broaden the range of possible experiments to violate all kinds of OCD relevant expectations, both metacognitive beliefs and the obsessions themselves. To obtain more clarity on hypotheses about underlying working

mechanisms during treatment process and to what extend these processes are responsible for the treatment effect, future research should include mediation analyses.

Drop-out rates were relatively low in both treatment conditions (20% in the ERP condition and 13% in the MCT condition). As drop-out rates are normally quite high for OCD in treatment effect studies (30%; Olatunji, Cisler, & Deacon, 2010; Whittal, Thordarson, & McLean, 2005), this is an important finding. After all, a more favorable drop-out rate suggests more OCD patients can benefit of the treatments. It might be that both MCT and ERP based on the inhibitory learning model are more tolerable alternatives than ERP based on the habituation-model, in which patients have to stay in the anxiety-provoking situation until their anxiety drops. More research is needed before definitive conclusions can be drawn on this topic.

High percentages of clinical significant change were found for both treatment conditions at post-treatment and at follow-up. Recovery rates appear at least comparable with findings from previous studies (Fisher & Wells; 2005, van der Heiden et al., 2016). There were no significant differences between treatment conditions and clinical recovery rates. On a descriptive level, MCT produced more recovered patients than ERP directly after treatment (71.8% for MCT vs. 61.1% for ERP) whereas ERP produced more asymptomatic patients (25.6% for MCT vs. 33.3% for ERP). At follow-up assessment, the difference in recovery status between treatment condition remained (72.4% for MCT vs. 66.6% for ERP), whereas the percentages of asymptomatic patients were comparable at this assessment point (31.0% for MCT vs 33.3% for ERP). Overall, since both treatment conditions produced equally high percentages of clinically significant change, future research should use predictor analysis including baseline variables (e.g., various subgroups of OCD) to enhance our knowledge on which method works better for whom. Such knowledge would be useful for clinical practice to assign patients to the treatment method they are most likely to benefit from.

Although not the focus of this study, it is of interest that we found good treatment results for both MCT and ERP in relatively few treatment sessions. Both treatments consisted of up to 15 weekly sessions of only 45 minutes duration, whereas ERP typically consists of 15 to 20 session of 90 minutes duration (Foa & Kozak, 1996). As recovery rates in both conditions were at least comparable with findings from previous studies (Fisher & Wells; 2005; van der Heiden et al., 2016), and were maintained at six-month follow-up, it is

suggested that treatment gains may be established with less face-to-face time with a therapist than is typically assumed. Another interesting finding is that the recovery rates in both conditions of our study seem to outperform those found in the study of Glombiewski et al. (2021; [MCT: 28.6% in the Glombiewski et al. study vs 71.8% in our study; ERP: 50% in the Glombiewski et al. study vs 61.1% in our study]). One explanation might be that ERP based on extinction learning is more effective than ERP based on the habituation model. However, this does not explain the differences in recovery rates between the MCT conditions. The results justify further investigations into the effectiveness of MCT and ERP based on extinction learning and possible advantages of both approaches, such as being less time consuming and therefore more economic alternatives.

The findings of this study should be interpreted in the context of several limitations. First of all, the same supervisor supervised the therapists in both treatment conditions, which might enhance the risk for deviations of treatment protocols. Second, the implementation of the therapist cross-over design was limited by the fact that two therapists left the organization during our trial and were replaced by other therapists. Also, it must be mentioned that the last eight patients in our study were treated by video-conference as a consequence of the COVID-19 pandemic. These eight patients were however equally distributed over the MCT and ERP condition. It is not clear whether this had an effect on treatment outcome, and if so, in which direction. Finally, although our study was not designed to detect small differences between the two treatment conditions, it is possible that subtle differences between the two treatment conditions might have been significant in a larger sample size.

The present study has also several strengths. The RCT provides unique data of a relatively unselected sample of patients with OCD collected within an outpatient mental health center. Analyses of relevant sample characteristics (e.g. comorbidity rates, duration of OCD in years before start of treatment) seem to indicate that our group was a representative sample of patients with OCD (American Psychiatric Association, 2013), and therefore study results can be generalized to clinical practice. Also, we included a six-month follow-up to examine whether the treatment effects were maintained. Furthermore, the interventions were applied by therapists who are experienced in the provision of ERP and received training in the provision of MCT. Also, we used a semi-structured interview as well as a self-report measurement to evaluate treatment outcome. Lastly, integrity checks were performed to ensure treatment quality.

In summary, both MCT and ERP provide positive treatment outcomes, that are retained at six-month follow-up. MCT seems equally effective to ERP and might be a valuable alternative for patients who refuse or drop-out from ERP prematurely, or when treatment outcomes with ERP are suboptimal. However, more randomized controlled trials are justified to reach more definitive conclusions on this matter. Also, future research should include predictor and mediation analysis to enhance our knowledge on which method or elements works best for whom and why.

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Chapter 7

General discussion

Love is many things,
non of them logical

General discussion

Obsessive compulsive disorder (OCD) is a common and debilitating disorder. OCD is characterized by recurring compulsive thoughts and/or behaviours. In DSM 5 compulsive thoughts (obsessions) are defined as 'recurrent and persistent thoughts, urges or images that are experienced as intrusive and unwanted'. Compulsive behaviours (compulsions) are defined as 'repetitive behaviours or mental acts that the individual feels driven to perform in response to an obsession'. The lifetime prevalence of this disorder has been estimated to 2% (American Psychiatric Association, 2013). Without proper treatment, the disorder is often chronic (Ruscio et al., 2010). Effective treatment of OCD is therefore of utmost importance. Meta-analytic reviews indicate that the psychological treatment of choice for OCD is exposure and response prevention (ERP; see Ost, Havnen, Hansen, & Kvale, 2015; Skapinakis et al., 2016). In ERP treatment, which is a specific type of cognitive behavioural therapy (CBT), patients are exposed to anxiety-provoking stimuli (situations, objects, thoughts) that are avoided and/or trigger obsessive thoughts, with the instruction to refrain from engaging in compulsive behaviour (Meyer, 1966). This procedure is based on learning theory, in which classical conditioning is considered to be responsible for the development of obsessions, and operant conditioning processes maintain compulsive behaviours (Mowrer, 1951).

Although numerous studies have found statistically significant change and large symptomatic improvements for ERP, the majority of patients still experience distressing OCD-symptoms after treatment. More specifically, only 60% of treatment completers achieve recovery, and only approximately 25% of patients are asymptomatic following treatment (Fisher & Wells, 2005). This means that the majority of patients treated with ERP continue to experience distressing OCD symptoms. So, although it can be concluded that ERP is efficacious, there is clearly room for improvement in the psychological treatment of OCD. It is assumed that this improvement could result from a better understanding of the mechanisms involved in the maintenance of the disorder, for example, metacognitions. Metacognition refers to knowledge and cognitive processes that are involved in the interpretation, monitoring, and control of thinking processes (Flavell, 1979). Wells (1997, 2000) developed a theoretical model based on metacognition, in order to explain the maintenance of OCD symptoms. Also, following this model, a treatment method is developed: metacognitive therapy (MCT). This metacognitive therapy is central in this thesis.

The aim of this thesis was threefold. The first aim was to provide an outline of the metacognitive model and metacognitive therapy for OCD. As detailed descriptions of the application of this treatment modality in patients with OCD are scarce, a case study to illustrate the content of this form of therapy was reported in this thesis. The second aim of this thesis was to provide an overview of the empirical evidence for the importance of the two proposed domains of metacognitive beliefs in OCD: metacognitive beliefs about obsessions and metacognitive beliefs about the necessity of performing ritual behaviors. We also introduced two self-report questionnaires to assess these belief domains. The Thought Fusion Instrument (TFI; Wells et al., 2001) measures metacognitive beliefs about the significance and consequences of intrusive thoughts and the Beliefs About Rituals Inventory (BARI; McNicol & Wells, 2012) assesses metacognitive beliefs about the necessity of performing ritual behaviors. Data about the validity and reliability of both measures were provided. The third and most important aim of this thesis was to evaluate the effectiveness of MCT for OCD. Two effectiveness studies were carried out: a pilot study and a randomized controlled trial (RCT) to assess the effectiveness of MCT in comparison to ERP. In this last chapter of this thesis, the conclusions from our studies about these three main subjects are summarized. Next, implications for clinical practice are discussed. Finally, the limitations of our studies and a research agenda for future research are presented.

Short summary

Outline of the metacognitive model and metacognitive therapy for OCD

The metacognitive model of OCD assumes that not the compulsive symptoms themselves, but the beliefs the patient has about his obsessions and compulsions, are the most important problem. These beliefs are named 'metacognitions'. It is proposed that two domains of metacognitive beliefs are fundamental in the development and maintenance of OCD: 1) metacognitive beliefs about the significance and consequences of intrusive thoughts, also called fusion beliefs, and 2) beliefs about the necessity of performing ritual behavior.

According to the metacognitive model, treatment should focus exclusively on modifying patients' beliefs about the importance and power of intrusive thoughts and the necessity of performing rituals, instead of challenging the actual content of the obsessions and compulsions (Fisher & Wells, 2008). MCT consists of up to 15 weekly sessions of 45 minutes and consists of four phases. In the first phase, the metacognitive model is explained to increase the patients' awareness of the role of metacognitions and to develop a

personal case conceptualization. In the second phase, verbal cognitive restructuring (e.g., questioning the evidence) and behavioral experiments are used to target metacognitive beliefs about intrusive thoughts. The third phase focuses on challenging metacognitive beliefs about rituals, through verbal techniques and specified behavioral experiments. In the fourth and final phase, a personal relapse prevention plan is formulated for responding to recurrent intrusive experiences.

The assessment of thought fusion beliefs and beliefs about rituals

There is a growing body of evidence that both thought fusion beliefs and beliefs about rituals contribute to OCD (see Wells, 2009). For instance, a high correlation has been found between metacognitive beliefs and OCD symptoms (Myers et al., 2009) and metacognitive beliefs have a predictive value for OCD symptoms (Wells & Papageorgiou, 1998). Since there is empirical evidence for the importance of metacognitive beliefs in OCD, there is a demand for well-validated instruments that measure these constructs in both normal and clinical populations, for research purposes and individual assessment. The Thought Fusion Inventory (TFI; Wells et al., 2001) was designed to measure fusion beliefs across fusion domains that are considered relevant in the metacognitive formulation and treatment of OCD. The Beliefs About Rituals Inventory (BARI; McNicol & Wells, 2012), is a unidimensional measurement to assess beliefs about the necessity of performing rituals. We evaluated the psychometric properties of the TFI and the BARI in both the general population and clinical populations. For both the TFI and the BARI, an explorative factor analysis revealed a one-factor solution. Both measurements obtained adequate reliability and validity coefficients. The internal consistency, convergent and divergent validity of the instruments appeared sufficient and they had a moderate test-retest reliability. The criterion validity turned out to be good for the BARI but low for the TFI in measuring OCD-specific metacognitions. In conclusion, it turned out both short questionnaires seem to have promising potential for research purposes and use in clinical settings.

The effectiveness of MCT for OCD

At the time our research group started the investigations into the effectiveness of MCT for OCD, only a few studies had examined the effectiveness of MCT for OCD. Using single-case methodology, Fisher and Wells (2008) found clinically significant improvements for four OCD patients with different clinical presentations who were treated individually with MCT. Two out of four participants were asymptomatic at both post-treatment and three-month

follow-up assessments. In an open trial of group MCT for OCD, Rees and Van Koesveld (2008) found that seven out of eight participants achieved recovery on the Yale-Brown Obsessive-Compulsive Scale (Y-BOCS) at three-month follow-up (87.5%).

We started our investigations with a pilot study among 25 OCD patients. We found significant improvements for all outcome measures**,** including OCD symptoms and depression symptoms. After finishing the therapy, 74% of patients who completed the treatment could be classified as recovered and 47% as symptom-free. These percentages had risen to 80% recovered and 67% percent symptom-free at the time of the follow-up measurement after 3 months. The dropout rate was 24% in this study (in comparison: this is 30% on average for ERP treatment; Clark, 2004). Based on this first study it was concluded that the outcome of MCT seems favorable compared to ERP, both in terms of clinically significant improvement and in terms of dropout rates and deserved controlled evaluation.

Next, we conducted a randomized controlled trial (RCT) with a pretest-posttest-6-month-follow-up-design to assess the effectiveness of MCT in comparison to ERP in an outpatient clinical sample of 90 patients with OCD. Inclusion criteria for participating patients were kept as limited as possible to keep the clinical representativeness of the sample as high as possible. The main outcome measure of this study was obsessive-compulsive symptoms, alongside common psychological complaints, and changes in metacognitive beliefs. Aside from statistically significant results, both treatment methods were also compared based on clinically relevant results (Jacobson & Truax, 1991). The results of our RCT indicate that ERP and MCT are equally effective treatments for OCD. Moreover, both treatments produced significant pre-treatment to post-treatment decreases in obsessive-compulsive, depressive, and comorbid psychological symptoms, with moderate to large effect sizes and high recovery rates. Both treatments also produced significant reductions in metacognitive beliefs and the percentage of OCD diagnoses. On all of the outcome measures mentioned above, the effect did not differ depending on the type of treatment.

Strengths and limitations

Our studies had several strengths. The first aim of this thesis was to provide an outline of the metacognitive model and MCT for OCD. Although the model and treatment are discussed in many papers and books, (e.g. Wells, 2000), detailed descriptions of the application of this treatment modality in patients

with OCD are scarce. Therefore, in chapter 2 of this thesis, we included a case study to illustrate the content of this form of therapy. To our knowledge, this is the first case study reporting on the application of MCT for OCD.

Also, our study into the psychometric properties of the TFI and the BARI was the first investigation into the factor structure of these measurements. Psychometric properties were assessed in both clinical and non-clinical control groups and the criterion validity was assessed by making a comparison with other clinical groups, like anxiety disorders and autism spectrum disorder (ASS). None of this had been previously assessed.

Our treatment effect studies also had some strengths we want to emphasize. Both the pilot study and the RCT were conducted within a routine outpatient community mental health center and exclusion criteria were kept to a minimum to enhance the clinical representativeness of the sample. Analyses of demographic variables seem to indicate that our group was, by all means, not a selective or an "OCD-light" representation. For example, before the start of treatment in our RCT, patients had experienced disturbing OCD symptoms for more than eleven years on average, more than two-thirds (72.2%) had followed at least one previous treatment for their OCD symptoms, and more than two-thirds (71.1%) met the DSM-IV criteria for at least one comorbid diagnosis. Also, both the treatment effect studies included a sufficient number of therapists and involved independent assessors of clinical diagnoses. Lastly, OCD symptom severity was not only assessed with self-report measurements but also with a semi-structured interview (Y-BOCS) at all assessment points.

Our studies had also some limitations. To start with, our study of the psychometric properties of the TFI and the BARI, was the first investigation into the factor structure of the measurements and also the first study into some other specific psychometric properties, like the test-retest reliability and criterion validity. Since the factor structure of both measurements was not investigated yet, we chose an explorative approach. Although this was the most suitable method at that point, explorative approaches also have limitations. The analyses in this study were only a first investigation into the factor structure of the measurements, and do not provide a test of the unidimensionality of the scales. Further research must take a closer look at the proposed single-factor solution by using confirmatory approaches. Other limitations of this study were the lack of data on comorbidity in the clinical

samples and the mental health status of the participants in the "healthy groups", and the use of snowball sampling, which eventually generated a homogenous sample of individuals with specific demographic characteristics.

Limitations with regard to our pilot study were the absence of a comparison group or treatment control group, the rather short 3-month follow-up period, and the absence of formal measures of therapists' competence and treatment adherence. These shortcomings were largely resolved in our subsequent RCT. In our RCT, an active control group was included (ERP), along with a longer follow-up interval of 6-months. Moreover, we used a therapist cross-over design and assessed therapists' adherence to and competence in carrying out the treatment protocols, to rule out therapist factors. However, our RCT also has some limitations. First of all, the same supervisor supervised the therapists in both treatment conditions, which might enhance the risk for deviations of treatment protocols. Second, the implementation of the therapist cross-over design was limited by the fact that two therapists left the organization during our trial and were replaced by other therapists. Also, it must be mentioned that the last eight patients in our study were treated by video conference as a consequence of the COVID-19 pandemic. These eight patients were however equally distributed over the MCT and ERP condition. It is not clear whether this affected treatment outcome, and if so, in which direction. Finally, although our study was not designed to detect small differences between the two treatment conditions, subtle differences between the two treatment conditions might have been significant in a larger sample size.

Discussion and implications for clinical practice

Our study into the psychometric properties of the TFI and the BARI shows that both measurements are potentially suitable questionnaires for assessing metacognitions in clinical and non-clinical populations. The internal consistency, convergent and divergent validity of the instruments appeared sufficient. Based on the explorative factor analysis, we recommend using the total score of both scales in clinical practice. We also conclude that both measurements are especially useful for setting up an individual case conceptualization within an OCD treatment. Both MCT and ERP are focused on expectation violation and prior to exposure exercises, expectations and their credibility are defined. Based on the metacognitive model, it can be argued that all kinds of OCD relevant expectations had to be inventoried,

both metacognitive beliefs and the obsessions themselves. The TFI and the BARI are useful instruments to facilitate this process. Especially the TFI, designed with a 0 to 100 range in order to indicate to what extent the patient beliefs the statements are true, can be used to set up an individual case conceptualization of expectations and their credibility. More research is needed into the psychometric properties of the TFI and the BARI before definitive conclusions for clinical practice can be made, for example for the application of the instruments in monitoring the treatment process.

Our main hypothesis for our effectiveness studies was that MCT is more effective than ERP at treating OCD. We found no support for this in this thesis. One explanation for not finding significant differences might be that underlying mechanisms of change are shared between the two treatment conditions. This hypothesis is supported by the fact that we found statistically significant decreases in dysfunctional (metacognitive) beliefs as indexed by the process measures in both treatment conditions without significant between-group differences. The implementation of the inhibitory learning model of extinction in our ERP condition might have reduced the differences in treatment protocols between MCT and ERP, as both treatments focus on expectation violation by utilizing mainly behavioral experiments (e.g., exposure exercises). Although theoretically different expectations are targeted (metacognitive beliefs about obsessions/rituals and obsessive thoughts respectively), it cannot be ruled out that the exposure exercises address the same expectations in both conditions, or even target both kinds of expectations at the same time. It can be argued that particular behavioral experiments as formulated in MCT (e.g. exposure and response commission) may be integrated into ERP treatments. This will broaden the range of possible behavioral experiments to violate all kinds of OCD-relevant expectations (both metacognitive beliefs and the obsessions themselves).

Although our main hypothesis was not supported, from our studies we can draw positive conclusions which allow us to say that MCT deserves a position in clinical practice. Both MCT and ERP appeared as highly effective treatment methods for OCD from our studies. Both treatments produced significant pre-treatment to post-treatment decreases in obsessive-compulsive symptoms, depressive and comorbid psychological symptoms, with moderate to large effect sizes and high recovery rates. Treatment gains were maintained at six-months follow-up. In Table 1, we present an overview of data of clinically relevant results we know so far with regard to MCT for OCD. As a reference, also the review analysis of Fisher and Wells (2005) with regard to ERP is

Table 1. Overview of clinical recovery rates after MCT.

		Pre to Post		3Month Follow-up		6Month Follow-up	
	n	% recovered	% symptom free	% recovered	% symptom free	% recovered	% symptom free
Review analysis into the effectiveness of ERP (Fisher & Wells, 2005)		60%	25%	-	-	-	-
Fisher and Wells (2008)	4						
MCT		100%	50%	100%	50%	66.7%	0%
Rees & van Koesveld (2008)	8						
MCT		37.5%	-	87.5%	-	-	-
Van der Heiden et al. (2016)	25						
MCT		74%	47%	80%	67%	-	-
Glombiewski et al. (2021)	37						
MCT		28.6%	-	28.6%	-	-	-
ERP		50%	-	54.5%	-	-	-
Melchior et al. (2021)	90						
MCT		71.8%	25.6%	-	-	72.4%	34.5%
ERP		61.1%	33.3%	-	-	66.7%	33.3%

Note. ERP = Exposure and Response Prevention; MCT = Metacognitive Therapy.

mentioned again. In this overview, also the results from a pilot randomized trial into the effectiveness of MCT and ERP for OCD is presented, very recently published by Glombiewski et al. (2021).

The results of our studies in this thesis are at least comparable with previous data about the effectivity of MCT for OCD . We conclude that MCT is equally effective to ERP and might be a valuable alternative for patients who refuse or drop-out from ERP prematurely, or when treatment outcomes with ERP are suboptimal. Some aspects of our studies had to be highlighted.

First of all, in both our effectiveness studies, exclusion criteria were kept to a minimum and analyses of relevant variables (e.g. comorbidity rates, previous treatment attempts) seem to indicate that our groups were by all means not a selected or an "OCD-light" representation. Usually, more selected groups of patients are used in clinical trials. That we found at least comparable results in our non-selected groups of patients is noteworthy.

Also, ERP protocols are usually at least 20 sessions, with a variable session duration (exceeding the common duration of 45 minutes) depending on the individual exposure progress. We choose a fixed number of sessions and duration (14 sessions of 45 minutes in both treatments) for two reasons. First of all, we wanted to enhance the comparability of our two treatment conditions. Secondly, in the last few years a shift has taken place in our knowledge of the proposed underlying working mechanism of ERP. Until 2014 (Craske et al., 2014), it was widely believed that the key component of exposure was fear habituation (Foa & Kozak, 1986; Foa & McNally, 1996). Models based on habituation state that fear reduction during an exposure trial is necessary to achieve long-lasting cognitive changes in the perceived harm associated with the phobic stimulus. However, more recent research found the amount of fear reduction by the end of an exposure trial or series of exposure trials is not predictive of the fear level expressed at follow-up assessment in fearful human samples (Prenoveau et al., 2014; Craske et al., 2014). Instead, it has been proposed that inhibitory learning is central to extinction (Bouton, 1993). This theory states that fear reduction results from the learning of new non-threat (i.e., inhibitory) associations that compete with instead of replacing older threat associations. Exposure therapy therefore should focus on the mismatch between expectancy and outcome so that the inhibitory association can become sufficiently strong and retrievable to compete with existing fear memories. Many studies have supported the inhibitory learning model of extinction (Baker et al., 2010; Deacon et al., 2013). Since the focus

is now on the mismatch between expectancy and outcome, instead of fear reduction, a fixed session duration is both achievable and desirable since exposure exercises are now only continued for the duration determined to be most effective to violate expectancies. Within our RCT, this has been implemented in the treatment protocol of ERP. In both treatments, the treatment duration was fixed (14 sessions with a duration of 45 minutes). As our both treatment protocols appeared highly and at least comparable effective in a less time-consuming way than earlier ERP protocols based on habituation, it is suggested that treatment gains may be established with less treatment time than is typically assumed. Another interesting finding is that the recovery rates in both conditions of our study seem to outperform those found in the study of Glombiewski et al. (2021; [MCT: 28.6% in the Glombiewski et al. study vs 71.8% in our study; ERP: 50% in the Glombiewski et al. study vs 61.1% in our study]). It might be that ERP based on extinction learning is more effective than ERP based on the habituation model. In a similar vein, as drop-out rates are quite high for OCD in treatment effect studies (Olatunji, Cisler, & Deacon, 2010; Whittal, Thordarson, & McLean, 2005), the low drop-out rates in both treatment conditions in our study is an important finding (20% in the ERP condition and 13% in the MCT condition dropped out from therapy). It might be that both MCT and ERP based on the inhibitory learning model are more tolerable alternatives.

In conclusion, both our MCT and ERP provide positive treatment outcomes in a relatively short time period, which were maintained at six-month follow up. Our results justify the conclusion that MCT is an equally effective therapy next to ERP and can be reliably imbedded for OCD-patients who refuse or drop-out from ERP prematurely or when treatment outcomes with ERP are suboptimal. Now more large-scale randomized controlled trials examining the short- and long-term effects of MCT are warranted. Future research should examine predictors of treatment outcome for both MCT and ERP to enhance our knowledge on which methods work best for whom. Also, the underlying working mechanisms of MCT and ERP could be examined and to what extent these processes are responsible for the treatment effect.

Agenda for future research

Future research should focus on several specific issues with regard to MCT for OCD. Table 2 listed an agenda of several issues which are not yet entirely clear.

Table 2. Agenda for future research

Research topic	Current status	Future recommendations
Psychometric properties of the Thought Fusion Instrument and the Beliefs About Rituals Inventory.	- Based on explorative factor analysis, using data from a normal population, both the TFI and the BARI seem to measure a single-factor construct. - Both measurements obtained adequate reliability and validity coefficients in normal and clinical populations.	- Research using confirmatory approaches must test whether the TFI and the BARI indeed measure a single-factor construct. Better powered studies could also test whether the scales behave similarly in clinical and non-clinical samples. - To permit definitive conclusions about the reliability and validity, more research is needed with more measurements for the examination of the construct validity and data collected in a broad range of clinical groups.
Relative effectiveness of MCT compared to the current treatment as usual for OCD.	-The results of our effectiveness studies indicate that MCT is an effective treatment for OCD and that ERP and MCT are equally effective treatments in terms of both statistically and clinically significant change.	- More large-scale randomized controlled trials by other research groups are needed to permit definitive conclusions about this topic. -More randomized controlled trials are needed in which MCT is directly compared to the current treatment as usual, not only with exposure and response prevention but also with pharmacotherapy. -Randomized controlled trials with larger samples sizes are necessary to detect potential small between-group effects.
Long-term effects of MCT for OCD.	- MCT produced significant and large reductions across all outcome variables, with high proportions of clinically significant change both post-treatment and at 6-month follow-up.	-Future research is recommended to study the long-term effects of MCT for OCD beyond the 6-month follow-up period. In our study, patients did not seem to relapse in the half-year after treatment. It would be of particular interest to see whether treatment gains are maintained over longer periods, for example with a 2-year follow-up period.

Insight in the question how metacognitive treatment works.	-In our RCT, three measurements were included for the assessment of changes in key metacognitive beliefs in the etiology and maintenance of OCD: The TFI, the BARI, and the Obsession Belief Questionnaire (OBQ).	-To permit conclusions about the underlying working mechanisms of MCT, and whether explicitly targeting metacognitive beliefs is crucial to diminish OCD symptoms, more research is needed. Future research should look at process variables (e.g. metacognitive beliefs) as possible mediators of changes on primary outcome variables. Therefore, future research is needed to measure those beliefs repeatedly during treatment and they have to be associated with treatment outcome. -Future research should add more measurement points during treatment to make it possible to evaluate whether some phases of treatment contribute to the overall treatment effect more than others and to make clear recommendations for a treatment protocol with the most crucial interventions from both MCT and already established effective treatment interventions z
Enhance our understanding of for whom and under what conditions treatment works.	-The sample size in our study was too small to test certain interaction effects between type of treatment and other variables. -In our RCT MCT and ERP did produce a relatively lower and thus more favorable dropout rate than earlier investigations into the effectiveness of psychological treatment for OCD.	-To detect possible predictors and moderators of treatment outcome, more controlled trials with larger patient samples are needed. Future research should examine the predictive value of different baseline values. It would be of interest to examine whether MCT works better for particular patient groups, for example by analyzing specific subtypes of OCD. -Future research should examine factors that contribute to the relatively low dropout rate in our ERP and MCT, factors that predict dropout and factors that may improve treatment adherence.

We think that this thesis has enhanced our knowledge on the topic of the metacognitive model and therapy for OCD. However, more research is needed, as can be seen in table 2. Recommendations to push this research area forward are now offered. We hope that both our research group and other research groups will contribute to this purpose.

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Chapter 8

Appendices

It always seems impossible until it's done

8.1 Summary

Obsessive compulsive disorder (OCD) is a common and debilitating disorder. OCD is characterised by recurring compulsive thoughts and/or behaviours. In DSM 5 compulsive thoughts (obsessions) are defined as 'recurrent and persistent thoughts, urges or images that are experienced as intrusive and unwanted'. Compulsive behaviours (compulsions) are defined as 'repetitive behaviours or mental acts that the individual feels driven to perform in response to an obsession'. OCD is a relatively common disorder: it is estimated that about 1% to 2% of the population will have to deal with this disorder within a lifetime. Without fitting treatment the symptoms tend to increase or eventually can become chronic. Effective treatment of OCD is therefore of utmost importance.

To start with, an overview of the diagnostic criteria of obsessive compulsive disorder and a description of the aetiology will be given in **chapter 1** of this dissertation. This chapter describes that the *Multidisciplinary guideline anxiety disorders* prescribes treatment with exposure and response prevention (ERP) as treatment of first choice for OCD. Despite this status, ERP for OCD is also a clear example of the discrepancy between a treatment that has been proven to be statistically significant but also with modest clinically relevant recovery and improvement percentages. The chapter describes that about 60% of patients has recovered from their symptoms, and only 25% can be classified as symptom free after finishing an ERP treatment. Chapter 1 ends with the claim that the implementation of a new and more fitting disorder specific model for OCD could help improve treatment results, and that the metacognitive model, developed by Wells serves as an opportunity for doing so.

Chapter 2 covers the metacognitive model of OCD and the promising metacognitive therapy (MCT) that is based on this model. The metacognitive model assumes that not the compulsive symptoms themselves, but the ideas that the patient has about his/her obsessions and compulsions, are the most important problem. These cognitions are named 'metacognitions'. In this model, it is proposed that two domains of metacognitive beliefs are fundamental in the development and maintenance of OCD: metacognitive beliefs about the significance and consequences of intrusive thoughts and feelings, also called *'fusion beliefs'*, and beliefs about the necessity of performing rituals behaviour. According to the metacognitive model, treatment should focus exclusively on modifying patients' beliefs about the

importance and power of intrusive thoughts and the necessity of performing rituals, instead of challenging the actual content of the obsessions and compulsions. An explanation of the most important differences between MCT and the current treatment of first choice, ERP, has been provided. The empirical support for both the metacognitive model of OCD and the therapy that is based on this model, will be described after that. To end with, the treatment, which consists of 4 phases and 15 therapy sessions, will be illustrated with a case description.

Chapter 3 expands on measuring OCD specific metacognitions. A description is given of how the metacognitive model for OCD distinguishes between beliefs about obsessions and beliefs about compulsions. Two questionnaires, that aim to measure these constructs have been developed, to determine OCD relevant metacognitions. The Thought Fusion Instrument (TFI) was developed for determining metacognitive beliefs about obsessions. The Beliefs About Rituals Inventory (BARI) is used to determine beliefs about the necessity of performing compulsions. Chapter 3 describes and further investigates the psychometric properties of both questionnaires based on 3 studies that were conducted within a general population (N=141), a clinical population (OCD, N=60; Anxiety Disorder, N=30; Autism Spectrum Disorder, N=50). Internal consistency, convergent and divergent validity and test-retest reliability were investigated for both questionnaires. The questionnaires turn out to be valid and reliable instruments for determining OCD specific metacognitions in both normal and clinical populations. It is concluded that the TFI and the BARI can be used to determine OCD specific metacognitions for example in treatment-effect studies with regard to OCD.

The results of a pilot study into the effect of MCT for OCD conducted among 25 OCD patients is described in **chapter 4**. We found significant improvements for all outcome measures**,** including OCD symptoms and symptoms of depression. After finishing the therapy 74% of patients who completed the treatment could be classified as recovered and 47% as symptom free. These percentages had risen to 80% recovered and 67% percent symptom free at the time of the follow-up measurement after 3 months. The dropout rate was 24% in this study (in comparison: this is 30% on average for ERP treatment). Based on this first study it is concluded that the outcome of MCT is favourable compared to ERP, both in terms of clinically significant improvement and in terms of dropout rates. It is concluded that MCT for OCD is a promising treatment method, that deserves further research in order to draw firm conclusions.

Chapter 5 presents a proposal for follow up research that aims at a direct comparison between MCT and the current gold standard ERP. This chapter argues in favour of a randomized controlled study (RCT) with a pretreatment-post-treatment-6 month and 30 month follow-up design. It is claimed that inclusion criteria for participating patients should be kept as limited as possible in order to keep the clinical representativeness of the sample as high as possible. Next, a power analysis is described which indicates that 90 patients are needed to show a medium difference in effectivity between the two treatment methods. Relevant outcome measures in order to assess OCD- and comorbid symptoms are described, as well as the proposal to use the TFI and BARI as relevant process measures in this trial. The chapter is finished by stating that the intended research has been approved by a Medical Ethical Committee and has started.

The results of the RCT that was carried out by our research group among 90 OCD patients are presented in **chapter 6**. Patients were assigned randomly to either MCT or ERP treatment. Besides statistical significance both treatment methods were also compared based on clinically relevant results. The results we found were as followed. Patients had significantly improved on all outcome measures, including those for OCD symptoms and comorbid symptoms, in both treatment conditions, just after treatment and also half year later. Drop-out rates were relatively low in both treatment conditions (20% in the ERP condition and 13% in the MCT condition). Large within group sizes were found on the primary outcome measure for the assessment of OCD symptoms (YBOCS, MCT: ES = 1.65 posttreatment, 1.78 at follow-up, ERP: ES = 2.03 posttreatment, 2.29 at follow-up). Also, high proportions of clinical recovery were found. After finishing the therapy 72% of patients who completed the MCT could be classified as recovered and 26% as symptom free. In the ERP condition, these percentages were respectively 61% and 33%. At follow-up, largely comparable findings were found (72% of the patients in the MCT condition were classified as recovered and 31% as symptom free, in the ERP condition 67% of the patients was recovered and 33% was symptom free). Treatment results were achieved in a relatively few treatment sessions. Since both the treatments consisted of up to 15 weekly sessions of only 45 minutes duration, whereas ERP typically consists of 15 to 20 session of 90 minutes duration, it is concluded that treatment gains for OCD may be established with less face-to-face time with a therapist than is typically assumed. The treatment effect did not significant differ between MCT and ERP. One explanation for not finding significant differences might be that underlying mechanisms of change are shared between the two treatment

conditions. This hypothesis is supported by the fact that we found statistically significant decreases in dysfunctional (metacognitive) beliefs as indexed by the process measures in both treatment conditions without significant between-group differences. It is concluded that both ERP and MCT are effective treatment methods for OCD. Our results justify the conclusion that MCT is an equally effective therapy next to ERP and can be reliable imbedded for patients who refuse or drop-our from ERP prematurely or when treatment outcomes with ERP are suboptimal. We also argue that specific behavioral experiments as formulated in MCT may be added to the current, more classical behavioral experiments, in ERP treatments. This will broaden the range of possible experiments to violate all kinds of OCD relevant expectations, both metacognitive beliefs and the obsessions themselves.

Chapter 7 consists of the final discussion. The findings from previous chapters are summarised once more. The limitations of the research that was carried out as well as the clinical implications of the results are described. Finally, suggestions for future research are given.

8.2 Samenvatting (Summary in Dutch)

De obsessieve-compulsieve stoornis (OCS) is een veelvoorkomende en invaliderende stoornis. OCS wordt gekenmerkt door steeds terugkerende dwanggedachten en/of handelingen. Dwanggedachten (obsessies) worden in de DSM-5 gedefinieerd als 'recidiverende gedachten, impulsen of voorstellingen die als intrusief en ongewenst worden ervaren'. Dwanghandelingen (compulsies) worden gedefinieerd als 'repetitieve handelingen of psychische activiteiten waartoe de betrokkene zich gedwongen voelt in reactie op een obsessie'. OCS is een relatief veelvoorkomende stoornis: naar schatting krijgt zo'n 1% tot 2% van de mensen er ooit in zijn of haar leven mee te maken. Zonder adequate behandeling gaat het vaak om een chronische aandoening die veelal verergert in de loop van de tijd. Effectieve behandeling van OCS is dan ook van groot belang.

Hoofdstuk 1 van dit proefschrift start met een overzicht van de diagnostische criteria van de obsessieve-compulsieve stoornis en een beschrijving van de etiologie. Beschreven wordt dat de *Multidisciplinaire richtlijn angststoornissen* behandeling met exposure met responspreventie (ERP) voorschrijft als behandeling van eerste keuze voor OCS. Ondanks deze status is ERP voor OCS echter ook een duidelijk voorbeeld van de discrepantie tussen een statistisch significant gebleken effectieve therapiemethode, maar ook bescheiden klinisch relevante herstel- en verbeterpercentages. Te lezen valt dat na het afronden van een ERP-behandeling ongeveer 60% van de patiënten hersteld is van zijn klachten, en slechts 25% kan geclassificeerd worden als symptoomvrij. Hoofdstuk 1 eindigt met de stelling dat het gebruik van een nieuw en passender stoornisspecifiek model voor OCS zou kunnen helpen om tot verbetering van therapieresultaten te komen, en dat het metacognitieve model, ontwikkeld door Wells, daar een mogelijkheid toe biedt.

Hoofdstuk 2 behandelt het metacognitieve model van OCS en de daarop gebaseerde veelbelovende metacognitieve therapie (MCT). Het metacognitieve model veronderstelt dat niet de dwangklachten zelf het belangrijkste probleem zijn, maar de opvattingen die de patient heeft over zijn dwanggedachten en -handelingen. Deze opvattingen worden aangeduid als 'metacognities'. In het metacognitieve model voor OCS wordt onderscheid gemaakt tussen opvattingen over de dwanggedachten, ook wel '*fusion beliefs*' genoemd, en opvattingen over de noodzaak tot het uitvoeren van dwanghandelingen. Overeenkomstig het metacognitieve model van OCS richt de metacognitieve therapie zich niet op de dwangklachten zelf,

maar op de manier waarop mensen denken over hun dwanggedachten en dwanghandelingen. Gevolgd wordt met een uiteenzetting van de belangrijkste verschillen tussen MCT en de huidige behandeling van eerste voorkeur, ERP. De empirische ondersteuning voor zowel het metacognitieve model van OCS als de daarop gebaseerde therapiemethode worden vervolgens beschreven. De behandeling, die uit 4 fases en 15 therapiesessies bestaat, wordt tot slot geïllustreerd aan de hand van een casusbeschrijving.

In **hoofdstuk 3** wordt nader ingegaan op het meten van OCS specifieke metacognities. Beschreven wordt dat in het metacognitieve model voor OCS onderscheidt word gemaakt tussen opvattingen over de dwanggedachten en opvattingen over de dwanghandelingen. Om deze voor OCS relevante metacognities in kaart te brengen, zijn er twee vragenlijsten ontwikkeld die deze constructen beogen te meten. The Thought Fusion Instrument (TFI) is ontwikkeld om metacognitieve opvattingen over de dwanggedachten in kaart te brengen. De Beliefs About Rituals Inventory (BARI) wordt afgenomen om opvattingen over de noodzaak van het uitvoeren van dwanghandelingen in kaart te brengen. In hoofdstuk 3 worden de psychometrische kwaliteiten van beide vragenlijsten beschreven en nader onderzocht aan de hand van 3 uitgevoerde studies binnen een algemene populatie (N=141), en klinische populaties (OCS, N=60; Angststoornis, N=30; Autisme Spectrum Stoornis, N=50). Beide vragenlijsten zijn onderzocht op interne consistentie, convergente en divergente validiteit en test-hertest betrouwbaarheid. De vragenlijsten blijken valide en betrouwbare instrumenten om OCS specifieke metacognities in kaart te brengen in zowel een normale als klinische populaties. Geconcludeerd wordt dat de TFI en de BARI gebruikt kunnen worden om OCS specifieke metacognities in kaart te brengen, bijvoorbeeld voor gebruik in therapie-effect studies bij OCS.

In **hoofdstuk 4** worden de resultaten gepresenteerd van een pilot-studie waarin het effect van MCT bij OCS werd onderzocht onder 25 OCS patiënten. We vonden significante verbeteringen op alle uitkomstmaten, waaronder voor OCS-symptomen en depressiesymptomen. Na afloop van de therapie kon 74% van de patiënten die de behandeling afmaakte geclassificeerd worden als hersteld en 47% als symptoomvrij. Ten tijde van de follow-up meting na 3 maanden waren deze percentages toegenomen naar 80% hersteld en 67% symptoomvrij. Het percentage uitval in deze studie was 24% (ter vergelijking: in een ERP-behandeling is dit gemiddeld 30%). Op basis van deze eerste studie wordt geconcludeerd dat de uitkomst voor MCT zowel in termen van klinisch significante verbetering als in termen van uitval gunstiger blijkt

dan die voor ERP. De tekortkomingen van deze studie worden beschreven, waarvan het geringe aantal proefpersonen en het ontbreken van een directe vergelijking met de huidige eerste voorkeurs evidenced-based behandeling voor OCS de belangrijkste zijn. Geconcludeerd wordt dat MCT bij OCS een veelbelovende behandelmethode is, die nader onderzoek verdient om gedegen conclusies te kunnen trekken.

Hoofdstuk 5 presenteert een voorstel voor vervolgonderzoek met als doel een directe vergelijking tussen MCT en de huidige gouden standard ERP mogelijk te maken. In dit hoofdstuk wordt gepleit voor het uitvoeren van een *randomized controlled trial* (RCT) met een voormeting-eindmeting-6 maanden en 30 maanden follow-up design. Gesteld wordt dat inclusie criteria voor deelnemende patiënten zo beperkt mogelijk gehouden dienen te worden om de klinische representativiteit van de steekproef zo hoog mogelijk te houden. Vervolgens wordt er een power-analyse beschreven welke uitwijst dat er 90 patiënten nodig zijn om een voor de klinische praktijk relevant *medium* verschil in effectiviteit tussen beide therapiemethodes te kunnen aantonen. Relevante uitkomstmaten voor het meten van OCS- en comorbide symptomen worden beschreven, evenals het voorstel de TFI en de BARI als relevante procesmaten mee te nemen in deze trial. Geëindigd wordt met de aankondiging dat het voorgenomen onderzoek inmiddels goedkeuring heeft ontvangen van een Medisch Ethische Toetsingscommissie en gestart is.

In **hoofdstuk 6** worden de resultaten gepresenteerd van de door onze onderzoeksgroep uitgevoerde RCT onder 90 patiënten met een OCS. Patiënten zijn random toegewezen aan MCT of ERP behandeling. Gezien er sprake is van ongelijke intervallen tussen de verschillende meetmomenten is gekozen voor het gebruik van *Mixed Models analyses voor repeated measures*. Naast de statistische significantie worden beide therapiemethoden ook met elkaar vergelijken op basis van klinisch relevante resultaten. De volgende resultaten worden vervolgens gepresenteerd. Zowel na afloop van de behandeling als een half jaar daarna waren patiënten in beide behandelcondities aanzienlijk verbeterd op alle uitkomstmaten, waaronder die voor OCS symptomen en comorbide symptomen. De drop-out is in beide condities laag (13% in de MCT conditie en 20% in de ERP conditie). Grote effectsizes worden gevonden op de primaire uitkomstmaat voor het in kaart brengen van OCS symptomen (YBOCS, MCT: ES = 1.65 posttreatment, 1.78 at follow-up, ERP: ES = 2.03 posttreatment, 2.29 at follow-up). Ook de verbeterpercentages voor klinisch relevant herstel zijn groot. Na het afronden van de therapie voldoet 72% van de patiënten in de MCT conditie aan

de criteria voor herstel. 26% kan geclassificeerd worden als symptoomvrij. In de ERP conditie is dit respectievelijk 61% en 33%. 6 maanden laten worden nagenoeg vergelijkbare resultaten gevonden (72% van de patiënten in de MCT conditie blijkt dan hersteld, en 31% symptoomvrij, in de ERP conditie is dit 67% en 33%). Het is noemenswaardig dat de goede behandelresultaten gevonden werden in een relatief korte behandelduur. Zowel de ERP als MCT behandeling bestond uit 15 sessies van 45 minuten, terwijl ERP doorgaans uit 15 tot 20 sessies bestaat van 90 minuten. Dit resultaat suggereert dat een goed therapieresultaat bij OCS mogelijk bereikt kan worden in een kortere tijd dan tot nog toe werd aangenomen. Er werden geen significante verschillen tussen behandelcondities gevonden. Een mogelijke verklaring is dat het onderliggende werkingsmechanismen voor beide behandelmethoden identiek is. Deze hypothese wordt ondersteund door de bevinding dat er voor beide condities een vergelijkbaar effect gevonden wordt op de procesmaten. We eindigen met de conclusie dat zowel MCT als ERP effectieve behandelmethoden zijn voor OCS. De onderzoeken rechtvaardigen de conclusie dat MCT betrouwbaar ingezet kan worden wanneer een OCS patient ERP behandeling weigert, vroegtijdig beëindigt of wanneer optimale behandeluitkomsten uitblijven. Ook wordt geopperd specifieke gedragsexperimenten vanuit de MCT toe te voegen aan ERP behandelingen om op deze manier een breed scala aan disfunctionele verwachtingen bij OCS (zowel obsessies en metacognities) te kunnen toetsen.

Hoofdstuk 7 betreft de afsluitende discussie. De bevindingen uit de voorgaande hoofdstukken worden nog eens samengevat. Ook worden de limitaties van de uitgevoerde onderzoeken alsmede de klinische implicaties van de resultaten beschreven. Tot slot worden er aanbevelingen gedaan voor toekomstig onderzoek.

8.4 Publications

The effectiveness of metacognitive therapy in comparison to exposure and response prevention for Obsessive-Compulsive Disorder: A randomized controlled trial (2021). Melchior, K., Heiden van der, C., Deen, M., Mayer, B., & Franken, I. H. A. Under review by to Behaviour Research and Therapy.

The assessment of thought fusion beliefs and beliefs about rituals in clinical and non-clinical populations: psychometric properties of the Thought Fusion Instrument (TFI) and Beliefs About Rituals Inventory (BARI) (2021). Melchior, K., Franken, I., Vuijk, R., Peerbooms, C. & Heiden van der, C. Psychological Test Adaptation and Development, 2021, 0, pp. 1-15.

Metacognitieve therapie voor de obsessieve-compulsieve stoornis: Theorie, behandeling en implicaties voor de praktijk (2019). Melchior, K. & Heiden van der, C. Gedragstherapie, 52, 274-295.

Metacognitive therapy versus exposure and response prevention for obsessive-compulsive disorder: study protocol for a randomized controlled trial (2019). Melchior, K., Franken, I., Deen, M. & Heiden van der, C. Trials, 20: 277.

Metacognitive therapy for obsessive-compulsive disorder: A case report (2018). Bulletin of Menninger Clinic, Melchior, K., Franken, I., & Heiden van der, C.

Metacognitive therapy for obsessive compulsive disorder: A Pilot study (2016). Heiden, van der C, Melchior, K., Dekker, A., Damstra, M., & Deen, M. Journal of Obsessive Compulsive Disorder, 9, 24-29.

A 30-month follow-up of generalised anxiety disorder: Status after metacognitive therapy and intolerance of uncertainty therapy (2014). Heiden, van der C, van Rossen, K. European Journal of Person Centered Therapy, 2 (4), 434-438.

The effectiveness of Group Metacognitieve Therapy for Generalised Anxety Disorder: a pilot Study (2013). Heiden, van der C, Melchior, K en Stigter, E. Journal of Contemporary Psychotherapy, 43 (3), 151 – 157.

Cognitive behavioural therapy for adjustment disorder: an open trial (2012). Heiden van der, C. & Melchior, K. *The Behavior Therapist, 35, 57-60.*

Metacognitieve therapie voor de gegeneraliseerde angststoornis - de stand van zaken (2011). Melchior, K & Heiden van der, C. Directieve therapie, 31 (2), 117-131.

Tiendaagse intensieve cognitieve gedragstherapie voor patienten met een paniekstoornis die onvoldoende baat hebben bij een reguliere behandeling: een pilot onderzoek (2010). Heiden van der, C., Melchior, K., Stolk, E. & Methorst, G. Gedragstherapie, 43, 293-306.

De psychometrische kwaliteiten van de Nederlandstalige versie van de Intolerance of Uncertainty Scale in een steekproef van patienten met een gegeneraliseerde angststoornis (2010). Heiden van der, C. & Melchior, K. Directieve therapie, 30 (3), 160-176.

A hierarchical model of the vulnerability of generalized anxiety disorder (2010). Heiden van der, C., Melchior, K., Muris, P., Bouwmeester, S., Bos, A., & Molen van der, H. Journal of anxiety disorders. 24 (2), 284-289.

8.5 Curriculum Vitae

Kim Melchior, geboren in Alkmaar op 4 januari 1986, behaalde in 2003 haar VWO diploma op het Stanislas College in Delft. In 2004 begon zij aan haar studie psychologie aan de Erasmus Universiteit Rotterdam, waar zij in 2008 cum laude afstudeerde in de klinische psychologie. In de slot fase van haar klinische master liep zij een gecombineerde praktijk en onderzoeksstage op de afdeling angststoornissen van PsyQ Rijnmond. Na haar stage werd zij hier in dienst genomen als psycholoog en onderzoeker. Zij deed de postdoctorale opleiding tot cognitief gedragstherapeut en is sinds 2013 geregistreerd bij de beroepsvereniging VGCt. In de eerste jaren van haar carrière werkte Kim als onderzoeksassistent mee aan verschillende onderzoeken naar angststoornissen en effectiviteitsstudies naar cognitieve gedragstherapie. In 2015 startte zij samen met Colin van der Heiden een pilot onderzoek naar de effectiviteit van metacognitieve therapie bij de obsessieve-compulsieve stoornis, waaruit het idee voor haar promotie-traject werd geboren. Momenteel is Kim werkzaam als gezondheidszorgpsycholoog en onderzoeker binnen de Parnassia Groep.

8.6 Appendix

Thought Fusion Instrument (TFI)

Adrian Wells, Petra Gwilliam, and Samantha Cartwright-Hatton
(Nederlandse vertaling: Colin van der Heiden)

Mensen kunnen verschillende opvattingen hebben over de invloed en de betekenis van hun gedachten en ervaringen. Hieronder staan een aantal van zulke opvattingen. Zou u elke opvatting willen lezen en aangeven in welke mate u hierin gelooft op een schaal van 0 (ik geloof deze opvatting helemaal niet) tot 100 (ik ben volledig overtuigd van deze opvatting). Denk er niet te lang over na, en omcirkel het getal dat aangeeft hoeveel u in het algemeen in de opvatting gelooft.

		ik geloof deze opvatting helemaal niet										ik ben volledig overtuigd van deze opvatting
1	Als ik aan een onplezierige gebeurtenis denk, dan wordt de kans groter dat het ook echt gebeurt.	0	10	20	30	40	50	60	70	80	90	100
2	Als ik de gedachte heb dat ik mezelf iets aandoe, dan zal ik dat uiteindelijk ook doen	0	10	20	30	40	50	60	70	80	90	100
3	Als ik denk dat er gevaar dreigt, dan betekent dat dat ik ook echt in gevaar ben	0	10	20	30	40	50	60	70	80	90	100
4	Slechte dingen denken betekent dat ik iets slechts ga doen	0	10	20	30	40	50	60	70	80	90	100
5	Als ik aan een nare gebeurtenis denk, betekent dat dat die gebeurtenis echt plaatsgevonden moet hebben	0	10	20	30	40	50	60	70	80	90	100
6	Als ik de gedachte heb dat ik iemand iets aan zal doen, zal ik dat ook gaan doen	0	10	20	30	40	50	60	70	80	90	100
7	Als ik denk dat dingen besmet zijn door de ervaringen van anderen, dan betekent dat dat ze ook echt besmet zijn	0	10	20	30	40	50	60	70	80	90	100
8	Mijn gedachten kunnen ervoor zorgen dat zaken anders lopen	0	10	20	30	40	50	60	70	80	90	100
9	Sommige dingen stralen een negatieve sfeer uit	0	10	20	30	40	50	60	70	80	90	100
10	Als ik slechte dingen denk, dan moet dat betekenen dat ik aan slechte dingen wil denken	0	10	20	30	40	50	60	70	80	90	100
11	Mijn gevoelens kunnen overgedragen worden op objecten	0	10	20	30	40	50	60	70	80	90	100
12	De gedachte dat ik iemand iets aan zal doen, zal die ander schade berokkenen	0	10	20	30	40	50	60	70	80	90	100
13	Mijn gedachten komen uit; als ik iets denk, dan wordt die gedachte bewaarheid	0	10	20	30	40	50	60	70	80	90	100
14	Mijn herinneringen/gedachten kunnen overgebracht worden op objecten	0	10	20	30	40	50	60	70	80	90	100

Beliefs About Rituals Inventory (BARI)

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Instructies: Rituelen zijn vaste, zich herhalende gedragingen of mentale activiteiten, die iemand uitvoert in reactie op nare gedachten, beelden, gevoelens of impulsen die tegen zijn of haar wil in iemands hoofd opkomen. Voorbeelden zijn herhaald gedrag zoals het afsluiten van deuren, het in gedachten tellen of herhalen van woorden, en het recht leggen van spullen. Deze vragenlijst bestaat uit een aantal stellingen over hoe men over zulke rituelen kan denken.

Lees elke stelling alstublieft goed en geef vervolgens aan in hoeverre u het met de stelling eens bent door het juiste getal te omcirkelen. Er zijn geen goede of foute antwoorden; we zijn alleen benieuwd naar hoe u tegen rituelen aankijkt.

		Niet mee eens	Beetje mee eens	Redelijk mee eens	Mee eens
Ik moet mijn rituelen uitvoeren, anders...					
1	Zal ik nooit meer rust vinden	1	2	3	4
2	Zal ik niet meer kunnen ontspannen	1	2	3	4
3	Zal ik niet meer functioneren	1	2	3	4
4	Zal ik de controle over mijn gedachten verliezen	1	2	3	4
5	Zal ik gestraft worden	1	2	3	4
6	Zal ik me altijd slecht voelen	1	2	3	4
7	Kan ik schuldgevoelens niet kwijtraken	1	2	3	4
8	Zal ik belangrijke dingen vergeten te doen	1	2	3	4
9	Zal ik mezelf of anderen in gevaar brengen	1	2	3	4
10	Zal ik iets doen waar ik spijt van krijg	1	2	3	4
11	Zal ik de controle over mijn gedrag verliezen	1	2	3	4
12	Zal ik iemand worden die ik niet wil zijn	1	2	3	4