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Improving outcomes of Cognitive Behavioural Therapy for Obsessive-Compulsive Disorder: exploring engagement and the potential of mindfulness-based interventions

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Declaration

The thesis conforms to an 'article format' in which the middle chapters consist of discrete articles written in a style appropriate for publication in peer-reviewed journals in the field. The first and final chapters present synthetic overviews and discussions of the field and the research undertaken. The format of the papers has been altered to suit the format of the thesis but the papers were prepared for and/or submitted to the journals using their required format.

The first paper, Chapter 2, has been submitted, revised and re-submitted to the Journal of Anxiety disorders as:

Leeuwerik, T., Cavanagh, K., & Strauss, C. (*under review*). Patient adherence to cognitive behavioural therapy for obsessive-compulsive disorder: A systematic review and meta-analysis.

The re-submitted paper is under review.

The author contributions are as follows: TL and CS were responsible for the design of the study. TL was responsible for data extraction, coding and analysis, under supervision of CS and KC. TL wrote the first draft of the manuscript and was responsible for corrections to the manuscript, preparation for publication and revision. CS and KC supervised all aspects of the research, contributed to and approved the final manuscript.

The second paper, Chapter 3, has been prepared for submission to the British Journal of Clinical Psychology as:

Leeuwerik, T., Caradonna, G., Cavanagh, K., Forrester, E.,., Jones, A., Lea, L., Rosten, C., & Strauss, C. (*in preparation*). Barriers and facilitators to patient engagement in group exposure and response prevention therapy for obsessive-compulsive disorder: A thematic analysis.

The author contributions are as follows: CS, LL, CR, AMJ, MH and EF designed the study. TL and GD conducted the thematic analysis and TL wrote and revised the manuscript, under the supervision of CS and KC, who contributed to and approved the manuscript. The other authors were part of the research team for the pilot RCT from which the interview data was drawn (Strauss et al., 2018). They will be invited to contribute to the manuscript prior to submission for publication.

The third paper, Chapter 4, has been submitted, revised and re-submitted to Cognitive Therapy and Research as:

Leeuwerik, T., Cavanagh, K., & Strauss, C. (*under review*). The association of trait mindfulness and self-compassion with OCD symptoms: Results from a large survey with treatment-seeking adults.

The re-submitted paper is under review.

The author contributions are as follows: TL and CS were responsible for design of the study. TL was responsible for data collection, management and analysis. TL wrote the first draft of the manuscript, was responsible for corrections to the manuscript, preparation for publication and revision. CS and KC supervised all aspects of the research process and contributed to and approved the final manuscript.

The fourth and final paper, Chapter 5, has been prepared for submission to the PlosOne journal:

Leeuwerik, T., Cavanagh, K., Forrester, E., Hayward, M., Hoadley, C., Jones, A., Leah, L., Rosten, C., & Strauss, C. (*in preparation*). A qualitative study of participant perspectives on the acceptability and effectiveness of mindfulness-based cognitive behaviour therapy approaches for obsessive-compulsive disorder

The author contributions are as follows: CS, LL, CR, AMJ, MH and EF designed study 1. CS and TL study 2. TL and CH transcribed the interviews for study 1. TL transcribed the interviews for study 2. TL conducted the thematic analyses and wrote and revised the manuscript, under the supervision of CS and KC who contributed to and approved the manuscript. The other authors were part of the research team for the pilot RCT for which the interview data for study 1 was collected (Strauss et al., 2018). They will be invited to contribute to the manuscript prior to submission for publication.

I hereby declare that this thesis has not been and will not be, submitted in whole or in part to another University for the award of any other degree.

C .															
Signature:															

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Disclaimer

None of the authors report financial or personal relationships that could inappropriately influence (or bias) their decisions or work on the articles in this thesis.

Abbreviations

ACT: Acceptance and Commitment Therapy

AD: Anxious-Depressed

ANOVA: Analysis of Variance

APA: American Psychiatric Association

Bca: Bias Corrected and Accelerated

BDI: Beck Depression Inventory

BMM: Brief Mindfulness Measure

BOS: Bristol Online Survey Platform

CAMS-R: Cognitive and Affective Mindfulness Scale – Revised

CBT: Cognitive Behavioural Therapy

CGI: Clinical Global Impression

CI: Confidence Interval

CRES: Clinician Rated Effort Scale

CS: Conditioned Stimulus

CT: Cognitive Therapy

DBT: Dialectical Behavioural Therapy

DSM: Diagnostic and Statistical Manual of Mental Disorders

DTS: Distress Tolerance Scale

EMDR: Eye Movement Desensitisation and Reprocessing

ERP: Exposure and Response Prevention

FFMQ: Five Facet Mindfulness Questionnaire

FFMQ-SF: Five Facet Mindfulness Questionnaire – Short Form

FFMQ-SF-O: Five Facet Mindfulness Questionnaire - Short Form Total Scale Score

Minus the Observe Facet

FMI: Freiburg Mindfulness Inventory

GAD: Generalised Anxiety Disorder

GBT: Group Behaviour Therapy

HC: Healthy Controls

HCRF: Homework Compliance Rating Form

HCS: Homework Compliance Scale

IAPT: Improving Access to Psychological Therapies

ICC: Intra-Class Correlation Coefficient

ICD: International Classification of Diseases and Related Health Problems

IIE: Intolerance of Internal Experiences

ILT: Inhibitory Learning Theory

ITT: Intention to Treat

KIMS: Kentucky Inventory of Mindfulness Skills

M: Mean

MAAS: Mindful Attention Awareness Scale

MBCT: Mindfulness-Based Cognitive Therapy

MBCT-OCD: Mindfulness-Based Cognitive Therapy Adapted for OCD (Study 4)

MB-ERP: Mindfulness-Based Exposure and Response Prevention

MBIs: Mindfulness-Based Interventions

MBSR: Mindfulness-Based Stress Reduction

MCAR: Missing Completely at Random

MCQ: Metacognitions Questionnaire

MCT: Meta-Cognitive Therapy

MICBT: Mindfulness-Integrated CBT

MINI: Mini-International Neuropsychiatric Interview

NHS: National Health Service

NICE: National Institute for Health and Care Excellence

OBQ: Obsessive Beliefs Questionnaire

OC: Obsessive-Compulsive

OCCWG: Obsessive-Compulsive Cognitions Working Group

OCD: Obsessive-Compulsive Disorder

OCI: Obsessive-Compulsive Inventory

OCI-R: Obsessive-Compulsive Inventory - Revised

OIT: Obsessive Intrusive Thoughts

PEAS: Patient Exposure Adherence Scale

PHLMS: Philadelphia Mindfulness Scale

PHQ-9: Patient Health Questionnaire-9

QQ Plot: Quantile-Quantile Plot

PP Plot: Probability-Probability Plot

RCT: Randomised Controlled Trial

RNT: Repetitive Negative Thinking

RR: Risk Ratio

SAD: Social Anxiety Disorder

SCS: Self-Compassion Scale

SCS-SF: Self-Compassion Scale - Short Form

SD: Standard Deviation

SE: Standard Error

SMQ: Southampton Mindfulness Questionnaire

SPFT: Sussex Partnership NHS Foundation Trust

SPSS: Statistical Package for the Social Sciences

TA: Thematic Analysis

TAF: Thought-Action-Fusion

TMS: Toronto Mindfulness Scale

UC: Unconditioned Stimulus

WHO: World Health Organization

Y-BOCS: Yale–Brown Obsessive Compulsive Scale

Summary

Research evidence shows that although Cognitive Behavioural Therapy (CBT) is a highly effective therapy and the gold standard in the treatment of Obsessive-Compulsive Disorder (OCD), a significant proportion of adults with OCD do not experience a clinically meaningful reduction in OCD symptoms post-treatment. As CBT for OCD is a challenging therapy, this may, at least in part, reflect poor patient engagement. The modest response rate also invites exploration of other psychological therapies that may enhance treatment outcomes.

The first aim of the thesis was to examine patient engagement in CBT for OCD. This was achieved through a systematic review and meta-analysis of the magnitude, predictors and reasons for patient non-adherence, specifically refusal, dropout, session attendance and CBT task engagement, to CBT for OCD (paper 1), followed by a qualitative exploration, employing thematic analysis, of patients' perceptions of the barriers and facilitators to engagement in group CBT for OCD (paper 2). The second aim was to explore whether mindfulness-based interventions (MBIs) show potential for adults with OCD. Towards this aim, the thesis first examined the relationship of obsessive-compulsive symptoms with mindfulness and self-compassion in a large sample of treatment-seeking adults and tested whether mindfulness and self-compassion contributed to explaining obsessive-compulsive symptoms over and above depression severity, obsessive beliefs and distress tolerance (paper 3). This was followed by a qualitative analysis of patient experiences of MBIs, specifically mindfulness-based ERP (MB-ERP) and Mindfulness-based Cognitive Therapy adapted for OCD (MBCT-OCD) to elucidate whether these MBIs were perceived as acceptable and potentially efficacious treatments for OCD and to explore how they might achieve their positive

effects (paper 4). After a general introduction, the four papers are presented, followed by a general discussion of results, a reflection on the strengths and limitations of the thesis and its clinical and research implications.

Chapter 1: Overview

1 General introduction

This chapter introduces the phenomenology and cognitive behavioural perspective on the aetiology, maintenance and treatment of obsessive-compulsive disorder (OCD). This is followed by theoretical and research literature on patient engagement in CBT for OCD. The concepts of mindfulness, self-compassion and mindfulness-based interventions (MBIs) are introduced, before exploring their theorised potential for OCD and concluding with the aims and objectives of the thesis.

1.1 What is OCD?

Obsessive-compulsive disorder (OCD) is a debilitating mental health condition characterised by persistent, unwanted intrusive thoughts, images or urges that cause significant distress (i.e. obsessions), and repetitive, ritualistic behaviours or mental acts aimed at neutralising distress and/or preventing negative outcomes (i.e. compulsions) (APA, 2013). To meet a diagnosis of OCD, obsessions or compulsions need to be time-consuming, distressing and/or impact significantly on daily functioning. Symptoms should not be a result of physical health conditions or psychotropic medication, or better explained by other mental health conditions (APA, 2013).

While OCD symptoms occur along a continuum of severity in the general population and can be studied in nonclinical populations (Gibbs, 1996), a diagnosis of OCD has a current prevalence of 1% and a lifetime prevalence of 2-3 % (e.g. Angst et al., 2004; Kessler, Petukhova, Sampson, Zaslavsky & Wittchen, 2012; Ruscio, Stein, Chiu & Kessler, 2010; Torres et al., 2006). Spontaneous remission is low yet many adults with OCD do not seek (early) help for their symptoms (Angst et al., 2004; García-Soriano, Rufer, Delsignore, & Weidt, 2014; Schwartz, Schlegl, Kuelz, &

Voderholzer, 2013; Skoog & Skoog, 1999). OCD has a high current and lifetime comorbidity with depression and anxiety (Angst et al., 2004; Macy et al., 2013; Ruscio et al., 2010; Schuurmans et al., 2012, Torres et al., 2006). The World Health Organization (WHO) considers OCD the 10th leading cause of disability; it presents a major public health burden and is associated with poor quality of life comparable, when severe, to impairments in schizophrenia (Bobes et al., 2001; Hollander et al., 1997; Macy et al., 2013; Murray & Lopez, 1996; Schuurmans et al., 2012; Veale & Roberts, 2014).

OCD is a heterogeneous disorder as obsessions can centre on a fear of contamination, (unintentionally) causing or preventing harm to self or others, symmetry or 'taboo' thoughts, such as unwanted aggressive, sexual or blasphemous thoughts, images or impulses (Mataix-Cols et al., 2005; Pinto et al., 2007; Williams et al., 2011). Obsessional intrusions can be distinguished as 'autogenous', i.e. sexual, aggressive or immoral intrusions without easily identifiable triggers that are ego-dystonic, repulsive and highly distressing, or 'reactive', i.e. intrusions with identifiable triggers that are perceived as sufficiently realistic and ego-syntonic, e.g. intrusions about contamination, risk of harm, making mistakes, asymmetry (Lee & Kwon, 2003; Moulding, Aardema, & O'Connor, 2014). An autogenous intrusion is considered ego-dystonic because it is 'inconsistent with one's character, or that one would not expect oneself to have, and therefore represents a threat to the self-view' (Purdon & Clark, 1999, p.106). By contrast, in the case of reactive obsessions, 'the main source of perceived threat is not the obsession itself but its possible negative consequences' (Belloch, Cabedo, Carrió, & Larsson, 2010, p.573). They reflect 'a concern for the safety of significant others', which does not present a threat to someone's self-view (Purdon & Clark, 1999, p.106).

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In other words, the content of autogenous intrusions 'contradict the individual's sense of self to a greater degree than thoughts about preventing harm that may occur in other doubt/contamination obsessions' (Moulding, Aardema, & Connor, 2014, p.162-163).

While some patients are convinced of the veracity of their obsessions to the point of delusion (APA, 2013), many have a degree of insight into the senselessness of obsessions and/or compulsions (Jacob, Larson, & Storch, 2014). Anxiety is a key response to intrusions but other feeling such as disgust or shame, e.g. in response to contamination fears or sexual intrusions, are also common (McKay et al., 2006; Rachman, 1971; Weingarden & Renshaw, 2015). This is reflected in the, albeit controversial (e.g. Abramowitz & Jacoby, 2015a; Krzanowska & Kuleta, 2017), reclassification of OCD from an anxiety disorders category (DSM-IV; APA (2000)) to a stand-alone 'Obsessive Compulsive and related disorders' category characterised by a prominence of obsessive preoccupation and repetitive behaviours (DMV-V; APA (2013).

Compulsions are ways to correct, cancel or atone for intrusions and/or their anticipated consequences (Rachman, 1997) and are similarly variable; they include overt, physical behaviours such as washing, cleaning, checking, counting, ordering, arranging and reassurance seeking, or mental, covert acts including self-reassurance, prayers, mantras and mental argument (e.g. Salkovskis & Westbrook, 1989).

Hypervigilant attention to and avoidance of triggers, thought suppression, safety-seeking behaviours, i.e. carrying antibacterial handwipes, and reassurance seeking, e.g. from family, are also common characteristics of OCD (Salkovskis, 1999).

Despite the heterogeneity in OCD symptoms, there are distinguishable sub-types or dimensions: i) contamination fears are typically associated with washing and

cleaning compulsions; ii) harm-related intrusions are commonly associated with checking rituals; iii) obsessions around order, symmetry or incompleteness are related to ordering, arranging and counting rituals, and; iv) sexual and/or aggressive thoughts are often associated with mental compulsions and (interoceptive) checking, e.g. scanning the body for signs of sexual arousal (Abramowitz et al., 2010; Jacoby & Abramowitz, 2016; Mataix-Cols, Rosario-Campos, & Leckman, 2005; McKay et al., 2004).

1.2 Aetiology and maintenance of OCD

This thesis is primarily informed by the cognitive behavioural model of OCD, which implicates classical and operant conditioning and/or maladaptive appraisals in the aetiology and maintenance of OCD symptoms. This thesis also draws on recent research into trait-like affective vulnerabilities, particularly distress tolerance, associated with OCD. Therefore, the following will briefly consider these factors. However, it is important to acknowledge other perspectives on the aetiology and maintenance of OCD including genetic models (e.g. Samuels, Grados, Plahalp, & Bienvenu, 2012), information processing biases (e.g. Calkins, Berman, & Wilhelm, 2013; Hezel & McNally, 2016; Radomsky & Alcolado, 2012) and cognitive deficits models (see Clark (2007) for an overview), which are underpinned by neurobiological models that explore neurochemical and neuroanatomical abnormalities associated with OCD (e.g. see Abramovitch, Abramowitz, & Mittelman, 2013; Abramovitch & Cooperman, 2015). Overall, the research evidence for role of these factors is considered less persuasive compared to the cognitive behavioural perspectives on OCD (Abramowitz & Jacoby, 2015b; Bream, Challacombe, Palmer, & Salkovskis, 2017).

1.2.1 Classical and operant conditioning

Behavioural or conditioning models of OCD evolved from Mowrer's (1939; 1947) two-stage learning theory of fear acquisition and maintenance: i) the acquisition of a conditioned fear response through classical conditioning where a previously neutral external or internal stimulus evokes fear due to its pairing with an unconditioned aversive (external or mental) stimulus (US) that naturally evokes fear and; ii) the maintenance of the conditioned fear response (CR) through operant conditioning processing, as escape and avoidance behaviours are negatively reinforced through the temporary relief of distress and prevent habituation to anxiety (Kozak & Foa, 1997; Rachman, 1976; Steketee, 1993). Mowrer's two-stage learning theory of fear was first applied to OCD by Dollard and Miller (1950) who proposed compulsions as active avoidance behaviours that, like passive avoidance and escape (e.g. in simple phobias), are negatively reinforced through the temporary relief of anxiety and sense of safety (Kozak & Foa, 1997). Rachman and colleagues conducted experiments that supported this model as compulsions reduced anxiety (e.g. Hodgson & Rachman, 1972; Roper, Rachman, & Hodgson, 1973) and preventing compulsions resulted in spontaneous decay of anxiety (Rachman, de Silva, & Roper, 1976). Research evidence is less supportive of the proposition that OCD symptoms are acquired through specific aversive conditioning experiences (Cassin & Rector, 2012; Foa & Kozak, 1986; Rachman, 1976). The limitations of learning theory in fully explaining OCD symptoms contributed to the development of cognitive models of OCD.

1.2.2 Maladaptive appraisals

Cognitive perspectives on OCD emerged in the 1970s and 80s, informed by Beck's cognitive model for anxiety and depression (Beck, 1991; Beck, Rush, Shaw, & Emery, 1979; Wells, 1997). Rachman and de Silva (1978) paved the way for an explicit cognitive theory of OCD by demonstrating that the content of obsessional intrusions is both common and indistinct from intrusions in the general population but that these intrusions are more frequent and persistent and cause significant distress in adults with OCD (APA, 2013). The guiding principle of the cognitive theory of OCD is that people with OCD appraise common intrusions as personally significant or important, believing they influence adverse real-life events or imply that they are 'bad, mad or dangerous' (Rachman, 1997; Shafran & Rachman, 2004, p.97). Consequently, intrusions are experienced as repugnant, disgusting, sinful or immoral (Rachman, 1997; 1998).

Compulsive behaviours leave maladaptive appraisals unchallenged; a lack of adverse consequences is attributed to the compulsions rather than the misappraisal of the intrusion (Clark & Purdon, 1993; Salkovskis, Shafran, Rachman, & Freeston, 1999).

The cognitive perspective on OCD proposes that the misappraisal of intrusions is informed by dysfunctional beliefs and assumptions, thought to stem from early life experiences, including over-protective parenting, being raised with rigid rules or being made to feel responsible for the happiness or safety of others, traumatic life events and general life stresses (Careau, O'Connor, Turgeon, & Freeston, 2012; Hezel & McNally, 2016; Salkovskis et al., 1999). Obsessive belief domains include inflated responsibility, intolerance of uncertainty, perfectionism, overestimation of threat, the need to control thoughts and the over-importance of thoughts (Obsessive-Compulsive Cognitions

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Working Group (OCCWG), 1997). There has been considerable theoretical debate among cognitive theorists about the primacy of different obsessive belief domains, which will be briefly outlined below.

The cognitive model of OCD developed by Salkovskis (1985) centres on inflated responsibility, or "the belief that one has power which is pivotal to bring about or prevent subjectively crucial negative outcomes. These outcomes may be actual, that is, having consequences in the real world, and/or at a moral level" (Salkovskis, Richards, & Forrester, 1995, p.285). This model foregrounds not the possibility of harm per se (pertinent to all anxiety disorders) but rather perceived personal responsibility for causing or preventing harm as a key characteristic of OCD (Steketee, 1993). See Figure 2 for a visual representation of this model.

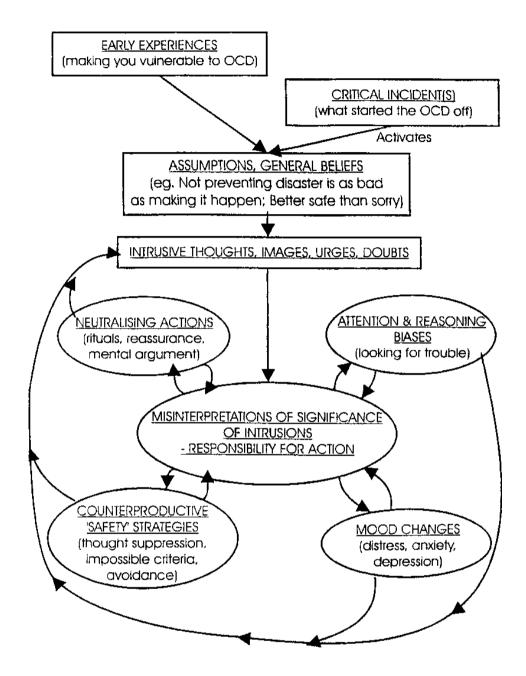


Figure 1 Cognitive model of OCD (Salkovskis, Forrester, & Richards, 1998)

Clark and Purdon (1993) propose that the **need to control thoughts** to avoid a loss of mental control (e.g. going crazy, being unhappy and unfulfilled) is a central belief in OCD. Their model asserts that this belief generates thought suppression strategies that inadvertently increase the frequency and salience of unwanted intrusions. This was informed by research showing a rebound effect after unwanted thought

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suppression, due to the enhancement of contextual cues for the recurrence of the unwanted thought (Wegner, Erber, & Zanakos, 1993; Wenzlaff & Wegner, 2000).

Rachman (1997, 1998) highlights beliefs about the **over-importance of thoughts**, including their personal significance; the occurrence of a thought is taken as a marker of its significance and pathological nature. Rachman and colleagues proposed that thoughts and actions become fused, i.e. having a bad thought is believed to be morally equivalent to acting on the thought (i.e. *moral* thought-action-fusion (TAF)) or to increase the likelihood of the bad event (i.e. *likelihood* TAF) (Shafran, Thordarson, & Rachman, 1996). **Thought-action-fusion** informs the misappraisal of intrusions as signalling a deviance in one's personality, e.g. madness, immorality or sinfulness, and is particularly pertinent to blasphemous, aggressive and sexual intrusions (Rachman, 1997).

Frost, Steketee, Cohn and Griesse (1994) highlighted the role of perfectionism and intolerance of uncertainty beliefs in OCD, particularly in relation to washing, checking compulsions, obsessional doubt and 'not-just-right' experiences (Frost & Steketee, 1997). **Perfectionism** is the belief that problems have perfect solutions, that small mistakes have major consequences and that it is important to achieve perfect outcomes (Frost & Steketee, 1997; OCCWG, 1997). **Intolerance of uncertainty** is an associated belief that encompasses 'beliefs about the necessity of being certain, about the capacity to cope with unpredictable change, and about adequate functioning in situations which are inherently ambiguous' (OCCWG, 1997, p. 678). This is evident in obsessional doubts about actions.

Foa and Kozak (1986) elaborated on Dollard and Miller's model of fear acquisition and maintenance by incorporating the work of Lang (1977) on the memory

encoding and recall processes implicated in conditioned fear; the conditioned fear response is an information structure held in memory that includes propositions about the stimulus, response and their meaning. It is characterised by impairments in the affective memory network, specifically the **overestimation of threat** including the likelihood of danger (probability) and harm (negative valence) associated with the stimulus and/or response (Kozak, Foa, 1997; Steketee, 1993). This, they argued, is attributable to impairments in epistemological reasoning; the person assumes the stimulus is dangerous unless proven safe (Steketee, 1993). Consequently, compulsions cannot provide safety but can only reduce the perceived likelihood of harm as exhaustive evidence cannot be presented to definitively conclude there is no risk of harm (Steketee, 1993).

Whilst there is considerable evidence for the collective positive association of these inter-related obsessive beliefs with OCD symptoms in non-clinical (e.g. Abramowitz, Lackey, & Wheaton, 2009; Taylor et al., 2010) and clinical samples (e.g. OCCWG, 2001), obsessive beliefs do not explain all the variance in OCD symptoms.

Research in this area is further complicated by the heterogeneity of OCD as each belief may be associated with different OCD symptom dimensions (e.g. OCCWG, 2005; Taylor et al., 2010; Tolin, Woods, & Abramowitz, 2010; Wheaton, Abramowitz, Berman, Riemann, & Hale, 2010). For example, Abramowitz et al. (2009) found that obsessive beliefs explained between 1 and 19% of the variance in OCD symptom subtypes in a college sample, after depression severity was controlled for. Wheaton et al. (2010) similarly found that in a sample of adults with OCD, obsessive beliefs accounted for 11(contamination) to 42% (responsibility for harm) of the variance in OCD symptoms, once depression severity was controlled for. The fact that the cognitive model of OCD does not fully explain OCD symptoms has generated interested in the

exploration of other theoretical constructs. This includes a consideration of trait-like constructs that represent affective vulnerabilities or risk factors.

1.2.3 Affective vulnerabilities

More recently, research into individual differences in susceptibility to OCD has included an examination of personality traits that reflect difficulties with emotional awareness, appraisal and tolerance (e.g. Calkins et al., 2013; Freeston & Robinson, 2014; Macdonald, 2003). Specifically, this has included the examination of anxiety sensitivity, i.e. 'exaggerated or amplified fear of the physical, social or cognitive consequences of anxiety-related sensations' (Keough, Riccardi, Timpano, Mitchell, & Schmidt, 2010, p.567) (e.g. Deacon & Abramowitz, 2006), disgust sensitivity (e.g. Olatunji, Ebesutani, & David, 2011; Tolin, Woods, & Abramowitz, 2006), alexythimia, i.e. a lack of emotional awareness or 'difficulty identifying and labelling emotions' (Robinson & Freeston, 2014, p.258) (e.g. Grabe et al., 2006) and distress tolerance. The latter constitutes the ability to 'experience or withstand negative psychological states' (Simon & Gaher, 2005, p. 83). People with low distress tolerance experience unpleasant emotions as unbearable, unmanageable or unacceptable (Robinson & Freeston, 2014) and display over-reactivity to distress (Garner et al., 2018). Adults with OCD often have some insight into the senselessness of their symptoms. However, they feel compelled to engage in compulsions, not only to avert adverse consequences but also to reduce associated anxiety, disgust, shame or discomfort. Low distress tolerance may play a role in the aetiology and maintenance of compulsions by compounding the unpleasant feelings evoked by unwanted intrusions and contribute to the urge to engage in the compulsions, avoidance, thought suppression and reassurance seeking to eliminate distress (Robinson & Freeston, 2014).

Evidence to date suggests low distress tolerance is associated with OCD symptoms, particularly obsessions, in both nonclinical (Abramowitz, Lackey & Wheaton, 2009; Cougle, Timpano, Fitch, & Hawkins, 2011; Cougle, Timpano, & Goetz, 2012) and clinical samples (r=-.43) (Laposa, Collimore, Hawley, & Rector, 2015), although Macatee, Capron, Schmidt and Cougle (2013) found that this relationship was moderated by life stressors; the relationship held only for people who had experienced greater life stressors. Evidence is mixed as to whether distress tolerance predicts OCD symptoms once other constructs are controlled for. For example, Blakey, Jacoby, Reuman and Abramowitz (2016) found that distress tolerance no longer predicted OCD symptoms once experiential avoidance (see below) was controlled for. Laposa et al. (2015) also found that distress tolerance, anxiety sensitivity nor intolerance of uncertainty were unique predictors of OCD symptom severity. Other studies did find evidence for distress tolerance as an independent predictor of OCD symptoms, particularly obsessions, after accounting for (generalised) anxiety, depression, obsessive belief(s) and/or anxiety sensitivity (Cougle et al., 2011; Cougle et al., 2012; Keough, Riccardi, Timpano, Mitchell, & Schmidt, 2010; Macatee et al., 2013), although in Keough et al. (2010) this association was weaker for OCD relative to anxiety disorders. Cougle et al. (2011) also showed that distress tolerance predicted an increase in obsessional symptoms and was associated with increased anxiety after experimental manipulation of obsessional intrusions. Evidence is also equivocal as to whether distress intolerance is uniquely associated with (particular) obsessivecompulsive symptoms or constitutes a transdiagnostic vulnerability factor. Hezel, Riemann and McNally (2012) found lower distress tolerance in adults with OCD relative to healthy controls (r=.67) but did not control for depression, which has an

association with both OCD symptoms and distress tolerance. Macatee et al. (2013) found that adults with OCD did not report lower distress tolerance relative to healthy controls once depression was controlled for. Cougle et al. (2011; 2012) and Macatee et al. (2013) found a specific association of distress tolerance with obsessions but not compulsions, whilst Laposa et al. (2015) reported comparable levels of distress intolerance in OCD, generalised anxiety disorder, social anxiety disorder and panic disorder (Robinson & Freeston, 2014).

Distress tolerance is closely associated with the concept of 'experiential avoidance', i.e. an unwillingness to experience unpleasant emotions, thoughts or memories (Manos et al., 2010, p.700), a construct that is central to Acceptance and Commitment Therapy (ACT) (Hayes, 2004), which proposes that 'psychological flexibility' can be brought to bear on unwanted experiences (Jacoby & Abramowitz, 2014; Twohig et al., 2015). Robinson and Freeston (2014) propose that distress intolerance and experiential avoidance are two facets of intolerance of internal experiences (IIE), which captures difficulty managing unwanted thoughts, feelings, sensations and behavioural urges (Blakey et al., 2016). Distress tolerance captures the ability to endure distress whilst experiential avoidance captures the willingness to endure distress. Abramowitz et al. (2009) did not find that experiential avoidance predicted OCD symptoms over and above obsessive beliefs in a nonclinical sample. Manos and colleagues (2010) found similar results, when controlling for depression using a sample of OCD patients. Abramowitz et al. (2009) concluded this may be because the construct of experiential avoidance is a more general construct than obsessive beliefs (Robinson & Freeston, 2014). Blakey et al. (2016) found that experiential avoidance but not distress tolerance independently predicted OCD

symptoms over and above depression severity. The construct of distress tolerance is implicated in recent inhibitory learning theory approaches to ERP (see below) that promote fear tolerance by teaching patients that anxiety does not need to be controlled or eliminated (habituation) but can be normalised and tolerated; anxiety is seen as a 'desirable difficulty' that allows inhibitory learning (Jacoby & Abramowitz, 2014).

1.3 Established psychological therapies for OCD

Cognitive behavioural therapy (CBT) is the most established psychological therapy for OCD. Different types of CBT therapies come under the umbrella of CBT for OCD; i) exposure and response prevention (ERP), ii) Cognitive Therapy (CT) and iii) CBT, which combines ERP with cognitive restructuring. Practice guidelines recommend ERP as the psychological therapy of choice for OCD (APA, 2007; NICE, 2005). NICE (2005) do not currently endorse cognitive therapy as a stand-alone treatment but suggest cognitive strategies may be added to ERP (see below). APA guidelines (2007) propose that patients showing insufficient response to CBT could benefit from further CT, ostensibly to process what is learnt from exposure more effectively and to address poor insight and comorbid difficulties that may adversely affect engagement. The following will describe ERP, CT and CBT, before setting out their proposed mechanisms of action.

1.3.1 Exposure and response prevention

Victor Meyer (1966) is credited with applying exposure and response prevention (ERP) to OCD, emerging from Wolpe's (1958) seminal work on systematic desensitisation for phobias and animal research into extinction of fear (e.g. Abramowitz,

Taylor, & McKay, 2012). Exposure and response prevention dissociates the conditioned stimulus from the conditioned fear response through repeated and prolonged *exposure* to the conditioned stimulus, i.e. the activation of the fear structure, while *preventing* avoidance and compulsive behaviours. For example, someone with contamination fears is invited to touch a contaminated object and refrain from washing their hands.

Treatment typically starts with psychoeducation about the vicious cycle of OCD, explaining the role of compulsions in maintaining symptoms, to inform the rationale for ERP (e.g. Kozak & Foa, 1997; Steketee, 1993). Psychoeducation about the fight-flight response, conveying that it is harmless and self-limiting, can also be included. This is followed by an individually tailored formulation of the patient's OCD symptoms. Subsequently, sessions focus on in-session in-vivo and imaginal exposure to situations that trigger obsessions. *In vivo* exposure involves real life exposure, e.g. touching a contaminated object, whilst imaginal exposure involves 'imagining a chain of negative outcomes that culminate at the core fear' (Gillihan, Williams, Malcoun, Yadin, & Foa, 2013, p.254). *In vivo* and imaginal exposure can be combined, e.g. the patient touches a contaminated object and vividly imagines their most feared outcome. For people with mental compulsions, imaginal exposure may involve writing down or audio-recording (e.g. the loop-tape technique) a feared scenario in as much vivid detail as possible and reading or listening to it repeatedly (e.g. Freeston & Ladouceur, 1999; Salkovskis & Westbrook, 1989).

The traditional approach to ERP, informed by the emotional processing (EP) model (Foa & Kozak, 1986) (see below), emphasises prolonged and repeated ERP and relies on a moderate degree of physiological arousal to achieve success. It takes a graded approach to ERP, devising a graded exposure hierarchy based on individual

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ratings of anticipated distress associated with each ERP task. Patients are asked to rate and monitor their distress over the course of the ERP task.

Inhibitory learning theory (ILT) approaches to ERP (see below) do not emphasise habituation per se, as it does not necessarily predict long-term outcomes (Craske Treanor, Conway, Zbozinek, & Vervliet, 2014), and instead emphasise that the key to fear extinction is to violate patient expectations (relating to the probability and negative valence of the feared stimulus). Therefore, ILT approaches to ERP aim to *maximise* expectancy violations to enhance (retrieval of) inhibitory learning and emphasise variability in the presentation of the stimulus, suggesting it can be advantageous to randomly go through the ERP hierarchy (Craske et al., 2014) (see below). From the ILT perspective, a successful ERP procedure does not require anxiety reduction but rather the ability to tolerate it; the experience of fear no longer signals treatment failure (Jacoby & Abramowitz, 2016). Regardless of which approach to ERP is taken, sessions typically start with a review of between-session ERP, followed by insession ERP and conclude with planning between-session ERP.

ERP treatment places great importance on between-session ERP tasks to consolidate learning, to ensure patients take responsibility for ERP without the implicit reassurance or safety offered by the therapist's presence and to enable exposure to triggers in their everyday environment (e.g. Franklin, Huppert, & Ledley, 2005). Patients are asked to keep a record of their home practice to check that the correct procedures were followed, to monitor progress and to facilitate learning and in-session discussion of home practice.

Most ERP treatment protocols (e.g. Foa & Kozak, 1997; Steketee, 1993) extend beyond 10 sessions, in line with APA (2013) and NICE (2005) guidelines. ERP is

typically conducted on an individual basis but can also be provided in group format, e.g. as part of a stepped care approach to treating OCD (NICE, 2005). Individual sessions typically range from 1 to 1.5 hours while group sessions are typically two hours long. Sessions can be held weekly or bi-weekly or at an even higher frequency (Abramowitz, Foa, & Franklin, 2003), although this is less common in routine clinical practice (NICE, 2005). Most studies of ERP are conducted in the clinic setting, mirroring how ERP is typically conducted in routine mental health services such as the NHS Improving Access to Psychological Therapies (IAPT) services (NICE, 2005).

1.3.2 Cognitive therapy

Whilst there are different cognitive models (stipulated above) of OCD, their similarities tend to outweigh their differences (Abramowitz, Taylor & McKay, 2005). Typically, CT has two phases (Rachman, 1998). The first stage starts with psychoeducation that conveys the key principle that people with OCD misinterpret common intrusions as significant and important (Rowa & Purdon, 2003). An individual formulation is drawn up and early home practice involves, e.g., self-monitoring tasks or informal surveys to investigate the notion that the patient is misappraising common intrusions as personally significant and important. During the second phase, cognitive restructuring strategies and behaviour experiments are used to test out alternative interpretations of intrusions. For example, likelihood TAF might be tested by inviting the patient to wish something bad happens, e.g. to the therapist, and to assess the consequences, whilst responsibility pie charts can be used to address inflated responsibility (e.g. Wilhelm & Steketee, 2006). Behavioural experiments are conducted to test out appraisals of threat. While this may involve exposure to a trigger and

prevention of compulsive behaviour, this does not involve systematic and prolonged ERP but rather serves the purpose of gathering evidence to support alternative interpretations of intrusions (Rachman, 1997; 1998). To further target the significance attached to intrusions, patients are encouraged not to conceal their difficulties, challenging their negative predictions about other people's responses (Rachman, 1998). Cognitive therapy approaches to OCD typically instruct patients to treat intrusions like the background noise of a turned-down radio (Rachman, 1997) and teach them to 'do nothing' in response to intrusions, i.e. drop compulsions (Clark & Purdon, 1993).

1.3.3 Cognitive behavioural therapy

As with CT, Salkovskis' (1985;1999) CBT approach to OCD starts from the premise that as obsessions are typically (distant) future orientated and cannot easily be disconfirmed, efforts should focus on helping patients to develop an alternative understanding of the nature of the problem (theory B, i.e. the problem is oversensitivity to danger, e.g. 'for understandable reasons I have become very sensitive to the idea of disaster and spend too much time trying to prevent it'), to contrast with their existing explanation (theory A, i.e. the problem is danger, e.g. 'a disaster will happen if I'm not careful enough') (Bream et al., 2017, p.91). After the initial phases of normalising intrusions, assessing alternative explanations for their problems and using cognitive restructuring strategies and behavioural experiments to explore this (as above), a more sustained ERP programme is commenced to bring about belief change (Salkovskis & Kirk, 1989).

1.3.4 Mechanisms of action

According to the cognitive model on which cognitive therapy and CBT are based, symptom change occurs because of the **re-evaluation of misappraisals** of common intrusions as meaningless (see, e.g. Adams, Riemann, Wetterneck, & Cisler, 2012; Diedrich et al., 2016; Farrell & Boschen, 2011; Solem, Haland, Vogel, Hansen, & Wells, 2009; Whittal, Thordarson, & Mclean, 2005; Woody, Whittal, & McLean, 2011). Meanwhile, behavioural perspectives on OCD propose that ERP extinguishes the conditioned fear response. Whilst the emotional processing model of ERP (Foa & Kozak, 1986) emphasises fear activation and habituation as the primary mechanism, the inhibitory learning perspective on ERP emphasises violations of expectations (e.g. Jacoby & Abramowitz, 2016). Foa and Kozak (1986) propose that ERP extinguishes the fear structure as corrective information (Conditioned Stimulus (CS)= not Unconditioned Stimulus (US)) is incorporated into it. This 'emotional processing' is evidenced through fear activation and within and between-session habituation, i.e. fear reduction (Ponniah, Magiati, & Hollon, 2013). Within-session habituation (short-term habituation) involves a reduction in physiological anxiety that follows a curvilinear pattern; anxiety rapidly increases, plateaus and decreases. This is a pre-requisite for between-session habituation, which facilitates new learning about the meaning of the stimulus (i.e. probability of danger and the severity of harm (or valence) associated with the event) or the response (i.e. anticipation of indefinite intensity and/or harmful consequences of the anxiety response) (Foa & Kozak, 1986).

The **inhibitory learning** model suggests that fear extinction does not result from the alteration (i.e. extinction) of the conditioned fear structure but from developing a new, non-fear structure or association, i.e. learning that the CS does not reliably predict

the US, that inhibits the existing fear structure (Arch & Craske, 2009; Craske, Treanor, Conway, Zbozinek, & Vervliet, 2014; Jacoby & Abramovitz, 2016). This model allows for the phenomenon of resurgence of the conditioned fear response (i.e. relapse) and takes account of the context in which the fear extinction occurred; the conditioned fear response may return in contexts in which inhibitory learning did not take place. Successful treatment therefore requires encoding non-fear associations and making them available for long-term recall to inhibit the conditioned fear response.

1.3.5 Summary

Despite their apparent distinctiveness, there is considerable procedural overlap between ERP, CBT and CT (Abramowitz, Taylor, & McKay, 2005) and it is thought they can target the same mechanisms of change; ERP tasks can lead to re-appraisals of intrusions whilst behavioural experiments used in cognitive therapy to challenge maladaptive appraisals can nonetheless lead to habituation (Olatunji et al., 2013). Therefore, rather than being radically different, these therapies differ in the relative emphasis placed on cognitive versus behavioural strategies.

1.4 Treatment outcomes

Öst, Havnen, Hansen and Kvale (2015) conducted the largest meta-analysis to date of the efficacy of CBT (all types) for OCD. Their meta-analysis included 37 randomised-controlled trials (RCTs) of individual, group, family or remote CBT and used the Yale–Brown Obsessive Compulsive Scale (Y-BOCS) (Goodman et al., 1989) as the primary outcome measure. They report a large pooled post-intervention effect size of CBT compared to waitlist (Hedges' g= 1.31, CI [1.08,1.55], k=15) and placebo

conditions (all placebo: g=1.33, 95% CI [.91-1.76], k=8, psychological placebo: g=1.29, 95% CI [.76,1.81], k=6) whilst no significant differences were found between individual and group treatment or between ERP and Cognitive Therapy. Outcomes for CBT were significantly better than for antidepressant medication (g=.55, 95% CI [.05, 1.04], k=4) whilst the difference between CBT with placebo compared to CBT with medication was non-significant.

As RCTs can have low external validity, effectiveness studies should complement their findings (Taylor, Abramowitz, & McKay, 2012a). Hans and Hiller (2013) conducted a meta-analysis of (non-randomised) effectiveness studies of face-to-face CBT for anxiety disorders that included 27 studies on OCD. Results showed a large pre-post effect size (d=1.45, CI [1.03-1.86], k=9). Although studies did not include a control group, results suggest that CBT for OCD can also be effective in research settings that are reflective of routine clinical practice.

Research on the sustained efficacy of CBT for OCD treatment at follow-up is limited and results are mixed. A meta-analysis of 16 RCTs found a CBT post-treatment effect size of Hedges' g = 1.39 (95% CI [1.04, 1.74], k=16) that reduced to g = 43 (95% CI [.12,.74], p=.01, k=3) at follow-up, suggesting improvements were not well-maintained over time, although the latter result is based on a very small number of studies (Olatunji et al., 2013). Hans and

Hiller's (2013) evaluation of effectiveness studies found sustained gains at 12 months follow-up as demonstrated by a non-significant, near-zero post-treatment to follow-up effect size: d = 0.09, 95% CI [-0.11, 0.28], k = 6).

1.4.1 Response and remission

Whilst CBT is the gold standard in the treatment of OCD, large effect sizes do not clarify whether all participants experienced a clinically meaningful reduction in symptoms (Jacobson & Truax, 1991). A popular method used to determine whether the patient has benefitted from psychotherapy is to apply Jacobson and Truax' (1991) criteria for clinically significant change (CSC). This two-part method calculates CSC based on: i) statistically reliable change from pre-to post-treatment, calculated as 1.96* the standard error of the difference between the pre- and post-treatment scores, and; ii) a post-treatment score that falls below clinical levels, typically determined by a Y-BOCS cut-off score in CBT for OCD, that can be calculated in three different ways: i) the mean Y-BOCS score in a normal population + 2SD (i.e. in direction of dysfunctionality) or iii) the mean Y-BOCS score in a dysfunctional population – 2SD (i.e. in direction of functionality) or iii) the average of these 2. Patients who meet both criteria have experienced CSC and are 'recovered' whilst patients meeting the first but not the second criterion are 'improved'.

Öst et al. (2015) reported a comparable mean response rate for ERP, CT and CBT ranging from 62 to 68%. The pooled CSC rate ranged from 42 to 52% for different types of CBT (CBT:42%, ERP: 50%, CT:52%). This suggests that at least 30% of adults with OCD do not respond to CBT and that only around 50% experience OCD symptom remission. However, the 21 primary studies contributing to this result employed varied operationalisations of treatment response, either based on: i) statistically reliable change, corresponding to a 7 to 14-point reduction in Y-BOCS scores (i.e. sample-dependent calculations); ii) a pre-determined % reduction in Y-BOCS scores to indicate response ranging from 25-50%, corresponding to a 5 to 10-

point reduction in Y-BOCS scores, or; iii) a score of 1-2 on the Clinical Global Impression Improvement (CGI-I) scale, to determine response. Similarly, eighteen of the 20 primary studies contributing to the pooled CSC rate based their calculations on the Jacobson and Truax method. However, determining the Y-BOCS cut-off score (criterion 2) is limited by the absence of relevant normative samples (Mataix Cols et al., 2016). Consequently, primary studies contributing to the pooled CSC rate used sample dependent calculations (pre-treatment Y-BOCS Mean – 2SDs), relied on evidence from empirical studies (e.g. Fisher & Wells, 2005; Lewin et al., 2011) or OCD expert guidance (e.g. Albert et al., 2013; Pallanti et al. 2002; Pallanti & Quercioli, 2006; Sookman & Steketee, 2007; 2010), which resulted in variable cut-off scores ranging from 7 to 16.

To resolve the variability in definitions of Y-BOCS scores, Mataix-cols et al. (2016) conducted a Delphi survey with hundreds of international OCD experts to arrive at a consensus of the conceptual and operational definition of response and remission (and other associated concepts such as recovery and relapse). Their consensus definitions are presented in **Table 1** and show that *partial response* can be operationalised as a 25-35% post-treatment reduction in Y-BOCS scores and Clinical Global Impression score of 1 or 2, and *full response* as a 35% post-treatment reduction Y-BOCS scores. In the absence of a structured diagnostic interview to confirm the patient no longer meets diagnostic criteria for OCD, remission should be operationalised as a Y-BOCS cut-off score of ≤12, together with a Clinical Global Index – severity (CGI-S) (Guy, 1976) rating of 1 ('normal, not at all ill') or 2 ('borderline mentally ill'), lasting at least one week.

From these recommendations, it follows that several of the primary studies that contributed to the pooled estimate of CSC in Öst et al. (2015) applied Y-BOCS cut-off scores that were either more stringent or more lenient than the recommended cut-off score of \leq 12. Fisher and Wells (2005) showed that applying consistent criteria for response (a 10-point reduction in Y-BOCS scores) and remission (a post-treatment Y-BOCS score of \leq 14) across 5 treatment trials suppressed the response and remission rates reported by individual studies by 10 to 20%. Furthermore, some of the primary studies in Öst et al. (2015) employed completer analyses, which might have resulted in an over-estimation of response rates. For example, a meta-analysis of a small number of RCTs of CBT for OCD showed that the 38% remission rate for CBT completers decreased to 25% for intention-to-treat samples (Eddy, Dutra, Bradley, & Westen, 2004). This means that the pooled estimates reported by Öst and colleagues do not necessarily capture the true rate of post-treatment remission following CBT for OCD. Despite these methodological limitations, the findings suggest that a substantial proportion of patients fail to benefit following CBT for OCD.

Table 1

Consensus definitions and operationalisation of treatment response and remission (Mataix-Cols et al., 2016)

(Mataix-Cois et al., 2016)		
	Definition	Operationalisation
Treatment response	A clinically meaningful reduction in symptoms (time, distress, and interference associated with obsessions, compulsions, and avoidance) relative to baseline severity in an individual who meets diagnostic criteria for OCD.	A ≥35% reduction in (C)Y-BOCS scores plus CGI-I rating of 1 ('very much improved') or 2 ('much improved'), lasting for at least one week.
Partial response		A ≥25% but <35% reduction in (C)Y-BOCS scores plus CGI-I rating of at least 3 ('minimally improved'), lasting for at least one week.
Remission	The patient no longer meets syndromal criteria for the disorder and has no more than minimal symptoms. Residual obsessions, compulsions, and avoidance may be present but are not time consuming and do not interfere with the person's everyday life.	If a structured diagnostic interview is feasible, the person no longer meets diagnostic criteria for OCD for at least one week. If a structured diagnostic interview is not feasible, a score of ≤12 on the (C)Y-BOCS plus CGI-S rating of 1 ('normal, not at all ill') or 2 ('borderline mentally ill'), lasting for at least one week.

1.4.2 Predictors of CBT outcomes for OCD

The predictors and moderators of CBT treatment outcomes are not well-understood. Clinically, it is thought that poor insight, i.e. highly overvalued ideation, OCD symptom severity and comorbid depression may be associated with poor outcomes (e.g. Foa & Abramowitz, 1999; Salkovskis & West, 1989; APA, 2013). However, research evidence is equivocal as to what might predict treatment outcomes (e.g. Keeley, Storch, Merlo, & Geffken, 2008; Steketee, Siev, Yovel, Lit, & Wilhelm, 2019). A meta-analysis of moderators of CBT for OCD based on 16 RCTs did not find that socio-demographic variables or clinical variables (e.g. pre-treatment OCD or

comorbid symptom severity) or treatment characteristics (e.g. format, duration or integrity of treatment) moderated treatment outcomes (Olatunji et al., 2013).

Meanwhile, a systematic review of predictors and moderators of outcomes for psychological therapy for OCD across 38 RCTs, quasi-randomised and cross-over studies, using a box-score approach, found that few sociodemographic factors appeared to consistently predict treatment response (Knopp, Knowles, Bee, Lovell, & Bower, 2013). There was some support for an association between being single or unemployed and poorer treatment outcome and a fairly consistent pattern of positive association between clinical variables such as pre-treatment severity of OCD, anxiety and depression and OCD symptom reduction(Knopp et al., 2013). Whilst these findings were not established through a meta-analysis, they drew on a large sample of studies using a range of study designs. Meanwhile, psychological variables such as treatment expectation and credibility, motivation and readiness for change were rarely examined; evidence for their associations with therapy outcome was inconsistent.

1.5 Improving treatment outcomes: the role of patient engagement

The previous section shows that there are few consistent sociodemographic, clinical and/or therapy-related predictors of treatment outcomes for OCD. CBT for OCD, and ERP in particular, is often seen as a challenging therapy by clients and therapists alike (Meyer, Farrell, Kemp, Blakey, & Deacon, 2014; Olatunji, Deacon, & Abramowitz, 2009); the therapy is anxiety-provoking by design and this is magnified by high levels of distress intolerance associated with OCD (Cougle et al., 2011). Therefore, poor engagement in therapy, also described as non-adherence, may be

associated with the variable response rates to CBT for OCD. The following will define engagement and adherence and explore them in relation to CBT for OCD.

1.5.1 Definition of patient engagement and adherence

Holdsworth, Bowen, Brown and Howat (2014) define patient engagement as 'all the efforts that clients make during the course of treatment (both within and between sessions) towards the achievement of changes (treatment outcomes)' (p.430). Tetley, Jinks, Huband and Howells (2011) similarly propose that client engagement can be understood as 'the extent to which the client actively participates in the treatment on offer' (p. 927). Holdsworth et al. (2014) propose that engagement consists of: i) session attendance ('minimum engagement effort'), ii) active participation or involvement within-session, and iii) active participation between-session, i.e. homework or practice. Their model is represented in **Figure 2** below. Tetley et al. (2011) more specifically suggest engagement can be operationalised behaviourally as: i) consistent attendance at sessions, i.e. whether the patient accessed the recommended 'dose' of therapy; ii) completion of therapy within the expected time-frame; iii) active participation insession through self-disclosure (of thoughts, feelings, problems and life history), participation in tasks or activities; iv) carrying out in between-sessions tasks, e.g. doing homework, practising skills, thinking about what was discussed; v) developing and maintaining an effective working relationship with the therapist; vi) developing and maintaining supportive and helpful behaviours towards other participants. Together, these facets capture 'the whole domain of the patient's behavioural contribution' (Drieschner et al., 2016, p.1127). Treatments differ on which treatment engagement

component is most relevant. Within the context of CBT, between-session task adherence plays a central role (Drieschner et al., 2016).

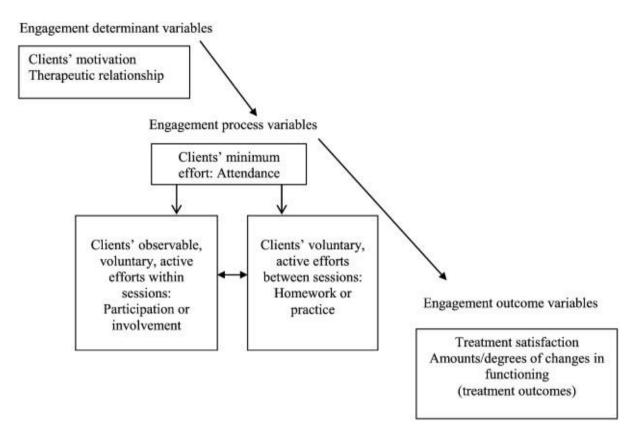


Figure 2 Model of client engagement in psychotherapy (Holdsworth et al., 2014).

Within the research literature, patient engagement is often used inter-changeably with adherence (or compliance) (e.g. Drieschner, Lammers & van der Staak, 2004). The WHO defines adherence as 'the extent to which a person's behaviour [...] corresponds with agreed recommendations from a health care provider' (Sabate, 2003, p.3). Holdworth et al. (2014) argue that engagement is not synonymous with compliance or adherence as the latter is limited to behaviours that are 'prescribed by the therapist, treatment approach or treatment setting' whereas behaviours that indicate patient engagement 'include any voluntary behaviors and efforts initiated and defined by clients as most relevant and useful to their progress in achieving change' (p.433). This highlights that patient engagement captures self-initiated, voluntary participation

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whereas adherence is a narrower definition of whether the patient follows the prescribed (recommendation for) treatment. However, within the context of quantitative research, the distinction between engagement and adherence is often lost.

Informed by the operationalisations of patient engagement described above and the research literature on CBT for OCD to date, this thesis broadly conceives of nonadherence or poor engagement as: i) therapy refusal by eligible patients, i.e. a patient who meets the eligibility criteria but declines to participate in therapy for any reason; ii) therapy dropout, i.e. a patient who starts treatment and attends at least 1 treatment session but discontinues treatment before the end of the treatment period - this does not include patients who complete treatment but do not attend post-treatment assessments (i.e. research dropouts); iii) low session attendance despite completion, and ; iv) poor engagement with key therapy tasks. This thesis will generally use the term patient engagement but employs the term patient adherence in the context of (meta-analytic) studies that calculate the magnitude, moderators/and or predictors of patient (non-) adherence as these statistics typically represent the extent to which patients followed prescribed recommendations (e.g. % of recommended sessions attended, % of recommended between-session tasks completed). The following provides a brief overview of research evidence to date for the magnitude, predictors of and reasons for these different facets of engagement in relation to CBT for OCD.

1.5.1.1 Treatment refusal

There is little research to date that has established a reliable estimate of the average CBT refusal rate among adults with OCD. For example, Öst et al. (2015) report a mean refusal rate of 15% (range: 0-63%, median: 11%) based on a simple averaging of refusal rates across 32 studies. Refusal was considered at the study level and

therefore included participants who declined participation based on the other treatments in the trial (e.g. medication). Also, in the absence of reasons for refusal, Öst et al. (2015) argued this refusal rate might not reflect participants' perception of the treatment per se. A naturalistic longitudinal study of OCD showed that, over a 2-year period, 25% of adults with OCD did not commence CBT despite professional recommendation (Mancebo, Eisen, Sibrava, Dyck, & Rasmussen, 2011). Examining reasons for failing to initiate CBT showed that whilst the perceived utility of CBT was a common reason for refusal (endorsed by 32% of participants), the primary reasons centred on concerns around the availability, convenience and cost of CBT (69%), the latter in the context of a lack of suitable health insurance. Levy, McLean, Yadin and Foa (2013) found that only 35% of eligible patients who contacted a speciality anxiety disorder clinic about treatment for OCD opted into a face-to-face intake evaluation and that of those only 66% continued to receive ERP. Thirteen percent of those who did not continue to receive ERP expressed a lack of interest in treatment whilst 10% did not respond to attempts to schedule the first therapy appointment (the remaining 12% ERP refusal was due to seeking treatment elsewhere or moving away).

1.5.1.2 *Treatment dropout*

Öst et al. (2015) found a mean CBT for OCD dropout rate of 15% (median 13%), based on averaging dropout rates across 37 RCTs. There was significant variability in dropout rates across studies (range = 0 - 32%). Meta-analysis of dropout showed that cognitive therapy had the lowest dropout rate at 11.4% (95% CI [7.4, 17], k=8), followed by waitlist controls (13.7%, 95% CI [7.9-22.6], k=8), CBT (15.5%, 95% CI [12.5-19.2], k=19), placebo (16.8%, 95% CI [9.3, 28.6], k=6), ERP (19.1%, CI [16.1-22.7], k=28) and ERP + antidepressants (32%, 95% CI[23.5, 38.3], k=7).

Subgroup analyses showed significantly higher dropout rates for ERP + antidepressants compared to CBT treatments (ERP, CBT or CT) without medication and/or placebo or waitlist controls.

Ong, Clyde, Bluett, Levin and Twohig (2016) found a 15% pooled dropout rate for face-to-face ERP (95% CI [11.4, 18.4]) based on 21 RCTs. Dropout rates for face-to-face ERP did not significantly differ from any of the other treatments that were provided, including remote ERP, ERP + medication, ERP + motivational interviewing, CT and CBT with and without medication, psychological placebo and waitlist controls.

It is often assumed that dropout in RCTs is significantly lower than dropout in real-world, routine clinical settings (Westbrook & Kirk, 2005). However, Hans and Hiller (2013) reported a 12% inverse variance weighted mean dropout rate for face-to-face CBT for OCD (95% CI [9.22-14.82], k=20) across clinically representative studies, which suggests that dropout rates may not substantially differ between RCTs and effectiveness studies. Swift and Greenberg (2014) meta-analysed dropout rates from CBT for OCD across a small number of controlled and uncontrolled studies and found a 19% dropout rate for ERP (95% CI [14.9, 23.1], k=21), 17% for CT (95% CI [10,28.1], k=4) and 14% for CBT (95% CI [11, 17.7], k=20). Differences between groups were not significant. Meanwhile, a longitudinal naturalistic study of OCD found that 21% of adults reported dropping out of CBT prematurely (Mancebo et al., 2011).

Overall, research to date suggests that on average, dropout rates for CBT fall between 10 and 20%. The high variability in dropout rates between studies points to possible moderator effects. None of the reviews considered at what session or stage of therapy dropout occurred. This is an important consideration as Aderka et al. (2011) showed that early dropouts had more severe OCD symptoms than late dropouts, who

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had experienced a substantial reduction in symptoms. This supports the assertion that different mechanisms might be at work at different stages of dropout and that late dropout is more akin to appropriate termination (Self et al., 2005).

Meta-analyses that consider predictors of dropout from CBT for OCD are few and far between. Knopp et al. (2013) found a reasonably consistent pattern of positive association between severity of OCD, anxiety and depression and drop-out status (examined in just 7 studies). No meta-analysis was conducted to confirm this. Öst et al. (2015) and Ong et al. (2016) examined type of CBT treatment (ERP, CT or CBT) as a moderator of dropout and did not find significant differences in dropout rates between ERP, CT and/or CBT (see above). Whilst Öst et al. (2015) found that dropout rates for ERP with medication were significantly higher than other CBT treatment conditions, Ong et al. (2016) did not replicate this result. Ong et al. (2016) also found that therapist qualification and experience and number of sessions did not predict dropout rates for ERP.

Along with examining predictors of dropout, it is important to consider the reasons people give for unilaterally terminating treatment, to inform what might help patients to remain in therapy (Swift, Greenberg, Whipple, & Kominiak, 2012).

Observational study data, reported by Mancebo et al. (2011), showed that among those participants who had dropped out of CBT (*N*=28) the main reasons for dropout were perceived environmental barriers, particularly being too busy for treatment or treatment being inconvenient (32%). Thirty-two percent of participants endorsed the (lack of) perceived utility of CBT, including too anxious to participate in CBT (29%). For 21% of participants this was the main reason for dropping out of CBT. Only one participant considered the relationship with the clinician the primary reason for dropout. These

results provide some support for the clinical impression that the challenging nature of CBT for OCD may considerably contribute to dropout. What is not known is how these responses related to the stage of dropout, e.g. conceivably feeling too fearful to participate in CBT might be associated with early dropout whereas environmental barriers such as cost and convenience might relate to early dropout and/or become more pertinent later on in therapy when costs accumulate and/or when some benefit might have been experienced.

1.5.1.3 Session attendance

US practice guidelines (APA, 2007) recommend 13-20 sessions of CBT and suggest intensive therapy (> twice weekly) may be more beneficial than weekly sessions. NICE (2005) distinguish between low intensity CBT, often offered in the first instance, of \leq 10 therapist hours per patient (e.g. therapist-assisted self-help or group CBT) and high intensity CBT of more than 10 therapist hours per patient for those patients with moderate to severe OCD or those with mild OCD who have failed to engage with or benefit from low intensity CBT. There are no existing meta-analyses that have estimated the magnitude of patient adherence to the recommended number (%) sessions of CBT for OCD.

1.5.1.4 *CBT task engagement*

CBT attaches great importance to between-session practice of therapy skills to consolidate and generalise the benefits of treatment (Franklin et al., 2005). For ERP, regular (daily) exposure is crucial for habituation to occur; if ERP is only conducted in weekly therapy sessions habituation is unlikely to occur and therefore the therapy will be seen to fail even if the person does not drop out. Whilst the ILT approach to ERP

does not necessarily emphasise habituation, it advocates that participants conduct ERP in a range of settings, with multiple cues/triggers, to enhance inhibitory learning (Jacoby & Abramowitz, 2016). Cognitive therapy, meanwhile, requires participants to conduct behavioural experiments and cognitive exercises that are not restricted to the clinic but take place in participants' everyday environment (e.g. Whittal & Steketee, 2006).

A meta-analysis of 27 studies that considered homework effects in CBT for a range of Axis I disorders found a significant effect of the use of homework assignments on therapy outcomes (causal homework effects: r=.36, 95% CI[.23, .48], N=375) and a significant positive association between the degree of homework compliance and outcome (r = .22, N=1327) (Kazantzis, Deane, & Ronan, 2000). An extension of this meta-analysis (Kazantzis, Whittington, & Dattilio, 2010) compared effect sizes of matched CBT therapies with and without homework assignments and found a pooled effect size d=.48 (95% CI [.25,.71], p<.0001, k=9) in favour of CBT with homework assignments. This confirmed that using homework assignments clearly has a beneficial impact on therapy outcomes. Mausbach, Moore, Roesch, Cardenas and Patterson (2010) found a significant pooled association of homework compliance with therapy outcomes in CBT (r=.26, 95% CI [.19,.33], p<.001, k=8). A more recent review and meta-analysis restricted to CBT found significant large effect sizes for both quality (Hedges' g=.78, 95% CI [.03, 1.53], k=3, n=417, $I^2=91$) and quantity (Hedges' g=.79, 95% CI [.57, 1.02], k=15, n=1537, $I^2=81$) of compliance with post-treatment outcomes (Kazantzis et al., 2016). These meta-analyses aggregated highly variable effect sizes across a wide range of homework tasks, target problems and adherence measures. Therefore, results

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were not specific to key homework tasks of CBT for OCD and did not assess the association of CBT task adherence with treatment outcomes for OCD.

Bryant, Simons and Thase (1999) and Kazantzis, Deane and Ronan (2004) propose a range of patient, therapist and task factors as necessary precursors to participants' engagement with homework. Patient factors include the client having a clear understanding of and involvement with homework assignments. Also, psychological factors such as clients' thoughts, beliefs and attitudes towards the task and their ability to achieve it are proposed to exert an important immediate effect on their willingness to engage in therapy tasks, e.g. perfectionism or fear of failure might interfere with engagement. Beliefs about the self and relationships with others could also influence task engagement. In turn, psychological factors are thought to be influenced by the patient's particular symptom profile and severity, sociodemographic factors and therapy characteristics such as the efficacy of the treatment. Therapist factors include the therapist's ability to provide a clear rationale and goal for homework assignments, to design such assignments in a highly specific and collaborative manner tailor-made to the client, and to effectively elicit and review feedback about homework. Also, therapists should be cognisant of practical obstacles within the client's environment and anticipate and problem-solve any difficulties. Task factors such as the nature and level of difficulty of the task at hand are also an important factor in homework compliance.

Whilst the factors that Bryant et al. (1999) propose are clinically plausible, there is little quantitative evidence to date for client, therapist and task factors as predictors of engagement and what evidence there is, shows an inconsistent pattern of association (Kazantzis et al., 2004). Furthermore, these investigations were not specific to CBT for

OCD; to date, there are no meta-analyses of predictors of task engagement in CBT for OCD. Single studies of predictors of task engagement found that treatment motivation affected between-session task adherence whilst pre-treatment expectations did not (Bachofen et al., 1999, Tolin et al., 2007). Regarding treatment characteristics, adding motivational interviewing to ERP did not improve adherence (Simpson et al., 2011) and there was no significant difference in task adherence between CT and ERP (Whittal et al., 2005). Research evidence is equivocal as to whether therapist-administered ERP is associated with better engagement than (guided) self-help ERP (Tolin et al., 2007; Kobak et al., 2015). The working alliance may predict patient adherence to ERP, particularly the extent to which the therapist and patient agreed on the tasks of therapy (Simpson et al., 2011; Wheaton, Huppert, Foa, & Simpson, 2016).

1.5.1.5 Qualitative perspectives on engagement

A few qualitative studies have explored participant perspectives on barriers and facilitators to engagement in CBT for OCD, without this necessarily being their primary focus. A thematic analysis of semi-structured interviews with eight adults with OCD who completed group or individual ERP (Lee & Rees, 2011) highlighted that the structured, graded approach to treatment, psychoeducation and combination with cognitive strategies aided engagement in ERP, which participants experienced as anxiety provoking and challenging. The support from fellow participants (which also helped normalise difficulties), the therapist and family and friends were also considered important. Personal motivation and courage further helped sustain engagement in ERP. However, this study provided only a brief account of participants' experience, lacking more in-depth information to guide understanding.

Marsden et al. (2018) conducted a comparative thematic analysis of data from semi-structured interviews with adults with OCD who completed individual CBT (n=10) and EMDR (n=14). Participants in both therapies perceived that general life difficulties such as physical illness, housing and employment issues and practical issues around timing and location of the sessions, impacted on their ability to get the most out of therapy. Participants in the CBT group also commented on the challenging nature of ERP. The provision of written worksheets to support exposure tasks at home received mixed support. Some participants reported that the structure of sessions did not provide enough opportunity to express themselves, to the detriment of the relationship with the therapist and resulting in dropout. This highlights that specific therapy characteristics could influence engagement.

Bevan et al. (2010) also provided a comparative thematic analysis of participants' experiences of an intensive (n=6) and weekly format (n=6) of individual CBT gathered through a semi-structured interview. Participants commented on the benefits of the intensive format in terms of reducing procrastination and managing anxiety raised by ERP tasks for the benefit of staying engaged in treatment. The intensive format was also experienced as motivating, which suggests that (preference for) therapy format can be an important barrier or facilitator to engagement.

1.5.1.6 *Summary*

Little is known about the rate of refusal for CBT for OCD whilst attempts to estimate the dropout rate for CBT for OCD have often been limited to RCTs and a relatively small number of uncontrolled studies. The (little) research that is available suggests that both refusal and dropout rates for CBT for OCD are considerable and therefore important to address but there is little research on the predictors of and reasons

given for refusal and dropout to guide this. There are no meta-analyses or reviews that estimate the magnitude of CBT task adherence, and the strength of its association with therapy outcomes for OCD, or the extent to which treatment completers attended the recommended number of sessions.

1.6 Improving treatment outcomes: the potential of mindfulness-based interventions

The variable response rate for CBT for OCD has generated interest in exploring the potential benefits of other psychological therapies. This thesis aimed to explore the acceptability and potential of MBIs for OCD. Mindfulness-based interventions (MBIs) place (regular and sustained) mindfulness practice at the heart of the intervention. The theoretical premise for MBIs for OCD is that they may help adults with OCD to: (1) allow obsessive thoughts into awareness and bring an interested, accepting attitude to such thoughts and their associated distress; (2) invite a non-judgmental, de-centred perspective on thoughts as passing mental events rather than facts (Segal et al, 2002), and; (3) perceive a wider range of choices about how to respond to intrusive thoughts and feelings of anxiety rather than to react habitually (e.g. by carrying out compulsions or avoiding situations) (Hale, Strauss, & Lever-Taylor, 2013).

The next section first introduces the concepts of mindfulness and self-compassion and how they are measured. This is followed by an introduction to MBIs and research evidence for their efficacy. The rationale for MBIs to target OCD symptoms is then introduced in more detail by reviewing the available literature on the association of trait mindfulness and self-compassion with OCD, the theoretical premise

for the potential benefits of MBIs for OCD and research to date on their acceptability and effectiveness.

1.6.1 Mindfulness

Mindfulness is rooted in Buddhism and other Eastern contemplative traditions and philosophies. There are different Buddhist traditions, i.e. Theravada, Mahayana (Zen), and Vajrayana, but all encompass mindfulness even if their precise conceptualisation, emphases and practices vary (Kabat-Zinn, 2003). Within these traditions, mindfulness meditation is 'nested within a larger conceptual and practicebased ethical framework oriented towards non-harming' or Dharma (Kabat-Zinn, 2003, p.146). Mindfulness can be broadly defined as 'paying attention in a particular way: on purpose, in the present moment, and nonjudgmentally', with nonjudgment referring to 'an affectionate, compassionate quality ... a sense of openhearted, friendly presence and interest' (Kabat-Zinn, 2003, p. 4). This well-known, widely accepted definition is derived from modern Buddhist understandings of mindfulness (Gethin, 2013). Despite its origins, Kabat-Zinn (2003) argues that mindfulness is not 'Buddhist' but represents a universal human capability that people possess to varying degrees. (Brown & Ryan, 2003) propose that this depends on people's individual capacity for mindfulness, their inclination towards it and the discipline they apply in being mindful. In this regard, mindfulness can be understood as a trait, i.e. the general tendency to act mindfully in daily life denotes inter-personal differences in mindfulness. Mindfulness also fluctuates within an individual depending on their circumstances and life events and, in this respect, has a state-like quality (Brown & Ryan, 2003). Therefore, mindfulness has trait- and state-like qualities. Mindfulness is often understood as a skill that can be

trained. For example, Kiken, Garland, Bluth, Palsson and Gaylord (2015) suggest that repeatedly inducing a state of mindfulness through mindfulness practice can consolidate into a general tendency to bring mindfulness to daily life. This notion is evident in the proliferation of MBIs (see below) that 'conceptualise mindfulness as a set of skills that can be learned and practised in order to reduce psychological symptoms and increase health and well-being' (Baer et al. 2006, p. 27; also see Bishop et al., 2004). This is seen as 'an extremely gradual developmental process' (Grossman & van Dam, 2010, p.233) as novice meditators are thought to 'possess incipient qualities of mindful awareness, characterized as elementary, undeveloped, and immature' (p.233). This notion is supported by moderate research evidence to date that indeed shows that an increase in (self-reported) mindfulness mediates the positive effects of MBIs on a range of mental health problems (Gu et al., 2015).

Kabat-Zinn's definition of mindfulness (2003) captures two facets of mindfulness; attention and attitude towards present moment experience. This is also reflected in a common operationalisation of mindfulness by Bishop et al. (2004): '[mindfulness is] a kind of nonelaborative, non-judgmental, present-centered awareness in which each thought, feeling, or sensation that arises in the attentional field is acknowledged and accepted as it is.' (p.232). Therefore, the attention component captures self-regulation of attention whilst the attitudinal component captures openness, curiosity and acceptance, or 'the ability to experience events fully, without resorting to either extreme or excessive pre-occupation with, or suppression of, the experience' (Keng et al., 2011, p. 1042). This conceptualisation of mindfulness acknowledges that it requires training to develop non-evaluative awareness of thoughts and feelings that prevents unhelpful secondary processing (e.g. obsessional thinking, worry, rumination)

(Keng et al., 2011; Sauer et al., 2012). Mindfulness therefore reflects a conscious effort process, a voluntary action to interrupt and limit evaluative thinking or meta-cognitive processes, i.e. bringing conscious awareness to something that often happens automatically (Keng et al., 2011; Sauer et al., 2012). There is some divergence between mindfulness researchers as to whether the attitudinal component is intrinsic to mindfulness. For example, Brown and Ryan (2003) understand mindfulness as a unidimensional construct, a perceptual and nonevaluative 'state of being attentive to and aware of what is taking place in the present'(p.822), i.e. a pre-reflexive mode of functioning. According to them, mindfulness emerges out of intertwined processes of awareness, i.e. the continual background monitoring of inner and external stimuli, and attention, i.e. 'a process of focusing conscious awareness, providing heightened sensitivity to a limited range of experience' (Brown & Ryan, 2003, p.822).

1.6.1.1 *Measurement*

Mindfulness is typically measured through self-report but studies have also employed biological or neuro(psycho)logical and cognitive measures of mindfulness, including EEC and brain scans, measures of cortisol, tests of attention and perception of images (Sauer et al., 2013). However, limitations of the latter measures include that it is difficult to capture the whole construct of mindfulness through physiological measures only; ultimately it is a subjective state that cannot be reduced to neural or physiological correlates only (Sauer et al., 2013). Also, mindfulness is not limited to attention control and is not easily induced in brief procedures as it develops through a process of repeated mindfulness practice (Hölzel et al., 2011).

Self-report measures can be distinguished based on whether they measure mindfulness as a one- or multi-dimensional construct. Also, whilst most mindfulness measures conceive of it as a trait, a few questionnaires measure it as a state. The Kentucky Inventory of Mindfulness Skills (KIMS) (Baer, Smith, & Allen, 2004), the Mindfulness Attention Awareness Scale (MAAS) (Brown & Ryan, 2003) and the FFMQ (Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006) are the most common measures of mindfulness (Sauer et al., 2013) (see below). Relatively less commonly used measures of mindfulness include the Toronto Mindfulness Scale (TMS) (Lau et al., 2006), which conceives of mindfulness as a one-dimensional construct, and the Philadelphia Mindfulness Scale (PHLMS) (Cardaciotto et al., 2008), informed by the two-faceted mindfulness definition by Bishop et al. (2004). The FFMQ was the result of a factor analysis of items from the MAAS and KIMS and the Freiburg Mindfulness Inventory (FMI) (Walach, Buchheld, Buttenmüller, Kleinknecht, & Schmidt, 2006), the Cognitive and Affective Mindfulness Scale - Revised (CAMS-R) (Feldman et al., 2007) and the Southampton Mindfulness Questionnaire (SMQ) (Chadwick et al., 2008). Whilst the 15-item MAAS conceives of mindfulness as a one-dimensional state, the 30item FMI is a two-factor measure of mindfulness, capturing attention and acceptance, which is closely aligned with the Buddhist concept of mindfulness and originally used for experienced meditators but shortened and adapted for nonmeditators (Baer, 2011). The 39-item KIMS is a four-factor measure of mindfulness (observing, describing, acting with awareness and nonreactivity) originally designed for evaluating treatment outcomes for Dialectical Behaviour Therapy (DBT) (Linehan, 1993). The 12-item CAMS-R is also multi-faceted as it measures attention, awareness, present -moment focus, acceptance and nonjudgment whilst the 16-item SMQ measures observation,

letting go, non-aversion and non-judgment at times when unpleasant thoughts or images arise (Baer, 2011).

The FFMQ is one of the most common questionnaires used in mindfulness research (Sauer et al., 2013). It measures the general tendency to be mindful in everyday life. Items are rated on a five-point Likert scale (1 (never or very rarely true) to 5 (very often or always true)). The FFMQ has five subscales: i) observing, or attending to internal (e.g. sensations) and external (e.g. sights) experiences (for experienced meditator samples); ii) describing, i.e. verbalising internal experiences; iii) acting with awareness, i.e. the opposite of acting on automatic pilot; iv) non-judging, taking a non-evaluative approach to thoughts and feelings (i.e. not judging thoughts, feelings, or oneself for having them, as bad), and; v) non-reacting, i.e. letting (unpleasant) thoughts and feelings come and go without acting to get rid of them (Baer et al., 2008).

This thesis used a short version of the FFMQ, the 24-item Five-Facet mindfulness questionnaire-Short-form (FFMQ-SF) (Bohlmeijer, ten Klooster, Fledderus, Veehof, & Baer, 2011), to measure mindfulness (paper 3, Chapter 4). The FFMQ-24 is highly correlated (r = .89) with the 39-item FFMQ and has the same five sub-scales. It has adequate to excellent internal consistency (ranging from α =.73 to .91) across the five subscales (Bohlmeijer et al., 2011). Since the development of the FFMQ, multiple studies have found that the observe facet was unexpectedly positively associated with markers of poor mental health in nonmeditating (e.g. Baer et al., 2006; 2008) and heterogeneous clinical samples (Curtiss & Klemanski, 2014). The authors of these studies concluded that in these samples, the observe facet might measure maladaptive, self-focused attention rather than the intended mindful observation of present-moment experiences with equanimity. There is better evidence for a four-factor

hierarchical structure than a five-factor hierarchical structure of the FFMQ-39 and/or FFMQ-15 (Baer, Carmody, & Hunsinger, 2012) among novice meditators and patients with heterogeneous mental health problems (e.g. Baer, 2008; Curtiss & Klemanski, 2014; Gu et al., 2016), suggesting that the observe facet should be excluded for these populations. Therefore, in response to the above concerns, this thesis excluded the observe facet from the FFMQ-SF (paper 3, Chapter 4).

1.6.2 Self-compassion

Compassion can have both other and self as the object; oriented towards the self it is understood as self-compassion (Barnard & Curry, 2011). Although compassion is not a uniquely Buddhist concept, it has strong roots in Buddhist teachings (Feldman & Kuyken, 2013). Self-compassion encapsulates a 'befriending' orientation towards unwanted experience, predicated on a *shift in perspective*; suffering is not a personal inadequacy or failure but rather an inevitable part of being human that cannot always be fixed or solved but can be made more bearable and approachable through compassion (Feldman & Kuyken, 2013; Gilbert, 2014). The main definition of self-compassion in the (clinical) psychology literature stems from the work of Kristen Neff (2003a), informed by Theravada Buddhist teachings:

Being touched by and open to one's own suffering, not avoiding or disconnecting from it, generating the desire to alleviate one's suffering and to heal oneself with kindness. Self-compassion also involves offering non-judgmental understanding to one's pain, inadequacies and failures, so that one's experience is seen as part of the larger human experience. (p.87).

Specifically, Neff (2003a) proposes that self-compassion is a non-evaluative positive attitude towards the self at times of difficulty that involves: i) self-kindness (rather than being self-critical), or 'being kind and understanding to oneself in instances of pain or failure' (p.85); ii) common humanity (rather than seeing one's own suffering as an isolating experience), or 'perceiving one's experience as part of the larger human experience' (p.85), and; iii) mindfulness, particularly equanimity towards unpleasant experiences (as opposed to identifying with them) or 'holding painful thoughts and feelings in balanced awareness' (p.85). Self-compassion is associated with, yet distinct from, self-esteem, which tends to be unstable or contingent on achievement and failure as it involves self-evaluation of competence and/or likability (Barnard & Curry, 2011).

1.6.2.1 *Measurement*

The most common measure of self-compassion is the Self-Compassion Scale (SCS) (Neff, 2003b), which consists of 26 items rated on a five-point Likert scale (1 (almost never) to 5 (almost always)) (MacBeth & Gumley, 2014; Ferrari et al, 2019). The SCS has a six-factor hierarchical structure: self-kindness, self-judgement, common humanity, isolation, mindfulness and over-identification. This thesis used the Self-Compassion Scale – Short Form (SCS-SF) (Raes, Pommier, Neff, & Van Gucht, 2011), a short version of the SCS consisting of 12 items with an identical six-factor hierarchical structure to the original (Garcia-Campayo et al., 2014; Neff, 2003b; Raes et al., 2011). It has good internal consistency ($\alpha \ge$.86) and test-retest reliability (intra-class correlation coefficient (*ICC*): 0.89 (95% CI: 0.87-0.93) and a near perfect correlation (r = 0.97) with the SCS (Garcia-Campayo et al., 2014; Raes et al., 2011). It has good construct validity shown through expected negative medium to large correlations with, among others, measures of depression and anxiety (Hayes, Lockard, Janis, & Locke,

2016). As internal consistency for (some of) the subscales was relatively low (ranging from .54 to .81), however, Raes et al. (2011) recommended limiting the use of the SCS-SF to the full-scale score. Therefore, this thesis used the SCS-SF full scale score to measure self-compassion.

1.6.3 Mindfulness, self-compassion and mental health

Whilst the potential benefits of mindfulness have been investigated in Western medicine since the 1970s, the last decade has seen an explosion of interest in mindfulness (Grossman & Van Dam, 2011) and, to a lesser extent, self-compassion and their potential to foster resilience, promote wellbeing and improve mental and physical health problems. Research shows that mindfulness is positively associated with wellbeing and life satisfaction and negatively associated with negative affect such as shame, guilt and anxiety, mental health difficulties such as depression, anxiety and stress and maladaptive cognitive processes such as rumination, worry and thought suppression (Barnard & Curry, 2011; Keng et al., 2011; Tomlinson, Yousaf, Vittersø, & Jones, 2018). Similarly, self-compassion is positively associated with wellbeing and life satisfaction, happiness, positive affect and optimism and negatively associated with, for example, anxiety, sadness, shame and anger, social withdrawal, procrastination and perfectionism and with mental health problems such as depression and anxiety, over and above self-esteem and self-criticism (e.g. MacBeth & Gumley, 2012; Zessin, Dickhäuser, & Garbade, 2015). Furthermore, self-compassion is negatively associated with rumination (brooding rather than reflective rumination), thought suppression and avoidant coping strategies (e.g. denial, mental disengagement), (e.g. MacBeth & Gumley, 2012). Indeed, some mediational studies have shown that the relationship of

self-compassion with anxiety and/or depression was mediated by rumination (brooding) and worry (Raes, 2010), reduced coherence (Ying, 2009) and emotion regulation (Inwood & Ferrari, 2019).

1.6.4 Mindfulness-based interventions

Evidence for the positive association of mindfulness and self-compassion with wellbeing and negative association with mental health problems supports the rationale that increasing self-compassion and mindfulness skills may increase its correlates, i.e. improve mental health. Mindfulness and self-compassion can be deliberately cultivated through regular mindfulness practice (Bishop et al., 2004), which is the 'scaffolding used to develop the mindfulness state (of consciousness) or skill' (Shapiro, Carlson, Astin, & Freedman, 2006, p.374).

Mindfulness practices are rooted in Buddhism but were adopted into Western medicine in the 20th century (Williams & Kabat-Zinn, 2013). Kabat-Zinn (2003) likens the overall intention of mindfulness practice to 'waking up' from 'living in our heads', caught up in automatic, habitual mental activity that is divorced from the present moment, the senses and the body. Mindfulness practices include 'formal' mindfulness practices, involving a period of silent practice following mindfulness guidance (by a teacher or audio file) (Kabat-Zinn, 2003) and 'informal' mindfulness practices, which involve bringing mindful awareness to routine activities, e.g. washing up, drinking tea. Formal mindfulness practices include the 'body scan', which involves carefully bringing attention to different parts of the body and bringing a kind, curious interest to what, if any, sensations are noticeable. Sitting practices invite participants to focus their attention on the body, breath, sounds, sights, thoughts or feelings. For novice

meditators, sitting practices tend to invite participants to notice when their mind has wandered and to gently bring it back to the breath, sights or sounds, which provide an 'anchor' for their attention (Segal, Williams, & Teasdale, 2002). With practice, the focus of sitting practices is brought to bear on (unwanted) thoughts, feelings and sensations. Formal practices also include mindful yoga and mindful movement. In addition, a brief formal mindfulness called the three-step (or three-minute) breathing space, teaches participants to apply mindfulness 'in the moment', e.g. when feeling distressed (Segal et al., 2002). The first step involves bringing one's attention to the body, thoughts and feelings, in the second step attention is directed to the breath, then in the third step attention is broadened out again to include the body and its surroundings.

Mindfulness practices were incorporated into a range of mindfulness-based interventions (MBIs) aimed at improving physical and mental health problems and wellbeing. The two best-known are Mindfulness-based stress reduction (MBSR) and mindfulness-based cognitive therapy (MBCT), which place mindfulness practice at the heart of the intervention. MBSR was developed in 1979 by Jon Kabat-Zinn (2003) to reduce pain and stress due to chronic health conditions. It consists of 10-12 weekly sessions lasting 2-2.5 hours each, with up to 30 participants. An all-day mindfulness session is included, usually around week six. Formal mindfulness practices include the body scan, sitting meditations, yoga and mindful movement and stretching. Participants are also invited to bring mindful awareness to everyday activities, including walking (Kabat-Zinn, 2013). Mindfulness-based cognitive therapy was originally developed as a relapse prevention therapy for recurring depression, based on a cognitive behavioural model of depressive relapse. It teaches mindfulness practices drawn from MBSR in conjunction with CBT strategies (Crane, 2009; Segal et al., 2002). Mindfulness-based

cognitive therapy consists of 8 weekly sessions lasting 2 to 2.5-hours and, where possible, includes an all-day mindfulness session, around week six (see Tale A1, Appendix A for details). Both MBSR and MBCT are group courses that are typically facilitated by two mindfulness teachers and emphasise the importance of the personal engagement and practice of mindfulness by the teachers, without which the intervention is thought to lack authenticity (Kabat-Zinn, 2013).

In MBSR and MBCT, there is a structured progression of formal mindfulness practices; early practices (first half) cultivate stabilising attention, noticing mind wandering and returning the mind to an intended focus, whilst later practices (second half) encourage observing mind wandering more generally and approaching the difficult with curiosity, acceptance and nonjudgment (e.g. Segal et al., 2002). Towards the end of the course, participants are invited to settle into a pattern of practice that fits with their daily life and can be sustained beyond the course.

MBIs place great importance on between-session mindfulness practice to consolidate learning (Kabat-Zinn, 2013; Lloyd, White, Eames, & Crane, 2018; Parsons, Crane, Parsons, Fjorback, & Kuyken, 2017; Segal et al., 2002). Participants are invited to engage in a daily (six days a week) routine of formal and informal mindfulness practice lasting approximately 45 minutes. Home practice is typically supported by audio-recordings of guided meditations. Both courses invite participants to discuss their weekly home practice in session.

Mindfulness-based stress reduction and MBCT do not include formal practices that explicitly cultivate self-compassion, such as 'loving kindness' meditation (Salzberg, 2011), as these have the potential to reactivate core beliefs around unlovability,

incompetence, unworthiness and reinforce negative self-perceptions (Segal et al., 2013). Self-compassion is nonetheless at the heart of the intervention; teachers adopt a kind and compassionate stance towards participants and themselves (Kabat-Zinn, 2013; Segal et al., 2013). Through the teachers' embodiment of a non-judging, patient stance, participants are invited to bring self-compassion to their own difficulties. Furthermore, mindfulness practices invite participants to attend to present-moment experiences with kindness and compassion (Segal et al., 2013); the attitudinal component of mindfulness therefore ensures that 'true mindfulness is imbued with warmth, compassion and interest' (Feldman; 2001, p.173).

Despite their apparent difference, CBT and MBIs share much common ground, reflecting both theoretical and procedural overlap (Baer, 2003; Fennel & Segal, 2013). Similarities include: i) a focus on skills; ii) raising awareness of unpleasant thoughts, feelings, physical sensations and behaviour; iii) teaching participants to develop a new perspective on thoughts; iv) normalisation of experience; v) habitual, automatic processing is seen as problematic as is personal identification with such thoughts; vi) acknowledgement of information processing biases, including attention, perception and interpretation; vii) a present moment focus; both are learning approaches that are highly experiential and require close observation of experience, and; viii) reflection on learning (Fennel & Segal, 2013). Clear points of divergence include that MBIs primarily teach these skills through mindfulness practice whilst CBT use cognitive restructuring, behavioural experiments and/or exposure. Also, whilst CBT works towards specific goals, MBIs embraces non-striving as participants are invited 'not to strive to relax, reduce their pain, or change their thoughts or emotions, although they may have sought treatment for these purposes. They are simply to observe whatever is happening in each

moment without judging it' (Baer, 2003; p.130). Unlike CBT, MBIs do not attempt to explicitly target and change the content and meanings attributed to thoughts and/or associated beliefs, but rather invite participants to observe their thoughts without judgment, teaching them to relate differently to the process of thinking (Baer, 2003; Fennel & Segal, 2013).

1.6.4.1 *Outcomes of mindfulness-based interventions*

Mindfulness-based interventions, as an alternative or adjunctive therapy to established treatments, have demonstrated positive outcomes for non-clinical and clinical samples with a range of psychological disorders, most notably (recurring) depression, stress, anxiety and physical health problems (e.g. Chiesa & Serretti, 2011; Fjorback et al., 2011). The benefits of MBIs are not restricted to symptom reduction and include improved quality of life (Koszycki et al. 2007; Nyklicke & Kuijpers, 2008; Shapiro et al. 2005). Furthermore, meditation is associated with changes in brain functioning and structure, specifically increased thickness in brain regions associated with attention, sensory processing and interoception, and with prefrontal cortical inhibition of the amygdala (Keng et al., 2011).

The evidence base for MBCT is strongest for recurring depression of three or more episodes; within the UK's NHS, MBCT is now a recommended treatment for adults with recurring depression (NICE, 2005). There is also evidence that people with *current* depression and, to a lesser extent, anxiety symptoms, may benefit from MBIs. For example, a recent meta-analysis showed that MBIs had equivalent effects to evidence-based treatments for depression and anxiety symptoms (Goldberg et al., 2018). However, in adults with anxiety and stress-related disorders, MBIs may be less effective

than CBT in addressing fear domain symptoms (e.g. de Abreu Costa, D'Alò de Oliveria, Tatton-Ramos, Manfro, & Salum, 2019) and de Abreu Costa and colleagues therefore caution against using MBIs as a first-line intervention to treat fear symptoms in anxiety disorders; CBT that includes deliberate exposure to feared stimuli may be more effective. An earlier meta-analysis of the effects of 12 RCTs of MBIs (MBCT, MBSR and Person-Based Cognitive Therapy) for people with current depression or anxiety disorders found a medium post-intervention between-group effect on primary depressive symptoms in favour of MBIs (Hedges *g*=-.73, 95% CI [-.09, -1.36]) but not on primary anxiety symptoms (Strauss, Cavanagh, Oliver, & Pettman, 2014). When the diagnosis was disregarded, there was still no significant between-group effect of MBIs on post-intervention anxiety symptoms. MBIs produced a greater reduction in primary symptom severity compared to inactive control conditions (Hedges *g*=-1.03, 95% CI [-.40, -1.66]) but not active controls (e.g. CBT, aerobic exercise, group psychoeducation). Therefore, like de Abreu Costa and colleagues, the authors cautioned against using MBIs as a first-line intervention for people with a current anxiety disorder.

1.6.4.2 *Mechanisms of action*

MBIs, similar to CBT, are often regarded as transdiagnostic approaches that target emotional and evaluative processes common to most mental health problems; they reduce an orientation towards the future and past, which fuels worry and rumination, and counter avoidance whilst alleviating bodily symptoms of distress (Hoffman et al., 2012). Hölzel et al. (2011) synthesised the mechanisms of action of three common, overlapping transdiagnostic theoretical models of the mechanisms of change of mindfulness (Baer, 2003; Brown & Creswell, 2007; Shapiro et al., 2006) (see Table B1 in Appendix B for details) as follows: i) attention regulation; ii) body

awareness; iii) emotion regulation, including reappraisal, exposure, extinction and reconsolidation, and; iv) change in perspective on the self. Attention regulation (i) is considered particularly important when starting to learn mindfulness and provides the gateway to the other mechanisms. Body awareness (ii) flows from the fact that many practices attend to bodily sensations; this is thought to facilitate affect regulation and empathy, as the body is the 'barometer', or bears the imprint of, feelings and thoughts, through tensing, bracing and tightening (Segal et al., 2002). Emotion regulation (iii) includes behavioural regulation and cognitive regulation, the latter of which emerges both from attentional control (inattention to emotions, distraction) and cognitive change strategies including reappraisal, which captures both positive reappraisal, i.e. 'the adaptive process through which stressful events are reconstrued as beneficial, meaningful or benign' (p. 544) and non-appraisal, i.e. the prevention of secondary cognitive processing. A change in perspective on the self (iv) involves viewing the self as impermanent and always changing. Whilst disidentification from the self is an advanced skill likely to only emerge from sustained, long-term meditation practice, disidentification from mental content, similar to the constructs of 'reperceiving' (Shapiro et al., 2006), 'decentering' (Safran and Segal, 1990) and meta-cognitive awareness (Teasdale et al., 2002), is possible in the earliest stages of meditation. Hölzel et al. (2011) relate self-compassion skills to emotion regulation and to a change in perspective on the self; self-compassion requires reappraisal and this re-framing of experience can lead to different perspective on self, in a less 'overidentified' manner. Together these mechanisms lead to self-regulation, 'a process that enables individuals to guide their goal-directed activities by modulation of thought, affect, behaviour, or

attention via deliberate or automated use of specific mechanisms' (Hölzel et al., 2011, p.549).

To explore evidence for the proposed mechanisms of mindfulness, Keng, Smoski and Robins (2011) summarised studies that either included formal mediation analyses or provided preliminary evidence for: i) changes in potential mediator variables from pre- to post-treatment, and/or ii) a significant association between changes in potential mediator variables and therapy outcomes, not necessarily measured within one and the same study. The latter approach is of limited value in establishing mediator variables but guides the initial search towards them. Keng and colleagues identified the following potential mechanisms of change: i) mindfulness, ii) meta-awareness, iii) exposure, iv) attention control, v) improved memory functioning, and vi) behavioural regulation.

A systematic review by Van der Velden et al. (2015) exploring potential mechanism of MBCT for recurrent depression similarly concluded (based on 23 studies) that changes in: i) mindfulness, ii) rumination, iii) worry, iv) compassion and v) meta-awareness were either associated with, predicted or mediated outcomes of MBCT. There was preliminary evidence that changes in attention, memory specificity, self-discrepancy, emotional reactivity or momentary positive and negative affect were implicated in the effects of MBCT on recurrent depression. However, only a small number of studies included formal mediation analyses (n=6), and temporal precedence was not measured (e.g. Kazdin, 2007).

Gu, Strauss, Bond and Cavanagh (2015) conducted a systematic review and meta-analysis of mediators of depression, anxiety and stress reduction following MBCT or MBSR. Their narrative synthesis of 20 studies concluded that there was moderate,

consistent evidence for mindfulness and for rumination, and worry (i.e. repetitive negative thinking or RNT) and some initial but insufficient evidence for self-compassion, psychological flexibility and cognitive and emotional reactivity as mediators of the effects of MBCT or MBSR on depression, anxiety or stress symptoms in clinical (physical and mental health) and non-clinical samples. A meta-analysis showed that mindfulness (c=.27, c'=.18; Sobel test: z=4.99, SE=.02, p<.001, k=12) and RNT (c=.31, c'=.24; Sobel test: z=4.88, SE=.02, p<.001, k=6) were significant mediators of the effects of MBIs on depression, stress, anxiety, negative affect and/or global psychopathology.

1.6.5 Mindfulness, self-compassion and OCD

Initial evidence suggests that MBIs improve mental health problems through mechanisms such as mindfulness and self-compassion. To inform the rationale for MBIs for OCD it is important to establish whether OCD symptom(s) (subtypes) are uniquely negatively associated with mindfulness and self-compassion skills and to examine the strength of the relationship of mindfulness and self-compassion with OCD symptoms relative to comparable mental health difficulties such as depression and/or anxiety. This would provide preliminary evidence that mindfulness and/or self-compassion deficits might play a causal role in OCD and could inform the decision whether to and how to adapt MBIs to OCD.

It is theoretically plausible that OCD is associated with lower trait mindfulness or poorer mindfulness skills because OCD is characterised by: i) over-identification with intrusive thoughts (rather than de-centering from thoughts, i.e. the ability to 'step outside of one's immediate experience, thereby changing the very nature of that

experience' (Safran & Segal, 1990, p.117) and, ii) heightened reactivity to (triggers of) such thoughts and associated feelings through avoidance, repeated, ritualistic and time-consuming compulsions and reassurance seeking, hypervigilant attention to triggers of obsessions, attempts to suppress and control intrusive thoughts (Didonna, 2009). Indeed, Didonna (2009) asserts that OCD is 'antithetical' to mindfulness. Mental and physical compulsions, reassurance-seeking and avoidance in response to intrusions reflect the problem-solving or 'doing mode' of mind, which works to bridge the perceived gap between unwanted states of mind, such as anxiety, shame and disgust, and desired states of mind, e.g. calm, relaxed, at peace (Williams, 2008).

Crowe and McKay (2016) argue that adults with OCD may have more considerable mindfulness and self-compassion skills deficits than adults with other common mental health problems, such as depression and anxiety. They suggest this is due to their unique tendency of people with OCD to appraise common and harmless intrusions as important and personally significant, informed by inflated responsibility and thought-action-fusion beliefs, and the extent to which they react to such thoughts with ritualistic, repetitive, time-consuming and often apparently senseless compulsions.

Self-compassion may protect an individual from judging themselves harshly for having unwanted intrusions (Wetterneck et al., 2013). Therefore, a lack of self-compassion is implicated in feelings of guilt and shame associated with OCD symptoms (Bream et al., 2017; Shapiro & Stewart, 2011; Weingarden & Renshaw, 2015; Wetterneck et al., 2013) and in the obsessive beliefs, such as inflated responsibility, perfectionism, the need to have control over thoughts and TAF, which inform the misappraisal intrusions.

There has been a relative dearth of research into the relationship between mindfulness and self-compassion and OCD. A single study examined the association of self-compassion with OCD (Wetterneck, Lee, Smith, & Hart, 2013) while five studies with relatively small clinical (Didonna, Rossi, et al., 2019; Hawley et al., 2017) and nonclinical samples (Crowe & McKay, 2016; Emerson, Heapy, & Garcia-Soriano, 2017; Solem, Thunes, Hjemdal, Hagen, & Wells, 2015) examined the association of mindfulness with OCD symptoms. A further correlational study with a student sample that tested mindfulness, emotion regulation, distress tolerance and interpersonal effectiveness as independent predictors of OCD symptoms was not accessible (Hosein, Esfand Zad, Shams, Pasha Meysami, & Erfan, 2017).

Wetterneck et al. (2013) examined the association between self-compassion and OCD symptom severity in 111 adults with a diagnosis of OCD. They reported a medium negative association (r=-30, p<.01) between OCD symptoms and self-compassion (measured with the SCS) and showed that participants reported a below-average degree of self-compassion. However, self-compassion did not significantly predict OCD symptom severity after two other constructs, courage and valued living, were controlled for. The study did not consider symptom dimensions of OCD so did not clarify whether self-compassion may be particularly pertinent to OCD dimensions centred on unwanted aggressive or sexual thoughts.

Crowe and McKay (2016) conducted a study of trait mindfulness in adults with OCD, depression, anxiety and healthy controls. Participants from a non-clinical sample (N=103) were allocated to OCD (n=42), depression (n=17), anxiety (n=19) groups based on clinical cut-off scores for measures of these symptoms. The healthy control group (n=25) consisted of participants scoring within the bottom 25% on the mental

health measures. Results showed that adults with clinically significant OCD symptoms reported significantly lower scores on the FFMQ 'describing' facet than healthy controls and scored significantly lower on the 'acting with awareness' and 'nonjudging' facets than both adults with anxiety and healthy controls. There were no significant associations between the FFMQ subscales and OCI-R subscales. However, this may have been due to a lack of power to detect potentially small effects.

Hawley et al. (2017) compared the FFMQ subscales scores of adults (*N*=820) with OCD (n=144), confirmed by diagnostic interview, generalised anxiety disorder (n=170), social anxiety disorder (n=344) and panic disorder with (out) agoraphobia (n=162), as part of an examination of whether trait mindfulness at baseline predicted post-treatment primary symptom reduction following group CBT. Obsessivecompulsive disorder symptom severity was measured by the Y-BOCS-self report (Baer, Brown-Beasley, Sorce, & Henriques, 1993). Diagnostic groups differed significantly on all 5 mindfulness facets but none of the differences were unique to OCD. There was a small significant positive correlation of the (baseline) FFMQ 'describing' facet with the baseline Y-BOCS-SR scale (r=.25, p<.05) but surprisingly none of the other mindfulness facets were significantly associated with OCD symptoms. Hierarchical linear regressions testing baseline FFMQ subscale scores as predictors of OCD symptoms reduction showed that FFMQ facets explained 20% of the variance. Only the FFMQ non-reactivity subscale was a significant independent predictor of OCD symptom change (partial correlation (pr) = -.52, p < .001). This clearly suggests that the cultivation of non-reactivity, in this case in response to CBT, could benefit OCD symptom change.

Emerson et al. (2017) explored the association between mindfulness facets, measured with the 10-item Brief Mindfulness Measure (BMM) that is derived from the FFMQ, and obsessive intrusive thoughts (OITs) in a nonclinical sample of 583 university students, staff and/or alumni. Participants were divided into nonclinical (n=394) and subclinical (n=189) OCD sub-samples based on a clinical cut-off of 21 on the Obsessive-Compulsive Inventory-Revised (OCI-R) (Foa, Kozak, Salkovskis, Coles, & Amir, 1998). The Obsessive Intrusive Thoughts Inventory (Garcia-Soriano et al., 2008) measured the frequency, emotional reactions to, difficulties controlling and dysfunctional appraisals of OITs and the frequency and type of control strategies used in response to the most unpleasant OITs. Subclinical groups achieved significantly lower scores than nonclinical groups on the BMM full scale score (F(2,581) = 86.58, d)=-.86) and on all mindfulness facets (describe: d=-.38; nonjudgment: d =-.1.00; nonreactivity: d = -.45, acting with awareness: d = -.59) apart from 'observing' (d = .35), which was significantly *higher* in the subclinical group. There was a medium negative correlation of the BMM total scale score with the frequency, distress, difficulty controlling and maladaptive appraisals of OITs and with the frequency of cognitive control strategies but not distraction, compulsions and general strategies such as reassurance seeking, self-reassurance, relaxation, reappraisal and cognitive restructuring. At the mindfulness facet level, acting with awareness, nonjudgment and non-reactivity were associated with less negative experiences of OITs whereas the observe facet appeared to reflect hypervigilance that was positively associated with unpleasant experiences of OITs.

Didonna, Rossi, et al. (2019) compared trait mindfulness in a sample of treatment seeking adults with a diagnosis of OCD (n=55), Borderline Personality

Disorder (BPD) (*n*=48) or Major Depressive Disorder (MDD) (*n*=50) and healthy controls (*n*=49). Healthy controls scored higher than the clinical groups on the FFMQ total scale and all subscales apart from the observe facet. Adults with OCD scored higher on the (39-item) FFMQ total scale and the 'acting with awareness' facet than adults with BPD, suggesting they were less likely than adults with BPD to act on automatic pilot. They also scored higher than adults with BPD and MDD on the 'describing' facet, suggesting that the ability to put one's present-moment experiences into words was relatively less impaired in adults with OCD compared to depression or BPD. Whilst healthy controls scored higher on the 'nonjudging' facet compared to the other three clinical groups, there were no differences in 'nonjudging' between the three clinical groups. Overall, this study showed that adults with OCD had mindfulness deficits relative to adults without mental health difficulties but not relative to depressed groups. However, group comparisons may have been underpowered to detect (small) effects.

Finally, Solem et al. (2015) reported associations of mindfulness (FFMQ) and OCD (OCI-R), as part of their exploration of the relative importance of meta-cognition and mindfulness in predicting OCD symptoms. Using a community sample (N=224), all FFMQ facets apart from observe (r=.04) correlated significantly (p<.01) with OCD symptoms (OCI-R) (describing: r=-.28,; awareness: r=-.46, nonjudging; r=-.46, nonreacting: r=-.24).

1.6.5.1 *Summary*

A handful of studies with clinical and nonclinical samples have established that OCD symptoms are negatively associated with mindfulness (facets) and a single study has demonstrated a negative relationship between self-compassion and OCD symptoms.

Research examining the unique association of self-compassion with OCD is absent while evidence is equivocal about the unique association of mindfulness with OCD relative to other common mental health difficulties, e.g. depression and anxiety disorders (Crowe & McKay, 2016; Didonna et al., 2018; Hawley et al., 2017). As the latter studies were conducted with relatively small samples, analyses may have been under-powered to detect (small) effects. As OCD, self-compassion and mindfulness have known associations with depression symptoms, correlational analyses should establish that any negative associations of OCD symptoms with self-compassion and mindfulness are not simply attributable to depression symptoms. Furthermore, research to date does not elucidate the (relative importance of the) relationship of mindfulness and self-compassion with OCD symptom subtypes and with proposed mechanisms of OCD, e.g. obsessive beliefs and distress tolerance. The association of mindfulness and self-compassion with obsessive beliefs, which play a central role in cognitivebehavioural models of OCD, has only been touched on in a recent RCT of MBCT adapted for OCD that showed that changes in mindfulness skills were associated with changes in obsessive beliefs (r=-.63, p<.001) (Key, Rowa, Bieling, McCabe, & Pawluk, 2017). Similarly, self-compassion may hold a significant association with obsessive beliefs, e.g. those pertaining to perfectionism and self-criticism in relation to unwanted thoughts. However, research to date has not explored this. Finally, the extent to which mindfulness and self-compassion skills contribute to our understanding of OCD over and above (more) established constructs such as obsessive beliefs and, to a lesser extent, distress tolerance is unclear.

1.6.6 Mindfulness-based interventions for OCD

Implicit in the growing interest in MBIs for OCD is the assumption that these interventions could achieve OCD symptom reduction through mindfulness practices and inquiry rather than ERP, behavioural experiments and/or cognitive restructuring strategies (e.g. Hale, Strauss, & Lever-Taylor, 2013). MBIs for OCD have included MBIs that augment CBT therapy (e.g. Key et al., 2017), provide a first-line treatment (e.g. Selchen et al., 2018) or integrate mindfulness with CBT to support engagement with ERP tasks (e.g. Didonna et al., 2019; Fairfax, 2008; Strauss et al., 2018).

Keng et al. (2011) argue that adaptations of MBIs for mental health problems that they were not originally developed for, should start from a sound rationale for how they might act on the maintaining mechanisms of the mental health problem they aim to target. A few theoretical accounts (e.g. Didonna, 2009; Hannan & Tolin, 2005) and an early recent systematic review of MBIs for OCD (Hale et al., 2013) have set out the theoretical premise for the potential benefits of MBIs for OCD, either as a stand-alone therapy or integrated with CBT. These will be briefly considered below before concluding this chapter with a short overview of the research evidence for MBIs for OCD that informed the thesis.

Didonna (2009) regards mindfulness as an attitude or 'mode of mind' at the 'radical and hierarchically superordinate level' (p.207) that 'prevents' or 'deactivates' maladaptive meta-cognitive processes, or 'secondary elaborative processes', i.e. maintaining factors, by encouraging participants to bring a nonjudging, accepting and self-validating attitude to unwanted thoughts, feelings and sensations, i.e. activating factors. The maladaptive meta-cognitive processes centre on misappraisals of intrusions

and their bi-directional relationship with i) 'doing mode' (neutralising, compulsions, reassurance seeking), ii) affective responses such as anxiety, shame, disgust, and iii) 'perceptive self-invalidation, or cognitive biases, including attentional biases, thought-action-fusion and non-acceptance.

Treanor (2011) proposes that mindfulness could enhance extinction learning, i.e. aid the effects of ERP for OCD, through: i) increasing awareness of and attention to multiple conditioned stimuli (or excitors), provided mindfulness maintains the salience of the target conditioned stimulus (CS); ii) acting as a retrieval cue to prevent renewal of fear (i.e. by setting the occasion for which association is in operation (CS-Unconditioned Stimulus (US), CS-not US). Neutral cues can steadily become conditioned inhibitors over the course of extinction trials. Therefore; iii) to ensure (ii), mindfulness would need to be presented prior to rather than simultaneously with exposure, be less salient than the CS and be presented intermittently, i.e. prior to exposure and not for all exposure sessions. Otherwise, mindfulness might function as a 'conditioned inhibitor cancelling out the positive associative strength of the excitor stimulus (CS), which protects the CS from extinction. For example, if mindfulness is associated with relaxation, then the state of relaxation can become a 'safety behaviour' (i.e. a conditioned inhibitor) that prevents extinction learning. Therefore, Treanor argues that relaxation is not the aim of mindfulness, even if may happen, and that it may not necessarily be desirable in the context of exposure, and, finally; iv) mindfulness encourages acceptance of unpleasant experiences and might therefore enhance distress tolerance, which facilitates engagement in exposure.

Fairfax (2008; 2014) addresses a potential concern that mindfulness could be coopted into a neutralising technique, alluded to above. Fairfax (2008) asserts that it stems from a misunderstanding of mindfulness, which reveals that suffering results from our attempts to avoid it and involves an immersion in the present moment (including unwanted experience) rather than an engagement with perceptions or expectations of a preferred reality. The non-reactivity inherent in mindfulness allows participants to experience that compulsive urges can be accepted but responded to in different ways. He therefore perceives mindfulness as an 'anti-avoidant' or 'anti-neutralising' strategy that brings acceptance, awareness and holistic involvement in the present moment; mindful awareness of intrusions is a type of exposure and returning to the present a form of response prevention. He suggests the accepting stance of mindfulness might also help people to feel less self-censorship and fear of humiliation, which would facilitate a better engagement with ERP. Hannan and Tolin (2005) similarly propose that MBIs might help to deliver ERP more effectively and/or provide a more comprehensive rationale for ERP that starts from a different philosophical premise that may be more palatable to participants. The fact that MBIs are not focused on anxiety reduction per se also fits with ILT approaches to ERP that emphasise distress tolerance rather than reduction (e.g. Jacoby & Abramowitz, 2016).

Hale et al. (2013), in their early review of MBIs for OCD, propose that MBIs may help adults with OCD to: i) allow obsessive thoughts into awareness and bring an interested, accepting attitude to such thoughts and their associated distress; ii) invite a non-judgmental, de-centred perspective on thoughts as passing mental events rather than facts (Segal et al, 2002), and; iii) perceive a wider range of choices about how to respond to intrusive thoughts and feelings of anxiety rather than to react habitually (e.g. compulsions or avoiding situations). Strauss et al. (2015; 2018) furthermore suggest that mindfulness could benefit engagement in ERP through these same mechanisms; the first

mechanism would allow full exposure to intrusions, the second mechanism would help patients to tolerate and accept anxiety and associated physiological sensations (anxious arousal) during ERP, and the third mechanism could help patients resist urges during ERP. This thesis adopts this theoretical premise for MBIs for OCD, whilst also considering that mindfulness might, in the early stages, aid attention control to address hypervigilant attention to OCD-related concerns (e.g. Salkovskis, 1985) by broadening awareness out to the wider environment (see **Figure 3**).

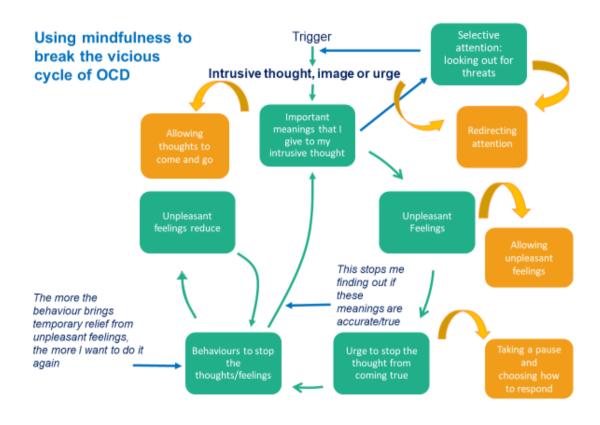


Figure 3 Using mindfulness to break the vicious cycle of OCD

Furthermore, as MBIs are shown to promote self-compassion, it is theoretically plausible that self-compassion could enhance meta-cognitive change and non-reactivity

in response to obsessive beliefs, e.g. those around responsibility and the need to control thoughts (and the self-reproach that might follow unsuccessful attempts to do so) and alleviate feelings a guilt and shame commonly associated with OCD (Shapiro & Stewart, 2011; Weingarden & Renshaw, 2015).

1.6.6.1 Research evidence for MBIs for OCD

Despite its theorised potential, research into the potential benefits of MBIs for OCD has been slow to emerge relative to MBIs for depression and anxiety. The review by Hale et al. (2013) included two single case studies (Patel, Carmody, & Simpson, 2007; Singh, 2004), one case-series design (Wilkinson-Tough, Bocci, Thorne, & Herlihy, 2010) and a quasi-randomised pilot wait list control trial (Hanstede, Gidron, & Nyklicek, 2008) with an analogue sample of students. They concluded that MBIs for OCD showed promise as an acceptable treatment and reported a reduction in OCD symptoms comparable to studies of CBT for OCD. Since then, research into MBIs for OCD has accelerated. What follows is a brief review of research evidence that emerged since this review, along with qualitative studies that the review did not include. Both stand-alone MBIs, e.g. MBCT adapted for OCD, and treatments integrating mindfulness with CBT are included. Several studies identified in searches on mindfulness for OCD were not accessible as they were written in foreign languages (Dantin, 2007; Firouzabadi, 2009; Liu, Han, & Xu, 2011) and/or were unpublished and could not be obtained (Brifcani, 2009). Research that was published after the studies in this thesis were designed and submitted for NHS ethical review are not included here, to reflect the state of research evidence that informed the thesis. Research that has emerged since (Didonna, Lanfredi, et al., 2019; Külz et al., 2019; Selchen et al., 2018) will be related to key findings from the thesis in the discussion (Chapter 6).

1.6.6.1.1 Qualitative studies

Three qualitative studies have explored participant perspectives on MBIs for OCD. Fairfax, Easey, Fletcher and Barfield (2014) report on their evaluation of patients' experiences of a routinely delivered course of group CBT integrated with mindfulness. From week 2, mindfulness practices (five-minute mindfulness of the breath) were introduced and patients were invited to practise these at home. Subsequent sessions introduced a range of (longer, up to 20 minute) mindfulness exercises (Fairfax & Barfield, 2010). Results showed that 12 out of 15 respondents who took part in the group over a six-year period, reported mindfulness as (very) helpful and for seven respondents it was the most remembered skill. Most patients (*n*=11) continued to practise mindfulness and perceived it helped with: i) focusing and concentration, ii) exposure, iii) awareness, iv) acceptance, v) challenging anxiety and the need to engage in compulsions, vi) slowing down thinking, and vii) relaxation and sleep. Unhelpful aspects included not understanding or being able to relate to mindfulness techniques.

A qualitative content analysis of post-treatment semi-structured interviews with 12 participants who took part in an adapted MBCT course as an augmentation therapy for CBT for OCD, showed participants valued the treatment in dealing with OCD and related difficulties (Hertenstein et al., 2012). Themes included 'being in a group', the 'evaluation and practical implementation of mindfulness exercises' (e.g. participants particularly valued the breathing space), and 'intervention effects', discussed in terms of benefits, undesired outcomes, struggles (e.g. to use the breathing space as soon as OCD symptoms were triggered) and suggested modifications (e.g. more and longer sessions). Two-thirds of patients reported a reduction in OCD symptoms. Researchers summarised from participants' qualitative reports that the MBCT course facilitated: i) increased

awareness of internal events, ii) the ability to purposefully re-direct attention away from intrusions, iii) acceptance of difficult emotions and thoughts, iv) willingness to experience unpleasant emotions, and v) relating differently to intrusions, i.e. 'thoughts are just thoughts'.

Sguazzin, Key, Rowa, Bieling and McCabe (2017) also conducted a qualitative evaluation of an adapted MBCT course as an augmentation therapy for CBT, which complements the quantitative analysis reported elsewhere (Key et al., 2017). Nine themes were generated from their thematic analysis of a semi-structured 21-question satisfaction interview with 32 participants with OCD: i) symptom change, ii) alternative response to obsessions/symptoms (e.g. refocusing attention, increased awareness of negative thoughts, decentering), iii) alternative response to stressors, iv) knowledge and skills (through psychoeducation and mindfulness practices; e.g. increased awareness of present moment, seeing obsessions as just thoughts), v) attitude (e.g. increased selfacceptance, feeling less anxious or worried), vi) quality of life, vii) treatment acceptability, and viii) social support. Overall, participant perceived that MBCT helped them to: i) become aware of unhealthy thoughts, ii) pause and reflect before engaging in compulsions, iii) refocus their attention away from thoughts to the present moment, iv) ground themselves in the present through coming back to the body and their surroundings, and v) decentre from thoughts and OCD triggers, also perceived as a process of 'stepping back'. Participants valued the course and most participants (63%) reported a moderate reduction in OCD symptoms whilst 37% did not experience notable improvements. Participants perceived the greatest benefit was their increased ability to cope with OCD symptoms rather than OCD symptom reduction per se. As OCD often has a chronic if fluctuating course (Skoog & Skoog, 1999; Visser et al., 2014), an

improved ability to cope with (residual) OCD symptoms could be an important outcome for patients with OCD who do not fully recover from OCD following CBT.

1.6.6.1.2 Uncontrolled pilot studies

Kumar, Sharma, Narayanaswamy, Kandavel and Janardhan Reddy (2016) trialled a 12-16 session Mindfulness-Integrated CBT (MICBT) intervention, consisting of 1.5 hour twice-weekly sessions, with 27 patients with OCD who experienced taboo thoughts without overt compulsions. Forty-minute sitting meditation practices were conducted at the end of each session and set as homework. Psychoeducation about OCD and cognitive restructuring techniques were also included. There was a significant reduction in obsession symptoms from pre- to mid-, post- and follow-up (F(3)=28.84, p<.001, η_p^2 =.56 (large effect)), including a mean 6.04 point pre-to post reduction in Y-BOCS scores. Anxiety, depression, functional impairment, quality of life (trend) also significantly improved. The mean percentage of OCD symptom reduction was 56% (SD=23) post-treatment and 63% (SD=21) at 3-month follow-up; remission rates (operationalised as \geq 55% reduction in Y-BOCS scores) were high at 67%. However, mindfulness skills did not increase as a result of the intervention, which carefully suggests the pre-to post- change in OCD symptoms may instead have resulted from the cognitive therapy training components.

Gasnier et al. (2017) conducted a pilot study testing group MBSR and MBCT with eight adults with OCD. None of the participants dropped out, suggesting the treatment was highly acceptable. Findings showed a non-significant 1.75 point mean reduction in Y-BOCS scores (pre-treatment M=21.63, post-treatment M=19.9). Full and partial response rates stood at 12.5% each, i.e. the non-response rate was 75%. The

authors suggested that younger patients with less chronic or severe OCD appeared to gain the most benefit from MBIs and concluded that MBIs are best delivered as augmentation therapies for ERP.

1.6.6.1.3 Experimental studies

Wahl, Heulle, Zuroswki, and Kordon (2014) conducted an experimental study with 30 adults with OCD randomised to a brief mindfulness instruction or a distraction instruction condition to cope with their most troublesome intrusive thoughts, which were audio-recorded and played to them. The results showed that a mindfulness coping strategy helped to reduce the urge to neutralise. The authors speculated that the invitation to bring mindful attention to their thoughts resulted in habituation. However, no initial peak in anxiety was witnessed during this instruction, which authors speculate may have been due to lack of power. The other proposed mechanism of change was 'letting go', or rather seeing thoughts as insignificant.

1.6.6.1.4 (Pilot) RCTs

Cludius et al. (2015) conducted an RCT comparing self-help mindfulness training (using a book and audio-files) (*N*=49) with progressive muscular relaxation (*N*=38) with former OCD patients at their university medical centre. Interventions were delivered through manuals and audio-files. Analyses reported for 'active participants' who had read the manual and regularly applied the techniques (Mindfulness: *n*=17, PMR: *n*=15) showed no differences in OCD symptom improvement between the two conditions; in fact, there was no perceptible shift in OCD symptoms from pre-to post-treatment for either condition. Among active participants, 65% regularly practised mindfulness, whilst 88% of all participants reported having to force themselves to do it.

Nearly half the participants struggled to find the time to do read the manual as intended and the same percentage (47%) would find it a more useful technique if applied with a direct psychotherapy.

Key, Rowa, Bieling, McCabe and Pawluk (2017) conducted a waitlist-control trial in which 18 participants who previously completed CBT undertook an 8-week MBCT adapted to OCD. Participants achieved a significantly greater reduction in OCD symptoms compared to waitlist controls (F(1,2) = 15.07, p=.001; d=.1.38). However, the mean reduction in OCD symptoms (a change score of -2.49 on Y-BOCS-SR) was modest and lower than the average OCD symptom reduction following ERP for OCD (Mean Y-BOCS change score: -11.4, 95% CI: 10.5-12.2) (Houghton et al., 2010). The authors argued that as participants had previously received CBT they were likely to have already achieved a degree of symptom reduction, limiting the potential range of change scores.

Finally, results from a pilot RCT comparing 10 weekly two-hour-sessions of group-based Mindfulness-based ERP (MB-ERP) (N=19) with ERP (N=18) in a routine clinical setting for adults with OCD informed this thesis (Strauss et al., 2018). The MB-ERP intervention incorporated 10-minute mindfulness practices followed by a 20-minute Socratic inquiry to complement a standard ERP protocol (delivered in the remaining 90 minutes of each session). Dropout from MB-ERP stood at 21% versus 6% for ERP. The post-treatment between-group difference in OCD symptom reduction of 2.4 points in favour of ERP (Cohen's d=.36, 95% CI [-.37, 1.08]) suggested that MB-ERP did not have added benefit compared to ERP as the 95% CI did not include the 5-point minimum clinically important difference between groups. Between-group differences in post-treatment obsessive beliefs (d=.28, 95% CI [-.47, 1.02]) were non-

significantly in favour of ERP. On average, MB-ERP participants completed five formal mindfulness practices each week. The point-estimate for mindfulness was in favour of MB-ERP at post-treatment (*d*=.53, 95%CI [-.20, 1.26]) and at six months follow-up (*d*=.70, 95% CI [-.18, 1.59]), suggesting that MB-ERP has the potential to improve mindfulness skills but without improving OCD symptoms and obsessive beliefs. The authors concluded that further research was needed to explore whether MB-ERP may yet benefit some OCD symptom subtypes and to ascertain the effects of MBIs that cultivate mindfulness more intensively, e.g. through adapting MBCT for OCD.

1.6.6.1.5 Summary

Findings from the qualitative studies suggest that patients with OCD perceive stand-alone MBIs that augment CBT and those integrated into CBT as acceptable and potentially efficacious treatments for OCD. Results from a few uncontrolled studies suggested that pre-to post-treatment OCD symptoms reduction was encouraging for MBIs integrated with CBT but results were more disappointing for a stand-alone MBI. A single experimental study showed that mindfulness may aid exposure, whilst results from a recent waitlist control trial of MBCT as an augmentation therapy for OCD suggested it held promise. Self-help mindfulness did not benefit OCD when compared to progressive muscular relaxation but this conclusion was complicated by low rates of treatment engagement. Furthermore, a pilot RCT comparing of MB-ERP with ERP suggested that adding mindfulness to ERP may not translate into a greater reduction in OCD symptoms, although this warranted further investigation. Evidently, at this early stage, research into MBIs for OCD has not included formal mediation analyses to test potential mechanisms of change. Nonetheless, findings from qualitative studies showed

that participants' accounts of how mindfulness helped them to target their OCD symptoms were broadly in line with theorised mechanisms.

1.7 Outline of the thesis

The research presented in this introductory chapter shows that while CBT is an effective treatment for OCD, a significant proportion of adults with OCD do not experience a clinically meaningful reduction in OCD symptoms. Variable patient engagement is likely to impact on patient response to CBT for OCD. However, little is known about the magnitude and predictors of patient non-adherence to CBT for OCD. Non-response to CBT for OCD has generated interest in the potential of MBIs for OCD. However, research into the acceptability and potential benefit of MBIs adapted for OCD remains relatively limited and there is little research evidence to support or challenge the theorised mechanisms of MBIs for OCD. Moreover, the assumption behind MBIs for OCD, i.e. that adults with OCD may benefit from MBIs because they have mindfulness and self-compassion skills deficits that can be effectively targeted through such interventions, has rarely been tested.

To address these evidence gaps, the first aim of the thesis was to explore what contributes to poor patient engagement in CBT for OCD. The aim was to understand this quantitatively, i.e. rates and moderators of (aspects of) nonadherence, and qualitatively, i.e. patients' perceptions of the barriers and facilitators to engagement. Towards achieving this aim, this thesis included: i) a meta-analysis and systematic review of patient adherence to CBT for OCD (paper 1, Chapter 2); ii) a qualitative exploration, using thematic analysis, of patients' perceptions of facilitators and barriers to engagement in group ERP (paper 2, Chapter 3).

The second aim of the thesis was to explore whether MBIs could benefit adults with OCD. This thesis explored this by examining the relationship of mindfulness and self-compassion with OCD, through a correlational study of the association of mindfulness and self-compassion with obsessive-compulsive symptoms within a large sample of treatment-seeking adults (paper 3, Chapter 4). This was followed by a qualitative analysis of patient experiences of the acceptability and potential benefits of MB-ERP and MBCT adapted for OCD (paper 4, Chapter 5) to facilitate a better understanding of whether and how different MBIs might benefit OCD. This thesis will present each of these studies (chapters 2-5), before concluding with a general discussion of the four studies, including a consideration of the strengths and limitations of the thesis and its clinical and research implications. Before presenting each of the studies, the following provides a brief overview of (the rationale for) the aims and methods of each study.

The first study (Chapter 2) of the thesis opted for secondary analysis of primary studies that reported data on patient adherence. Specifically, the aim of the first paper was to systematically review and meta-analyse the magnitude, moderators and reasons for poor patient adherence to CBT for OCD in terms of: (1) treatment refusal, (2) treatment dropout, (3) session attendance/module completion, and (4) between-session CBT task adherence. This was informed by the fact that research to date has failed to establish a reliable estimate of (all) these aspects of adherence, which hampers a shared understanding among OCD researchers as to the scale of the problem of non-adherence. Furthermore, previous meta-analyses of categorical and continuous predictors of non-adherence tested few predictors and limited their focus on a single aspect of patient adherence, i.e. dropout. Therefore, this first study aimed to test a range of

sociodemographic, clinical, treatment characteristics as potential moderators of multiple aspects of patient adherence to CBT for OCD, in line with models of health service utilisation (Andersen, 2017; Barrett et al., 2008; Owens et al., 2002). Study characteristics were also examined as they may influence adherence (e.g. Fernandez et al. 2015; Swift & Greenberg, 2012). In addition, exploring the reasons given for non-adherence would help to inform endeavours to prevent non-adherence. To achieve the aims of the study, broad literature search criteria were used to capture all outcome studies of CBT for OCD that may have included data on any of these aspects of adherence as study titles and abstracts do not necessarily mention adherence data collected and reported in the main text. The systematic search identified 123 studies including 5627 participants taking part in CBT or control conditions. This meant the meta-analysis included a much larger number of studies than previous meta-analyses of dropout from CBT for OCD (Öst et al., 2015; Ong et al., 2016).

Findings from the systematic review and meta-analysis informed the decision to conduct a qualitative exploration of barriers and facilitators of patient engagement in group ERP (paper 2, Chapter 3). Specifically, there was an absence of significant moderator effects on refusal and dropout, other than a therapy format effect on dropout (see below), and insufficient studies to test moderator effects on session attendance and between-session CBT task adherence. Secondly, the meta-analysis showed that group CBT (all types) was associated with significantly lower dropout than individual therapy, which suggested that peer support may benefit treatment completion. However, whilst little was known about the magnitude of patient adherence to between-session ERP tasks in general, even less data was available for group ERP, despite the fact that group CBT for OCD appears to be as effective as individual CBT (Öst et al., 2015), has the

potential to increase patient access to treatment, and is one of the NHS treatment formats recommended for OCD by NICE (2005) (along with guided self-help and individual therapy). These findings, and their limitations, suggested that a qualitative evaluation of patient experiences of CBT for OCD could help to identify (relationships between) potential predictors of engagement to benefit a more theory-driven approach to examining and addressing engagement in ERP. A qualitative exploration of patient experiences of group ERP in particular would allow further exploration of whether and how the group therapy format might benefit patient engagement. This informed the decision to conduct a qualitative exploration of patient perspectives on the barriers and facilitators of engagement in group ERP for OCD (study 2, Chapter 3). The study involved a thematic and content analysis of semi-structured interview data collected at six-month follow-up from 15 adults with OCD who had participated in group ERP.

To address the second aim of the thesis, i.e. to explore whether MBIs could benefit adults with OCD, it was considered important to first examine the unique relationship of obsessive-compulsive symptoms with mindfulness and self-compassion (study 3, Chapter 4). This was informed by the fact that the growing interest in MBIs for OCD is based on the assumption that adults with OCD will have (relative) deficits in mindfulness and self-compassion skills, yet few studies have researched this (in any great detail). A better understanding of whether mindfulness and self-compassion skills uniquely predict OCD symptoms would provide preliminary evidence towards this assumption; the absence of a unique association of mindfulness and self-compassion with OCD would question the potential causal importance of these skills in OCD and suggest that targeting these skills, i.e. through offering MBIs for OCD, would be of little therapeutic benefit. Conversely, significant unique associations of mindfulness and

self-compassion with OCD symptom(s) subtypes would support further exploration of the role of mindfulness and self-compassion in understanding, assessing and treating OCD. To achieve the aims of the study, two large samples of treatment-seeking adults and non-treatment-seeking adults were recruited, based on a-priori power calculations, and invited to complete an anonymous on- or offline survey consisting of mindfulness, self-compassion, OCD, anxiety, depression, obsessive beliefs and distress tolerance questionnaires.

Overall, the results from study 3 suggested further exploration of MBIs for OCD was warranted. Therefore, the fourth paper (Chapter 5) presents findings from two qualitative studies of the perceived acceptability and potential benefits and mechanisms of MBIs for OCD. Specifically, the two studies involved thematic and content analyses of semi-structured interviews conducted with participants in a 10-week Mindfulness-Based ERP (MB-ERP) course (study 1) and a 9-week Mindfulness-Based Cognitive Therapy (MBCT) adapted for OCD (MBCT-OCD) (study 2). The second study in the paper followed on from the first study, after the pilot RCT data suggested that MB-ERP did not improve on ERP in reducing OCD symptoms post-treatment (Strauss et al., 2018). Possible explanations offered for the lack of positive results were that the mindfulness component was small relative to the ERP component of the therapy and that the integration of a goal-directed therapy (ERP) with an acceptance-orientated approach (mindfulness) may have been awkward for participants. This informed the decision to explore a stand-alone MBCT therapy for OCD (MBCT-OCD), developed and delivered as part of the thesis (see Table A2, Appendix A for details), that excluded ERP and foregrounded mindfulness skills training as the primary vehicle of change. The paper brought these studies together to facilitate an understanding of common and

unique experiences associated with these different approaches to teaching mindfulness skills to patients with OCD. As the quantitative analysis of MB-ERP had already shown that it did not improve on OCD symptoms relative to ERP alone (Strauss et al., 2018), the qualitative exploration of patient perspectives on MB-ERP would also help to contextualise these results.

Chapter 2: Patient adherence to Cognitive Behavioural Therapy for Obsessive-Compulsive Disorder: A systematic review and meta-analysis

Abstract

Whilst Cognitive Behavioural Therapy (CBT) is the treatment of choice for obsessivecompulsive disorder (OCD), around half of the participants do not experience remission following treatment. As yet, there is no comprehensive systematic review of the extent to which patient non-adherence presents a challenge to the overall benefit of CBT for OCD. The aim of this systematic review and meta-analysis was to identify the magnitude, moderators and reasons for poor patient adherence to CBT for OCD in terms of: (1) treatment refusal; (2) treatment dropout; (3) session attendance/module completion, and (4) between-session CBT task adherence. Sociodemographic and clinical variables, treatment and study design characteristics were examined as moderators of adherence. The systematic search identified 123 studies including 5627 participants taking part in CBT or control conditions. A pooled rate of 15.6% of eligible patients refused CBT and a further 15.9% of treatment starters dropped out from treatment. Group CBT had significantly lower dropout rates than individually-delivered CBT. No other significant moderators were found. Most studies reported moderate to good adherence to between-session CBT tasks, which had a significant medium to large association with post-treatment OCD symptom reduction. Recommendations for enhanced measurement and reporting of patient adherence to CBT for OCD are made along with clinical implications of findings.

Keywords: Obsessive compulsive disorder; adherence; refusal; attrition; CBT; meta-analysis

2.1 Introduction

2.1.1 Background

Obsessive compulsive disorder (OCD) is a mental health condition characterised by persistent intrusive thoughts, images or urges that cause significant anxiety (obsessions), and repetitive, ritualistic behaviours or mental acts aimed at neutralising anxiety or preventing a dreaded event (compulsions) (American Psychiatric Association (APA), 2013). It has a high current and lifetime comorbidity with depression and anxiety and is associated with poor quality of life (Macy et al., 2013).

England and Wales and US practice guidelines recommend exposure and response prevention (ERP), delivered with or without cognitive therapy strategies, as the psychological therapy of choice for OCD (APA, 2007; National Institute for Health and Care Excellence (NICE), 2005). Exposure and response prevention is a behaviour therapy during which patients engage in repeated, prolonged exposure to obsessions whilst refraining from compulsions (Kozak & Foa, 1997). Cognitive strategies, rooted in the cognitive therapy (CT) model of OCD, help patients re-evaluate the accuracy of appraisals (e.g. exaggerated beliefs about personal responsibility for preventing harm) that result in the misinterpretation of common intrusive thoughts as significant and therefore anxiety-provoking (OCCWG, 1997; 2005). In this review, CBT is the umbrella term for ERP, CT and a combination of both.¹

Öst and colleagues (2015) conducted a large meta-analysis of the efficacy of CBT for OCD. They report a large post-intervention between-group effect size for CBT

¹ In the meta-analysis, CBT also denotes the combination of ERP and cognitive therapy strategies, contrasted with ERP and CT on their own.

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compared to waitlist (Hedges' g= 1.31, CI [1.08,1.55], k=15) and placebo (g=1.33, 95% CI [.91-1.76], k=8) conditions and a medium effect size compared to antidepressant medication (g=.55, 95% CI [.05, 1.04], k=4), using the Yale–Brown Obsessive Compulsive Scale (Y-BOCS) (Goodman et al., 1989) as the outcome measure.

Whilst CBT is the gold standard in the treatment of OCD, not all patients achieve post-treatment OCD symptom remission. A patient is in remission when they no longer meet diagnostic criteria for OCD and have minimal to no symptoms and no functional impairment, lasting for at least one week (Mataix-Cols et al., 2016). Research trials of CBT for OCD typically determine remission based on whether the patient moved from above to below a nominated Y-BOCS cut-off score from pre- to posttreatment (Mataix-Cols et al., 2016). However, attempts to establish a reliable remission rate have been marred by the variability in nominated Y-BOCS cut-off scores (Mataix-Cols et al., 2016). For example, Öst et al. (2015) found that just 42 to 52% of patients experienced remission following CT, ERP or CBT. Eighteen of the 20 primary studies contributing to these pooled estimates determined remission based on a Y-BOCS cut-off score. In the absence of normative data for the Y-BOCS, studies used cut-off scores derived from sample-dependent calculations (e.g. pre-treatment sample mean - 2SDs) (Jacobson & Truax, 1991), or from empirical studies (e.g. Fisher & Wells, 2005; Lewin et al., 2011) or followed recommendations from OCD experts (e.g. Pallanti et al., 2002). Consequently, Y-BOCS cut-off scores ranged from 7 to 16 across studies. To address the variability in the definition of Y-BOCS cut-off scores, international OCD experts recently reached consensus that a Y-BOCS score of \leq 12 should be used. Therefore, several of the primary studies in Öst et al. (2015) used Y-BOCS scores that were either too lenient or too stringent. Despite these methodological limitations, these figures

suggest that a significant proportion of people with OCD do not experience OCD symptom remission following CBT.

CBT for OCD is often seen as a challenging therapy; it is anxiety provoking by design and this is magnified by high levels of distress intolerance associated with OCD (Cougle, Timpano, Fitch, & Hawkins, 2011; Olatunji, Deacon, & Abramowitz, 2009). It is often suggested this may result in poor patient adherence to treatment and account for the moderate remission rates for CBT for OCD (e.g. Whittal, Thordarson & McClean, 2005). However, little is known about the magnitude and moderators of patient adherence to CBT for OCD and the extent to which non-adherence may be attributable to patients finding the therapy challenging. This is an important evidence gap to address – understanding these factors could lead to therapy modifications to improve adherence and ultimately to improve patient outcomes. This is the focus of the present study.

The World Health Organisation defines adherence as 'the extent to which a person's behaviour... corresponds with agreed recommendations from a health care provider' (Sabate, 2003, p.3). In this study, we consider four adherence factors that could contribute to disappointing outcomes: (1) therapy refusal, i.e. choosing to decline treatment despite professional recommendation; (2) therapy dropout, i.e. the patient prematurely discontinues therapy recommended by their health care provider and is unlikely to have received the full benefit of treatment; (3) poor attendance at therapy sessions despite treatment completion, which can result in people not receiving the therapist recommended 'dose' of the therapy; and (4) poor adherence to therapist recommended between-session ERP/behavioural tasks considered key in achieving symptom improvement.

2.1.1.1 *Refusal*

Research to date has not yet established a reliable estimate of the refusal rate for CBT for OCD. Öst et al. (2015) report an average 15% rate of refusal, pre- and post-randomisation, across 32 RCTs of CBT for OCD. Refusal rates were highly variable across studies (*SD*: 11.6, range: 0-63%). Assessing the magnitude of CBT refusal in the context of RCTs can be problematic as it may reflect refusal unrelated to CBT, e.g. refusal to be randomised. To gain a reliable estimate of the magnitude of CBT refusal, it may be more appropriate to examine patient refusal of CBT for OCD in uncontrolled studies.

2.1.1.2 *Dropout*

Dropout occurs when the patient accepts the offer of CBT and attends at least one session but does not complete the full recommended course of treatment. There are a few meta-analyses of the magnitude of dropout from CBT for OCD, with a modest number of studies. Öst et al. (2015) report a pooled dropout rate for (remote and face-to-face) CBT ranging from 11% (CT, k=8) to 19% (ERP, k=28). Swift & Greenberg (2014) found a CBT (all types) dropout rate of 16.3% across a combination of controlled and uncontrolled studies (k=45), whilst Hans and Hiller (2013) report a dropout rate of 12% for face-to-face CBT for OCD across 20 nonrandomised effectiveness studies.

2.1.1.3 *Session Attendance*

US practice guidelines (APA, 2007) recommend a minimum of 13 sessions of CBT whilst guidelines for England and Wales (NICE, 2005) propose high intensity CBT (> 10 therapist hours per patient, i.e. individual CBT) for those patients with moderate to severe OCD or those with mild OCD who failed to engage with or benefit

from low intensity CBT (<10 therapist hours per patient, i.e. guided self-help, group CBT). It is therefore important to consider whether among patients completing therapy, session attendance or module completion (for remote therapies) was optimal. However, this aspect of adherence is infrequently considered (Tetley, Jinks, Huband, & Howells, 2011).

2.1.1.4 Between-Session Tasks

Cognitive behavioural therapy places central importance on the regular completion of between-session therapy tasks. A recent meta-analysis found significant large effect sizes for the association of quality (Hedges' g=.78, 95% CI [.03, 1.53], k=3, n=417, I²=91) and quantity (g=.79, 95% CI [.57, 1.02], 1.53], k=15, n=1537, I²=81) of homework compliance with post-treatment outcomes for CBT for a range of mental health conditions and physical health issues (Kazantzis et al., 2016). However, results were not specific to key homework tasks of CBT for OCD.

2.1.1.5 Reasons for Non-adherence

An examination of moderators of adherence to CBT for OCD is key in the identification of risk factors for nonadherence, to drive a targeted approach to keeping patients engaged with therapy (Barrett, Chua, Crits-Christoph, Gibbons, & Thompson, 2008). To date, there are no meta-analyses that consider moderators of refusal, session/module completion and therapy task adherence, but a few studies have tested moderators of dropout from CBT for OCD. Öst et al. (2015) examined CBT type and found that dropout from ERP + antidepressant medication (32%, k=7) was significantly higher than from CT, ERP or CBT (15.5%, k=19), suggesting that the elevated dropout rate might be due to the addition of medication (dropout from antidepressant medication

alone was 30%). Ong, Clyde, Bluett, Levin, and Twohig (2016) found that treatment type and format did not moderate dropout from ERP. Therapist experience (coded as: i) no professional experience, ii) professional experience not specific to CBT and, iii) professional experience with or expertise in CBT) and qualification (coded as: i) student, ii) non-psychologist professional or therapist, or iii) doctoral level therapist or psychologist) and number of sessions also did not predict dropout. These meta-analyses examined a small number of moderators and some were conducted with a relatively small (sub)group of studies and could have been under-powered to detect moderator effects (Borenstein et al., 2009).

To understand what might help patients to engage with therapy, it is important to consider the reasons participants give for not adhering to therapy. However, few studies have foregrounded this. An observational study found that environmental barriers (e.g. costs, inconvenience) was the main reason for refusing (55%) and dropping out (46%) from CBT for OCD (Mancebo, Eisen, Sibrava, Dyck, & Rasmussen, 2011). Interestingly, 20 % of refusal and 12% of dropout was primarily due to feeling too anxious or fearful to participate in CBT. This suggests that (patient perceptions of) the challenging nature of CBT for OCD may contribute to nonadherence. Further studies are needed to establish if this is a consistent finding.

2.1.2 Objectives for a systematic review and meta-analysis

Developing a better understanding of the magnitude and moderators of adherence to CBT to OCD is crucial if we want to improve patient outcomes. To the best of our knowledge, this is the first systematic review and meta-analysis with a primary focus on patient adherence to CBT for OCD. The aim was to examine the

magnitude of refusal and dropout, session attendance, step/module completion and between-session task adherence and to summarise participants' reasons for refusing or dropping out from CBT across studies. In line with models of health service utilisation (Andersen, 2017; Barrett et al., 2008; Owens et al., 2002), a range of sociodemographic, clinical, treatment characteristics were tested as potential moderators of patient adherence to CBT. Study characteristics were also examined as they may influence adherence (e.g. Fernandez et al. 2015; Swift & Greenberg, 2012). The aim was also to examine the strength of the association of session attendance and therapy task adherence with post-treatment OCD symptom reduction, to further our understanding of the importance of these aspects of adherence to therapy outcomes. Findings will help inform recommendations for improving adherence to CBT for OCD and thereby improving patient outcomes.

2.2 Method

2.2.1 Literature search

PsycINFO, PsycArticles, Medline, Web of Science and SCOPUS were searched from their inception until 31st October, 2017, using the search terms: (*OCD OR* "Obsessive compulsive disorder" OR obsess*) AND (cognitive therapy OR behavio?r* therapy OR exposure* OR CBT). OCD terms were searched in the title and CBT terms were searched in the title, abstract or keyword/subject.

Results from electronic searches were checked against systematic reviews of CBT for OCD (Mataix-Cols & Marks, 2006; Öst et al., 2015; McKay et al. 2015; Olatunji, Davis, Power & Smits, 2013; Ponniah, Magiati & Holland, 2013; Rosa-Alcazar, Sanchez-Meaca, Gomez-Conesa & Marin-Martinez, 2008). International

clinical trial registries (ClinicalTrials.gov, ISRCTN, EU clinical trials register) were searched using the terms OCD and obsessive-compulsive disorder. Finally, the references of all eligible articles were hand-searched.

2.2.2 Selection criteria

Studies were included if: 1) they evaluated CBT for OCD using any design, except single case; 2) they were published in English; 3) they recruited a working age adult sample (majority of participants aged 18+); 4) with participants who met diagnostic criteria for OCD, based on DSM/ICD or equivalent criteria; 5) intervention participants received CBT for OCD in an outpatient setting; 6) quantitative or qualitative data on (reasons for) CBT treatment refusal, treatment drop-out and/or degree or quality of client adherence to therapy sessions and/or therapy tasks was provided. In this meta-analysis, CBT type is defined as ERP, CT or a combination of (components of) the two (CBT). Face-to-face and remote therapies were included as were therapies delivered in combination with psychotropic medication or (psychological) placebo. Studies were excluded if they: 1) included participants who met diagnostic criteria for psychosis, autistic spectrum disorder or a learning disability; 2) were single case studies; 3) lacked details of the CBT provided, e.g. no information about duration or content; 4) recruited inpatients, as inpatient treatment refusal may reflect refusal of a hospital stay more generally; and 5) if identical adherence data from the same study were reported in multiple papers only the first published paper was selected for review.

2.2.3 Data extraction and coding

The following information was extracted and coded for each study: authors, year of publication, design, treatment type (ERP, CT or CBT with or without medication and/or (psychological) placebo), treatment format (i.e. (therapist assisted or self-help) remote therapies versus face-to-face (individual, family, couple or group) therapies), protocol treatment duration in weeks, number and hours of sessions, weekly frequency of treatment sessions, therapist experience, sample characteristics (age, % female, % married or co-habiting, % working full-time or part-time, mean years of education, pretreatment scores on measures of OCD, anxiety and depression; % of sample with prior (adequate) CBT, % on medication at the start of therapy, % comorbidity), refusal data (number of eligible participants, number of eligible participants refusing participation, reasons for refusal), dropout data (number of participants starting and dropping out from treatment, stage of dropout, reasons for dropout), session and task adherence data (percentage or average number of sessions attended, percentage or average number of (hours of) between-session CBT tasks completed; (source, type and timing of) measures of therapy task adherence; the association between task adherence and therapy outcome; predictors of adherence). In addition, this review coded the clinical representativeness of the study sample. Based on guidelines set out in Hans & Hiller (2013), the following criteria were applied: 1) routine referrals (vs some active recruitment, e.g. through advertising); 2) allowance of medication; 3) common exclusion criteria for routine outpatient treatment (vs additional exclusion criteria). A score of 1 meant the criterion for clinical representativeness was met (see Appendix A for the scale).

2.2.4 Categorisation of variables

The following sets out how the different adherence variables examined in this review were categorised.

2.2.4.1 *CBT refusal*

Any patient who was eligible to commence CBT but declined participation for any reason counted as a refusal. Assessing refusal in RCTs is challenging because prerandomisation refusal could reflect refusal of conditions other than CBT (e.g. medication, wait-list) or of randomisation, whereas post-randomisation refusal of CBT underestimates the refusal rate as it excludes patients who refused pre-randomisation based on the possibility of receiving CBT. Therefore, only refusal data from uncontrolled studies was used to calculate the CBT treatment refusal rate as it was clear which treatment patients refused.

2.2.4.2 *CBT dropout*

A patient was counted as a treatment dropout if they attended at least 1 treatment session but discontinued treatment before the final planned session. Patients who completed treatment but did not attend a post-treatment assessment were not counted as CBT dropouts. For studies comparing more than one treatment, separate dropout rates were recorded for each treatment. The reasons for CBT treatment dropout were not taken into consideration, to ensure equivalence between studies that did and did not report this information. Reasons for dropout were analysed separately (below).

2.2.4.3 *CBT session attendance or step/module completion*

The mean number and percentage of attended sessions, as a proportion of the total number of planned sessions, were recorded. For remote therapies, the number and percentage of completed modules or steps completed were recorded.

2.2.4.4 *CBT task adherence*

The mean degree of adherence to between-session CBT tasks, e.g. mean number or percentage of tasks completed or the mean score on a CBT task adherence questionnaire, was extracted. Where available, ratings of the quality of task adherence were also recorded.

2.2.5 Statistical analyses

All data analyses were conducted using Comprehensive Meta-Analysis version 3 (Borenstein et al., 2009).

2.2.5.1 *Mean adherence*

Where possible, the following inverse variance weighted effect sizes were calculated and pooled using random effects models, as the true effect size was expected to vary between studies (Borenstein et al., 2009): i) Meta-proportions of refusal and dropout using logit-transformed proportions (Borenstein et al., 2009; Lipsey & Wilson, 2001). Dropout rates were calculated at the treatment level. To ease interpretation, logit-transformed proportions and 95% confidence-intervals were back-transformed into proportions; ii) Mean number and percentage of completed CBT sessions or modules, calculated at treatment level; iii) Mean number, percentage and/or mean score for between-session CBT task adherence, calculated at treatment level; iv) Risk ratio of

early (session 1-5) versus late (sessions 6 and after) dropout, calculated at treatment level. The sensitivity of the pooled effect sizes to the impact of individual studies was examined by removing one study at a time and obtaining the re-calculated mean rate, number or percentage (Borenstein et al., 2009).

2.2.5.2 *Moderator/subgroup analysis*

The following categorical study and therapy characteristics were tested as potential moderators of adherence: 1) study design (controlled versus uncontrolled); 2) type of CBT (ERP, CT, CBT with/without medication or pill/psychological placebo); 3) therapy format (i.e. face-to-face versus remote therapies; individual versus group, couple or family therapies; therapist-assisted versus self-help remote therapies) 4) intensity (face-to-face and remote therapies involving 10 hours or less of sessions or modules are considered 'low intensity' whereas those of more than 10 sessions or modules are considered high intensity (from the patient perspective); 5) face-to-face session frequency (more than twice weekly; twice weekly; once weekly or less); 6) face-to-face therapy duration (in weeks); 7) therapist experience for therapist delivered treatment (pre-attainment, post-attainment, mixed); 8) recruitment (routine vs active (e.g. using advertising)); 9) patients (routine vs non-routine exclusion criteria); 10) medication (allowed, not allowed).

Subgroup effect sizes were calculated if there were at least 4 studies per subgroup (Fu et al., 2011). A mixed-effect model was used to compare differences between subgroup effect sizes as effect sizes of studies within each subgroup were expected to vary (Borenstein et al., 2009). Differences between subgroup effect sizes were tested with the Q-statistic, which is analogous to using ANOVA or t-tests for

testing group differences in primary studies (Borenstein et al., 2009), i.e. it determines if differences in effect size between subgroups are statistically significant.

Moderator analyses of the following continuous socio-demographic and clinical variables were carried out where possible, using a mixed-effects model of meta-regression (Method of Moments) (Borenstein et al. 2009; Kelley & Kelley, 2012): 1) mean age; 2) gender (% female); 3) ethnicity (% Caucasian); 4) marital status (% married or cohabitating); 5) employment status (% working full- or part-time); 6) mean years of education; 7) pre-treatment mean OCD symptom severity (Y-BOCS); 8) % patients with comorbid axis I or II disorders; 9) pre-treatment depression and/or anxiety symptom severity; 10) % patients with prior CBT, and 11) % patients on concurrent medication. Only covariates for which at least 10 studies (k) provided data were included (Borenstein et al., 2009).

2.2.5.3 Association of CBT task adherence with post-treatment OCD symptom reduction.

The association between task adherence and post-treatment OCD symptom reduction was tested by meta-analysing Fisher's *z*-transformed correlations of mean between-session CBT task adherence with post-treatment OCD symptom reduction. Where correlations were not reported, the available statistics were converted into correlations using standard formulas (Borenstein et al., 2009). Where possible, correlations based on post-treatment OCD symptom severity adjusted for pre-treatment OCD symptom severity were selected; otherwise correlations with change scores or post-treatment scores were used. The type of correlation and outcome measure needed to be equivalent across studies to pool effect sizes (Aloe & Thompson, 2013).

2.2.5.4 *Homogeneity analysis*

The *Q*-statistic (Hedges & Olkin, 1985) was calculated to test for statistically significant heterogeneity of results. As the *Q*-statistic is affected by the number of studies, I² was also calculated to assess the degree of heterogeneity using the following guidelines: 25% (small), 50% (moderate), 75% (large) heterogeneity (Higgins, Thompson, Deeks & Altman, 2003).

2.2.5.5 Publication bias

Risk of publication bias was analysed using Egger's regression intercept (Egger, Davey Smith, Schneider, & Minder, 1997) and Duval and Tweedie (2000) trim-and-fill methods (Borenstein et al., 2009).

2.2.6 Reasons for dropout or refusal

Reasons for refusal or dropout were recorded as stated by study authors, along with the number of participants that the reason applied to. The frequencies for identical reasons (that differed minimally in their wording), were totalled across studies and grouped into different low-level categories, using conventional content analysis (Hsieh & Shannon, 2005) (see result for further details).

2.3 Results

2.3.1 Study flow and characteristics

The database and hand searches identified 7725 references. After the removal of 3527 duplicates, 4198 references remained. After excluding 3812 references based on their title, abstract or source, 386 full-text articles were read to assess their eligibility.

This resulted in the inclusion of 123 studies (see Fig. 1). Six studies that conducted further analyses with adherence data drawn from outcome studies already included in the meta-analysis were not included in the study characteristics below. The 117 remaining studies included 59 controlled and 58 uncontrolled studies, published between 1984 and 2017. A total of 5627 participants took part in CBT or control conditions. Averaging the unweighted sample means, the mean age was 34.9 (range: 25.71 - 47.93) and 58% of participants were female (range: 17-100%). Pre-treatment total Y-BOCS scores ranged from 14.35 to 30.38 with a mean of 24.49 (severe symptoms). Mean pre-treatment depression severity (measured with the Beck Depression Inventory (BDI) (Beck, Steer & Garbin, 1988) was 17.58 (mild depression) (range: 10.40-28.50). Mean duration of OCD symptoms was 14.10 years (range: 4.6 -26.40) and 53% of participants were on medication (range: 13 - 100%). The studies delivered 161 CBT treatments in total, including ERP (68), CBT (55), CT (16), ERP + medication (12), ERP + Placebo pill (6), CBT + medication (2), CT + medication (1), and ERP + Psychological Placebo (1). Treatments were delivered face-to-face (k=125) and remotely (k=36). See Appendix B for study references, Table C.1., Appendix C for details of primary studies included under each adherence variable and Table C.2 and C.3, Appendix C for study characteristics.

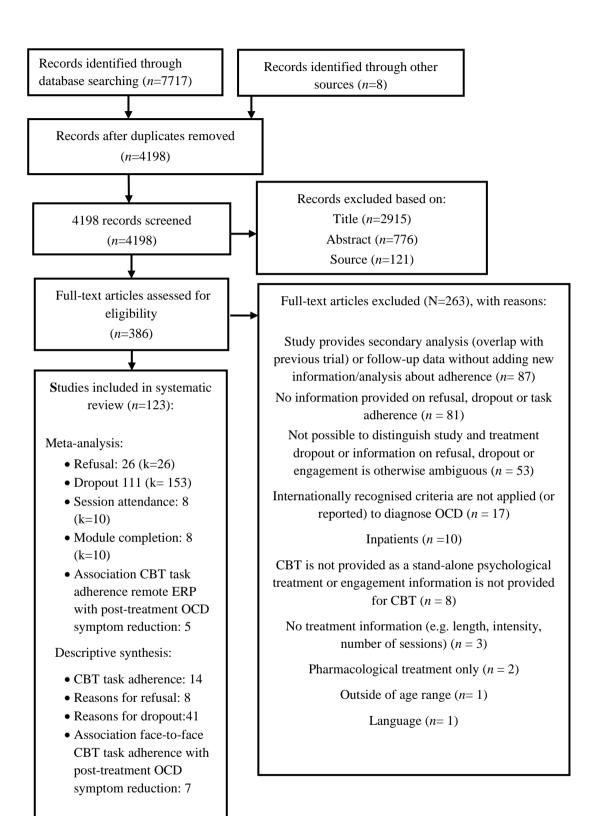


Fig. 1: Study flow

2.3.2 Mean adherence

Twenty-six uncontrolled studies contributed to the **refusal rate**. CBT treatments included CBT (13), ERP (12) and ERP + Medication (1). The pooled mean **dropout rate** was calculated with data from 111 studies (controlled studies: 55, uncontrolled studies: 56) that included 153 treatments: ERP (62), CBT (53), CT (16), ERP + Meds (12), ERP + Pill Placebo (6), CBT + Meds (2), CT + Meds (1), ERP + Psych Pla (1). The **mean number of sessions** attended by patients completing face-to-face CBT could be extracted from only 8 studies, whilst the **mean percentage sessions attended** was calculated with data from 7 studies. Treatments included ERP (7), CBT (2) and CT (1) using group (2) and individual (8) formats. Eight studies reported the **average number of steps or modules** completed in remote therapies. Eight out of 10 treatments involved CBT (i.e. ERP and cognitive strategies combined). All were internet-based apart from one bibliotherapy treatment. Seven of the 10 treatments involved (a degree of) therapist assistance.

The pooled CBT refusal rate was 15.6% (95% CI [11.9, 20], k=26, I² =52.36, Q = 52.47, p <.001) and pooled dropout rate was 15.9% (95% CI [14.2, 17.8], k=153, I² =50.8, Q =308.95, p <.001). Participants who completed face-to-face therapy attended a mean of 12.8 sessions (95% CI [12.03, 13.56], k=10, I² =95.79, Q =213.64, p<.001) or 87.32% of all scheduled sessions (95% CI [82.63, 92.09], k=9, I² =95.4, Q =174.03, p<.001). Participants accessing remote therapies completed a mean of 5.69 steps/modules (95% CI [4.28, 7.1], k=10, I² =98.76, Q =724.35, p<.001) or 75.7% of all scheduled steps/modules (95% CI [60.61, 91.12], k=10, I² =97.73, Q =397.13, p<.001). Due to the use of varied measures of between-session CBT task adherence and a mix of

ITT and completer samples, it was not possible to meta-analyse mean CBT task adherence scores (see descriptive summary below).

There was moderate heterogeneity of study refusal and dropout rates. Sensitivity analyses showed that the pooled rate of refusal (range: 14.7 - 16.5%) and dropout (range: 15.6 - 16.1%) was stable when removing one study per pass. The study estimates for session attendance and module completion were highly heterogeneous, which suggests session attendance and step/module completion were influenced by moderator effects. The mean number (range: 12.7 - 13.6) and percentage of sessions attended (range: 86.7% - 89.1%.) was stable across studies. For remote therapies, the mean number (range: 4.6 - 6.9) and percentage (range: 66.4% - 92.4%) of completed steps/modules was less stable.

2.3.3 Mean between-session CBT task adherence

Table 1 provides an overview of the 14 studies (*k*=20) that reported mean between-session CBT task adherence. Treatments included therapist-delivered (face-to-face) ERP (9), CBT (1) ERP + meds (2), ERP + Placebo (2; pill=1, psychological = 1) and CT (2), and remotely delivered ERP (3; self-help (1), therapist-assisted (2)) and CBT (1, self-help). Thirteen out of 14 studies rated adherence to between-session ERP tasks and one study rated adherence to CT appraisal change exercises such as behavioural experiments and surveys (Whittal, Woody, McLean, Rachman & Robichaud, 2010). Two studies also rated the extent to which participants read ERP self-help materials (Tolin et al., 2007; Tolin, Diefenbach & Gilliam, 2011). Rowa et al. (2007) and Tolin et al. (2011) reported a combined score for within- and between-session task adherence. Five studies rated task adherence at or after the final therapy

session (Abramowitz et al., 2002; Fals-Stewart et al., 1993; Seol et al., 2016; Tolin et al., 2004; Tolin et al., 2007). The remaining nine studies rated task adherence at each session.

Three therapist-rated measures were used in more than one study: i) Patient Exposure Adherence Scale (PEAS) (Simpson, Maher, et al., 2010); ii) Homework Compliance Scale (HCS) (Primakoff, Epstein, & Covi, 1986; Leung & Heimberg, 1996), and iii) Clinician Rated Effort Scale (CRES) (Tolin, Maltby, Diefenbach, Hannan, & Worhunsky, 2004). The PEAS calculates a total score based on an aggregate of participant scores on a 7-point Likert scale for: a) quantity of exposure, b) quality of exposure, and c) degree of ritual prevention. Scores are aggregated across these items for each session, then averaged across all sessions. The PEAS has good content validity and excellent inter-rater reliability ($ICC \ge .97$) (Simpson, Maher et al., 2010). The HCS rates the extent to which participants attempted to complete their assigned ERP tasks on a 6-point Likert scale. It has no reported evidence for its psychometric properties. The CRES is a 5-point Likert scale rating the degree of effort participants put into assigned ERP tasks and, for bibliotherapy, the proportion of assigned reading completed (Tolin et al., 2007, 2011). Tolin et al. (2004) demonstrated good inter-rater reliability for the CRES (r=.82) but other psychometric properties are unknown. Tolin et al. (2011) elaborated on the CRES with the Homework Compliance Rating Form (HCRF), using 6-point Likert scales to score i) the amount of effort participants put into ERP, ii) the time spent on exposure and, iii) the amount of assigned reading completed (bibliotherapy). Both patients and therapists scored the HCRF. See Table D.1 in Appendix D for an overview of anchor points for these scales.

Other measures of adherence included: iv) a therapist-rated 7-point Likert scale of compliance (0 (poor) to 6 (outstanding)) with homework exposure instruction and self-monitoring of rituals (refraining from rituals/accuracy of recording rituals) (Abramowitz, Franklin, Zoellner, & DiBernardo, 2002), v) the number of ERP assignments completed (Vogel, Stiles, & Gotestam, 2004) or uncompleted (Fals-Stewart & Lucente, 1993); vi) participant and/or therapist rated % ERP homework tasks completed (or effort made) (0-100%) (Cottraux et al., 1990; Rowa et al., 2007); vii) patient-rated extent of participation in remote CBT (0-100%) (Seol, Kwon, Kim, Kim & Sin, 2016).

For therapist-delivered treatments (13 studies including 17 treatments (face-to-face =16, videoconference = 1), the results from 5 studies suggest good/above average mean adherence to between-session ERP tasks, based on study authors' interpretation of mean adherence ratings as 'good' (75-90 % good quality task completion with some to minimal compulsions) or 'high' (77-82.5 % task completion) (Cottraux et al.,1990; Goetter et al. 2013; Rowa et al., 2007; Simpson, Zuckoff, et al., 2010; 2013). Three further studies report moderate/average mean adherence, as mean ratings showed patients were 'moderately compliant' and put in 'between some to much' and 'between some to average' effort, respectively (Abramowitz et al., 2002; Tolin et al., 2007; 2011). One study reported poor/below average mean adherence as authors describe patients as putting in 'minimal to some' effort (Tolin et al., 2004). The latter study attributed the relatively poor adherence to their treatment refractory sample of participants with severe OCD, high rates of comorbidity and relatively poor insight. The results from 4 further studies were not entirely clear. Fals-Stewart and Lucente (1993) did not stipulate the number of assigned homework tasks so it was not possible

to calculate the proportion of completed assigned tasks. However, the authors report that participants, who on average missed 3 assigned homework tasks, were compliant. Vogel et al. (2004) also do not report the exact number of assigned tasks but results suggest that mean adherence was at least adequate as on average participants engaged in a total of 17-20 weekly tasks ERP tasks over a 9-week period. Results from studies involving the HCS were also more ambiguous (Whittal et al., 2005; Whittal et al., 2010) as the mean CBT task adherence score represented participants doing 'a portion' of the assigned homework tasks (scale-point 4), without specifying the size of the portion or the quality of exposure (Primakoff et al., 1986). Whittal et al. (2010) did specify that participants did 'most of their assigned tasks each week' (p. 298), which suggests a good degree of adherence. For **self-administered ERP**, mean adherence to CBT tasks was reported by 3 studies and ranged from below average for self-help ERP (Tolin et al., 2007) to moderate adherence for ERP with at least some therapist assistance (Seol et al., 2016; Tolin et al., 2011).

 Table 1

 Descriptive summary of studies measuring mean CBT task adherence.

Adherence Measure	Study	Treatment	M (SD)	Study authors' description***
PEAS (Simpson et al., 2010)	Simpson (2010)	Twice-weekly ERP (<i>N</i> =15)	5.08 (.88) total	Good
7-point Likert scales:			5.37 (.93) quantity	75-90%
Item a) quantity of			5.04 (.97) quality	Good
attempted exposure compared to quantity			4.83 (1.21) ritual	Some to minimal compulsions /safety
assigned (1= 0%, 7=100%)			prevention	aids (between 50-75% response prevention)
Item b) quality of exposures attempted (1=	Simpson (2013)/	Twice-weekly ERP	5.33 (.89) total	Good
refused, 7=excellent)	Wheaton (2016)	augmentation therapy	5.33 (1.14) quantity	75-90%
Item c) degree of ritual prevention (1= refused,		(<i>N</i> =37)	5.34 (.82) quality	Good
7=>90%)			5.30 (.97) ritual	Minimal compulsions/safety
See table D.1, Appendix D for further details			prevention	aids (between 75-90% response prevention)
	Goetter (2013)	Once-weekly remote ERP (video conference)	5.19 (1.13) total	Good
HCS (Primakoff et al., 1986)	Whittal (2005)	Once-weekly CT (<i>N</i> =30)	4.58 (.42)	[4= The patient did a portion of the
6-point Likert scale: 1 = did not attempt the assigned homework, 6 = attempted more than was requested.		Once-weekly ERP (<i>N</i> =29)	4.59 (.43)	assigned homework, 5= the patient did the homework]
HCS (Primakoff et al., 1986) 6-point Likert scale: 0 =	Whittal (2010)	Once-weekly CT (<i>N</i> =37)	3.50 (.95)	'did most of their assigned tasks each week' (p.298)
did not attempt the assigned homework, 5 = attempted more than was requested.				[3= The patient did a portion of the assigned homework, 4= the patient did the homework]
CRES (Tolin et al., 2004)	Tolin (2004)	Once-weekly ERP (<i>N</i> =15)	1.61 (1.20)	Minimal to some effort
5-point Likert scale (0=made no effort to do	Tolin (2007)	Once-weekly ERP (<i>N</i> =17)	2.76 (1.15)	Between some and much effort
ERP; 4=put their best effort into ERP)		Self- administered ERP	1.50 (1.15)	minimal to some effort
For remote ERP: therapist considered amount of book read, frequency and		(bibliotherapy) (N=17)		

1				
duration of exposure				
exercises and degree of				
effort to abstain from				
compulsive behaviours.	T. II. (2011)	G 10	2.54 (.54)	/ G
Homework Compliance	Tolin (2011)	Self-	2.54 (.71)	'Some' to 'average'
Rating Form (Tolin et al.		administered	overall effort	effort
2011).		ERP	(therapist)	
		(bibliotherapy,	2.99 (1.01)	'Average' amount of
6-point Likert Scales: i)		<i>N</i> =18)	overall effort	effort
amount of effort put in			(participant)	
(0=no effort, 5=best			3.48 (1.34)	'Half' to 'most 'read
effort), ii) time spent on			reading	
daily self-exposure			(participant)	
(0=none, 5=more than 2			2.08 (1.11)	30-60 mins. daily
hours), iii) reading :			time spent	self-exposure
amount of the book read			(participant)	
(0=none, 5=all)		Once-weekly	2.56 (.87)	'Some' to 'average'
		ERP (<i>N</i> =22)	overall effort	effort
			(therapist)	
			2.88 (.95)	60-90 mins daily self-
			time spent	exposure
			(participant)	•
			3.41 (.77)	'Average' to 'a lot'
			amount of	S
			effort	
			(participant)	
7-point Likert Scale (0 =	Abramowitz	Twice-weekly	3.56 (1.93)	Moderately compliant
poor, $6 = outstanding$)	(2002)	to intensive	(Homework	, , , , , , , , , , , , , , , , , , ,
rating compliance with: i)	,	ERP (<i>N</i> =28)	exposure)	
patient understanding of		(/	· · · · · · · · · · · · · · · · · · ·	
treatment rationale (not				
reported here), ii)			(2.20 (1.72)	-
compliance with in-			(3.30 (1.73)	
session exposure			Self-	
instruction (not reported			monitoring	
here), iii) compliance with			of rituals)	
homework exposure				
instruction, iv)				
compliance with self-				
monitoring of rituals				
Non-compliance =	Fals-Stewart	Twice-weekly	2.9 (2.1)	Compliant. On
number of homework	(1993)	ERP for 12	2.7 (2.1)	average, participants
assignments (ERP) that	(1775)	weeks (24		did not complete
were not completed.		session total)		almost 3 assigned
Based on patient logs.		(N=121)		homework tasks.
Completion = daily		(11-121)		nome work tasks.
Completion – dally				
practice at least once a				
practice at least once a				
day and no compulsions				
day and no compulsions for at least 1 hour after				
day and no compulsions for at least 1 hour after exposure	Vogel	Once wealth	17.2 (10)	At least 19
day and no compulsions for at least 1 hour after exposure Number of home exposure	Vogel	Once-weekly	17.3 (10)	At least 18
day and no compulsions for at least 1 hour after exposure Number of home exposure exercises completed.	Vogel (2004)	CBT (ERP +	17.3 (10)	assignments were set
day and no compulsions for at least 1 hour after exposure Number of home exposure exercises completed. (Minimum of 2 tasks after	•	•	17.3 (10)	assignments were set and on average 17
day and no compulsions for at least 1 hour after exposure Number of home exposure exercises completed. (Minimum of 2 tasks after each session (sessions 3-	•	CBT (ERP + CT) (<i>N</i> =15)		assignments were set and on average 17 tasks were completed
day and no compulsions for at least 1 hour after exposure Number of home exposure exercises completed. (Minimum of 2 tasks after	•	CBT (ERP + CT) (N=15) Once-weekly	17.3 (10) 20.6 (7.2)	assignments were set and on average 17 tasks were completed At least 18
day and no compulsions for at least 1 hour after exposure Number of home exposure exercises completed. (Minimum of 2 tasks after each session (sessions 3-	•	CBT (ERP + CT) (<i>N</i> =15)		assignments were set and on average 17 tasks were completed

		(relaxation) (N=10)		and on average 20 tasks were completed
Percentage of completed homework tasks	Cottraux (1990)	Once-weekly ERP + meds (<i>N</i> =16)	70%	Good compliance
		Once-weekly ERP + Pla (<i>N</i> =15)	78%	-
0-100% scale (0= 'I did not try at all or I did not complete any of the exercises', 100 = 'I gave the exercise a 100% effort	Rowa (2007)	Twice-weekly ERP in clinic (N=8-9)	77% (average of client and therapist rating)	High
and I completed exercise as discussed') applied to both within- and between- session ERP		Twice-weekly ERP at home (<i>N</i> =9-11)	82.5% (average of therapist and client rating)	-
Extent of participation on 0-100% scale	Seol (2016)	Remote CBT (minimal therapist contact) (<i>N</i> =27)	67.9% (17.16)	'participated relatively hard' (participant-rated)

Note: * T=Therapist, P = participant; ** S= sessional, PT= post-treatment/final session, C = completer sample, ITT = intention-to-treat sample, ***primary study authors

2.3.4 Stage of dropout

Twenty-four studies reported the stage of dropout, coded as early (after sessions 1-5) or late (after session 6). Across studies, 690 participants started CBT treatment and 130 dropped out. Treatments included ERP (12), CBT (11), CT (3) and ERP + meds (2). The pooled risk ratio (RR) was **2.45** (95% CI [1.38, 4.35], k=28, z=3.044, p=.002; I² = 31.39, Q (27) = 39.35, p =.06) towards early dropout (see Appendix E for the forest plot).

2.3.5 Moderators of adherence

There were no significant categorical **moderators of refusal**; treatment and study design characteristics did not predict refusal (see Table F.1 in Appendix F). As studies did not include patients refusing participation in their reported

sociodemographic and clinical sample characteristics, it was not possible to conduct a meta-regression with these variables.

There was just one significant moderator effect for dropout (see Table F.2 in Appendix F). The dropout rate for group therapy (12.9%, 95% CI [10.0, 16.6], k=23, I² = 18.36, Q=28.17, p=.17) was significantly lower (Q=4.28, p=.039) than for individual face-to-face therapy (17.3%, 95% CI [15.4, 19.4, k=99, I² = 38.36, Q=158.99, p<.001). Meta-regression showed that none of the pre-determined socio-demographic (age, gender, ethnicity, educational attainment, employment and marital status) or clinical variables (OCD, depression and anxiety symptom severity, OCD duration, rates of Axis 1 comorbidity, major depression, medication and prior CBT) of treatment starters were significant moderators of dropout (see Table F.3 in Appendix F).

There were too few cases (in each subgroup) to conduct moderator analyses of mean number and % session attendance and/or module completion (Borenstein et al., 2009). As mean CBT task adherence could not be meta-analysed it was also not possible to test moderator effects.

2.3.6 Reasons for non-adherence

Reasons for refusal were reported by just 8 of the 26 uncontrolled studies for which refusal rates were established. Reasons for refusal were given for a total of 29 participants. Treatment conditions included ERP (3), CBT (4), ERP + medication (1). Therapies were delivered individually (2), in a group (3), couple (1) and remotely with therapist assistance (2).

Forty-one (controlled: 24, uncontrolled: 17) of the 111 primary studies contributing to the pooled dropout rate provided reasons for 211 dropouts. A total of 50

treatments included CBT (21), followed by ERP (13), ERP + medication (6), CT (5), CBT + medication (2), ERP + Placebo (2) and CT + medication (1). Studies involved therapist-delivered individual (27), group (12), family (1), couple (1) and a combination of group and individual (1) therapy. Remote, internet-based therapist-assisted (7) and self-help (1) therapies were also included.

For each included study, reported reasons for refusal or dropout were recorded together with the number of participants the reason applied to. The frequencies for semantically identical reasons were totalled across studies and grouped into different low-level categories, e.g. 'preferred to wait for individual therapy' and 'did not want group therapy' were grouped together under 'did not want group treatment (preferred individual therapy)'. These low-level categories were grouped together under higher-level categories, e.g. refusal due to 'treatment type and format'.

Table 2 reports the total number and proportion of participants (out of 29) to which each refusal reason and category applied. Results show that within this small group of 8 studies, not having one's treatment preferences met was the most common reason for refusal (79%), particularly participants not wanting to take part in group therapy (41%) or rejecting ERP (21%).

Table 3 provides an overview of the reasons for dropout. The most common reason was low motivation or a lack of engagement (28%). For 14% of the participants, feeling too anxious about ERP or a reluctance to engage with (further) ERP was specifically listed as the reason for dropout. The second most common reason for dropout was (adverse) life-events (13%), followed by practical barriers (11%). A (perceived) lack of improvement/benefit, patient dissatisfaction with treatment and/or

wish for different treatment, together accounted for 14% of dropout. Just over 4% of dropout was due to symptom improvement.

 Table 2

 Summary of reasons given for refusal (aggregated across studies)

Categories (N, %)	Reason	N(%)
Treatment type and format	Did not want group treatment/preferred to	12
(23, 79.3)	wait for ind. therapy	(41.4)
	Rejected ERP	6 (20.7)
	Wanted face-to-face sessions	2 (6.9)
	Preferred group treatment	2 (6.9)
	Rejected computerized treatment programme	1 (3.4)
Comorbidity	Wanted/needed treatment for comorbid	2 (6.9)
(3, 10.3)	conditions	
	Too anxious to participate (due to other	1 (3.4)
	anxiety problems)	
Practical barriers (3, 10.3)	Too far/long to travel to clinic	1 (3.4)
	Moved out of area	1 (3.4)
	Sought treatment elsewhere	1 (3.4)
Total	·	29

N=number of patients to which reason applied, %=percentage of patients (out of 29) to which reason applied.

 Table 3

 Summary of reasons given for dropout (aggregated across studies)

Category (<i>N</i> , %)	Reason	<i>N</i> (%)
Lack of engagement	Did not wish to engage (further) in ERP	25
(60, 28.4)		(11.8)
	Low/lack of motivation*	23
		(10.9)
	Noncompliance**	7 (3.3)
	Too anxious about exposure	5 (2.4)
Life events (27,12.8)	Adverse life events (incl. medical	16 (7.6)
	illness)	
	Moved out of area	7 (3.3)
	Pregnancy	4 (1.9)
Practical barriers	Too little time to participate/work	20(9.5)
(24,11.4)	commitments	
	Too far/long to travel to clinic	3 (1.4)
	Technical problems (remote therapies)	1 (.5)
No longer meets eligibility	Stop/start medication	18 (8.5)
criteria (23,10.9)	alcohol misuse, change in diagnosis	5 (2.4)
Deterioration in mental health	Deterioration in mental	21 (10)
(21,10)	health/suicidality (requiring treatment)	
Medication (18,8.5)	Medication/placebo side effects	12 (5.7)
	Medication side-effects and/or	6 (2.8)
	noncompliance	
Lack of improvement (16, 7.6)	Lack of improvement	7 (3.3)
-	Patient reports treatment ineffective	5 (2.4)
	Limited benefit	4 (1.9)
Dissatisfaction with	Wants more intensive treatment (than	3 (1.4)
treatment/wish for different	remote therapy)	
treatment	Wants to pursue	1 (.5)
(13, 6.2)	psychopharmacological treatment	
	Treatment no longer corresponded to	2 (.9)
	patient goals	
	Not willing to continue group therapy	1 (.5)
	No longer wants treatment	3 (1.4)
	Doesn't feel ready to change	1 (.5)
	Treatment too emotionally burdensome	1 (.5)
	Dissatisfied with treatment	1(.5)
Symptom improvement	Treatment no longer required due to	9 (4.3)
(9, 4.3)	symptom improvement	
Total		211

Note: * ERP (+/- medication/placebo) ** ERP + meds (n=20), CT (n=2), CBT (n=1), N=number of patients to which reason applied, %=percentage of patients (out of 211) to which reason applied

2.3.7 Association of CBT task adherence with post-treatment OCD symptom reduction

2.3.7.1 *Face-to-face therapies*

Table 4 provides a descriptive summary of 7 studies (including one study reporting findings for therapist-delivered and self-help ERP combined (Tolin et al., 2007)) that tested the association between CBT task adherence and post-treatment OCD symptom severity. Studies used a range of task adherence measures and types of correlation (i.e. bivariate, partial and semi-partial), making it inadvisable to pool effect sizes (Aloe & Thompson, 2013). All 7 studies report a significant medium to large association of between-session CBT task adherence with post-treatment OCD symptom reduction.

Three studies also considered the relationship between CBT task adherence and post-treatment OCD symptom remission (Mataix-Cols et al., 2016). Simpson and colleagues (2011) showed that participants needed to achieve a mean total PEAS score of at least 5.6 (i.e. a minimum of 75-90% good quality adherence to between-session ERP tasks as assigned and with minimal to no compulsions or safety aids) to achieve OCD symptom remission post-treatment. Wheaton, Galfalvy, et al. (2016) furthermore showed that when the three sub-scales of the PEAS were considered, i.e. a) quantity of exposure, b) quality of exposure, c) degree of success with response prevention or percentage resisted urges to ritualise, only item c was independently and positively associated with post-treatment OCD symptom severity and increased odds for achieving post-treatment remission. Abramowitz et al. (2002) also found that patients who achieved remission were significantly more adherent to between-session ERP task assignments and had a better understanding of the treatment rationale than those who

did not. However, the authors used a Y-BOCS cut-off score of \leq 16 to define remission rather than the recommended score of \leq 12 (Mataix-Cols et al., 2016). Therefore, as some patients may not in fact have been in remission, these results need to be considered with caution.

Table 4Descriptive summary of studies of therapist-delivered therapies examining the association of between-session task adherence with post-treatment OCD symptom reduction

Task adherence measure	Study	Treatment	Outcome measure	N	Type of Effect	ES value
HCS	Goodwin et al. (2002)	Daily/twice weekly ERP combined	Post- treatment Y- BOCS score	28 (ITT)	pr (a)	61**
	Whittal et al. (2005)	ERP + CT samples combined	Post- treatment Y- BOCS Score	58 (C)	pr (a)	40**
CRES	Tolin (2004)	ERP	% reduction post- treatment Y- BOCS score	15 (C)	r	.53*
	Tolin et al. (2007)	Self-administered and therapist-administered ERP combined	% reduction post- treatment Y- BOCS score	34 (C)	r	.50**
PEAS	Simpson et al. (2011)	Twice-weekly ERP + ERP-MI combined (no sig. difference in adherence/outcomes)	Post- treatment Y- BOCS score	25 (C)	sr(a)	70***
(TOTAL)	Wheaton et al. (2016), using Simpson et al. (2013) data	Twice- weekly ERP	Post- treatment Y- BOCS score	37 (C)	sr(a)	56***
% completed exposure tasks (in week 1)	De Araujo et al. (1996)	Weekly (in vivo ± imaginal) ERP	Target obsession change score	46 (C)	r	.33

Note: Y-BOCS = Yale-Brown Obsessive-Compulsive Scale, HCS=Homework Compliance Scale, CRES= Clinician Rated Effort Scale, PEAS = Patient Exposure Adherence Scale, ITT= intention to treat sample, C= completer sample, ES= effect size, a = controlled for baseline Y-BOCS /baseline Y-BOCS entered in step 1, pr = partial correlation, sr = semi-partial correlation, * p<.05, ** p<.01, *** p<.001

2.3.7.2 *Remote therapies*

Six studies of remote therapies tested the relationship between the number of completed exposure tasks and post-treatment OCD symptom reduction, measured by the Y-BOCS. All studies involved the BT-STEPS programme, delivered via a web-based format (Diefenbach, Wootton, Bragdon, Moshier, & Tolin, 2015; Kobak et al., 2015) or interactive voice response system (Bachofen et al., 1999; Greist et al., 1998, 2002; Kenwright et al., 2005). The BT-STEPS programme consists of 9 steps; the first 3-4 involve self-assessment, the remainder self-treatment. Within the latter phase, ERP sessions can be completed as many times as needed.

To meta-analyse the relationship between task adherence and post-treatment OCD symptom reduction, effect types other than correlations were converted into correlations using standard formulae (e.g. Borenstein et al., 2009). Diefenbach et al. (2015) was not included in the meta-analysis as it measured adherence differently, rating the highest step (out of 9) rather than the number of ERP tasks completed.

There was a medium positive association between the number of ERP tasks/remote sessions completed and post-treatment OCD symptom reduction: r = .39 (95% CI [.23, .52], k=5, z= 4.66, p<.001; P=31.9, Q(4) = 6.67, p = .16) (see Appendix G for forest plot). The correlation was reasonably stable (range: .34 - .43) when removing one study per pass. Heterogeneity of study estimates was small to moderate.

2.3.8 Publication bias

There was no significant potential publication bias for the CBT refusal rate as Egger's intercept test indicated the funnel plot asymmetry was not significant. For dropout, Egger's intercept test shows significant funnel plot asymmetry (Intercept: -

1.88, t=8.36, p <.001), indicating a potential publication bias towards excluding smaller studies with larger dropout rates. The trim-and-fill method showed that 52 study treatments should be trimmed to achieve an adjusted higher dropout rate of 21.6% (95% CI [20.3, 23]). Too few studies contributed to the mean number and percentage of completed sessions or modules and to the association between remote ERP and post-treatment symptom reduction to consider publication bias (Borenstein et al., 2009, Sterne, Egger & Moher, 2011).

2.4 Discussion

This meta-analysis found refusal and dropout rates of 15.6% and 15.9% respectively, suggesting that over 30% of eligible patients who are recommended CBT for OCD fail to initiate or complete treatment. Whilst a pooled refusal rate for CBT for OCD has not previously been reported, the dropout rate is consistent with two earlier meta-analyses of studies evaluating CBT for OCD (Öst et al, 2015; Swift & Greenberg, 2012). The risk of early dropout was 2.5 times greater than for late dropout. As early rather than late dropout appears to be related to poor outcomes (Aderka et al., 2011), it suggests most patients who drop out from CBT for OCD are unlikely to have experienced clinically significant benefit. Indeed, the examination of reasons for dropout showed that dropout was rarely due to clinically significant symptom improvement. This reinforces the need to better understand and address the risk of refusal and (early) dropout from CBT for OCD.

This meta-analysis failed to find any significant moderators of refusal to inform our understanding of potential risk factors of refusal of CBT for OCD. Although refusal rates were not significantly higher for group than individual CBT, the exploration of

reasons for refusal carefully suggests that a mismatch between patient preference and the treatment on offer, particularly when the treatment is group CBT, may affect patients' opt-in to therapy. Feelings of unease or shame or comorbid social anxiety may contribute to a reluctance to engage in group therapy, or perhaps participants anticipated insufficient individually tailored treatment within a group setting. As dropout was significantly lower for group than individual therapy, it suggests that the group format may enhance adherence once participants commence therapy, e.g. being with other patients with OCD might help to normalise difficulties and support participants during challenging times in therapy. However, this finding could reflect a selection bias; e.g. group CBT participants may be more motivated or less (socially) anxious than participants in individual CBT. We would therefore urge caution in drawing the conclusion the group CBT is inherently more engaging than individual CBT.

The examination of patient reasons for nonadherence lends some support to the notion that negative perceptions of CBT and a lack of satisfaction or perceived benefit from therapy may contribute to treatment refusal and dropout (Mancebo et al., 2011). Interestingly, a sizeable portion of dropout was due to patients violating research eligibility criteria, e.g. changes in medication. This would typically not require withdrawal from CBT in routine clinical settings.

This review did not find a significant difference in dropout for different types of CBT (i.e. ERP, CBT, CT), which is consistent with other meta-analyses (Ong et al. 2016; Öst et al., 2015; Swift & Greenberg, 2014). Also, whilst one would assume that participants are more likely to stay motivated in therapy with increased therapist support, dropout from remote therapies was not significantly higher than for face-to-face therapies and therapist assistance in remote therapies did not moderate dropout

from remote therapies. Therapist experience also did not affect dropout, which mirrors results from a meta-analysis of dropout from ERP (Ong et al., 2016).

Results suggest that, on average, participants who completed face-to-face CBT received a therapeutic 'dose' of therapy, commensurate with US and UK practice guidelines (APA, 2007; NICE, 2005). However, results were highly heterogeneous and a significant number of treatment completers may not have received the recommended minimum 13 sessions; studies did not report the data needed to examine this further. Session/module completion for remote therapies appeared lower than for therapist-delivered therapies but, as most remote therapy studies reported figures for ITT rather than completer samples, a direct comparison was not possible.

This review showed a consistent medium to large significant association between CBT task adherence and post-treatment OCD symptom reduction, in line with previous research into the association of homework with outcomes for CBT for a range of psychological disorders (e.g. Kazantzis et al., 2016). Most studies of CBT task adherence reported that adherence was at least satisfactory. However, as between-session task adherence likely needs to be high to achieve post-treatment OCD symptom remission (e.g. Simpson et al., 2011), this may not necessarily be adequate (Mataix-Cols et al., 2016).

2.4.1 Strengths and limitations

To the best of our knowledge, this is the first comprehensive systematic review of the magnitude, moderators and reasons for poor adherence to CBT for OCD. It included a larger number of studies than previous meta-analyses of refusal and dropout (e.g. Ong et al., 2016; Öst et al., 2015; Swift & Greenberg, 2015) and considered both

controlled and uncontrolled studies. This review adopted a wider focus on adherence by examining session attendance, module completion and between-session task adherence and reasons for non-adherence. By adopting a broad search strategy, it highlighted findings that were not necessarily foregrounded in study titles or abstracts. The large number of included studies allowed the examination of a range of moderators of refusal and dropout.

Whilst a broad range of moderators were included, potentially important moderators may have been missed and some moderator analyses may have been underpowered. The quality of the included studies was not formally assessed. However, as quality assessment tools typically assess study features pertinent to a potential bias in effect sizes for therapy outcomes, they were not directly relevant to the current review (e.g. Jadad et al., 1996; Öst et al., 2008; Schulz, Altman, & Moher, 2010).

This review attempted to include studies reflective of real-life settings by including uncontrolled studies and examining the moderating effect of the sample's clinical representativeness. However, other features of effectiveness studies were not coded for (e.g. absence of manualised treatment, additional supervision) (Hans & Hiller, 2013)) and only published papers were included. The current refusal and dropout rates might therefore not adequately reflect attrition in routine clinical settings. For example, Di Bona and colleagues (2014) found that 48% of respondents referred to Improving Access to Psychological Therapy (IAPT) services that routinely treat patients in England with common mental health difficulties including OCD, reported not attending the service. Richards and Borglin (2010) showed that, over a three-year period, 23% of IAPT patients dropped out of treatment. Attrition from CBT for OCD in routine settings may therefore be higher than the current rates suggest.

Many studies reported a two-step eligibility check; an initial (telephone) screening for eligibility, followed by face-to-face assessment to confirm the OCD diagnosis and severity of symptoms. Often a considerable number of patients met the inclusion criteria at telephone screening but disengaged prior to the confirmation of their eligibility following clinic-based assessment (when the refusal rate was calculated). This suggests that the current refusal rate is probably a conservative estimate. Reasons for refusal and dropout were based on a small subset of studies and may not adequately represent reasons for dropout for all studies included in the aggregation of refusal and dropout rates.

The reported mean dropout rate was affected by a potential publication bias; the trim-and-fill test proposed an upwardly adjusted dropout rate (21.6%). Whilst small studies may have lower dropout rates associated with study design characteristics, the latter did not significantly moderate dropout. Alternatively, smaller studies were perhaps more often excluded due to ambiguous reporting on dropout. However, in that case, a small study absence would be observed at both the low and high end of study dropout. It is therefore possible that smaller studies with higher dropout rates are indeed less likely to be published.

Studies spanned a period of more than 30 years, during which conceptual and technical aspects of ERP and CT have evolved (e.g. Jacoby & Abramowitz, 2016; Sookman, 2016). This means that studies of the same type of intervention (i.e. ERP, CBT, CT) may not have been directly comparable and, together with the fact that there is considerable procedural overlap between these three treatment types (Abramowitz, Taylor, &McKay, 2005), limits the conclusions that can be drawn from testing treatment type as a moderator of patient adherence.

There were several limitations of the primary studies. Fifty percent of excluded full-text articles were discarded as they did not (clearly) report attrition data. Few of the 123 included studies reported on CBT task adherence. This is surprising, given the central importance attributed to participants practising therapy tasks between sessions for the success of CBT. The variability in the (quality of) measurement and reporting of CBT task adherence for face-to-face therapies made it impossible to pool study data.

2.4.2 Clinical implications

Therapists should elicit and address any concerns and misconceptions patients have about CBT, and ERP in particular, at the earliest opportunity, i.e. during the patient's initial assessment, perhaps with the aid of accounts from patients who have successfully completed therapy (using vignettes, audio or video material). Also, patients should ideally have a choice about their preferred treatment format.

It would benefit patients to know that there is a significant relationship between task adherence and OCD symptom reduction and that recovery is more likely when task engagement is high. As is good clinical practice, therapists need to make sustained efforts (early on) to maximise patient engagement with key therapy tasks. It is also important to assess psychological factors such as patients' degree of insight into their OCD symptoms and motivation for treatment (e.g. Bachofen et al., 1999; De Araujo et al., 1996; Tolin et al., 2004). Whilst Simpson, Zuckoff, et al. (2010) found that adding motivational interviewing to CBT did not enhance adherence, this was in a context of high patient engagement and therefore motivational interviewing may still have a role to play with patients showing poor motivation. Therapists should achieve a clear agreement with the patient on the tasks of therapy as Wheaton, Huppert, et al. (2016)

found that this predicted greater adherence to between-session exposure tasks. As some studies show that task adherence predicted therapy outcomes early on in therapy (Simpson et al., 2011; De Araujo, Ito & Marks, 1996), any difficulties and misconceptions about between-session therapy tasks should be addressed at the earliest opportunity and clinicians should consider offering additional support, e.g. offering between-session phone-calls, increasing session frequency and/or including home visits, at this stage. Within the context of remote therapies, it would be advisable to build in (more) therapist assistance when patients first commence self-exposure, as this may enhance task adherence (e.g. Tolin et al., 2007). Wheaton, Galfalvy et al. (2016) show that the degree to which patients engage successfully in response prevention, rather than exposure per se, was predictive of post-treatment symptom reduction. Therefore, clinicians reviewing between-session ERP need to gain a clear understanding of patients' degree and quality of response prevention during between-session ERP.

2.4.3 Research implications

We recommend that studies of CBT for OCD routinely report refusal and dropout rates and consistently distinguish patient- from clinician/researcher-initiated dropout, to aid research into predictors of patient-initiated dropout. Reasons for refusal and dropout should also be reported, aided by formal therapy adherence measures (e.g. Mancebo, Pinto, Rasmussen & Eisen, 2008). Qualitative, interview-based studies will enable a more in-depth understanding of reasons for non-adherence than a simple tally of refusal or dropout reasons. Enhanced within-study data on differences in sociodemographic and clinical characteristics between eligible patients, refusers, treatment completers and dropouts would enable pooling within-study data to inform

our understanding of whether participant-level sociodemographic and clinical variables can predict non-adherence. More research is needed on whether psychological variables, such as participants' beliefs about their mental health difficulties and mental health services, expectations of and motivation for treatment predict non-adherence (Santana & Fontenelle, 2011; Taylor, Abramowitz, & McKay, 2012; Wierzbicki & Pekarik, 1993). The relationships between the client-therapist relationship and patient adherence is also an area for further research (Simpson et al., 2011; Wheaton, Huppert, Foa, & Simpson, 2016). An examination of group dynamics and peer relationships, in the context of group CBT, would also aid our understanding of whether and how peer support benefits patient adherence.

The effect of different types of CBT (ERP, CT, CBT) on patient adherence requires further investigation, taking account of the conceptual and technical evolvement of these treatments over time. It would also be helpful to examine whether the way in which ERP tasks are completed, i.e. in a gradual, hierarchical manner (as informed by emotional processing theory (Foa & Kozak, 1986)) or a random, variable manner (as informed by inhibitory learning theory (Jacoby & Abramowitz, 2016)), affects patient dropout, sessions attendance and task adherence.

The OCD research community should also aim to routinely report on task-adherence. It would benefit research in this area if researchers use the same measure of adherence to allow direct comparison between studies. We would recommend the PEAS (Simpson, Maher, et al., 2010) as this is a measure of ERP task adherence that has already been used in multiple studies and it separately scores the degree of exposure and of response prevention and also captures the quality of exposure. This measure could be developed further, based on a shared understanding of the key features of well-designed

exposure tasks that maximise exposure gains, e.g. informed by recent research on inhibitory learning theory (Craske, Treanor, Conway, Zbozinek, & Vervliet 2014), and markers of successful adherence (e.g. Wheaton, Galfalvy, et al., 2016). Further research is needed to establish a suitable measure of adherence to other CBT tasks, e.g. cognitive restructuring, behavioural experiments, in the context of OCD. More objective measures of adherence, e.g. blind rating of video recordings of within- or between-session ERP, would enhance research in this area. Also, using apps to help patients record home practice might benefit self-report. Whilst CBT task adherence is an important predictor of OCD symptom reduction, without repeatedly measuring both over the course of treatment, it is not possible to firmly establish the direction of this relationship.

Consistent application of agreed criteria for symptom remission (e.g. Farris, McLean, Van Meter, Simpson, & Foa, 2013) is also needed to advance our understanding of the role of patient adherence in symptom remission and longer-term recovery (Mataix-Cols et al., 2016). These are important areas of research to inform how best to achieve a high degree and quality of adherence to CBT for OCD for the benefit of patients.

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Conflict of Interest

All authors declare that they have no conflict of interest.

Chapter 3: A thematic analysis of barriers and facilitators to patient engagement in group Exposure and Response Prevention Therapy for Obsessive Compulsive Disorder

Abstract

Exposure and response prevention (ERP) is the gold standard in the treatment of obsessive-compulsive disorder (OCD). Nonetheless, a sizeable proportion of patients do not experience OCD symptom remission following ERP. Research suggests that patient engagement with ERP tasks predicts therapy outcomes, but little is known about barriers and facilitators of patient engagement to develop a targeted approach to improving engagement. There is a lack of consistent quantitative evidence linking patient, therapy or social environmental characteristics to patient engagement whilst qualitative studies of patient engagement are few and far between. ERP can be delivered in an individual or group format, with the latter having the potential to increase patient access to therapy. Meta-analyses suggest that group ERP is as effective as individual ERP and has a comparatively lower dropout rate. This study conducted a qualitative exploration of what helps or hinders patients' engagement in group ERP. It involved a thematic analysis of Change Interviews data collected at six-month follow-up from 15 adults with OCD who participated in group ERP. The study identified five main themes that captured participants' perceived facilitators and barriers to engagement in therapy: 'understanding how to overcome OCD', 'personal relevance', 'group processes', 'patient attitudes towards ERP' and 'personal circumstances', which captured dynamically inter-related barriers and facilitators at the level of the client, therapist, therapy and social environment. Each theme, and associated sub-ordinate themes, was discussed in turn, followed by a consideration of the limitations and implications of the study.

Keywords: Obsessive-Compulsive Disorder (OCD), Exposure and Response Prevention (ERP), thematic analysis, patient engagement, barriers, facilitators

3.1 Introduction

3.1.1 Background

Obsessive-compulsive disorder (OCD) is a debilitating mental health condition, characterised by recurring intrusive thoughts, images or urges that cause significant distress or anxiety, and repetitive physical behaviours or mental acts aimed at preventing anticipated adverse consequences and alleviating distress (American Psychological Association [APA], 2013; Torres et al., 2007). Exposure and response prevention (ERP) is a form of behaviour therapy that requires patients to engage in repeated, prolonged exposure to obsessions whilst refraining from compulsions. This is purported to break the vicious cycle of OCD through a process of habituation (Kozak & Foa, 1986) and/or inhibitory learning (Craske, Treanor, Conway, Zbozinek, & Vervliet, 2014). ERP delivered with or without added cognitive therapy (CT) strategies, is the psychological therapy of choice for OCD (e.g. APA, 2007; NICE, 2005), however, a recent meta-analysis found that 35% of patients experienced no discernible change in OCD symptoms following ERP whilst approximately 50% did not achieve remission (Öst, Havnen, Hansen, & Kvale, 2015).

ERP is anxiety-provoking by design and often perceived as a challenging therapy (e.g. Olatunji, Deacon, & Abramowitz, 2009). Therefore, the moderate response rate for ERP may reflect variable patient engagement. Patient engagement can be operationalised as: 1) consistent attendance, 2) completing therapy on time, 3) active participation in-session, 4) conducting in-between-sessions tasks, 5) developing and maintaining an effective patient-therapist relationship, and 6) developing and

maintaining supportive, helpful interactions with other participants (Tetley, Jinks, Huband, & Howells, 2011).

Research suggests ERP dropout, i.e. a patient starts but does not complete therapy, is approximately 15-19 % (Leeuwerik, Cavanagh, & Strauss, 2019; Ong et al., 2016; Öst et al., 2015). Whilst relatively modest, the fact that (early) dropout from ERP for OCD is associated with poor outcomes (e.g. Aderka et al., 2011) suggests that it is important to understand and address it. Participation in daily between-session ERP tasks is considered crucial to consolidate learning and maximise treatment effects, e.g. through facilitating re-appraisal of feared outcomes without the (safety of the) presence of the therapist (Franklin, Huppert, & Ledley, 2005). This is supported by research showing that a high degree (and quality) of patient adherence to between-session ERP tasks is required to achieve OCD symptom remission (Abramowitz, Franklin, Zoellner, & DiBernardo, 2002; Simpson et al., 2011; Wheaton et al., 2016).

NICE (2005) recommends guided self-help, group and individual ERP interventions as part of a stepped care approach to treating OCD. Group ERP, delivered with or without cognitive strategies, appears as effective as individual ERP therapy (e.g. Öst et al. 2015) and has the potential to increase patient access to treatment, provided patients feel able to engage in it. A recent meta-analysis of 123 studies found a significantly lower dropout rate for group Cognitive Behavioural Therapy (CBT) (13%) (all types: ERP, CT and CBT, which combined ERP with CT) than individual CBT (17%) for OCD (Leeuwerik, Cavanagh, & Strauss, 2019). This review showed that little was known about the magnitude of patient engagement in within- and between-session ERP tasks in group ERP.

A better understanding of the barriers and facilitators of client engagement in group ERP, including whether the group format benefits engagement, could help inform a targeted approach to improving patient engagement (Barrett, Chua, Crits-Christoph, Gibbons, & Thompson, 2008). However, although Kobak, Rock and Greist (1995) theorised early on that the group format may facilitate engagement, quantitative research to date has failed to establish unequivocally what enables and hinders patient engagement with ERP therapy in general and group ERP in particular (Knopp, Knowles, Bee, Lovell, & Bower, 2013; Leeuwerik, Cavanagh, & Strauss, 2019; Olatunji, David, Power, Smits, 2013). Therefore, qualitative studies are well-suited to identify (relationships between) potential predictors to benefit a more theory-driven approach to examining and addressing engagement in group ERP (Tetley, Jinks, Huband, & Howells, 2011; Bryant et al., 2012).

Existing qualitative studies of patients' experience of ERP suggest that a number of individual, interpersonal, therapy specific and extra-therapeutic factors may influence engagement (Bevan, Oldfield, & Salkovskis, 2010; Lee & Rees, 2011; Marsden, Teahan, Lovell, Blore, & Delgadillo, 2018), but no previous research has offered an in-depth consideration of the obstacles and facilitators of (the process of) engagement in group ERP that could contribute to our understanding of how to improve engagement in group ERP to benefit outcomes for patients.

3.1.2 Aims and objectives

This study aimed to understand perceived barriers and facilitators of engagement in group ERP for OCD, through a thematic analysis of semi-structured interview data

collected at six-month follow-up from 15 adults with OCD who had participated in group ERP.

3.2 Methods

3.2.1 Design and procedure

Study data was collected as part of a pilot RCT comparing group ERP (n = 18) to mindfulness-based ERP (MB-ERP) (n = 19) therapy for OCD (Strauss et al., 2015; 2018). A lived experience advisory panel consulted on the development and implementation of the pilot RCT, which received full ethical approval through the South East Coast (Surrey) arm of the National Research Ethics System in the UK (reference: 13/LO/1768).

All pilot RCT participants were invited to participate in a semi-structured interview at six-month follow-up. The current study reports on the qualitative analysis of the interview data from group ERP participants. All interviews, ranging from 30-60 minutes, were conducted on NHS premises by a research assistant and were audio-recorded. The interviews were transcribed verbatim and anonymised by the first author.

3.2.2 Participants

Participants in the pilot RCT were recruited from an NHS mental health trust in the South of England. The inclusion criteria were: i) 18 + years of age; ii) met DSM-IV diagnostic criteria for OCD (APA, 1994) based on the Mini International Neuropsychiatric Interview [MINI 6.0.0] (Sheehan et al., 2010); iii) if on psychiatric medication, stable dosage for a minimum of 3 months prior to starting therapy; iii) no plans to change psychiatric medication during the study; and iv) had not received any

psychological therapy in the three months before the current study, nor planned to engage in psychological therapy during the study. Exclusion criteria were: i) identified organic cause for OCD symptoms; ii) a diagnosed learning disability, psychotic disorder, post-traumatic stress disorder, anorexia nervosa, alcohol dependence or substance addiction; iii) hoarding-only compulsions (see Strauss et al., 2015; 2018 for further details). Fifteen of the 18 participants randomly allocated to the ERP condition completed the semi-structured interview. They all had a diagnosis of OCD at the start of treatment (as above). Mean depression severity of the sample was in the moderate range (M=27.80, SD=14.37), as measured with the Beck Depression Inventory-Second edition (BDI-II) (Beck, Steer, & Brown, 1996). See **Table 1** for further details on sample characteristics.

Table 1Sample characteristics (N=15).

Variable		M (SD)	N (%)
Age		32.2 (10.08)	
Age of onset		11.5 (5.06)	
Gender	Female		8 (53)
Ethnicity	White British		15 (100)
Education	Secondary		7 (47)
	Higher		8 (53)
Employment	Employed		5 (33)
	Self-employed		2 (13)
	Unemployed		6 (40)
	Other (e.g. retired)		2 (13)
Current medication	-		8 (53)
(some) prior CBT			9 (60)
Dropout		1 (7)	
Sessions attended		7(3) (range:1-10)	
ERP tasks completed ^a		24 (9.69)	

Note: a based on 30% return homework sheets

3.2.3 Interview schedule

The semi-structured Change Interview (Elliott, Slatick, & Urman, 2001) was used in the pilot RCT to explore the perceived acceptability and benefits of ERP and MB-ERP as it was designed to ask participants about their experience of a psychological intervention (see Table 2 for interview questions). The interview invites interviewees to reflect on therapy change processes, helpful and unhelpful aspects of therapy and factors contributing or hindering engagement and was therefore also well-suited to the aims of this study.

Table 2 *Change Interview sections and questions*

1	Changes			
1a	What changes, if any, have you noticed in yourself since the course started?			
1b	Has anything changed for the worse for you since the course started?			
1c	Is there anything that you wanted to change that hasn't since the course started?			
2	Change Ratings			
2a	For each change, please rate how much you expected it vs. were surprised by it?			
2b	For each change, please rate how likely you think it would have been if you hadn't done the course?			
2c	How important or significant to you personally do you consider this change to be			
3	Attributions			
	In general, what do you think has caused the various changes you described?			
4	Helpful Aspects			
	Can you sum up what has been helpful about the course so far?			
5	Resources			
5a	What personal strengths do you think have helped you make use of the course to			
	deal with your problems?			
5b	What things in your current life situation have helped you make use of the course			
	to deal with your problems?			
	Problematic Aspects			
6a	What kinds of things about the course have been hindering, unhelpful, negative			
-Ch				
OD	perhaps helpful?			
6c				
7				
7a				
	•			
7b	What things in your life situation have made it harder for you to use the course to			
	deal with your problems?			
8	Suggestions			
	Do you have any suggestions for us, regarding the research or the course?			
6b 6c 7 7a 7b	or disappointing for you? Were there things in the course which were difficult or painful but still OK or perhaps helpful? Has anything been missing from your treatment? Limitations What personal limitations do you think have made it harder for you to use the course to deal with your problems? What things in your life situation have made it harder for you to use the course to deal with your problems? Suggestions			

Note: ratings for 2a:(1='very much expected the change to happen' to 5= 'very much surprised by the change'), 2b: (1='very unlikely without the therapy course' to 5='very likely without the therapy course'), 2c: (from 1='not at all important' to 5='extremely important').

3.2.4 Intervention: group ERP

Treatment involved 10 two-hour weekly sessions of group ERP (delivered through two courses). The protocol (Van Noppen, Steketee, & Pato: Group Behaviour Therapy (GBT) Treatment Manual for OCD, unpublished) was adapted to incorporate

recommendations for delivering ERP in line with inhibitory learning theory

(Abramowitz & Arch, 2014; Arch & Abramowitz, 2015). Two experienced clinical psychologists, one of whom was an accredited CBT therapist (CS) with OCD expertise, delivered the treatment. An expert in ERP (EF) provided supervision to both group facilitators. The first session provided psychoeducation about OCD and introduced the rationale for ERP. From session 2 onwards, participants were required to design and conduct within- and between-session ERP tasks (i.e. home practice). Participants were strongly encouraged to complete their planned ERP tasks at least daily between sessions and record this using worksheets. All sessions included reviewing between-session practice and planning ERP tasks for the following week. Session 10 reviewed the course and invited participants to devise a personalised plan to consolidate learning (see Strauss et al. (2015) for further details).

3.2.5 Thematic analysis

The Change Interview transcripts were analysed using reflexive thematic analysis (TA) (Braun & Clarke, 2006; 2019), which offers a flexible approach to identifying, analysing and reporting themes within the dataset, allowing for a detailed and thorough description and rich interpretation of the data. Reflexive TA follows six phases (Braun & Clark, 2006), set out in Table 3. Initial codes were applied to any participant statement on facilitators or barriers to engagement in group ERP, where engagement included session attendance and course completion, within- and between-session ERP task engagement. GC, a clinical psychology master's student, and TL, an experienced clinical psychologist and doctoral researcher, completed the initial coding of two

interviews, comparing and discussing their initial coding to enhance the credibility of the analysis (Archibald, 2016). GC completed the initial coding of the remaining transcripts (phase ii) and clustered them into initial (sub-) themes, capturing both endorsing and disconfirming views across participants (Elliott, Fischer, & Rennie, 1999) (phase iii). Decisions about the relevance and clustering of initial codes into (sub- and higher-order) themes (phase iv) were reached through group consensus (GC, TL and CS) (Harry, Sturges, & Klingner, 2005), ensuring that the interpretation of the data followed from the initial codes and associated extracts (Elliott et al., 1999; Madill, Jordan, & Shirley, 2000). TL completed the final two phases of the analysis. QSR International's NVivo 12 software was used to conduct the analysis.

Table 3Analytic phases of reflexive thematic analysis (Braun & Clarke, 2006).

	Phase	Description	
i.	Familiarising yourself with your data	In-depth familiarisation with the data through repeated reading of all interview transcripts	
ii.	Generating initial codes	Application of initial codes (i.e. single units of meaning) to transcript extracts that are pertinent to the research question	
iii.	Searching for themes	Initial codes are examined for commonalities and differences and clustered into overarching themes, and potential sub-themes within these	
iv.	Reviewing themes	Themes and sub-themes are reviewed in relation to the coded extracts that support them to ensure that each theme/sub-theme relates to the coded extracts and the whole data set, confirming that the aim of the investigation is maintained and that the research question is answered appropriately	
v.	Defining and naming themes	The themes and sub-theme names, descriptions and relationships within the data are finalised	
vi.	Producing the report	Analysis continues into the write-up of the study report, whereby themes are related back to the research question. The most representative extracts are selected for inclusion in the write-up.	

3.3 Results

Five main themes captured participants' perceived facilitators and barriers to engagement in group ERP. Main themes are described in Table 4 whilst associated subthemes are discussed below. Pseudonyms were used to protect participant confidentiality. In line with Braun and Clarke's reflexive thematic analysis (2019), the presentation of results does not include the number of participants contributing to each (sub-) theme.

Table 4Main and sub-themes.

Theme	captures	Sub-themes
Understanding how to overcome OCD	the importance of having a good understanding of the cognitive behavioural model of OCD, including	Insight into OCD
002	how ERP targets the maintaining factors in OCD. This also included understanding how to conduct ERP and what to expect during ERP	Understanding the treatment rationale
Personal whether participants felt that ERP was relevance relevant to their difficulties, tied in with the fact that compulsions can be overt or covert		Perceived relevance of ERP for obsessions without overt compulsions
		Perceived relevance of within-session ERP
Group processes	participants' experiences of the group format, specifically group processes that were beneficial or inhibiting in engaging with therapy	(Fear of) opening up Belonging and accountability Therapist support
		Continuity Individual attention
Personal	the impact of mental health problems, other commitments and life transitions and the support of loved ones, on session attendance and ERP task engagement	Mental health
circumstances		Other challenges
		Support from family and friends
Attitude towards	reflections on the ways in which expectations, motivation, readiness to change and commitment and perseverance affected participants' engagement in therapy	Expectation
ERP		Motivation
		Readiness to change
		Self-efficacy
		Commitment and perseverance

3.3.1 Understanding how to overcome OCD

3.3.1.1 *Insight into OCD*

Several participants stated that psychoeducation about OCD, particularly how avoidance and compulsions maintained OCD, changed their perspective on their symptoms and helped them gain the resolve to engage with ERP tasks, as illustrated by Michelle: 'I'm trying to make myself realise that I'm not achieving anything by doing that [the rituals], it's just the OCD taking over [...]'.

3.3.1.2 *Understanding the treatment rationale*

Most participants found that learning how and why ERP works, including psychoeducation about the (self-limiting) fight-flight response, motivated them to engage in ERP, e.g. '... it [...] made me want to tackle it instead of dwelling on it' (Helen), and increased their self-efficacy '[...] you can be like 'oh I can do this thing that I find really scary and it won't always be scary''(Isabel). Psychoeducation was revisited throughout therapy, which helped participants get to grips with ERP: '...it took quite a long time to actually grasp what I needed to do and why' (Charlotte).

3.3.2 Personal relevance

3.3.2.1 Perceived relevance of ERP for obsessions without overt compulsions

Participants with obsessions without overt compulsions experienced challenges in successfully conducting (imaginal) ERP tasks: '...a lot of people suffer inside their heads, so that was difficult for them [the facilitators], to make a situation relevant' (Adam). This created a sense that there was not a good fit between their symptoms and the therapy: 'I didn't really fit into their system of exposure' (Chloe). Several

participants described trial and error in successfully triggering intrusive thoughts: '[...] they suggested things, and I tried it and they weren't really working for me so I had to sort of keep trying different things' (Luke).

3.3.2.2 Perceived relevance of within-session ERP

Several participants experienced difficulties with within-session ERP tasks because their OCD symptoms predominantly occurred within their home environment. This contributed to their perception that engaging in within-session ERP tasks was not particularly relevant, e.g. 'it wouldn't do anything for me' (Adrian). For others, the artificiality of intentionally provoking their obsessional intrusions in the session rendered it ineffective, perhaps because it reduced their perceived responsibility for the consequences: '[...] sometimes trying to provoke that anxiety, because I knew I was doing it for that reason, was quite tricky' (Jessica).

3.3.3 Group processes

3.3.3.1 (Fear of) opening up

A third of participants felt anxious about joining a group and opening up to the other participants, who were 'total strangers' (Brian). Participants were not used to talking about their OCD to other people, feared people's reactions, or generally did not feel comfortable in group situations. However, most participants tolerated their anxiety, e.g. by reminding themselves it was a recommended treatment, and it generally decreased quickly once they got to know the other group members. Hearing about other people's OCD symptoms caused several participants some initial concerns about 'catching other people's OCD'(Charlotte) and contributed to Sadie dropping out because: 'I didn't think I was strong enough to handle the worry of taking on everyone

else's situation'. Oscar expressed ambivalence about hearing others talk about recognisable difficulties, as it 'is sometimes much more acutely distressing than it is valuable'. Mostly, however, participants highly valued sharing experiences and feeling listened to and understood; it helped them to normalise their own intrusive thoughts and made them feel less alone.

3.3.3.2 *Belonging and accountability*

Several participants developed a sense of belonging, 'feeling part of the group' (Alex), and accountability that motivated them to attend sessions. Anticipating group discussion about home practice acted 'like a prompt' (Alex) to do between-session ERP whilst the sense of accountability also facilitated within-session ERP, as described by Luke 'you think 'well I've got to do something to sort of keep sort of on the same level as everyone''. Seeing other participants struggling to engage with ERP motivated some participants to keep on track, e.g. 'it makes you think to yourself 'well you didn't do it either, then help yourself out'' (Charlotte).

3.3.3.1 *Therapist support*

Therapist support included practical assistance and emotional support, e.g. helping participants to correctly conduct and persist with ERP tasks, talking them through their home practice, providing encouragement and praise. Participants positively reflected on the therapists' expertise, understanding, warmth or 'pastoral care' (Oscar), which helped them to remain engaged, e.g. '...they were so understanding [...] that really helped 'cos otherwise I wouldn't have come back' (Charlotte). Knowing that therapists were there to support them made some participants feel less alone in dealing with OCD. Participants perceived that therapists moved at the

group's pace, showing an interest in their feelings and doubts, adjusting sessions to their needs. Discussing home practice and praising achievements increased participants' confidence in their ability to conduct ERP independently. Moreover, therapists reflected on shared difficulties in conducting ERP, which enabled the group to come up with solutions. However, a couple of participants lacked the confidence or inclination to ask the facilitators for help, which affected their ability to engage in ERP.

3.3.3.2 *Continuity*

Non-attendance of group members resulted in different group configurations for some sessions, which several participants found frustrating, disappointing or difficult to understand: 'it's like, 'if me, you, you and you is doing it then why is no-one else?' (Brian). One participant lamented that this invariably resulted in some repetition of course content. Nevertheless, a couple of participants felt that a smaller number of attendees allowed more time to talk and receive individual attention from therapists.

3.3.3.3 *Individual attention*

Several participants found the relative lack of individual attention from the therapists, resulting from the group format, challenging. They would have liked some time alone with the therapists to discuss problems that were difficult to share in a group, making therapists aware of important personal circumstances or feeling reassured about their difficulties. This theme reflected that not all participants felt comfortable talking in the group ('opening up' sub-theme) or did not wish to take up time to discuss individual difficulties. However, some participants felt there was still ample scope for individually tailored therapy, appreciating '...the ability of the staff to react to your specific needs' (Oscar).

3.3.4 Personal circumstances

3.3.4.1 *Mental health*

Some participants experienced depression and anxiety and/or severe OCD symptoms, which impacted on their ability to confront OCD, e.g. Alex stated he 'couldn't summon the kind of strength to ... take the illness on'. It contributed to Adam missing sessions: 'I was disappointed with myself that I didn't go as much as I wanted to ... maybe 'cos I do suffer with depression'. For some participants, OCD or comorbid depression and/or anxiety symptom severity did not affect their attendance but hampered their ability to engage with between-session ERP tasks, e.g. 'the anxiety mixed with like depression, made it kind of difficult [to prevent rituals]' (Chloe).

3.3.4.2 *Other challenges*

For participants with children, difficulties securing childcare contributed to missing sessions. Other factors, such as the clinic's central location and job flexibility made it easier for some participants than others to attend (day-time) sessions. Life commitments made it hard to prioritise between-session ERP tasks for some.

Several participants experienced stressful life events and instability, e.g. moving to a new house, which affected their engagement. Conversely, suitable accommodation, e.g. having privacy, facilitated engagement in between-session ERP tasks for others. For some participants, life transitions preoccupied them and made them question the timing of the course '...it's quite a bad time to like do anything' (Isabel).

3.3.4.3 *Support from family and friends*

Family support with childcare enabled participants with children to attend sessions. Loved ones also encouraged participants to continue to attend sessions, or as

Charlotte described: 'helping me to find the wherewithal to go to the group each week'.

Some participants found it helpful to ask family members to remind them to do their

ERP tasks.

3.3.5 Attitudes towards ERP

3.3.5.1 *Expectations*

Several participants longed to be rid of OCD altogether, often coupled with an appreciation this was not necessarily realistic: 'I have an illusion that you can be completely fine afterwards and not have it affect you at all but I think that's obviously not the case' (Isabel) as OCD can be a 'life-long battle' (Brian), and 'it's more about learning how to cope with it' (Charlotte). As therapy progressed, hopes of getting better typically increased but some participants described that this fluctuated: [...] there are always times when you're uncertain if it's the right thing' (Isabel). Therapists played an important role in helping participants to know what to expect, e.g. that starting ERP was going to be challenging. Therapists managed expectations about the chance of remission, which caused Charlotte some initial anxiety: 'I suddenly thought 'oh my god, I might not be fine, I might not be cured'. She subsequently felt that having a more realistic perspective helped to galvanise her: 'My new goal was to understand what we were trying to achieve and to be able to take things away to help myself afterwards'.

3.3.5.2 *Motivation*

Many participants described an inner drive or determination to face OCD headon and engage in the ERP tasks. Many participants felt they owed it to themselves to succeed and no longer wanted the OCD to take over their lives. Other participants were primarily motivated to engage with therapy for the sake of their children and families, wanting to set a good example, make their family proud or reduce the impact that OCD had on them, e.g. 'I'd like to show that I can change and I can make life easier' (Michelle).

3.3.5.3 *Readiness to change*

Most participants talked about whether they felt ready to change, e.g. 'I'm at a point in my life when I thought 'enough is enough, I'm ready to receive help'

(Charlotte), with some expressing they had no other choice than 'facing things head on', e.g. 'I was just at the end of my tether [...] I had to do it' (Adam). Several participants with very longstanding OCD symptoms wanted more sessions to settle into treatment and fully engage in between-session ERP: '[...] with the knowledge of this session every week, I think in time [...] I would have got better at that' (Alex).

3.3.5.4 *Self-efficacy*

Many participants expressed that self-efficacy contributed to their engagement in therapy and vice versa: 'I think my confidence and being able to do things has gone up [...] realising it [ERP] is actually not that bad' (Luke), 'Some things you thought were impossible ... you can sort of do them' (Derrick). Other participants understood the rationale for ERP but lacking confidence in their ability to do it: 'I don't really believe I can follow it' (Oscar).

3.3.5.5 *Commitment and perseverance*

Commitment and perseverance were considered important attributes in tolerating the anguish associated with ERP, particularly when motivation was at a low ebb: 'having the willpower, you know you don't like it, if you don't have that, it would be a very difficult thing' (Derrick). This was also related to a belief that ERP would

work and make them feel better, i.e. the credibility of the treatment, e.g. '...when I really did not want to do the tasks [...] knowing that if you do these things, things can get better, has made me sort of push through when things seemed a bit hard' (Luke).

3.4 Discussion

This qualitative study examined participant perspectives on facilitators and obstacles to engagement in group ERP for OCD. Given the nature of ERP, most participants found the therapy challenging, which mirrored other qualitative studies (Bevan et al., 2010; Lee & Rees, 2011; Marsden et al., 2018). The five themes highlighted that engagement in group ERP for OCD was influenced by therapy, client and social, contextual factors. Therapy factors included the group therapy format. Participants' social confidence and feelings about disclosing their OCD symptoms to other participants, their sense of belonging and accountability, the quality and availability of (individualised) therapist support, and (reactions to the) continuity of the group all had the potential to positively or negatively affect engagement. Participants in a study of individual CBT (Marsden et al., 2018) similarly reported feeling anxious about self-disclosure (to the therapist) but that it helped to normalise their concerns. Participants in Lee and Rees (2011) also highlighted that being in a group was normalising and encouraging and that therapist support benefitted their engagement. The group processes highlighted by participants as potentially hindering engagement were also mentioned by eligible patients in a trial comparing individual versus group therapy, who refused the group format due to general social anxiety, fears about catching other people's OCD symptoms, lack of personal attention and/or a sense of shame about their OCD symptoms (O'Connor et al., 2005). Overall, group processes

create a unique 'group climate' (Tasca, Balfour, & Bissada, 2011; Paquin & Kivlighan, 2016) or group cohesion (e.g. Burlingame, McClendon, & Yang, 2018; Kobak, Rock, & Greist, 1995) that has the capacity to promote or inhibit engagement.

Other therapy factors included the extent to which psychoeducation about OCD and the rationale for ERP resonated with participants and made the therapy seem credible. Lee and Rees (2011) similarly found that psychoeducation affected engagement. Psychoeducation is tied up with therapist expertise and quality of delivery and this theme therefore also bore the imprint of the client-therapist working alliance. The perceived personal relevance of (within-session) ERP also impacted on participants' capacity to engage in ERP tasks, including through the effect this had on participants' sense of belonging to the group and their hopes and expectation of improvement.

Participants' social context, including stressful life events and changes, job flexibility, childcare commitments and access to social support, also had the potential to foster or hinder session attendance and between-session ERP task engagement, including through affecting people's readiness for change, motivation, commitment and perseverance. Marsden et al. (2018) similarly reported that general life problems affected engagement among CBT participants.

Client characteristics such as the nature and severity of (comorbid) mental health difficulties and attitudinal factors, specifically expectations, readiness to change, motivation and perseverance and commitment, also contributed to the process of engagement. This resonates with studies of patient engagement in psychological therapy more generally (e.g. Holdsworth et al., 2014) and with a few quantitative studies of engagement in individual or remote ERP for OCD that found that OCD symptom

severity and/or degree of insight (De Araujo et al., 1996; Simpson et al., 2011; Tolin et al., 2004) and motivation (Bachofen et al., 1999) predicted ERP task engagement. Participant expectations, readiness to change and self-efficacy all fuelled motivation whilst commitment and perseverance, at times when motivation was low, was influenced by both self-efficacy and the perceived relevance, or suitability, of the therapy. These findings resonate with theoretical perspectives that propose motivation is shaped by treatment expectations and self-efficacy (Drieschner et al., 2004).(Comorbid) symptom severity, including anxiety and depression, appeared to adversely affect motivation to engage in between-session ERP tasks.

There appeared to be many reciprocal relationships between themes. For example, understanding how to overcome OCD impacted on participants' motivation to initiate and persevere with ERP. Whilst psychoeducation may have a direct effect on motivation, participant accounts also suggested an indirect effect through enhancing self-efficacy and shaping realistic expectations about therapy, including participants' understanding that full engagement in ERP was essential for symptom improvement. Motivation was also enhanced through support from therapists, loved ones and a sense of accountability and belonging to the group. Bevan et al. (2010) also found that motivation was influenced by treatment format, in their case intensive (vs weekly) CBT, whilst participant accounts in Marsden et al. (2018) suggested that the therapeutic alliance influenced motivation, including by creating positive treatment expectations through (persuasive) psychoeducation about the treatment rationale. Therefore, study findings resonate with Holdsworth et al. (2014), who conclude that motivation is 'a dynamic treatment target to enhance participation' (p.435). The perceived personal relevance of the therapy affected engagement in within- and between-session ERP,

including through the effect on participants' sense of belonging to the group and ability to share and compare experiences. Participants also described a reciprocal relationship between early success with ERP and therapy engagement, seemingly through increasing motivation, perceived self-efficacy and the credibility of the therapy.

3.4.1 Limitations

The study was conducted with participants recruited through two UK NHS IAPT services in a single mental health trust in the South of England, which limits the transferability of the results. Participants took part in a pilot RCT and all but one of them completed the therapy, which means they may have been more motivated than routine group ERP participants. Their accounts nonetheless reflected various struggles with (all aspects of) engagement that may resonate with adults who seek treatment for OCD through routine clinical services.

Whilst the Change Interview invites participant reflection on possible

(un)helpful aspects of treatment and personal characteristics and circumstances that may influence engagement, it does not exhaustively probe potential facets of patient engagement. The interviews were conducted by someone independent of therapy delivery but were nonetheless potentially subject to social desirability bias.

3.4.2 Research and clinical implications

The findings suggest a dynamic interplay between therapy, therapist, client and social environmental factors that facilitate and hinder engagement in group ERP, which should be examined further. Psychometrically robust measurement of multiple predictor and engagement variables over the course of therapy (Holdsworth et al., 2014) would

elucidate the engagement process and its relationship with therapy outcomes. Studying patients who dropped out from group ERP is likely to further elucidate what hinders patient engagement. Capturing 'live' engagement processes, e.g. through recording sessions, would provide fruitful ways of exploring how the group climate affects engagement (Elliott, 2010; Rhodes, 2011). The development of a semi-structured interview specifically designed to probe the various aspects of patient engagement would also benefit research in this area. The therapeutic alliance has been researched widely as a common factor of therapeutic change (e.g. Wampold, 2015). However, the interactions and relationships between participants are not normally the focal point of therapeutic exploration and change in group ERP, yet clearly can influence engagement in ERP and warrant further investigation. Findings also highlight the importance of taking account of OCD symptoms subtypes when examining engagement.

Whilst some themes were specific to ERP (understanding how to overcome OCD; personal relevance, influenced by OCD symptom-subtype and imaginal vs in vivo ERP) whereas others were reflective of non-specific factors (group processes, attitude to therapy, personal circumstances), albeit influenced by ERP therapy characteristics; e.g. accountability to the group was influenced by the fact that therapy required both within- and between-session ERP. This too warrants further investigation.

Group ERP is less resource-intensive than individual therapy (NICE, 2005) and has the potential to facilitate engagement relative to individual therapy, but may be particularly challenging for patients with taboo thoughts; they may experience difficulties disclosing OCD symptoms to other participants, although the group also provides normalisation and opportunities for testing shame-related beliefs about these

intrusions (e.g. Fals-Stewart & Lucente, 1994; Kobak et al., 1995). Initial assessments provide a vital opportunity for assessors to anticipate and respond to patients' reservations about group therapies.

Patients' attitudes to group ERP, including expectations, motivation, selfefficacy, commitment, perseverance and readiness to change, appear to interact with group processes (Holdsworth et al., 2014). Group composition and group cohesion need careful consideration; group processes that may get in the way of engagement in ERP need to be openly addressed, e.g. therapists should anticipate and discuss the anxiety that patients may experience in the group. Non-attendance could impact on remaining participants in both positive and negative ways (Paquin & Kivlighan, 2016) and this must be addressed proactively, e.g. through facilitating discussion and expression of doubts and ambivalence. The extent to which participants achieve success with ERP tasks, also influenced by their perceived personal relevance, could also affect the morale of the group. Therapist training and supervision should foreground the interpersonal and communication skills required to facilitate a positive group climate. Therapists need to create a positive but realistic expectancy of the efficacy of therapy, aided by appropriate psychoeducation, and anticipate that disclosing OCD symptoms to the group may be challenging for patients with 'forbidden' thoughts (e.g. Kobak et al., 1995). As withinsession ERP was not necessarily experienced as effective by all participants, home treatment should be considered when required (e.g. Rowa et al., 2007), taking into account the additional resource demands in publicly funded healthcare services. Patients with comorbid depression may require more between-session support, e.g. betweensession phone calls or home visits, to support their engagement in ERP. Finally, practical and logistic considerations are not trivial in enhancing engagement; offering

sessions at convenient locations and times are all important in ensuring participants can attend and remain engaged in therapy.

Chapter 4: The association of trait mindfulness and selfcompassion with OCD symptoms: Results from a large survey with treatment-seeking adults

ABSTRACT

Little is known about the role of mindfulness and self-compassion in obsessivecompulsive disorder. This cross-sectional study examined associations of mindfulness and self-compassion with obsessive-compulsive disorder symptoms and with the obsessive beliefs and low distress tolerance thought to maintain them. Samples of treatment-seeking adults (N = 1871) and non-treatment-seeking adults (N = 540) completed mindfulness, self-compassion, obsessive-compulsive disorder, anxiety, depression, obsessive beliefs and distress tolerance questionnaires. Participants with clinically significant obsessive- compulsive disorder symptoms reported lower trait mindfulness and self-compassion compared to participants with clinically significant anxiety/depression and to non-clinical controls. Among the clinical sample, there were medium-large associations between mindfulness and self-compassion and obsessivecompulsive disorder symptoms, obsessive beliefs and distress tolerance. Mindfulness and self-compassion were unique predictors of obsessive-compulsive disorder symptoms, controlling for depression severity. Once effects of obsessive beliefs and distress tolerance were controlled, a small effect remained for mindfulness (facets) on obsessing symptoms and for self-compassion on washing and checking symptoms. Directions for future research and clinical implications are considered in conclusion.

Keywords: Obsessive-compulsive disorder; mindfulness; self-compassion; obsessive beliefs; distress tolerance.

4.1 Introduction

4.1.1 Background

Obsessive-compulsive disorder (OCD) is a debilitating mental health condition characterised by obsessions, i.e. persistent unwanted intrusive thoughts, images or urges that can cause significant distress, and compulsions, i.e. repetitive, ritualistic behaviours aimed at alleviating distress and/or preventing negative outcomes (APA, 2013). OCD is a heterogeneous disorder as obsessions can centre on contamination, harm, symmetry or taboo thoughts and compulsions include physical behaviours like washing, checking, ordering, counting and mental acts (e.g. mantras) (Wheaton, Abramowitz, Berman, Riemann, & Hale, 2010). Hypervigilant attention, avoidance of obsessional triggers, thought suppression and reassurance seeking also characterise OCD (Salkovskis, 1999). While obsessive-compulsive symptoms lie on a continuum (Abramowitz et al., 2014), OCD affects 2-3 % of the population (e.g. Ruscio, Stein, Chiu, & Kessler, 2010) and has a high comorbidity with depression and anxiety disorders (Macy et al., 2013). Obsessional intrusions are indistinct in content from intrusions in the general population (e.g. Berry & Laskey, 2012) but are more persistent and distressing in OCD (APA, 2013). The cognitive behavioural model of OCD asserts this is because people with OCD appraise normal intrusions as personally significant or important, believing they influence real-life events and imply they are 'bad, mad or dangerous' (Shafran & Rachman, 2004, p.97). These misappraisals are informed by obsessive beliefs, including inflated personal responsibility, intolerance of uncertainty, perfectionism, overestimation of threat, the need to control thoughts and the over-importance of thoughts (OCGWG, 1997). The latter meta-cognitive belief includes 'thought-action fusion', the belief that having a bad thought is morally equivalent to, or increases the

likelihood of, acting on the thought (e.g. Rachman & Shafran, 1999; Shafran & Rachman, 2004). The cognitive-behavioural model furthermore proposes that compulsions leave maladaptive appraisals of intrusive thoughts unchallenged.

Whilst obsessive beliefs play a central role in the cognitive model of OCD, they do not explain all the variance in OCD symptoms(s) (subtypes) in nonclinical and/or OCD samples (e.g. Abramowitz, Lackey, & Wheaton, 2009; Wheaton, Abramowitz, Berman, Riemann, & Hale, 2002). Whilst adults with OCD endorse obsessive beliefs to a greater extent than healthy controls, evidence for the specificity of (all) obsessive beliefs to OCD (subtypes), compared to depression and anxiety disorders, is mixed (e.g. Belloch et al., 2010; Steketee, Frost, & Cohen, 1998; OCCWG, 2003; Taylor et al., 2006; Tolin, Worhunsky, & Maltby, 2006; Viar et al., 2011; Wu & Carter, 2008). This reflects the heterogeneity of OCD but also suggests other theoretical constructs play a role in the maintenance of OCD symptoms.

Recently, the potential role of distress tolerance, i.e. 'the ability to experience and withstand negative psychological states' (Simon & Gaher, 2015, p.83) has been explored (e.g. Cougle, Timpano, Fitch, & Hawkins, 2011). Low distress tolerance is proposed to compound the unpleasant feelings evoked by unwanted intrusions and contribute to the urge to engage in the maladaptive behaviours, specifically compulsions, avoidance, thought suppression and reassurance seeking to eliminate distress (Robinson & Freeston, 2014). Research evidence to date suggests low distress tolerance is associated with OCD symptoms, particularly obsessions, in both nonclinical (Cougle, Timpano, Fitch, & Hawkins, 2011; Cougle, Timpano, & Goetz, 2012) and clinical samples (Laposa, Collimore, Hawley, & Rector, 2015). However, evidence is mixed as to whether distress tolerance uniquely predicts OCD symptoms once

depression, anxiety and/or anxiety sensitivity are controlled for (Blakey, Jacoby, Reuman, & Abramowitz, 2016; Cougle et al., 2011; Cougle et al., 2012; Keough et al., 2010; Laposa et al., 2015; Macatee, Capron, Schmidt, & Cougle, 2013; Robinson & Freeston, 2014).

Yet more recently, the theoretical constructs of mind-fulness and selfcompassion have also started to receive attention in relation to OCD, in light of the emerging interest in mindfulness-based interventions (MBIs) for OCD. Mindfulness is broadly defined as 'the awareness that emerges through paying attention on purpose, in the present moment, and nonjudgmentally to the unfolding of experience moment by moment', with nonjudgment referring to a friendly, open and accepting stance (Kabat-Zinn, 2003, p.145). Mindfulness is commonly operationalised as a multi-faceted construct consisting of: i) observing, i.e. attending to internal (sensations) and external (e.g. sights) experiences; ii) describing, i.e. giving words to internal experiences; iii) acting with awareness, i.e. the ability to attend to activities in the present moment (the opposite of acting on automatic pilot); iv) non-judging inner experience, i.e. not judging thoughts and feelings as good or bad, and; v) non-reactivity to inner experience, i.e. letting (unpleasant) thoughts and feelings pass without acting to get rid of them (Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006; Baer et al., 2008). Self-compassion is an associated construct, commonly defined as a non-evaluative positive attitude towards the self at times of difficulty that involves: i) self-kindness (rather than being selfcritical); ii) common humanity (rather than seeing one's own suffering as an isolating experience), and; iii) mindfulness, particularly equanimity towards unpleasant experiences (as opposed to identifying with them) (Neff, 2003). Self-compassion is associated with, yet distinct from, self-esteem, self-criticism and self-pity (Barnard &

Curry, 2011). As these definitions show, mindfulness, self-compassion and distress tolerance are related, yet distinct constructs. Mindfulness involves non-judgmental awareness of present-moment experiences, whatever these may be, including pleasant, unpleasant and neutral experiences (Kabat-Zinn 2003). Self-compassion is argued to necessitate mindfulness but is a broader construct that includes an attitude of kindness towards the self and an appreciation of shared human experience (Neff 2003). Distress tolerance, on the other hand, specifically involves tolerance of unpleasant emotional or physical states when it is not possible to change these experiences (Leyro et al. 2016). Therefore, mindfulness and self-compassion are broader constructs that could have the potential to explain OCD symptoms over and above distress tolerance.

Mindfulness and self-compassion are understood as universal human dispositions or skills that individuals possess to varying degrees (Brown & Ryan, 2003; Sauer et al., 2013). This is borne out in research showing that dispositional mindfulness and self-compassion have a positive association with wellbeing and a negative association with negative affect (e.g. shame, guilt and anxiety), mental health difficulties (e.g. depression) and maladaptive cognitive processes such as rumination, worry and thought suppression (Barnard & Curry, 2011; Keng et al., 2011; MacBeth & Gumley, 2012; Tomlinson, Yousaf, Vittersø, & Jones, 2018; Zessin, Dickhäuser, & Garbade, 2015).

Mindfulness and self-compassion are central to mindfulness-based interventions (MBIs), which improve mindfulness and self-compassion skills (Gu, Strauss, Bond, & Cavanagh, 2015) through mindfulness meditation practices and teacher-led inquiry (e.g. Segal, Williams, & Teasdale, 2013). Research shows that MBIs benefit (recurrent)

depression and, to a lesser extent, anxiety symptoms (e.g. Goldberg et al., 2018; Khoury et al., 2013; Kuyken et al., 2016; Strauss et al., 2014).

The growing interest in MBIs (adapted) for OCD (e.g. Key et al., 2017; Külz et al., 2019; Selchen et al., 2017; Strauss et al., 2018) is informed by the fact that approximately 50% of patients do not experience OCD symptom remission following cognitive behavioural therapy for OCD (Öst et al., 2015). The rationale for MBIs for OCD is predicated on the assumption that poor mindfulness and self-compassion skills contribute to OCD symptoms (e.g. Didonna, 2009; Külz et al., 2014). Conceivably, OCD can be considered 'antithetical' to mindfulness (Didonna, 2009) as poor mindfulness skills are reflected in the over-importance given to obsessional intrusions and heightened reactivity to (triggers of) such thoughts through avoidance, compulsions and reassurance seeking, hypervigilant attention to triggers of obsessions, thought suppression and control. Poor self-compassion skills are implicated in feelings of guilt and shame and obsessive beliefs such as inflated personal responsibility, perfectionism, the belief that one should be able to exercise control over thoughts and moral thoughtaction fusion (e.g. Bream, Challacombe, Palmer, & Salkovskis, 2017; Shapiro & Stewart, 2011; Weingarden & Renshaw, 2015; Wetterneck, Lee, Smith, & Hart, 2013, 2013). Crowe and McKay (2016) argue that adults with OCD may have poor mindfulness and self-compassion skills even when compared to adults with other common mental health problems such as depression and anxiety because of their unique tendency to appraise common and harmless intrusions as important and personally significant, informed by inflated personal responsibility and thought-action-fusion beliefs, and the extent to which they react to such thoughts with ritualistic, repetitive, time-consuming and often apparently senseless compulsions.

Few studies have examined the unique relationship of mindfulness or selfcompassion with OCD symptoms to inform the proposed potential benefit of MBIs for OCD. A single study examined self-compassion in 111 adults with OCD and found a medium negative association (r=-.30, p<.01) with OCD symptom severity (Wetterneck, et al., 2013). Whilst this suggests that lower self-compassion is associated with increased OCD symptom severity, the specificity of the association of self-compassion with OCD was not examined. Also, the study did not explore whether this association varied according to OCD symptom subtype, e.g. symptoms that centre on perfectionism (e.g. ordering compulsions) or unacceptable thoughts (e.g. Külz et al., 2014) and whether self-compassion explains OCD symptoms once more established constructs, e.g. obsessive beliefs, are accounted for. Five further studies with clinical (Didonna et al., 2018; Hawley et al., 2017) and nonclinical samples (Crowe & McKay, 2016; Emerson, Heapy, & Garcia-Soriano, 2017; Solem, Thunes, Hjemdal, Hagen, & Wells, 2015) found that OCD symptoms were negatively associated with (facets of) mindfulness and that adults with clinically significant OCD symptoms demonstrated lower trait mindfulness (facet) relative to healthy controls.

Research examining the unique association of self-compassion with OCD is absent while evidence is equivocal about the unique association of mindfulness with OCD relative to other common mental health difficulties, particularly depression and anxiety disorders (Crowe & McKay, 2016; Didonna, 2018; Hawley et al., 2017). The latter studies were conducted with relatively small samples of participants with a diagnosis, or clinically significant symptoms of, OCD (ranging from 42 in Crowe and McKay to 144 in Hawley et al.), depression (from 17 in Crowe and McKay to 50 in Didonna et al.) and/or anxiety (from 19 in Crowe and McKay to 162-344 in Hawley et

al.). Therefore, analyses may have been under-powered to detect potentially small differences in mindfulness (facets) between OCD and depression and/or anxiety disorders, as the latter disorders are also associated with low mindfulness and selfcompassion relative to healthy controls (e.g. Arch, Landy, Schneider, Koban, & Andrews-Hanna, 2018; Didonna et al., 2018; Nejati, Zabihzadeh, Maleki, & Tehranchi, 2012; Roemer et al., 2009). The correlational analyses did not control for depression severity (apart from Solem et al., 2015) to establish the unique association of mindfulness and self-compassion with OCD. This is an important omission as OCD has a high degree of comorbidity with depression and self-compassion and mindfulness have known associations with depression (see above). Research to date also does not elucidate the (relative importance of the) relationship of mindfulness and selfcompassion with different OCD symptom subtypes. Finally, it is unclear if, and how strongly, trait mindfulness and self-compassion are related to obsessive beliefs and whether mindfulness and self-compassion significantly contribute to our understanding of OCD symptoms, over and above obsessive beliefs, a construct central to the cognitive model of OCD and distress tolerance, examined more recently as an aspect of emotion regulation difficulties associated with OCD (Robinson & Freeston, 2014).

The current study aimed to address these evidence gaps to gain a better understanding of whether mindfulness and self-compassion skills uniquely predict OCD symptoms. This would provide preliminary evidence towards the assumption, inherent in the recent interest in MBIs for OCD, that OCD is associated with deficient mindfulness and self-compassion skills that can be targeted to benefit OCD symptom reduction; the absence of a unique association of mindfulness and self-compassion with OCD would question the potential causal importance of these skills in OCD and suggest

that targeting these skills, i.e. through offering MBIs for OCD, would be of little therapeutic benefit to OCD symptoms.

4.1.2 Aims & objectives

This study aimed to gain a better understanding of the unique relationship of mindfulness and self-compassion with obsessive-compulsive symptoms and the obsessive beliefs and distress intolerance thought to maintain them. These relationships were examined using both a disorder (hypothesis 1) and continuum model (hypotheses 2-4) of OCD. Specifically, informed by the research and theoretical literature described above, this study tested the following hypotheses: 1) Treatment-seeking adults with clinically significant OCD symptoms would report lower trait mindfulness and selfcompassion compared to treatment-seeking adults with clinically significant depression/anxiety symptoms and non-treatment-seeking adults (student sample) without clinically significant symptoms of OCD, depression or anxiety; 2) In treatmentseeking adults, mindfulness (facets) and self-compassion would be negatively associated with OCD symptom severity, obsessive beliefs and distress tolerance; 3) In treatment-seeking adults, mindfulness and self-compassion would predict OCD symptom severity, controlling for depression severity, and; 4) In treatment-seeking adults, mindfulness and self-compassion would continue to independently predict OCD symptom severity once the effects of depression severity, obsessive beliefs and distress tolerance were accounted for.

To achieve the study aims, an anonymous survey was conducted with adults awaiting treatment in National Health Service (NHS) Improving Access to Psychological Therapies (IAPT) services, which deliver evidence-based psychological

therapies for common mental health problems across England, in accordance with National Institute for Health and Care Excellence (NICE) guidelines. The survey was also conducted with a student sample from a university in the South of England to obtain a healthy control group (hypothesis 1).

4.2 Methods

4.2.1 Participants

A treatment-seeking **clinical sample** of participants was recruited through 28 IAPT services across England. Inclusion criteria were: i) adults aged 18+; ii) assessed and offered treatment in IAPT; iii) able to read and communicate in English (assumed by their participation). Exclusion criteria were: i) patients who had declined, started or completed treatment when services sent out the study invitations. As IAPT services are open to adults of all ages, an upper age limit was not applied to ensure the sample was representative of routine IAPT treatment seeking adults. The total clinical sample consisted of 1871 participants who were mostly White (93%), female (71%), (self-) employed (56%) with at least secondary education (96%, 41% with a university qualification). A small proportion of participants had mindfulness experience (18%) and/or had started an intervention at the time of survey completion (19%) (guided self-help typically starts shortly after assessment).

A student sample was recruited to represent non-treatment seeking adults, from among whom a sub-sample of healthy controls were selected to test the first hypothesis (see further details below). Inclusion criteria for the **student sample** were: i) adults 18 +; ii) able to read and communicate in English. Students awaiting or receiving treatment in an NHS mental health or NHS psychological therapies service were excluded. The total student sample consisted of 540 participants, who were predominantly White (84%) and female (82%) without mindfulness experience (87%), had achieved at least secondary education (99%, 25% with a university qualification) and self-identified as students (93%). See Table A.1, Appendix A for further details about the samples.

To test the first hypothesis, a subset of clinical sample participants who scored above the clinical cut-off on the OCI-R formed the obsessive compulsive (OC) group (n=833) while a subset of clinical sample participants who scored below the clinical cut-off on the OCI-R but above the clinical cut-off for the GAD-7 questionnaire and/or the PHQ-9 formed the anxious depressed (AD) group (n=738). A subset of student sample participants scoring below the clinical cut-off on the OCI-R, PHQ-9 and GAD-7 formed the healthy controls (HC) group (n=231). Only those participants making up the OC, AD and HC groups were included in the statistical analysis testing hypothesis 1. See table A.2, Appendix A for further group details. Selecting healthy controls from a student rather than a community sample was informed by pragmatic considerations, given that the size of the sample would require considerable financial resources to remunerate community sample participants for taking part in the study. Sociodemographic variables were not anticipated to substantively affect the variables of interest.

4.2.2 Procedure

IAPT services posted or handed out a letter of invitation to eligible patients, containing a link to the online information sheet and survey. Participants were also given the option to request a paper copy to complete the survey offline. To recruit the student sample, the study was advertised at university using posters and flyers, an online research participant system, student forums and emails sent by academic staff on the researchers' behalf.

The clinical sample completed the survey on the Bristol Online Survey platform (BOS, Bristol, UK). Qualtrics (Qualtrics, Provo, UT) was used with the student sample

to ensure compatibility with university IT systems. Survey completion took approximately 20-30 minutes. As the survey was anonymous, participants were informed in the participant information sheet that consent was assumed by their submission of the online or paper survey. Ethical approval for the study was granted by an NHS research ethics committee.

4.2.3 Measures

The **Five-facet mindfulness questionnaire -Short Form** (FFMQ-SF) (Bohlmeijer, ten Klooster, Fledderus, Veehof, & Baer, 2011) is a 24-item measure of trait mindfulness, also described as mindfulness skills, that is highly correlated (r = .89) with the FFMQ-39 (Baer et al., 2006) that it derived from. Items are rated on a five-point Likert scale (1 (never or very rarely true) to 5 (very often or always true)). The FFMQ-SF has five subscales: observing (for experienced meditator samples), describing, acting with awareness, nonjudging and non-reacting. Bohlmeijer et al. (2011) reported adequate to excellent internal consistency (ranging from α =.73 to .91) across the five subscales.

Since the development of the FFMQ, multiple studies have called the construct validity of the observe facet into question (also see Rudkin, Medvedev, & Siegert, 2018) as it was unexpectedly positively associated with markers of poor mental health in nonmeditating (e.g. Baer et al., 2006; 2008), heterogeneous clinical (Curtiss & Klemanski, 2014) and/or OCD (Emerson et al., 2017) samples. The authors of the studies concluded that in these samples, the observe facet might measure maladaptive, self-focused attention rather than the intended mindful observation of present-moment experiences with equanimity. Therefore, as research has shown better evidence for a

four- than a five-factor hierarchical structure of the FFMQ-39 and/or FFMQ-15 among novice meditators and patients with heterogeneous mental health problems (e.g. Baer et al., 2008; Curtiss & Klemanski, 2014; Gu et al., 2016), the current study excluded the observe facet from the FFMQ-SF. The FFMQ-SF full scale minus the observe facet will be referred to as the FFMQ-SF-O. For this study, the internal consistency of the FFMQ-SF-O was α =.83 in the clinical sample and α =.84 in the student sample.

The Self-compassion scale - Short Form (SCS-SF) (Raes, Pommier, Neff, & Van Gucht, 2011) is a 12-item measure of self-compassion rated on a five-point Likert scale (1 (almost never) to 5 (almost always)). It has good internal consistency ($\alpha \ge .86$) and test-retest reliability (intra-class correlation coefficient (ICC) = 0.89 (95% CI [0.87-0.93]) and a near perfect correlation (r = 0.97) with the original 26-item SCS (Neff, 2003) (Garcia-Campayo et al., 2014; Raes et al., 2011). It has good construct validity evidenced through expected negative medium to large correlations with, a.o., measures of depression and anxiety (Hayes, Lockard, Janis, & Locke, 2016). Confirmatory factor analysis showed a good fit for the same six-factor hierarchical structure (subscales are: self-kindness, self-judgement, common humanity, isolation, mindfulness and over-identification) as the original SCS. However, as internal consistency for (some of) the subscales was relatively low (ranging from .54 to .81), Raes et al. (2011) recommend limiting the use of the SCS-SF to the full-scale score. Internal consistency: clinical sample α = .84, student sample: α = .86.

The **Obsessive-Compulsive Inventory - Revised** (OCI-R) is an 18-item measure of OCD symptoms adapted from the long-form OCI (Foa, Kozak, Salkovskis, Coles, & Amir, 1998), with good reliability and validity indices and a clinical cut-off score of 21 (Foa et al., 2002; Huppert et al., 2007). Items are rated on a five-point rating scale (0

(not a lot) to 4 (extremely)). Six sub-scales relate to OCD symptom subtypes: washing, checking, ordering, obsessing, neutralising and hoarding. Since its inception, hoarding symptoms have been re-classified as a separate hoarding disorder (APA, 2013). As only one study has re-examined the specificity and sensitivity of the OCI-R without hoarding items (Wootton et al., 2015), this study preserved the 18-item OCI-R full scale (and associated cut-off score). Internal consistency of the OCI-R was excellent: clinical sample (α =.90; student sample α =.92).

The **Obsessive Beliefs Questionnaire** (OBQ-20) is a 20-item version of the original OBQ-87 (OCCWG, 2005). Four subscales measure overestimation of threat, inflated responsibility, over-importance of (need to control) thoughts and perfectionism/ intolerance of uncertainty. Items are rated on a 7-point Likert scale (1 (disagree very much) to 7 (agree very much)). The OBQ-20 has adequate to good internal consistency (ranging from .78-.83 across three community or student samples) (Moulding et al., 2011) and correlates highly (r= .93 -.99) with the 38-item OBQ-TRIP from which it was derived (Fergus & Carmin, 2014). Subscales showed a moderate to strong correlation with OCD symptoms (r=.48-.74) in a clinical sample (Fergus & Carmin, 2014), suggesting good convergent validity. Internal consistency was excellent in the current study (clinical sample: α =.94; student sample α =.94).

The **Distress Tolerance Scale** (DTS) is a 15-item measure of distress tolerance that is most commonly used to study distress tolerance in OCD (Robinson & Freeston, 2014). Items are rated on a 5-point scale (from 1 (strongly agree) to 5 (strongly disagree)). The four subscales are: i) tolerance (of emotional distress); ii) absorption (of attention by negative emotions); iii) appraisal (of (one's responses to) emotional distress); and iv) regulation (efforts to get rid of or avoid distress). The DTS has good

discriminant validity, internal consistency (α =.83-.85) and test-retest reliability over 6 months (ICC=.61) (Simons & Gaher, 2005). In the current study, internal consistency was excellent (clinical sample α =.93, student sample α =.92).

Patient Health Questionnaire-9. (PHQ-9) is a widely used 9-item questionnaire of depression severity rated on a four-point scale (0 (not at all) to 3 (nearly every day)) (Kroenke et al., 2001). It has good construct validity (evident in strong positive correlations with functional impairment, disability days, and symptom-related difficulty) and excellent internal consistency (α =.86-.89 across two studies) and testretest reliability (r=.84) (Kroenke et al., 2001). The recommended clinical cut-off score of \geq 10 had good sensitivity (88%) and specificity (88%) against a mood disorder diagnosis criterion (Kroenke et al., 2001). The choice to use the PHQ-9 was informed by its excellent psychometric properties and the fact that it is routinely used in IAPT to screen for depression symptoms (Hay, 2011). Furthermore, its brevity helped to minimise the burden on participants. Internal consistency was good (clinical sample: α =.87, student sample: α =.85).

Generalized Anxiety Disorder-7 (GAD-7) is a widely used 7-item questionnaire rated on a four-point scale (0 (not at all) to 3(nearly every day)) (Spitzer et al., 2006). The GAD-7 has excellent internal consistency (α=.92) and good test-retest reliability (*ICC*=0.83), factorial, procedural and construct validity (showing expected correlations with general health and depression questionnaires) (Spitzer et al., 2006). Designed as a screening measure for generalised anxiety disorder, the GAD-7 also detects panic disorder, social phobia and PTSD and is now recommended as a broadspectrum screening tool for anxiety symptoms (Beard & Bjorgvinsson, 2014). The GAD-7 is a primary screening and outcome measures in IAPT services (Hay, 2011).

IAPT services apply a cut-off score of 8, following the recommendation by Kroenke et al. (2007) that it is a reasonable cut-off score for the identification of possible cases of anxiety disorders. Therefore, the current study applied this cut-off score to identify adults with clinically significant anxiety symptoms. Internal consistency was excellent (clinical sample α =.89, student sample α =.90).

Participants were asked seven multiple-choice **sociodemographic questions about** their age group, gender, ethnicity, highest education qualification, current employment status, and prior mindfulness experience (MBI completion or regular mindfulness practice). Clinical sample participants were asked to indicate their IAPT treatment status.

4.2.4 Sample size & power calculations

Power calculations for the first hypothesis (using the statistical programme G^*Power , power set to .90, d=.2, two-tailed, p<.05) showed at least 527 participants per group were needed in to detect potentially only small differences in mindfulness and self-compassion between the OC and AD groups (see participant and statistical analysis (hypothesis 1) sections), resulting in a recruitment target of at least 1581 participants across the two samples (clinical: 1054, student: 527). Recruitment continued for a year, until each group's target was reached. This sample size was also ample to detect even small effects in correlational, hierarchical regression analyses conducted to test the second and third hypotheses (e.g. Fritz & MacKinnon, 2007).

4.2.5 Missing data

Following ethical guidelines and consultation with members of a lived experience advisory panel, participants could complete the study without being forced to answer all questions. Just 1.4% of (sub)scale data was missing, across 17% of cases and all variables. Data was missing completely at random (Little's MCAR test: γ^2 (2661) = 2773.53, p = .063). There was relatively more missing data for the clinical sample (1.8% of the total clinical sample versus .1% of total student sample). This may be because the survey platform for the clinical sample did not prompt participants who missed a question. Also, approximately 15% of the clinical sample completed the survey offline (through active patient requests and research site recruitment strategies) whereas student sample participants exclusively accessed the survey online. Scrutinising paper copies, which generated approximately 25% of all missing data, suggested that unintended changes to the survey layout and participants (accidentally) skipping an entire page contributed to missing data. List- or pair-wise deletion methods are increasingly considered outdated in dealing with missing data (Enders, 2010). However, in case of a very low percentage of missing data, particularly if missing completely at random, the specific method chosen to address missing data is unlikely to significantly affect results (e.g. Dong & Peng, 2013; Enders, 2010). Therefore, default (IBM SPSS version 25) pair- or list-wise deletion methods were used.

4.2.6 Statistical analyses

Descriptive statistics included mean scores and standard deviations for questionnaire data and frequencies and percentages for categorical sociodemographic

questions. Visual inspection of histograms, quantile-quantile (QQ) plots and probability-probability (PP) plots was used to assess normality of scaled variables. To test the first hypothesis, Chi-square tests were first conducted to test (OC, AD, HC) group differences on sociodemographic variables. Cramer's *V* tests examined the strength of the association. One-way between-group Analysis of Variance (ANOVA) tested the group effect on mean FFMQ-SF-O and SCS-SF full-scale scores. Contrast tests used bootstrap p-values and were converted into Cohen's *d*, using the pooled SD (Field, 2013). Cohen's (1992) guidelines were used to interpret effect sizes: .20 = small .50=medium .80 = large.

To test the second hypothesis, robust Pearson's zero-order correlations of the questionnaire data were calculated for the total clinical sample. Correlations were inspected for multi-collinearity and interpreted as follows: .10=small, .30 = medium, .50= large (Field, 2013). Robust hierarchical regression analyses tested SCS-SF and FFMQ-SF-O (sub-)scales (step 2) as independent predictors of OCI-R (sub)scale scores, controlling for depression severity (PHQ-9) (step 1) (hypothesis 3). Analyses were repeated with SCS-SF and FFMQ-SF (sub-)scales entered in step 3, controlling for obsessive beliefs and distress tolerance (step 2) and depression severity (step 1) (hypothesis 4). An effect was statistically significant if the BCa 95% CI did not contain 0. Effect sizes for R^2 , ΔR^2 and sr^2 were calculated using Cohen's f^2 (0.02=small, 0.15=medium, 0.35=large) (Cohen, 1988; Selya, Rose, Dierker, Hedeker, & Mermelstein, 2012).

All analyses were conducted using IBM SPSS (version 25). All analyses were repeated without participants who had mindfulness experience and/or started IAPT treatment (see participants section) to check the significance and size of effects

remained unchanged. Bonferroni corrections (p criterion =.05/k) were applied to calculate the familywise error rate (Field, 2013).

4.3 Results

4.3.1 Hypothesis 1

To examine the first hypothesis, one-way ANOVA was conducted to test the group effect (OC, AD, HC) on mindfulness (FFMQ-SF-O) and self-compassion (SCS-SF). Prior to this, group effects on sociodemographic variables were tested, using Chisquare.

The obsessive-compulsive (OC) (n=833), anxious-depressed (AD) (n=738) and healthy controls (HC) (n=231) groups differed significantly on the distribution of employment (χ^2 (12) = 1021.48, p <.001, Cramer's V=.53, p<.001), age groups (χ^2 (12) = 618.1, p<.001, Cramer's V:.42, p<.001), education (χ^2 (4) = 58.30, p<.001, Cramer's V=.13, p<.001), and mindfulness experience (χ^2 =18.88, p=.001, Cramer's V=.07, p<.001, small effect: HC vs (OC & AD)). See Table A.2 in Appendix A for further details. As all but the last variables were intrinsic to the student sample and/or not independent of the group effect (Field, 2013; Miller & Chapman, 2011), they were not controlled for when testing the group effect on mindfulness and self-compassion. As mindfulness experience enhances mindfulness skills (e.g. Baer, 2008), all analyses (below) were repeated without participants with mindfulness experience as a sensitivity analysis to establish whether statistical significance and size of effects remained unchanged.

One-way ANOVA showed a significant group effect on SCS-SF and FFMQ-SF-O (see **Table 1**). Nonorthogonal contrast tests (contrast 1: OC vs HC, contrast 2: OC vs

AD) showed all effects were in the expected direction; the OC group scored significantly lower on mindfulness and self-compassion than the HC (large effect) and AD groups (medium effect) (See **Table 2**). Excluding OC, AD or HC participants who had mindfulness experience and/or started IAPT treatment did not alter the significance or size of effects. See Tables B1 and B2, Appendix B for group effects on OBQ-20 and DTS.

Table 1

One-way ANOVA testing group (OC, AD, HC) effect on FFMQ-SF and SCS-SF

	Group	n	M	SD	df	Welch's F
FFMQ-SF-O	OCD	785	48.7	8.8	683.27	410.43*
	AD	691	54.15	9.2		
	HC	231	65.7	7.66		
SCS-SF	OCD	813	24.1	6.56	626.51	326.10*
	AD	716	27.44	7.42		
	HC	230	37.75	7.37		

Note: HC= healthy controls, AD=anxious/depressed group, OC= obsessive-compulsive group, FFMQ-SF-O= Five-Facet Mindfulness Questionnaire-Short Form full scale minus observe subscale, SCS-SF= Self-Compassion Scale -Short Form, * *p*<.001

Table 2Contrast tests for FFMS-SF and SCS-SF. Contrast 1 = OC vs HC, contrast 2 = OC vs AD

Scale	Contrast	df	t	Hedges' g [95% CI]	Conclusion **
FFMQ-SF-O	1	424.73	-28.62*	-1.99 [-2.16, -1.82]	OC <hc< td=""></hc<>
	2	1432.26	-11.60*	60 [71,50]	OC <ad< td=""></ad<>
SCS-SF	1	338.45	-25.43*	-2.02 [-2.19, -1.85]	OC <hc< td=""></hc<>
	2	1438.72	-9.33*	48 [5838]	OC <ad< td=""></ad<>

Note: HC= healthy controls, AD=anxious/depressed group, OC= obsessive-compulsive group, FFMQ-SF-O= Five-Facet Mindfulness Questionnaire-Short Form full scale minus observe subscale, SCS-SF= Self-Compassion Scale -Short Form, g = Hedges' g, * p < .001, ** indicates which of the two groups had the significantly lower mean score for the scale.

4.3.2 Hypothesis 2

To test the hypothesis that mindfulness (facets) and self-compassion would be negatively associated with OCD symptom severity, obsessive beliefs and distress tolerance in the clinical sample, Table 3 reports the robust Pearson zero-order correlations between all measures for the total clinical sample. There were medium to large negative correlations of the FFMQ-SF-O and SCS-SF with the OCI-R. The BCa 95% CI of these correlations did not overlap; the association of mindfulness with OCD symptoms was significantly larger than for self-compassion. See Table C1, Appendix C for zero-order correlations between OCI-R subscales, FFMQ-O-S subscales and SCS-SF.

There were large, negative zero-order correlations of mindfulness and self-compassion with obsessive beliefs and distress tolerance. Partial correlations with obsessive beliefs were similar for mindfulness (*pr* (controlling for self-compassion) =-.33, BCa 95% CI [-.37, -.29]) and self-compassion (*pr* (controlling for mindfulness) =-.35, BCa 95% CI [-.39, -.31]). The partial correlation between self-compassion and distress tolerance (*pr* =.31, BCa 95% CI [.26,.35]) was stronger than for mindfulness (*pr* =.21, BCa 95% CI [.15, .27]). See Table C2 in Appendix C for zero-order correlations between OBQ-20 subscales, FFMQ-O-S subscales and SCS-SF.

The known association of depression with mindfulness, self-compassion and OCD was borne out in the current study as **Table 3** shows significant medium to large correlations of the PHQ-9 with the OCI-R, FFMQ-SF-O and SCS-SF. The fact that anxiety is often a key feature of OCD was reflected in a large positive correlation between the OCI-R and anxiety symptoms (GAD-7). Sensitivity analyses excluding clinical sample participants with mindfulness experience and/or who had started IAPT

treatment, left the significance and size of effects unchanged. See Appendix C for clinical sample inter-correlations between FFMQ-SF-O (Table C3), OCI-R (C4), OBQ-20 (C5) and DTS (C6) subscales.

Table 3Clinical sample descriptive statistics and robust Pearson zero-order correlations [BCa 95% CI, 1000 samples] for all measures

Measure	М	SD	FFMQ_SF-	SCS-SF	OCI-R	OBQ-20	DTS	PHQ-9
			O					
FFMQ-SF-O	52.49	10.00						
SCS_SF	26.56	7.82	.62*					
			[.59,.65]					
OCI-R	21.6	13.2	44*	35*				
			[47,40]	[39,31]				
OBQ-20	86.46	25.97	57*	58*	.57*			
			[6054]	[61,54]	[.54,.60]			
DTS	2.32	.88	.43*	.46*	36*	51*		
			[.38,.47]	[42,.50]	[40,32]	[[55,47]]	
PHQ-9	14.72	6.36	49*	43*	.42*	.44*	33*	
			[53,45]	[47,39]	[.38,.46]	[.40,.48]	[38,28]	
GAD-7	13.16	5.54	49*	44*	.48*	.51*	41*	.68*
			[53,45]	[48,40]	[.45,.52]	[.48,.54]	[46,37]	[.65,.71]

Note: FFMQ-SF-O= Five-Facet Mindfulness Questionnaire-Short Form full scale minus observe subscale, SCS-SF= Self-Compassion Scale-Short Form, OCI-R=Obsessive Compulsive Inventory-Revised, OBQ-20 = Obsessive Beliefs Questionnaire-20, DTS = Distress Tolerance Scale, PHQ-9=Patient Health Questionnaire-9, GAD-7=Generalised Anxiety Disorder-7

4.3.3 Hypothesis 3

Robust hierarchical regression analyses tested mindfulness facets and self-compassion as independent predictors of OCD symptoms (step 2), controlling for depression severity (step 1). Results show that at the full-scale level, the PHQ-9 predicted 19% of the variance in the OCI-R, while FFMQ-SF-O (facets) and SCS-S explained a further 7% (small to medium effect) (see **Table 4**). Mindfulness was the more substantive

^{*}*p*<.001.

predictor of OCD symptoms (small to medium effect) than self-compassion (small effect). At the mindfulness facet level, all facets apart from 'acting with awareness' independently predicted OCD symptom severity, after controlling for depression severity ($\Delta R^2 = .07$) (small effects). At the OCD symptom subtype level (controlling for depression severity) there was a medium effect of the four mindfulness facets and selfcompassion on obsessing symptoms ($\Delta R^2 = .16$) and a small effect on neutralising and physical compulsions (ordering: $\Delta R^2 = .03$; checking: $\Delta R^2 = .03$, washing: $\Delta R^2 = .02$; neutralising: $\Delta R^2 = .02$) (all F-change statistics significant at p < .001) (see Table D1, Appendix D for further details). The 'non-reactivity' and 'nonjudging' facets were independent negative predictors of obsessing symptoms (non-reactivity: pr = -.29, sr^2 =.055, p=.001); nonjudging: pr = -.25, $sr^2 = .039$, p =.001) (at Bonferroni-corrected pvalue .008). The 'describe' facet independently predicted washing (pr = -.10, $sr^2 = .009$, p = .001), checking (pr = -.07, $sr^2 = .005$, p = .002) and neutralising symptoms (pr = -.07, sr^2 =.004, p=.006), but effects were small. The 'nonjudging' facet also significantly but marginally predicted checking symptoms (pr = -.07, $sr^2 = .005$, p=.002). Self-compassion was an independent negative predictor of ordering symptoms (pr = -.08, $sr^2 = .006$, p =.003) (small effect). All analyses were repeated with mindfulness experience (Y/N) and treatment status (not received vs (partly) received) entered in step 1, followed by PHQ-9 (step 2) and FFMQ-SF and SCS-SF (step 3). Results showed these variables did not significantly independently predict OCI-R total or subscale scores (all F-change statistics non-significant (at p < .05).

Table 4Hierarchical regression of PHQ-9, FFMQ-SF-O total and subscales and SCS-SF on OCI-R total scale. BCa 95 % CI, SE and p-values based on 1000 bootstrap samples

Outcome	Model	Predictor	В	lower	upper	SE	β	p	ΔR^{2^*}	pr	sr^2
OCI-R tota	l <u> </u>	PHQ-9	0.92	0.81	1.01	0.05	.44	.001	.19		
<i>N</i> =1606	2	PHQ-9	0.58	0.48	0.69	0.05	.28	.001	.07	.27	.057
		FFMQ-SF-O	-0.32	-0.24	-0.38	0.04	24	.001		20	.032
		SCS-SF	-0.17	-0.07	-0.26	0.05	10	.001		09	.006
	2	PHQ	0.61	0.49	0.72	0.06	.30	.001	.07	.28	.06
		Describe	-0.32	-0.47	-0.17	0.08	10	.001		11	.009
		Act aware	-0.16	-0.34	0.03	0.11	05	.11		04	.001
		Nonjudge	-0.43	-0.6	-0.27	0.09	12	.001		13	.013
		Nonreact	-0.42	-0.63	-0.20	0.11	11	.001		10	.008
		SCS-SF	-0.14	-0.25	-0.04	0.05	08	.004		07	.004

Note: OCI-R=Obsessive Compulsive Inventory-Revised, PHQ-9=Patient Health Questionnaire-9, FFMQ-SF-O= Five-Facet Mindfulness Questionnaire-Short Form full scale minus observe subscale, SCS-SF= Self-Compassion Scale-Short Form, ΔR^2 =(change) explained variance, pr=partial correlation, sr^2 = semi-partial correlation squared.

4.3.4 Hypothesis 4

To examine whether trait mindfulness and self-compassion predicted OCD symptoms over and above obsessive beliefs and distress tolerance, robust hierarchical regression of mindfulness and self-compassion (step 3) on OCD symptoms was repeated with obsessive beliefs and distress tolerance entered in step 2, after controlling for depression severity (step 1). **Table 5** shows that after depression severity (R^2 =.19), obsessive beliefs and distress tolerance (ΔR^2 =.19), mindfulness (facets) and self-compassion significantly but marginally predicted OCD symptoms (ΔR^2 =.01). Mindfulness (pr =-.10, sr^2 =.006) and not self-compassion, was a statistically significant but small independent negative predictor of OCD symptoms. At the mindfulness facet level, none of the mindfulness facets independently predicted total OCD symptoms. However, at the OCD symptom subtype level (see table D2, Appendix D for further

^{*} *F*-change statistic significant at p < .001

details), there was a small effect of mindfulness and self-compassion on the obsessing symptom dimension (ΔR^2 =.05), specifically a small to medium effect for 'nonreactivity' (pr=-.27, sr^2 =.04, p<.001), followed by 'nonjudging' (pr=-.15, sr^2 =.01, p=.001). Self-compassion also significantly independently predicted checking (pr=-.09, sr^2 =.008, p=.002) and washing symptoms (pr=-.07, sr^2 =.004, p=.005) but effects were small. None of the four mindfulness facets or self-compassion significantly independently predicted ordering or neutralising symptoms.

Table 5Hierarchical regression of PHQ-9, OBQ-20, DTS, FFMQ-SF-O total and subscales and SCS-SF on OCI-R total scale. BCa 95 % CI, SE and p-values based on 1000 bootstrap samples

sampies											
Outcome	Model	Predictor	В	lower	upper	SE	β	p	ΔR^2 *	pr	sr^2
OCI-R total	1	PHQ-9	0.91	0.81	1.01	0.05	.44	.001	.19		
<i>N</i> =1497		PHQ-9	0.44	0.35	0.53	0.05	.20	.001	.19	.23	.040
	2	OBQ-20	0.23	0.20	0.26	0.01	.45	.001		.41	.125
		DTS	-0.95	-1.71	-0.19	0.39	06	.016		07	.003
		PHQ-9	0.41	0.31	0.5	0.05	.20	.001	.01	.21	.027
		OBQ-20	0.22	0.19	0.25	0.02	.44	.001		.37	.097
	3	DTS	-0.95	-1.71	-0.19	0.39	06	.02		07	.003
		FFMQ-SF-O	-0.14	-0.21	-0.07	0.04	11	.001		10	.006
		SCS-SF	0.12	0.02	0.21	0.05	.07	.018		.07	.003
		PHQ	0.41	0.31	0.51	0.05	.20	.001	.01	.21	.026
		OBQ-20	0.23	0.19	0.26	0.02	.44	.001		.37	.097
		DTS	-0.93	-1.71	-0.11	0.39	06	.021		07	.003
	2	Describe	-0.15	-0.29	-0.01	0.07	05	.033		06	.002
	3	Act aware	-0.12	-0.32	0.06	0.09	04	.173		04	.001
		Nonjudge	-0.07	-0.23	0.09	0.09	02	.437		02	.000
		Nonreact	-0.26	-0.45	-0.54	0.10	07	.009		07	.003
		SCS-SF	0.14	0.03	0.24	0.05	.08	.009		.07	.003

Note: OCI-R=Obsessive Compulsive Inventory-Revised, PHQ-9=Patient Health Questionnaire-9, OBQ-20 = Obsessive Beliefs Questionnaire-20, DTS = Distress Tolerance Scale FFMQ-SF-O= Five-Facet Mindfulness Questionnaire-Short Form full scale minus observe subscale, SCS-SF= Self-Compassion Scale-Short Form, ΔR^2 =(change) explained variance, pr=partial correlation, sr^2 = semi-partial correlation squared.

^{*} F-change statistic significant at p < .001

4.4 Discussion

4.4.1 Summary of results

This study aimed to test if people with clinically significant OCD symptoms showed disproportionately poor mindfulness and self-compassion skills when compared to non-OCD clinical controls and to healthy controls, to explore the relationship between mindfulness and self-compassion with OCD symptom severity and to examine whether these constructs helped to explain OCD symptoms over and above depression, obsessive beliefs and intolerance of distress. The rationale for the study was to seek initial evidence for whether and how interventions that enhance mindfulness and self-compassion skills may benefit OCD symptom reduction.

The first hypothesis was supported as treatment-seeking adults with clinically significant OCD symptoms reported significantly lower trait mindfulness and self-compassion than healthy controls (in line with findings from Crowe and McKay (2016), Didonna et al. (2018) and Emerson et al. (2017)) and treatment-seeking adults with clinically significant depression and/or anxiety symptoms. This provides initial support for the notion that adults with OCD may experience particular challenges with being mindful and self-compassionate, even relative to people with other common mental health problems.

In support of the second hypothesis, there were significant medium to large negative associations of mindfulness and self-compassion with OCD symptoms among treatment-seeking adults, mirroring results from previous studies (Solem et al., 2015; Wetterneck et al., 2013). Results furthermore showed that mindfulness and self-compassion predicted OCD symptoms (small effect), independent of depression severity (hypothesis 3). Mindfulness was a stronger independent predictor of overall

OCD symptoms (small effect) than self-compassion, which suggests that mindfulness skills may be more pertinent to OCD symptom reduction than self-compassion. At the mindfulness facet level, there was a small to medium effect of 'nonreactivity' and 'nonjudging' facets on obsessions. The describe facet predicted washing, checking and neutralising symptoms and self-compassion predicted ordering symptoms but effects were small. The acting with awareness facet was not independently associated with any OCD symptoms. This is perhaps surprising given the theorised central importance of acting with awareness to interrupting unhelpful repetitive thinking processes, such as rumination and worry (supported by the fact that Emerson et al. (2017) found a small effect for acting with awareness on the frequency and distress associated with obsessive intrusions) and habitual, behavioural responses (e.g. Segal et al., 2013). The lack of association possibly reflects that compulsions in OCD are perhaps not best understood as automatic, habitual behaviours carried out with little awareness, but rather as functional behaviours aimed at reducing anxiety (Abramowitz & Jacoby, 2015).

As predicted, mindfulness and self-compassion had a (comparable) negative association with obsessive beliefs (large effect) and a positive association with distress tolerance (medium to large effect), which was stronger for self-compassion than mindfulness. The latter is unsurprising as self-compassion and distress tolerance are both measured in relation to times of difficulty whereas the mindfulness measure also captured everyday life. Also, the distress tolerance measure incorporates appraisal of one's ability to tolerate distress which reflect self-criticism (e.g. 'I am ashamed of myself when I feel distressed or upset').

While mindfulness and self-compassion independently contributed to the prediction of OCD symptoms beyond depression severity, these associations were

attenuated once the role of obsessive beliefs and distress tolerance with OCD symptoms was accounted for; mindfulness but not self-compassion continued to independently, if marginally, predict OCD symptoms (hypothesis 4). Interestingly, distress tolerance did not independently predict OCD symptom subtypes other than obsessing symptoms (small effect), which is in line with results from a study on the associated construct of experiential avoidance (Abramowitz, Lackey, & Wheaton, 2009). None of the mindfulness facets independently predicted (total) OCD symptoms. At the OCD symptom subtype level, however, the ability to bring a nonreactive stance to inner experiences, i.e. to let unpleasant thoughts and feelings pass without acting to get rid of them, made a relatively substantial contribution to predicting obsessing symptoms (small to medium effect), followed by the ability to take a non-evaluative stance towards distressing thoughts and images (nonjudging). Self-compassion independently predicted washing and checking symptoms but effects were very small.

4.4.2 Strengths and limitations

The current study was conducted with a large clinical sample of treatment-seeking adults from a wide, varied geographical area. A priori power calculations ensured the study was sufficiently powered to test group differences in mindfulness and self-compassion. The study accounted for the known association of depression with mindfulness, self-compassion and OCD, and tested the unique association of mindfulness and self-compassion with OCD symptoms, over and above (more) established constructs that contribute to explaining OCD symptoms, i.e. obsessive beliefs and distress tolerance.

Limitations of the study included that respondents, who were predominantly White females, may not adequately represent all adults who experience OCD symptoms. To minimise the study's demands on participants and IAPT services, it was not possible to establish a formal diagnosis through a structured diagnostic interview or to administer the clinician-administered Y-BOCS, which is the gold standard for assessing OCD symptom severity (e.g. Moritz et al., 2002) Instead, groupings were guided by clinical cut-off scores on well-established measures of OCD, depression and/or anxiety. Due to the significant overlap of depression and anxiety symptoms and in the absence of a formal diagnosis, it was not possible to make separate group comparisons of OCD with anxiety and with depression disorders, respectively. No upper age limit was applied to the clinical sample to ensure it was representative of routine IAPT treatment-seeking adults. Whilst aging processes could conceivably affect the variables of interest, supplementary analyses showed that excluding adults aged 65+ did not substantively alter the size or significance of effects for any of the analyses. The healthy control group was drawn from a student sample with resultant significant differences in age, education and employment between the clinical groups (OC and AD) and healthy controls. It would have been preferable to recruit a community sample as it would have been more likely to match clinical sample participants on sociodemographic variables, but it was not feasible to resource for the recruitment of a large community sample. A large proportion of students presented with clinically significant symptoms of depression, anxiety and/or OCD, mirroring other studies of student mental health (e.g. Hunt & Eisenberg, 2010). As a result, it was not possible to achieve a larger healthy controls sample, which contributed to unequal sample sizes. Significant, large effects

were nonetheless found for all OC vs HC group comparisons, showing the study was sufficiently powered.

The study results cast doubt on the specificity of the recommended cut-off score the OCI-R (e.g. Foa et al., 2002) as a very large proportion of treatment-seeking adults scored within the clinical range of OCD symptoms. Nonetheless, the OCI, from which the OCI-R is derived, is the primary outcome measure of OCD symptom severity within IAPT (Hay, 2011). Also, the fact that the OC group endorsed obsessive beliefs and distress tolerance to a significantly greater degree than the AD group (Tables B1 and B2 in Appendix B) is in line with the cognitive behavioural model of OCD. Supplementary analyses showed that dividing the sub-groups based on an OCI-R cut-off score of 34, derived from the mean + 1 SD (total sample), did not have any notable impact on the size and significance of between-group effects.

While results were largely in line with predictions, it is evidently not possible to assume that mindfulness and self-compassion are causally related to OCD symptoms and by extension to conclude that enhancing mindfulness and self-compassion skills will reduce OCD symptoms. Instead, it is possible that OCD symptom reduction leads to improvements in mindfulness and self-compassion skills. Furthermore, the cross-sectional nature of the study precludes any firm conclusions about the nature of the relationship between mindfulness, self-compassion and obsessive beliefs. For example, there may be an indirect effect of mindfulness and self-compassion on OCD symptoms through obsessive beliefs. Also, the relationship of mindfulness and self-compassion with obsessive beliefs may reflect their shared association with constructs such as decentering (Bernstein et al., 2015) or meta-cognitive awareness (Teasdale et al., 2002) and further research is needed to ascertain their shared and unique conceptual elements.

4.4.3 Research and clinical implications

Future studies should attempt to replicate results with adults with a confirmed diagnosis of OCD and draw comparisons with matched adults with a diagnosis of depression and anxiety disorders (without OCD) to further examine the unique associations of mindfulness and self-compassion with OCD. As results from recent factor analytic studies of the SCS-SF are mixed (e.g. Garcia-Campayo et al.,2014; Gu, Cavanagh, Bear, & Strauss, 2017; Hayes, Lockard, Janis, & Locke, 2016; Strauss et al., 2016), future studies should test the association of self-compassion with OCD using new measures of self-compassion once available.

The nature of the relationship of mindfulness and self-compassion with obsessive beliefs also needs to be explored further; the conceptual overlap of nonjudging and nonreactivity facets and obsessive beliefs with decentering or metacognitive awareness should also be examined further in the context of OCD (Bernstein et al., 2015; Segal et al., 2013).

Also, it is conceivable that the small effect of mindfulness and self-compassion on OCD symptoms is mediated through obsessive beliefs. Studies that use experimental designs and include mediation analyses based on longitudinal data involving repeated measurement will be particularly helpful in confirming whether mindfulness and self-compassion skills have a direct effect on OCD symptoms or primarily impact on OCD symptoms through their effect on obsessive beliefs (Kazdin, 2007). Given the mixed evidence for (all) obsessive beliefs as a significant unique predictor of (dimensions of) OCD symptoms (e.g. Belloch et al., 2010; Steketee et al., 1998; OCCWG, 2003; Taylor et al., 2006; Tolin et al., 2006; Viar et al., 2011; Wu & Carter, 2008), it is also worth exploring how mindfulness and self-compassion relate to other psychological processes

implicated in the maintenance of OCD symptoms (e.g. see Treanor, 2011). The recent re-categorisation of OCD as a neuropsychiatric disorder (APA, 2013), albeit controversial (Abramowitz & Jacoby, 2015), also invites further research into the relationship of mindfulness and self-compassion with excessive habit formation, goal-directed behaviour deficits and the brain circuitry implicated in OCD.

Overall, results suggest that teaching mindfulness and self-compassion skills is likely to have only a small overall effect on OCD symptoms, with possibly a small-tomedium effect on the dimension of obsessing symptoms. This notion is supported by recent RCTs of Mindfulness-Based Cognitive Therapy (MBCT), either as a first -line (Selchen et al., 2017) or augmentation therapy for CBT (Key et al., 2017, Külz et al., 2018, Selchen et al., 2018), which overall show modest effects. The findings furthermore suggest that training mindfulness skills, particularly nonjudging and nonreacting skills, may be more pertinent to OCD symptom reduction than training selfcompassion skills, although the latter may have a small benefit for physical compulsions. Targeting obsessive beliefs is likely to be more beneficial to OCD symptom reduction than training mindfulness and self-compassion skills per se, although training mindfulness skills may have a small additional benefit for obsessing symptoms, e.g. unwanted sexual or aggressive thoughts. It is possible that teaching mindfulness skills that are directly targeted at OCD symptoms may be more potent than the current study of the association between the general tendency to be mindful in daily life and OCD symptoms suggests. Also, mindfulness-based interventions for OCD may still effectively target obsessive beliefs (e.g. Key et al., 2017; Külz et al., 2018; Selchen et al., 2017). Whilst reductions in obsessive beliefs following MBIs would not necessarily demonstrate that enhanced self-compassion and mindfulness skills

accounted for the change, Key et al. (2017) found that an increase in mindfulness skills was significantly correlated with a reduction in obsessive beliefs (r=-.63). Mediation analyses would need to explore the causality of this relationship. In conclusion, this study showed that mindfulness and self-compassion contribute to explaining OCD symptoms. The nature of their relationship with other constructs used to explain OCD, specifically obsessive beliefs, needs to be explored further, in order to more clearly assert that teaching mindfulness and self-compassion skills may bring added benefits to adults with OCD above and beyond CBT.

Chapter 5: Participant perspectives on the acceptability and effectiveness of Mindfulness-based Cognitive Behaviour Therapy approaches for Obsessive-Compulsive Disorder

Abstract

Cognitive behavioural therapy (CBT), which includes exposure and response prevention (ERP), is a highly effective, gold standard treatment for obsessive-compulsive disorder (OCD). Nonetheless, not all patients with OCD significantly benefit from CBT. This has generated interest in the potential benefits of Mindfulness-Based Interventions (MBIs), either integrated with CBT, to enhance engagement with ERP tasks, or delivered as a stand-alone, first-line or therapy to augment CBT. This paper reports on two qualitative studies that involved a thematic analysis of interview data with participants in a 10-week Mindfulness-Based ERP (MB-ERP) course (study 1) and a 9week Mindfulness-Based Cognitive Therapy course adapted for OCD (MBCT-OCD) (study 2). Whilst MB-ERP integrated a mindfulness component into a standard ERP protocol, MBCT-OCD adapted the psychoeducational components of the standard MBCT for depression protocol to suit OCD, but without explicit ERP tasks. Three common main themes emerged across MB-ERP and MBCT-OCD: 'satisfaction with course features', 'acceptability of key therapeutic tasks 'and 'using mindfulness to respond differently to OCD'. Sub-themes identified under the first two main themes were mostly unique to MB-ERP or MBCT-OCD, with the exception of '(struggles with) developing a mindfulness practice routine' whilst most of the sub-themes under the last main theme were shared across MB-ERP and MBCT-OCD participants. Findings suggested that participants generally perceived both MBIs as acceptable and potentially beneficial treatments for OCD, in line with theorised mechanisms of change.

Keywords: Obsessive Compulsive Disorder (OCD), Exposure and Response Prevention (ERP), Mindfulness-based Interventions (MBIs), Mindfulness-based

Exposure and Response Prevention (MB-ERP), Mindfulness-Based Cognitive Therapy (MBCT), Thematic Analysis

5.1 Introduction

Obsessive-compulsive disorder (OCD) is a debilitating mental health condition characterised by persistent intrusive thoughts, images or urges that cause significant anxiety or discomfort, and repetitive, ritualistic behaviours (e.g. hand washing) or mental acts (e.g. repeating special words) aimed at reducing anxiety or preventing anticipated adverse consequences of the intrusions (American Psychiatric Association, [APA], 2013).

The treatment of choice for OCD is exposure and response prevention (ERP), delivered with or without added cognitive strategies(APA, 2007; National Institute for Health and Care Excellence [NICE], 2005). ERP is a form of behaviour therapy that involves patients exposing themselves to their OCD triggers whilst refraining from compulsive behaviours, resulting in habituation (Foa & Kozak, 1986) and/or new learning that inhibits the existing conditioned response (Abramowitz & Arch, 2014; Craske et al., 2014). Cognitive strategies aim to re-evaluate maladaptive appraisals of intrusions (e.g. Salkovskis, 1999), as they derive from the cognitive model of OCD that posits that a person with OCD attributes significant meaning to common intrusive thoughts (e.g. Rachman & De Silva, 1978) due to maladaptive beliefs such as inflated responsibility, intolerance of uncertainty, perfectionism, overestimation of threat, the need to control thoughts and the over-importance of thoughts (Frost et al., 1997).

ERP is not a panacea; approximately 30-35% of people do not experience a statistically reliable reduction in symptoms post-treatment whilst 50-55% do not experience remission (Öst, Havnen, Hansen, & Kvale, 2015). Clinically, poor insight, i.e. highly overvalued ideation, OCD symptom severity and comorbid depression and/or anxiety are thought to be associated with poor outcomes (e.g. Foa, Abramowitz, Franklin, & Kozak, 1999). However, research evidence to date is equivocal as to predictors of treatment outcomes (Keeley, Storch, Merlo, & Geffken, 2008; Steketee, Siev, Yovel, Lit, & Wilhelm, 2019a).

ERP is often seen as a challenging therapy by clients and therapists alike (Keeley et al., 2008; Olatunji et al., 2009); the therapy is anxiety-provoking by design and this is magnified by high levels of distress intolerance associated with OCD (Cougle, Timpano, Fitch, & Hawkins, 2011). An observational study of OCD over a two-year period found that around 20% of participants who had refused (26%) or dropped out (31%) from CBT for OCD primarily did so due to fears about the treatment (Mancebo et al., 2011). This may also contribute to non-response among treatment completers as patient engagement with between-session ERP tasks is variable (Leeuwerik, Cavanagh, & Strauss, 2019) and research shows that only a high level of patient engagement is associated with remission (Simpson et al., 2011).

The variable response rate for ERP for OCD informed the exploration of cognitive therapy (CT) (i.e. without ERP) (Cottraux et al., 2001; Oppen et al., 1995). Most approaches to CT include behavioural experiments to gather evidence to evaluate the accuracy of existing and alternative interpretations of intrusions (Rachman, 1997). This may involve exposure to a trigger and prevention of compulsive behaviour but does not involve systematic and prolonged ERP.

More recently, Jacoby and Abramowitz (2016), proposing an inhibitory learning approach to ERP for OCD to maximise treatment outcomes, stressed the importance of patients being supported to develop 'open-mindedness' (p.32) towards the experience of anxiety and fear during ERP. This notion is also reflected in an emerging interest in the potential of innovative (add-on) interventions such as meta-cognitive therapy (MCT) (Fisher & Wells, 2008; Rees & van Koesveld, 2008; Rupp, Jürgens, Doebler, Andor, & Buhlmann, 2019), Acceptance and Commitment Therapy (ACT) (Twohig, 2009), and mindfulness-based cognitive therapy (MBCT) for OCD (Key, Rowa, Bieling, McCabe, & Pawluk, 2017; Külz et al., 2019). We suggest that a mindfulness-based approach could facilitate engagement with ERP tasks by enabling greater acceptance of intrusive thoughts, greater tolerance of distress, increased self-efficacy in relation to ERP task initiation and completion and greater self-compassion in response to intrusion-related shame.

Mindfulness can be defined as 'paying attention in a particular way: on purpose, in the present moment, and nonjudgmentally' (Kabat-Zinn, 1994, p. 4). Meta-cognitive therapy and ACT can be conceived of as mindfulness-*informed* interventions; they share theoretical underpinnings with mindfulness-*based* interventions (MBIs), such as Mindfulness-based stress reduction (MBSR) (Kabat-Zinn, 2003) and MBCT (Segal, Williams, & Teasdale, 2002) and include some mindfulness meditation practice or exercises in their approach. However, they do not include the 'systematic and sustained training in formal and informal mindfulness meditation practices (for both teacher and participants)' that characterises MBIs (Crane et al., 2017, p. 991) (also see Rees & Anderson, 2013).

Likewise, cognitive therapy and MBCT share much common ground, reflecting both theoretical and procedural overlap (Baer, 2003; Fennell & Segal, 2011), but clear points of divergence include that MBCT primarily teaches these skills through mindfulness practice whilst CT uses cognitive restructuring and behavioural experiments. Whilst cognitive therapies can include cognitive strategies that instruct patients to treat intrusions like the background noise of a turned-down radio (Rachman, 1997) and teach them to 'do nothing' in response to intrusions, i.e. drop compulsions (Clark & Purdon, 1993), these are mindfulness-informed strategies rather than the sustained mindfulness meditation practice that characterises MBCT; daily lengthy mindfulness practice per se is seen as key to successful MBCT outcomes (Segal, Williams, & Teasdale, 2013). Also, whilst CT works towards specific goals, MBIs such as MCBT embrace non-striving as participants are invited to 'simply to observe whatever is happening in each moment without judging it' (Baer, 2003), p.130) and do not attempt to explicitly target and change the content and meanings attributed to thoughts and/or associated beliefs; rather, they invite participants to observe their thoughts without judgment, teaching them to relate differently to the process of thinking (Baer, 2003; Fennell & Segal, 2011).

Research evidence to date suggests that MBIs are effective at reducing symptoms of depression and, to a lesser extent, anxiety (Goldberg et al., 2018; Strauss, Cavanagh, Oliver, & Pettman, 2014) and reduce the risk of relapse for depression (Kuyken et al., 2016). There is some research evidence that MBIs achieve their positive effects by enhancing mindfulness and self-compassion and reducing worry, rumination, the suppression or avoidance of negative thoughts, feelings or physical sensations and

through altering emotional and cognitive reactivity, e.g. (Gu, Strauss, Bond, & Cavanagh, 2015; van der Velden et al., 2015).

It is theoretically plausible that MBIs may also benefit OCD, through helping patients to: i) allow intrusive thoughts, images and urges into awareness and bring an interested, accepting attitude to this mental content and associated distress; ii) invite a non-judgmental, de-centred perspective on thoughts as passing mental events rather than facts (Segal et al., 2002), and; iii) perceive a wider range of choices about how to respond to intrusive thoughts and feelings of anxiety, rather than to react habitually (e.g. compulsions) (Hale, Strauss, & Taylor, 2013). In these ways, mindfulness may also facilitate engagement with ERP by enabling greater acceptance and tolerance of unpleasant thoughts, feelings and physical sensations that arise during ERP tasks (e.g. Didonna, 2009; Fairfax, 2008; Strauss et al., 2014; Treanor, 2011). This is an important area to explore as only a high degree and quality of engagement with ERP appears to predict post-treatment symptom remission, e.g. (Simpson et al., 2011). MBIs also cultivate self-compassion, which may further help to reduce conviction in obsessive beliefs (e.g. about the importance of thoughts or perfectionism) and allow greater acceptance towards feelings of guilt and shame associated with OCD (Shapiro & Stewart, 2011; Weingarden & Renshaw, 2015).

Quantitative studies of MBIs for OCD include a pilot RCT comparing standard ERP with Mindfulness-based ERP (MB-ERP), which integrates mindfulness practice with a standard ERP protocol (Strauss et al., 2018). The 95% confidence interval for the post-treatment between-group difference in OCD symptom reduction did not include the 5-point minimum clinically important difference in favour of MB-ERP, suggesting that a larger trial would be unlikely to show that MB-ERP outperformed ERP in terms

of OCD symptom reduction. Although results suggested that the addition of the mindfulness component would not likely improve OCD symptom outcomes, the authors concluded that further research would need to ascertain the effects of MBI formats that cultivate mindfulness more intensively. MBCT is a well-established MBI that was designed as a group therapy for depressive relapse prevention, integrates teaching mindfulness skills with psychoeducation, strategies and exercises drawn from cognitive behavioural therapy (CBT) for depression (Segal et al., 2002). Two recent RCTs of MBCT adapted for OCD as an augmentation therapy for CBT showed small benefits relative to waitlist controls (Key et al., 2017) and psychoeducation (Külz et al., 2019). A further uncontrolled study of MBCT as a first-line therapy for OCD suggested potentially moderate benefits of MBCT, e.g. Selchen, Hawley, Regev, Richter and Rector (2018), although this warrants further investigation using an RCT design that compares MBCT against CBT.

Understanding mechanisms of change in therapies helps to identify, modify and optimise key treatment components and aids the identification of suitable patients for whom the treatment is likely to be beneficial (Kazdin, 2007, 2009). This is particularly true for multicomponent psychological therapies where effective outcomes could be due to one or more components whilst other components may not enhance outcomes and could be omitted. So far, however, quantitative studies of MBIs for OCD have not formally tested the theorised mechanisms of change and do not necessarily elucidate the perceived acceptability of different adaptations of MBIs. Qualitative research can help to elucidate potential change mechanisms through detailed exploration of participants' experience of the intervention and their accounts of their own change processes (Higginson & Mansell, 2008; Moore et al., 2015; Thirsk & Clark, 2017); findings could

aid change mechanism theory development and refinement (O'Cathain et al., 2015). Guidance by the Medical Research Council on process evaluation of complex interventions also highlights that qualitative research, including through participant interviews, can play a crucial role in developing an understanding of the mechanisms of change of new interventions (Moore et al., 2015). Therefore, qualitative studies could contribute preliminary evidence towards the acceptability and possible mechanisms of change of adapted MBIs for OCD but they are few and far between. Hertenstein et al.(2012) and Sguazzin, Key, Rowa, Bieling, and McCabe (2016) conducted qualitative analyses of interviews with patients who had previously completed CBT (including ERP) but continued to experience (residual) OCD symptoms. While participants generally perceived the treatment as acceptable and beneficial, their accounts do not necessarily elucidate whether MBIs might provide a viable treatment for patients who have dropped out from or did not wish to opt-in to CBT. Fairfax, Easey, Fletcher, and Barfield (2014) conducted a thematic analysis of brief interviews to explore patient perspectives on a routinely delivered treatment combining mindfulness with CBT. Their findings also suggest a mindfulness approach could potentially enhance CBT in acceptable ways. However, their report did not provide a more in-depth exploration of patients' experiences and involved secondary care patients, which may not necessarily reflect the experiences of the majority of patients who access treatment for OCD through primary care services.

5.1.1 Research aims & objectives

This paper reports on two qualitative studies that explored patient perspectives on the acceptability and potential benefits of MBIs for OCD, specifically MB-ERP

(Strauss et al., 2018) (study 1) and MBCT adapted for OCD (MBCT-OCD) (study 2). MB-ERP was based on ERP as the primary vehicle of change but included a mindfulness skills training component aimed at enhancing engagement in ERP to improve outcomes. Study 2 followed on from study 1, after the pilot RCT data suggested that MB-ERP would be unlikely to improve on ERP in reducing OCD symptoms post-treatment (Strauss et al., 2018). Study 2 involved an adapted course of MBCT for OCD, positing mindfulness skills training as the primary vehicle of change in OCD symptoms; it did not involve ERP and included longer and more intensive mindfulness practice than MB-ERP. Unlike previous qualitative studies of MBCT as an augmentation therapy for CBT for OCD (Hertenstein et al., 2012; Sguazzin et al., 2016), study 2 explored whether MBCT-OCD was perceived as an acceptable and beneficial treatment for patients who did not wish to engage with (further) CBT and/or had achieved insufficient benefit from CBT. This was informed by the fact that there are no alternative recommended psychological therapies on offer for such patients (APA, 2007; NICE, 2005). Therefore, it is important to explore viable alternatives, including MBIs for OCD.

This paper reports the findings from each study in turn and then brings these findings together to facilitate an understanding of common and unique experiences associated with these different approaches to teaching mindfulness skills to patients with OCD. The qualitative exploration of patient perspectives on the acceptability and potential benefits of the MB-ERP intervention (study 1) would also help to contextualise the finding that MB-ERP did not appear to improve on ERP outcomes (Strauss et al., 2018).

5.2 Methods study 1

5.2.1 Design and procedure

This study reports on the thematic and content analysis of semi-structured interviews with MB-ERP participants at six-month post-intervention, conducted as part of a pilot RCT comparing group ERP to group MB-ERP for OCD (see Strauss et al. (2014, 2018) for further details). The pilot RCT was pre-registered (ISRCTN52684820. Registered on 30 January 2014).

All interviews were conducted on NHS premises by a research assistant blind to the group allocation. Interviews were audio-recorded and lasted 30-60 minutes. The interviews were transcribed verbatim and anonymised by CH, a clinical psychology masters' student and TL, an experienced clinical psychologist and doctoral researcher. This research project was given full ethical approval by an NHS Research Ethics Committee (see Appendix A).

5.2.2 Participants

Participants in the pilot RCT were recruited through two Improving Access to Psychology Therapy (IAPT) services (a primary care public health talking therapies service) in a National Health Service (NHS) mental health Trust in the South of England. Inclusion criteria were: i) 18 + years of age; ii) met DSM-IV diagnostic criteria for OCD (APA, 1994) based on the Mini International Neuropsychiatric Interview [MINI 6.0.0] (Sheehan et al., 1997); iii) if on psychiatric medication, stable dosage for a minimum of 3 months prior to commencement of the therapy; iv) no plans to change psychiatric medication during the study course; v) had not received any

psychological therapy in the 3 months before the current study, nor planned to engage in psychological therapy during the study course. Exclusion criteria were: i) identified organic cause for OCD symptoms; ii) a diagnosed learning disability, psychotic disorder, post-traumatic stress disorder, anorexia nervosa, alcohol dependence or substance addiction; iii) hoarding-only compulsions (see Strauss et al. (2014, 2018) for further details).

Fourteen (74%) of the 19 participants randomly allocated to MB-ERP completed the semi-structured interview. All participants taking part in the pilot RCT were invited and supported to take part in an interview, even if they dropped out of the group. Five participants declined the offer of an interview or attempts to contact them were unsuccessful. Four out of the five participants had dropped out of MB-ERP, for reasons including family or marital problems, pregnancy, difficulty getting time off work and childcare commitments.

All participants had a diagnosis of OCD at the start of treatment (see above). Mean depression severity of the sample was in the moderate range (M =26.93, SD =11.18), as measured with the Beck Depression Inventory-Second edition (BDI-II) (Beck, Steer, & Brown, 1996). See Table 1 for further sample characteristics.

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Table 1
Sample characteristics for Study 1 (MB-ERP) (N=14)

Variable		M(SD)	n (%)
Age (years)*		34.57 (8.28)	
Age of onset		16.07 (6.87)	
(OCD)*		10.07 (0.07)	
Female			11 (79)
White British			13 (93)
Education	Up to secondary (\leq		10 (71)
	12 years education)		10 (71)
	Higher education		
	(university, 12+		4 (29)
	years)		
Employment	(Self-)employed		7 (50)
	Unemployed		7 (50)
On			
psychotropic			7 (50)
mediation at			7 (30)
baseline			
Prior CBT	Started		6 (43)
(self-reported)	Completed (at least 1		
	course of NHS		3 (21)
	routine treatment for		3 (21)
	OCD)		
No of MB-		8.00 (3.00)	
ERP sessions		range: 1-10	
attended		141150. 1 10	
Dropout from			$2(14)^2$
MB-ERP			2 (11)

Note: 1 = after 1-2 sessions

5.2.3 Interview schedule

The semi-structured Change Interview (Elliott, Slatick, & Urman, 2001) was designed to ask participants about their experience of a psychological intervention. The first two sections of the Change Interview ask participants to describe up to five

changes they noticed over the course of therapy and to rate, on a 5-point scale, the extent to which they were surprising (1='very much expected the change to happen' to 5= 'very much surprised by the change'), likely to have occurred without the therapy (1='very unlikely without the therapy course' to 5='very likely without the therapy course') and important (from 1='not at all important' to 5='extremely important'). Subsequent questions invite participant attributions for these changes (Q3), perceived beneficial or unhelpful aspects of the treatment (Q4 and Q5), and personal and social resources (Q6) and limitations (Q7) to aid therapy engagement, before concluding by inviting participants to suggest ways to improve the course and/or the research (Q8) (see Appendix B for interview schedule). The Change Interview was therefore well-suited to the qualitative exploration of participant perspectives on the acceptability and potential benefits of MB-ERP.

5.2.4 Intervention: MB-ERP

The first of the 10 weekly, two-hour sessions of MB-ERP introduced the rationale for ERP and the inclusion of mindfulness principles and practice. Subsequent sessions (2-10) began with a 10-minute mindfulness practice followed by a 20-minute inquiry into "participants' direct experience of meditation practices, and exploration of pleasant and unpleasant experiences, which has implications for recognizing established patterns of reactivity and the possibility of responding differently" (Crane et al., 2017, p.994-995), with a view for new learning to support participant engagement in ERP. Mindfulness practices included mindfulness of; i) the breath and body (session 1), ii) breath, body, sounds and thoughts (sessions 2-3); iii) intrusive thoughts (session 4-5), and: iv) the body, (intrusive) thoughts, urges and action (sessions 6-10). Verbal

guidance for the mindfulness practice was developed by an expert in MBIs and OCD. A three-minute daily mindfulness breathing space practice (Segal et al., 2002) was also taught from session 6. Practice guidance explicitly invited participants to notice intrusive thoughts, bodily sensations associated with intrusive thoughts/anxiety and compulsive urges and to bring a sense of acceptance to these experiences. Following the mindfulness practice and inquiry, the remaining 90 minutes of each session followed an adapted standard in-vivo ERP protocol (Van Noppen, Steketee, & Pato: Group Behaviour Therapy Treatment Manual for Obsessive Compulsive Disorder, unpublished), including psychoeducation about OCD, planning and reviewing betweensession ERP practice and designing and completing within-session ERP. The approach to ERP was adapted to incorporate more recent recommendations derived from inhibitory learning theory (Abramowitz & Arch, 2014; Arch & Abramowitz, 2015). Furthermore, therapists invited participants to apply learnt mindfulness skills to ERP tasks. Session 10 focused on consolidating learning from the therapy. Participants were asked to complete between-session ERP tasks and formal mindfulness practices daily, using provided audio-recordings, and to cultivate mindfulness during daily routine activities. Sessional engagement data, collected for the pilot RCT, showed that participants practised ERP tasks a mean of 16 times a week (SD = 8.78, range = 3.78-34.00) (based on 58% completed home practice logs) and completed 4 weekly formal mindfulness practices during the course (SD = 0.60, range = 3.67-5.00) (based on 57% completed logs). At the time of the interview, 32% of the participants continued to engage in (some) mindfulness practice.

Two clinical psychologists facilitated the course, one of whom (CS) was an accredited CBT therapist and accredited MBCT teacher. Supervision was provided for

both group facilitators by an expert in ERP. Mindfulness supervision was provided by an accredited MBCT supervisor. A lived experience advisory panel provided consultation on the development and implementation of MB-ERP.

5.2.5 Data analysis

T The first two sections of the Change interview, which invite participants to list up to five changes they noticed over the course of therapy and to rate each change for expectedness, importance and likelihood the change would have occurred without the course on 5-point Likert scales, was analysed to explore the perceived (value of) benefits stemming from MB-ERP. Content analysis, which reports frequencies of important content categories in qualitative data, was well-suited to analysing this interview data (Barker, Pistrang, & Elliott, 2015). All changes reported by participants were collated into an Excel sheet. Low-level categorisation of these changes was conducted, achieved through group consensus (TL, KC, CS), using conventional content analysis (Hsieh & Shannon, 2005). Descriptive statistics were used to report the frequency (*n*, %) of each change, along with the average rating (*M*, *SD*) of expectedness, likelihood and importance for each change category.

The remainder of the interview (sections 3-8, see Appendix B) invited participants to reflect on attributions for perceived changes, helpful and unhelpful aspects of therapy and personal and social resources and limitations that affected personal engagement with therapy. This data was analysed using reflexive thematic analysis (TA) (Braun & Clarke, 2006, 2019) as it allowed a rich exploration of the acceptability of the therapy course, benefits and potential mechanisms of change from the participants' point of view, capturing commonalities and differences between

participant accounts. If participants discussed these issues in response to the first two sections of the interview, their reflections were included in the TA. Only interview extracts relating to the mindfulness component were included in the analysis, e.g. participants' reflections on psychoeducation and struggles, engagement in and satisfaction with ERP that did not incorporate a reflection on mindfulness were excluded.

Reflexive TA consists of six phases (Braun & Clarke, 2006), set out in Table 2. TL conducted phases i. to iii. and vi. of the analysis. The research team (TL, CS, KC) completed phases iv-v together. Making decisions as a group, whereby the different perspectives of multiple researchers converged in a process of mutual confirmation, served as a credibility check (Elliott, Fischer, & Rennie, 1999). NVivo 12 software was used to conduct the analysis.

Table 2Analytic phases of reflexive thematic analysis

Phase		Description	
i.	Familiarising yourself with your data	In-depth familiarisation with the data through repeated reading of all interview transcripts	
ii.	Generating initial codes	Application of initial codes (i.e. single units of meaning) to transcript extracts that are pertinent to the research question	
iii.	Searching for themes	Initial codes are examined for commonalities and differences and clustered into overarching themes, and potential sub-themes within these.	
iv.	Reviewing themes	Themes and sub-themes are reviewed in relation to the coded extracts that supported them to ensure that each theme/sub-theme related to the coded extracts and the whole data set, confirming that the aim of the investigation is maintained and that the research question is answered appropriately	

v. Defining and naming themes	The themes' and sub-themes' names, descriptions and relationships within the data are finalised	
vi. Producing the report	Analysis continues into the write-up of the study report, whereby themes are related back to the research question. The most representative extracts are selected for inclusion in the write-up.	

5.3 Results study 1

5.3.1 Thematic analysis

Table 3 provides an overview of the (definitions of the) main and sub-themes that were developed through the reflexive thematic analysis. Associated sub-themes are discussed below. Pseudonyms were used to protect participant confidentiality. In line with Braun and Clarke's reflexive thematic analysis (2019), the presentation of results does not include the number of participants contributing to each (sub-) theme.

 Table 3

 Main themes and sub-themes for MB-ERP and MBCT-OCD

Common (sub-)themes Unique sub-themes				
Main themes	Captures	Sub-themes	MB-ERP	MBCT-OCD
Satisfaction with course features	positive and negative perceptions of the course features		Combining mindfulness and ERP	Mindfulness approach MBCT compared to CBT Course and session structure Workbook & forms Therapist embodiment
				of mindfulness

Acceptability of key therapeutic tasks	how participants engaged with the core aspects of the course,	(Struggles with) developing a mindfulness	Preference for type of formal practice
usks	specifically mindfulness	practice routine	Comparing practice at
	practice and/or	Toutine	home and in-
	MB-ERP		session
			(Noticing)
			reactions to practice
Using	how participants	Calm and	Noticing and
mindfulness to respond	perceived mindfulness	relaxation	awareness
differently to	helped them to	Coming back	Kindness to
OCD	respond differently to	to the present	self
	OCD	Observing and	
		allowing	
		Giving less	
		meaning to	
		intrusions	

5.3.1.1 Theme 1: Satisfaction with course features

5.3.1.1.1 Combining mindfulness and ERP

Several MB-ERP participants reported finding mindfulness meditation beneficial, e.g. describing it as 'nice' (Louise), 'really useful' (John), and 'really good' (George). A few were pleasantly surprised by the treatment rationale: 'I had never thought of the idea of [...] using mindfulness to [...] deal with the anxiety that results or to [...] help you to do it in the first place.' (George). The combination of mindfulness with ERP was perceived as credible and superior to either treatment alone.

5.3.1.2 Theme 2: Acceptability of key therapeutic tasks

5.3.1.2.1 (Struggles with) developing a mindfulness practice routine

Whilst several participants really valued the (10-15-minute) mindfulness practices, practical barriers to (regular) home practice included finding (uninterrupted) time and space, often due to juggling other commitments, including childcare. The latter meant having to practise in the evening when 'it would just make me feel really sleepy' (Sarah). A few participants did not want daily formal meditation to feel like a 'job' (Louise). Other obstacles included the repetitiveness of using the same practices, physical discomfort or pain and difficulties concentrating. Due to these challenges, most participants adapted the formal meditation practices to suit them, e.g. listening to the audio-recordings whilst walking the dog, or doing everyday activities mindfully, e.g. washing up. Louise described adopting a mindful 'way of thinking' into her life. In doing so, several participants touched on their perception that this was perhaps 'not strictly how you're supposed to do it' (John).

5.3.1.3 Theme 3: Using mindfulness to respond differently to OCD

This theme captured participants' perspectives on the ways in which mindfulness helped them to respond differently to OCD.

5.3.1.3.1 Calm and relaxation

Mindfulness practice made some participants feel calmer or more relaxed. This helped two participants to gain a different perspective on thoughts and to cope with the anxiety of doing ERP.

5.3.1.3.2 Coming back to the present

Practising mindfulness helped some participants to bring themselves back to the present moment, e.g. coming back to sounds, sights and touch sensations, particularly when they became overwhelmed by intrusive thoughts, associated anxiety and urges to engage in compulsive behaviours. Emma noted this reduced the frequency of her obsessional intrusions. Others similarly described that coming back to the present e.g. by focusing on the breath, interrupted unhelpful repetitive thinking, prevented worrying thoughts from spiralling out of control and helped the mind to 'clear' (Hannah). Some participants found that coming back to the present reduced their compulsions "because sometimes I do it [compulsive checking] on autopilot and therefore I would go back to it because I couldn't actually remember whether I'd done it or not.' (Sarah).

5.3.1.3.3 Observing and allowing

Mindfulness helped participants to observe and allow unwanted thoughts, feelings and sensations. This increased awareness of and exposure to intrusions, which could be challenging at first. Emma, Olivia and George referred to avoiding any attempts to resist, control or suppress their intrusive thoughts, which they related to increased acceptance, e.g. 'It has taught me how to deal rather than push away the thoughts' (Emma), de-escalation: 'I don't let it spiral out of control [...] you just ride with the thought rather than just thinking on and on.' (Olivia), and the realisation that intrusions were transient: 'you don't have to identify with it [...] you can kind of observe it and also realise it will pass.' (George). John used mindfulness to stay with physical sensations of anxiety until they decreased naturally: '[...] as soon as I feel that cold rush, the tightening of the chest, I immediately focus in on that [...] it's a really good way of deflating that kind of anxiety spiral'. Several participants found this ability

also helped them engage with ERP, e.g. 'if I didn't want to do any exposure task [...] [...] you can like observe a sensation but then [..] just do it anyway.' (George) and 'kind of ride the anxiety' (John).

5.3.1.3.4 Giving less meaning to intrusions

A few participants described that mindfulness facilitated new insights into their obsessive thought patterns, realising that 'thoughts are just thoughts' (Olivia). For example, Sarah described 'I don't sort of believe every anxious thought I have is going to become real [...] they are not necessarily going to happen just because I'm thinking about them.'

5.3.2 Content analysis

Table 4 summarises the mean (%) perceived changes reported by MB-ERP participants, together with the mean (*SD*) ratings for the extent to which they were surprising, likely to have occurred without the therapy and important. The most frequently reported changes included OCD symptom reduction (reported by 71% of participants), followed by increased ability to manage OCD (64%) and reduced anxiety (50%). Mean ratings for these three changes revealed they were considered very important and unlikely without the therapy course.

Table 4Summary of types of changes reported by participants in Study 1 (MB-ERP) (N=14) and the Mean (SD) ratings for the expectedness, likelihood and importance of each type of change.

Type of change	n (%)	Surprise	Likelihood	Importance
		M(SD)	M(SD)	M(SD)
OCD symptom	10 (71)	3.35 (1.29)	1.56 (0.53)	4.22 (0.71)
reduction				
Perceived ability to	9 (64)	3.50 (1.12)	1.5 (0.50)	3.94 (1.02)
manage OCD				
Reduced anxiety	7 (50)	3.57 (1.40)	1.86 (0.38)	4.21 (0.39)
Increased (confidence	5 (36)	3.20 (1.64)	1.60 (0.55)	4.25 (0.96)
in) mindfulness skills				
(to deal with OCD)				
Greater awareness or	4 (29)	4.25 (0.50)	1.63 (1.25)	4.75 (0.50)
understanding of OCD				
Feeling less isolated	4 (29)	3.75 (1.26)	1.50 (0.58)	4.25 (0.50)
Improved mood	4 (29)	3.25 (1.50)	2.25 (1.50)	4.33 (1.15)
Ability to tolerate or	2 (14)	3.00 (1.41)	1.50 (0.71)	4.00
manage unpleasant				
feelings				
Greater self-	1 (7)	4.00	1.00	5.00
compassion or less				
perfectionism				
Deterioration in mood	1 (7)	4.00	3.00	3.00
Functional	1 (7)	4.00	2.00	4.00
improvement				
Improved	1 (7)	5.00	1.00	5.00
communication				

Note: n = number of participants reporting this type of change, % = number of participants reporting this type of change/total number participants.

Surprise = extent to which this change was surprising (1='very much expected the change to happen' to 5= 'very much surprised by the change'), Likelihood = likelihood that this change would have occurred without the therapy (1='very unlikely without the therapy course' to 5='very likely without the therapy course'); Importance = perceived importance of the change (from 1='not at all important' to 5='extremely important').

5.4 Methods study 2

5.4.1 Design and procedure

Interview data was collected as part of an uncontrolled feasibility study of MBCT adapted for OCD. The course was offered to adults with OCD who did not wish to engage in (further) routine CBT (i.e. ERP combined with cognitive strategies) and/or still experienced clinically significant symptoms of OCD after completing CBT. The feasibility study was not pre-registered.

All participants were invited to take part in the Change Interview two to four weeks post-treatment. All interviews were conducted by a research assistant independent of therapy delivery, on NHS premises or at the participant's home.

Interviews were audio-recorded and were 30-60 minutes long. This research project received full ethical approval by an NHS Research Ethics Committee (see Appendix C).

5.4.2 Participants

Participants were recruited through an NHS IAPT service in South East England. Inclusion criteria were as follows: i) aged 18+; ii) met diagnostic criteria for OCD, based on the Mini International Neuropsychiatric Interview, MINI, version 6.0.0 (Sheehan et al., 1997) and scored above the clinical cut-off (40 +) on the distress subscale of the Obsessive-Compulsive Inventory (OCI) (Foa, Kozak, Salkovskis, Coles, & Amir, 1998); iii) scored above the clinical cut-off (>16) on the Yale-Brown Obsessive-Compulsive Scale (Y-BOCS) (Goodman et al., 1989) at the baseline research assessment meeting; iv) willing to refrain from another form of psychological therapy during the study; and v) sufficient English language ability to take part in the

intervention and complete the study measures. Exclusion criteria were: i) organic cause for OCD; ii) likely diagnosis of learning disability, autistic spectrum disorder, psychosis, anorexia, bipolar disorder, PTSD or reporting a previous diagnosis of psychosis; iii) hoarding-only compulsions; iv) severe symptoms of depression, i.e. score 20+ on the Patient Health Questionnaire-9 (PHQ-9) (Kroenke, Spitzer, & Williams, 2001) at the IAPT assessment and/or latest administration of the PHQ-9; v) recorded as presenting a medium to high risk to self or others on the IAPT risk assessment tool; and vi) concerns raised by the assessing clinician about the patient's suitability for a group intervention.

All seven participants met a diagnosis of OCD at the start of treatment. Mean depression severity of the sample was in the moderate range (M = 12.43, SD = 2.38), as measured with the PHQ-9 (Kroenke et al., 2001). Two participants were recruited after completing a course of CBT within IAPT and five participants were recruited at the point of IAPT assessment. One of the latter participants had no prior experience of CBT. Among the six participants with prior CBT experience, four completed at least one course of routine CBT treatment whilst one participant had started but prematurely discontinued CBT treatment. See Table 5 for further sample characteristics

The mean pre-to post-change in Y-BOCS scores was .43 (SD = 3.29, 95% CI [-2.01, 2.87], range = -3 - +6) with 1 patient (who completed the intervention) in remission (Y-BOCS \leq 12 (Mataix-Cols, Do Rosario-Campos, & Leckman, 2005) (also see discussion). Treatment completion was defined as attending at least 4 of the main 8 sessions, consistent with MBCT guidelines (Segal et al., 2002).

Table 5Sample characteristics for study 2 (MBCT for OCD) (N=7)

Variable		M(SD)	n(%)
Age (years)*		39.29 (18.72)	
Age of onset		10.71 (4.54)	
(OCD)*		10.71 (4.54)	
Female			2 (29)
White British			5 (71)
Education	Up to secondary (≤ 12 years education)		6 (86)
	Higher education (university, 12+ years)		1 (14)
Employment	(Self-)employed		5 (71)
	Unemployed		2 (29)
On			
psychotropic mediation at baseline			4 (57)
(self-reported)	Started		6 (86)
Prior CBT	Completed (at least 1 course of NHS		` '
	routine treatment for OCD)		5 (71)
No of MBCT-	101 OCD)		
OCD sessions		7.00 (1.50)	
attended		range:4-9	
Dropout			1 (14) ³

Note: a after 4 sessions (including introductory session).

5.4.3 Interview schedule

The Change Interview (Elliott et al., 2001) was also used in study 2. The research team added a further section (9, see Appendix B) to the interview schedule, after a lived experience advisory panel recommended them to clarify participant views

on whether the intervention facilitated a different way of relating to OCD symptoms, even in the absence of significant symptom reduction.

5.4.4 Intervention: MBCT-OCD

The MBCT for OCD course (MBCT-OCD) was adapted from the standard MBCT course for recurrent depression (Segal et al., 2002), in consultation with a lived experience advisory panel. Adaptations included adding an introductory session to the standard 8 weekly 2-hour group sessions and changing the psychoeducational content and cognitive exercises to suit OCD. Psychoeducation included discussing how mindfulness could be used to break the vicious cycle of OCD and was reiterated in each session. In the final two sessions, participants were encouraged to develop an individual action plan and signposted to NHS (e.g. drop-in mindfulness sessions)and other mindfulness resources (e.g. bibliotherapy). See Appendix D for course structure and sessional content.

Participants were encouraged to practise formal mindfulness meditations daily (6 days out of 7), aided by standard audio-recordings, and log them on home practice monitoring sheets (Segal et al., 2002). Following consultation with an experienced MBCT supervisor, participants who experienced persistent difficulties in finding time to practise were given the option to use short versions (10-15 minutes) drawn from standard MBCT self-help (Williams & Penman, 2011) (these resources were made available to all participants from the third session onwards). Participants were also encouraged to apply mindfulness to everyday activities. Between-session tasks included occasional written exercises, as per standard MBCT. All participants were given a workbook containing (adapted) handouts from the standard MBCT course and standard

CBT manual used in the IAPT service. The course was facilitated by two experienced clinical psychologists (TL and CS), one of whom was an accredited Cognitive Behavioural Therapy therapist and MBCT teacher (CS). The course facilitators accessed supervision from an accredited MBCT supervisor.

5.4.5 Data analysis

The thematic analysis and content analysis were conducted in line with the procedure outlined for Study 1.

5.5 Results study 2

5.5.1 Thematic analysis

Table 3 shows the main and sub-themes that were developed through the thematic analysis. Sub-themes are discussed below. Pseudonyms were used to protect participant confidentiality.

5.5.1.1 Theme 1: Satisfaction with course features

The MBCT-OCD course was generally well-received. Participants described it as, e.g. helping 'very quickly' (Mia) and 'super useful' (Peter) and reported a range of positive changes and benefits (see content analysis). However, some limitations were also noted and not all participants found the course beneficial.

5.5.1.1.1 Mindfulness approach

Participants commented on the invitational language used by the facilitators (and in the workbook and audio-recordings). Mia found this really helped her to reduce self-criticism when she 'felt like a naughty child' for not practising mindfulness at home.

This contrasted with Mark's perception that it conveyed 'a lack of urgency', explaining further: 'I need a certain firmness [...] in the initial stages.'. George struggled to grasp the non-striving stance of mindfulness, e.g. when practising the body scan: '[...] 'if you're meant to get some particular thing out of something, there has got to be a way of doing it, you're supposed to feel something.'.

5.5.1.1.2 MBCT-OCD compared to CBT

Six participants had (some) previous experience of CBT (ERP with added cognitive strategies). Whilst one participant liked the course precisely because it was an alternative to ERP, most participants described the combination of previous CBT and MBCT-OCD as useful, beneficial or 'perfect' (Peter). Several participants doubted that mindfulness alone would sufficiently target and reduce OCD symptoms and perceived that it complemented CBT by reducing anxiety associated with intrusions or by bringing an observing stance to intrusions and associated distress: 'it's almost like a left brain and a right brain approach' (Peter). They felt that CBT helped to challenge their thinking, which mindfulness might not achieve in isolation: 'because I wouldn't know how to control my thoughts, what the logical thinking was.' (Thomas). He also thought that mindfulness was not sufficiently direct in targeting OCD symptoms when triggered: 'in that moment I don't think it would do much', explaining further: 'you kind of need to know how to rationalise it in the first place'. George had not found CBT useful in the past, but his difficulties with engaging in mindfulness helped 'the penny to drop' that he could only reduce his OCD symptoms by 'facing the fear', through self-directed ERP.

5.5.1.1.3 Course and session structure

Some participants commented that the course was well-structured, with a good balance between well-explained, systematic mindfulness practices and opportunities for discussion and reflection. However, a few participants felt that the course did not allow enough time to share and discuss individual struggles with OCD and others would have liked further sessions to consolidate their mindfulness meditation routine to increase the benefits.

5.5.1.1.4 Workbook and forms

Some participants found the workbook a well-structured, useful resource, e.g. to catch-up after missing a session, re-visit course content, recall the weekly home practice, and to motivate themselves and consolidate learning: 'They [...] gave a kind of impetus to carry out the work out of sessions [...] I like to read something as well as listen to something being explained.'(Mark). However, a couple of participants found the workbook too comprehensive and complicated, which left them feeling 'overwhelmed' (Mia). George felt guilty for '[...] not studying the book page to page'. These participants also found filling in home practice forms or (occasional) written exercises very challenging. They related these difficulties to OCD symptoms that centred on perfectionism and/or feelings of guilt or the impact OCD had on their concentration. Suggestions included simplifying and shortening the manual and including further visual information.

5.5.1.1.5 Therapist embodiment of mindfulness

All participants commented on the course facilitators, who were perceived as 'kind' (Mia), 'friendly' (Peter), 'approachable' (Mark) and 'trying to understand'

(Helen), including in relation to participants' struggles with home practice and/or attendance, e.g. 'I don't normally experience that, like if I haven't done something or supposed to be somewhere, normally I put on a bulletproof vest and go deal with it [laughs].' (Peter). The therapists' perceived compassionate stance supported participants to become more self-compassionate, e.g. 'certain things that they would say would make me think and realise and now I hear those words' (Mia). The fact that therapists took part in the meditation practices themselves was also positively received: 'It gave the group a more integrated feel [...] it also made me feel as though they were all more invested in the experience and also that [...] they believed in the practices themselves' (Mark).

5.5.1.2 Theme 2: Acceptability of key therapeutic tasks

5.5.1.2.1 (Noticing) reactions to formal mindfulness practice

All participants noticed reactions during formal mindfulness practices, including boredom, frustration, annoyance, concentration difficulties and mind-wandering, confusion, anxiety, (physical) discomfort, sleepiness and exhaustion, feeling lost or overwhelmed, relaxation and enjoyment. These reactions occurred both within sessions and at home and were sometimes noted in relation to specific practices (see below). Struggles to concentrate could be stressful or frustrating and at times resulted in impulses, not necessarily acted upon, to stop the meditation and engage in other activities, particularly when at home. Feelings of irritation and frustration emerged in response to the (standard MBCT) audio recordings; several participants disliked or lacked 'affinity' (Mark) with the voice, finding it 'robotic' (Thomas), 'annoying' (Helen) or 'off-putting' (Thomas), or felt there weren't enough pauses in the guidance. Participants were encouraged to kindly observe any unpleasant thoughts, feelings or

sensations or discomfort they noticed, which Helen reflected on in relation to mind wandering: 'knowing that your mind wanders, but just bring it back, the more you practise that kind of thing, the easier things will get.'.

5.5.1.2.2 Preference for type of formal practice

Several participants talked about disliking and/or struggling with the body scan meditation, finding it too long and challenging. Paying attention to parts of the body during the body scan could bring heightened awareness of painful sensations and physical discomfort, which for one participant triggered OCD symptoms. Conversely, experiencing little or no sensation during the body scan generated frustration, boredom and sleepiness, mind wandering and difficulties concentrating or focusing. Some participants experienced the body scan as valuable, relaxing and calming and persisted with this practice at home. Others expressed preferences for sitting practices with a single focus, e.g. on the breath, or movement practices, which they found easier to concentrate on. The length of formal practice was often discussed; most participants found it easier to focus on shorter practices, fit them into daily life, e.g. whilst on the bus or at work, or build them into a routine. Participants also found it easier to engage with bringing mindful awareness to everyday activities.

5.5.1.2.3 (Struggles with) developing a mindfulness practice routine

Most participants realised that developing mindfulness skills takes time and effort and that they were more likely to reap benefits with regular practice. They expressed a wish to get in the 'flow' (Mia) and 'schedule' mindfulness practice rather than it being 'on and off' (Thomas) but also voiced various struggles with developing a regular mindfulness routine during and after the course. Participants' reactions to being

set home practice included feeling it was 'formulaic' (Thomas) or that there were too many set practices. Helen also described the human tendency to 'object' to anything that you are set to do, through connotations with 'homework' (Mia). Participants often felt they should practise more or longer than they did. Obstacles included ongoing health problems, distractions, other commitments, difficulties prioritising practice and finding an appropriate place to practise. Considering these obstacles, several participants chose to engage in the shorter (versions of) formal practices or prioritised bringing mindfulness to everyday life, e.g. walking the dog, even if some perceived that this was not quite the 'right' way to practise.

5.5.1.2.4 Comparing mindfulness practice at home and in session

Most participants found it easier to practise mindfulness in session, without the usual distractions and other commitments at home. Having made time for the session or feeling that it would not possible to 'make excuses' (Mia) helped participants to immerse themselves in the practices. Several participants had a more favourable reaction to 'live' guidance than audio-recordings, finding it much more engaging. However, one participant preferred practising alone, in the comfort of his own home.

5.5.1.3 Theme 3: Using mindfulness to respond differently to OCD

5.5.1.3.1 Becoming (more) aware

Mindfulness helped some participants to become more aware of intrusions and self-critical thoughts and how these tend to escalate, e.g. 'I realise quickly when I interact with my OCD' (Robert). This could be difficulty initially, e.g. Mia described it increased her awareness of the extent of her self-critical thoughts. Increased awareness of OCD was related to an ability to (sometimes) disengage from it and 'eventually stop

the cycle.' (Robert). Peter described a general increase in body awareness, including physical sensations associated with anxiety, 'I can actually feel the adrenaline more', which helped him to regulate his emotions. Bringing mindful awareness to everyday activities such as washing up also helped him to 'come back to normal very quickly' when he felt unsettled.

5.5.1.3.2 Coming back to the present

A few participants reflected on how mindfulness helped them to come back to the present moment, e.g. coming back into the body when experiencing anxiety. This had a calming effect and allowed a degree of detachment from unhelpful thinking processes, seeing them from a different perspective: 'what goes on in your head [...] doesn't seem as real anymore' (Robert). Focusing on 'the here and now' (Peter) also benefitted other mental health difficulties, including depression and coping with painful memories, because '[...] you understand everything is like memories or future projections, it's not actually happening.' (Peter).

5.5.1.3.3 Observing and allowing

Several participants commented on their ability to observe unpleasant experiences with a degree of detachment. This 'observer status of mind' (Peter) or ability to 'step back' (Helen) and 'look at it from a distance' (Robert) was considered an important skill that could be applied to intrusions, anxiety and depressed mood. Allowing difficult feelings at times heightened their intensity because, e.g. 'I'm not hammering them away or ignoring them or doing something to get rid of them' (Peter). Over time, the process of observing difficult feelings could to reduce their intensity. Being able to observe and allow intrusions also contributed to participants' ability to

respond differently to compulsions, e.g. allowing thoughts to become more 'rational' (Thomas) and dealing with compulsions more calmly. Peter connected it to an ability to pause and reflect on compulsive urges and make a choice how to respond: 'I can either do that compulsion knowing full well that it's a compulsion or I can not do it and get on with my life'. This was a challenging, time-consuming process that was not always achievable when compulsions were pervasive.

5.5.1.3.4 Giving less meaning to intrusions

Several participants reflected that noticing unpleasant thoughts, coming back to the present or allowing them to remain in awareness and observing them with kindness, facilitated a change in perspective on intrusions, or a 'different point of view' (Helen). Robert also described this process of looking at intrusions 'from a different perspective' as 'detaching from those thoughts', realising 'I don't have to pay attention to it' and 'you don't have to react to them', whilst Helen experienced that 'standing back' allowed her to 'not give so much meaning to everything that's in your head.'

5.5.1.3.5 Calm and relaxation

A few participants experienced that mindfulness practice had a calming, relaxing effect on the body and allowed them to be 'more logical' (Thomas) and think more clearly. Thomas described this as a first step in re-evaluating his thoughts, which he related to skills learnt during CBT. It also allowed him to have more control over compulsions. Peter also linked mindfulness practice to turning 'the volume of the anxiety right down' and to a cessation of 'mental chatter'.

5.5.1.3.6 Kindness to self

Some participants who struggled with perfectionism and self-critical thoughts really connected with the 'kindness' or 'nonjudgment' and 'being curious' that mindfulness invited them to bring to their intrusions. This helped them not to get caught up in the OCD cycle: '[...] I might say 'Okay, this is you being unkind to yourself, remember to be kind' and then it moves on. So, yes, it doesn't sort of escalate.' (Mia). The ability to be kind to oneself was also noted as a consequence of coming back to the present: 'cos it's just kind of seeing what's real, as in like, it's the present and that's it, that's all that matters' (Robert). Peter also felt that responding to depressed mood with kindness helped to alleviate it.

5.5.2 Content analysis

Table 6 summarise the results of the content analysis. The main reported changes were reduced anxiety (reported by 71 % of participants) followed by OCD symptom reduction and increased ability to manage OCD (both 43%). Ratings for these changes suggested that the changes were considered very important and unlikely without the therapy course.

Table 6Summary of types of changes reported by participants in study 2 (MBCT for OCD) (N=7) and the mean (SD) ratings for the expectedness, likelihood and importance of each type of change

Change	N (%)	Surprise	Likelihood	Importance
		M(SD)	M(SD)	M(SD)
Reduced anxiety	5 (71)	2.40 (1.52)	1.80(0.84)	4.80 (0.45)
OCD symptom	3 (43)	2.67 (1.15)	1.67 (0.58)	4.67 (0.58)
reduction				
Perceived ability to	3 (43)	3.50 (2.12)	1.67 (1.15)	4.67 (0.58)
manage OCD				
Greater awareness or	2 (29)	3.50 (0.71)	2.50 (1.41)	5.00
understanding of OCD				
Greater self-	2 (29)	3.50 (0.71)	1.50 (0.71)	4.50 (0.71)
compassion or less				
perfectionism				
Feeling less isolated	2 (29)	2.00	2.00	3.50 (0.71)
Ability to manage	1 (14)	5.00	1.00	5.00
other mental health				
problems				
Increased (confidence	1 (14)	3.00	2.00	4.00
in) mindfulness skills				
(to deal with OCD)				
Deterioration in mood	1 (14)	5.00	3.00	1.00
Improved sleep	1 (14)	3.00	3.00	3.00
Motivation to	1 (14)	4.00	1.00	5.00
overcome OCD				
Random anxiety	1 (14)	3.00	3.00	1.00

Note: N = number of participants reporting this type of change, % = number of participants reporting this type of change/total number participants. Surprise = extent to which change was surprising (1='very much expected the change to happen' to 5= 'very much surprised by the change'), Likelihood = likelihood that change would have occurred without the therapy (1='very unlikely without the therapy course' to 5='very likely without the therapy course'); Importance = perceived importance of the change (from 1='not at all important' to 5='extremely important').

5.6 General discussion

5.6.1 Summary of results

This paper reports on two consecutive studies that explored participants' perceptions of the acceptability, potential mechanisms and benefits of MBIs that integrated mindfulness with CBT in different ways. The reflexive thematic analyses of the Change Interview data for study 1 (MB-ERP) and 2 (MBCT-OCD) had all three main themes in common, i.e. 'satisfaction with course features', 'acceptability of key therapeutic tasks' and 'using mindfulness to respond differently to OCD'. Most participants in both MB-ERP and MBCT-OCD were satisfied with their course and considered it an acceptable treatment for OCD. This discussion will first discuss unique sub-themes for study 1 and 2, respectively, followed by common sub-themes across both studies, before discussing the content analysis of participant reported changes, limitations of the study and recommendations for future research.

5.6.1.1 Sub-themes unique to study 1

Most participants liked the integration of mindfulness with ERP and felt it had added benefit to ERP and psychoeducation. This resonates with the theoretical premise for using mindfulness to enhance exposure, e.g. (Treanor, 2011), and the views of the lived experience advisory panel consulting to the study.

5.6.1.2 *Sub-themes unique to study 2*

Most participants had prior experience of CBT for OCD and conveyed a positive orientation towards CBT. They appeared to find the combination of MBCT with CBT beneficial, suggesting these approaches complemented each other well and that the two in combination might lead to improved outcomes than either on its own. The

invitational, non-striving stance of mindfulness received a mixed reception and participants questioned the potency of mindfulness as a stand-alone therapy for OCD. Among the couple of participants who were less favourably disposed towards ERP, there was a mixed response to MBCT-OCD; it helped one participant to develop the capacity for self-compassion to benefit OCD symptoms centred on perfectionism, whereas the other participant did not feel able to engage with MBCT-OCD and concluded that ERP would now be a preferable treatment.

Whilst the course structure and content was generally well-received, some participants wanted further sessions to consolidate their skills. Also, MBCT is an experiential, process-orientated group intervention (Segal et al., 2002); some participants wanted more opportunities to discuss individual OCD symptoms. Participant reflections on the therapists' kindness and understanding highlights the importance placed on the 'embodiment' of mindfulness by course facilitators of MBCT (Segal et al., 2002). Seemingly more peripheral features of the course, i.e. workbooks and forms, also had the potential to influence engagement.

Whilst many participants wished to establish a sustained mindfulness practice, many noticed aversion or attachment to certain experiences during mindfulness meditation. These experiences are 'par for the course' and provide fertile soil for learning to develop an accepting, kinder attitude towards such experiences rather than interpreting this as a personal failure or incompetence (Segal et al., 2002). However, this is undoubtedly challenging and some participants opted for shorter or informal mindfulness practices rather than continuing with practices that gave rise to unpleasant experiences.

The issues raised by participants in relation to the potency and duration of the course and the opportunity for discussion of individual OCD symptoms were also reported by Sguazzin et al. (2016), as were impatience, being put off by the voice in audio recordings and lacking motivation as obstacles to mindfulness practice. These issues may not be unique to OCD, e.g. Mason and Hargreaves (2001) touch on similar 'initial negative experiences' in their study of MBCT for depression while participants with current depression or anxiety thought the MBCT course was too short and similarly struggled with longer practices, particularly the body scan (Finucane & Mercer, 2006). A meta-synthesis of themes from 15 qualitative studies of group MBIs for a range of mental health problems included sub-themes, i.e. 'biggest challenge', 'mix and match' and 'I focused on having to achieve something', that highlighted similar issues (Wyatt, Harper, & Weatherhead, 2014).

Overall, participant responses to the course content and structure also brought home the complexities of understanding and untangling the role of both treatment-specific and common factors, patient sociodemographic, clinical and/or psychological characteristics in understanding patient engagement (Holdsworth, Bowen, Brown, & Howat, 2014; Taylor, Abramowitz, & McKay, 2012b; Wierzbicki & Pekarik, 1993).

5.6.1.3 *Common sub-themes across study 1 and 2*

Mindfulness-based interventions attach key importance to home practice (C. Crane et al., 2014), to develop and consolidate mindfulness skills (Segal et al., 2002).

MBCT-OCD participants were invited to engage in longer practices (both within- and between sessions) compared to MB-ERP participants. The sub-theme '(struggles with) developing a mindfulness practice routine' nonetheless highlighted challenges that both MB-ERP and MBCT-OCD participants faced in engaging (consistently) with the

recommended formal mindfulness practice at home. This does not appear to be unique to people with OCD as similar challenges were noted by participants in MBCT for current depression or anxiety (Finucane & Mercer, 2006) and recent meta-analyses found that participants with a range of physical and mental health problems did not necessarily fully adhere to the recommended weekly mindfulness practices (Lloyd, White, Eames, & Crane, 2018; Parsons, Crane, Parsons, Fjorback, & Kuyken, 2017). Many participants established personalised ways of practising mindfulness that were perceived as more accessible and suited their lifestyles. This resonates with the finding in Hertenstein et al. (Hertenstein et al., 2012) that participants modified practices to suit their needs. Some participants felt that their OCD symptoms prevented them from engaging in mindfulness practice. Squazzin et al. (2016) and Hertenstein et al. (2012) also reported that OCD symptoms were perceived to 'conflict' with practice and/or were all-consuming, not dissimilar to research showing that depressive rumination can affect engagement in MBCT for (recurrent) depression (Crane & Williams, 2010). As consistent formal home mindfulness practice is associated with the alleviation of depression and anxiety symptoms, e.g. (Lloyd et al., 2018; Parsons et al., 2017), the current findings, i.e. that participants did not necessarily feel able to engage consistently with recommended formal mindfulness practice, complicates the consideration of the potential efficacy of MBIs for OCD.

Both MB-ERP and MBCT participants reflected on similar, inter-related, ways in which mindfulness helped them to relate differently to obsessional intrusions and compulsions. This included: i) 'coming back to the present'; ii) 'observing and allowing'; iii) 'giving less meaning to intrusions'; and iv)'calm and relaxation'. MBCT-OCD participants also noted; v) (becoming more aware) of OCD (closely associated

with subtheme ii)) and; vi) kindness to self, particularly in relation to OCD symptoms that centre on (negative) perfectionism (e.g. Frost et al. (1997)). MB-ERP participants also appeared to support the proposition that mindfulness could aid engagement with ERP (Treanor, 2011) and this resonates with another qualitative evaluation of a similar integration of mindfulness with CBT(Fairfax, Easey, Fletcher, & Barfield, 2014).

In ERP the evocation of anxiety (through presenting an appropriate trigger for obsessional intrusions) is necessary to facilitate emotional processing (Foa & Kozak, 1986) and/or inhibitory learning (Craske et al., 2014). Therefore, the perceived calming, relaxing effect of mindfulness practice could potentially function as a distraction or neutralising technique that prevents inhibitory learning during ERP (Treanor, 2011) and thereby could be a barrier to overcoming OCD. It highlights that the intention of mindfulness practice in this context should be to facilitate an aware, welcoming and accepting attitude towards intrusive thoughts and associated feelings and body sensations rather than to support disengagement or distraction from intrusive thoughts.

In the current studies, however, participants described that reducing anxiety associated with intrusions through mindful, non-judging, acceptance of these experiences, benefitted wiser choices about how to respond to OCD. The fact that 'observing and allowing' appeared to aid exposure to intrusions, associated distress and compulsive urges in ways that benefitted reappraisal of intrusions (reflected in the 'giving less meaning to thoughts' sub-theme) also supports the assertion that mindfulness could encourage an accepting awareness of intrusions and associated distress compatible with inhibitory learning theory approaches to ERP (e.g. Fairfax et al., 2014; Külz et al., 2019; Wahl, Huelle, Zurowski, & Kordon, 2012). The fact that only MBCT-OCD participants noted 'kindness to self' may result from the primary

emphasis placed on mindfulness practice and inquiry in MBCT-OCD relative to MB-ERP. This perhaps more clearly conveyed the mindfulness approach, which has (self-)compassion at its heart (Segal et al., 2002). The fact that MBCT-OCD participants reflected on 'therapist embodiment of mindfulness' and the 'mindfulness approach', e.g. invitational language and non-striving, also supports this notion.

Together, the ways in which participants reported 'using mindfulness to respond differently to OCD' mapped onto theorised mechanisms of action of mindfulness for OCD (Hale et al., 2013). The overlap in sub-themes between MBCT-OCD and MB-ERP participants lends further credibility to these findings as does the fact that findings mirrored other qualitative evaluations of mindfulness integrated with CBT (including ERP) (e.g. Fairfax et al., 2014) and MBCT adapted for OCD (Hertenstein et al., 2012; Sguazzin et al., 2016).

5.6.1.4 *Content analysis*

The content analysis highlighted significant overlap in perceived benefits and changes reported by MB-ERP and MBCT participants, despite the fact that MB-ERP foregrounded ERP whilst MBCT emphasised mindfulness as the primary vehicle for change. Changes included a reduction in OCD symptoms (71% of MB-ERP and 43% of MBCT-OCD participants), whilst increased awareness of, and ability to manage, OCD together were also reported by the majority of participants (MB-ERP: 93%, MBCT: 72%). Reduced anxiety was also frequently reported (MB-ERP:50%, MBCT-OCD: 71%). Perceived changes extended beyond OCD to include beneficial effects on other mental health problems, stress reduction and functional improvement. Participants in Hertenstein et al. (Hertenstein et al., 2012) and Sguazzin et al. (2016) similarly reported improved knowledge and understanding of OCD along with functional improvement,

reductions in comorbid symptoms, stress relief and general well-being. This lends further credibility to the content analysis.

5.6.2 Limitations

All participants were recruited through (one of) two psychological therapy services in South East England. This, and the lack of ethnic diversity among participants in MB-ERP, limits the transferability of the findings. Furthermore, there were differences between the study samples that may limit conclusions drawn from comparing the findings of the two studies. MB-ERP participants were recruited at the point of routine IAPT initial assessment, whereas MBCT-OCD participant were recruited during IAPT initial assessment or after completing CBT treatment in IAPT. MB-ERP incorporated ERP, i.e. the NHS recommended treatment for OCD, and, therefore, was offered to all eligible patients irrespective of previous experience of ERP. MBCT-OCD did not include ERP and, therefore, all patients eligible at the point of assessment were made aware that ERP was the recommended treatment and that it was available to them within IAPT. MBCT-OCD was explored as an alternative for those patients with clinically significant OCD symptoms who did not want to engage in (further) routine CBT and who would ordinarily be discharged from IAPT. Consequently, half of the MB-ERP participants had no previous experience of CBT versus only 14% of MBCT-OCD participants. Furthermore, MB-ERP participants were interviewed at follow-up whereas MBCT-OCD participants were interviewed posttreatment. Nonetheless, the convergence of results relating to benefits and potential mechanisms of MB-ERP and MBCT-OCD participants and other qualitative studies on MBIs for OCD lends some support to the potential transferability of the findings.

Evidently, participants in MB-ERP were invited to participate in shorter and less varied formal mindfulness meditation practices (within and between-sessions) compared to participants in MBCT-OCD. Within the MBCT-OCD group of participants, some participants opted for shorter versions of body scan and sitting meditation practices for their home practice. This will have influenced participant perceptions of the potential benefits of these interventions. Nonetheless, MB-ERP and MBCT-OCD participant reports on how mindfulness benefitted their OCD symptoms had much in common, reflected in common themes.

The Change Interview did not explicitly enquire about participants' perceptions of mindfulness. Specific questions about the (dis)advantages of mindfulness may have generated further information, particularly for MB-ERP participants for whom mindfulness was the smaller component of the course.

The first author was a co-facilitator of the MBCT-OCD course. This has the potential to influence what is inferred from participant reports. Care was taken to stay close to participants' verbal accounts, represent 'negative' aspects highlighted by participants and to reach group consensus on main and sub-themes, clearly derived from initial coding (Elliott et al., 1999).

5.6.3 Clinical implications and directions for future research

The preliminary evidence towards theorised mechanisms of change could be taken forward through experimental research and mediational analyses in the context of treatment studies. Specifically, facets of mindfulness (observing, acting with awareness, nonjudging, nonreactivity) could be explored as potential mechanisms of change. The 'giving less meaning to thoughts' and 'observing and allowing' subthemes also suggest

that concepts that are similar to the nonjudging facet of mindfulness, i.e. reperceiving (S. L. Shapiro, Carlson, Astin, & Freedman, 2006), decentering (Safran & Segal, 1990), meta-cognitive awareness (Teasdale et al., 2002) and/or thought-action fusion (the belief that having a bad thought is morally equivalent to, or increases the likelihood of, acting on the thought) (Rachman & Shafran, 1999; Shafran & Rachman, 2004) should be explored as potential mechanisms of change. The 'kindness to self' sub-theme for MBCT-OCD suggests that self-compassion skills may help to target OCD symptoms, particularly those that centre on order, symmetry and perfection and/or self-critical thoughts associated with unacceptable (sexual or aggressive) intrusions and feelings of shame (Bream, Challacombe, Palmer, & Salkovskis, 2017; Wetterneck, Lee, Smith, & Hart, 2013).

Participants in both MBIs found the combination of mindfulness with CBT beneficial. We speculate that barriers to successful CBT for OCD for some people (e.g. appraising intrusive thoughts as facts, distress intolerance, carrying out compulsions in automatic pilot and lack of self-compassion) could be directly addressed through the integration of a mindfulness-based approach that is intended to target these barriers. Through successfully targeting these barriers, such people may be able to successfully engage in CBT for OCD tasks (e.g. appraising intrusive thoughts as unimportant mental events, distress tolerance, conscious awareness of compulsive urges and self-compassion) and as such have a positive treatment outcome, given that task engagement is key to positive outcomes (Simpson et al, 2011). Therefore, research could further explore the effect of different types of integrations of CBT with mindfulness on OCD symptoms.

The discrepancy between patient satisfaction and personally valued changes on the one hand and a lack of substantive OCD symptom reduction on the other (see participant information above; also see a recent RCT of MBCT as an augmentation therapy for CBT (Külz et al., 2019) requires further investigation before drawing more definitive conclusions about the efficacy of delivering MBIs for OCD.

Obsessive-compulsive disorder is a heterogeneous disorder as obsessions can centre on a fear of contamination, (unintentionally) causing or preventing harm to self or others, symmetry or 'taboo' thoughts, such as unwanted aggressive, sexual or blasphemous thoughts, images or impulses (Kenwright, Marks, Graham, Franses, & Mataix-Cols, 2005; Pinto et al., 2007). OCD symptom subtypes characterised by taboo thoughts and strongly associated with thought-action-fusion beliefs (Shafran, Thordarson, & Rachman, 1996) and/or feelings of shame (e.g. Weingarden & Renshaw, 2015; Wetterneck, Singh, & Hart, 2014) may be less responsive to ERP (Brakoulias et al., 2013; Williams, Mugno, Franklin, & Faber, 2013). Also, OCD symptoms characterised by mental rather than overt compulsions may be more difficult to treat with (imaginal) ERP than overt compulsions (Clark & Purdon, 1993; Steketee, Siev, Yovel, Lit, & Wilhelm, 2019; Whittal, Woody, McLean, Rachman, & Robichaud, 2010). These OCD subtypes may therefore be particularly suitable for the exploration of innovative (add-on) interventions including MBIs, which invite participants to develop a different relationship to their symptoms through mindfulness meditation practice rather than ERP. OCD symptoms characterized by high levels of perfectionism may also derive benefit from MBIs, which place self-compassion is at the heart of the intervention (Didonna & Williams, 2019; Kabat-Zinn & Hanh, 2013; Segal et al., 2013). However, the notion that MBIs may bring differential benefit according to OCD subtype is conjecture at present and requires further exploration.

Whilst research into well-established MBIs such as MBCT and MBSR has not yet included dismantling the effects of mindfulness from common factors/group processes, it will be important to examine the extent to which (lack of) benefits of MBIs for OCD may be attributable to the common factors, such as the group format, or mindfulness meditation practice; this understanding will help to maximise therapy outcomes (Kazdin, 2007). Delivering MBIs for OCD in group format may not necessarily be most effective given the heterogeneity of OCD; the idiosyncratic nature of OCD may mean that participants do not necessarily feel that able to generalise from presentations other than their own.

The MBIs studied here might have lacked a more potent effect because most participants reported that they did not necessarily engage in regular, sustained formal mindfulness practice as recommended in the protocols. This could reflect the 'counter-cultural' quality of mindfulness approaches (Kabat-Zinn, 2003), transdiagnostic experiential avoidance (e.g. Hayes, Luoma, Bond, Masuda, & Lillis, 2006) and/or challenges specific to OCD, e.g. high levels of distress intolerance (e.g. Cougle et al., 2011) or the relentless, consuming nature of obsessional intrusions. Further research is needed into the role of specific and non-specific treatment factors, sociodemographic and/or clinical patient characteristics and psychological processes in treatment response.

Further research could investigate ways of making formal mindfulness practices more accessible. For example, although there is a well-considered rationale for using the body scan as the first meditation practice (Segal et al., 2002), most participants found this a very challenging meditation to begin with (Finucane & Mercer, 2006). A more

gradual build-up in length of mindfulness practices might help to build distress tolerance (Cougle et al., 2011) and enhance engagement. Increased use of mindful movement practices in the early stages of the course may also benefit engagement as they enable participants to notice physical sensations more readily. Didonna (2009) similarly proposed that for people with severe OCD symptoms, it may be helpful to gradually introduce mindfulness. For example, it might be advisable to progress from walking practices (that generate proprioceptive sensations) to the body scan (interoceptive sensations), from short to long exercises and from informal to formal practice. A case study by Patel, Carmody, and Simpson (2007) similarly described introducing mindfulness practices gradually and starting with most preferred/least intrusive practices. Offering practices on preference, e.g. depending on OCD symptom presentation, may help enhance mastery and ease people into committing to daily practice. Evidently, this requires careful consideration as it could potentially lead to avoidance of practices that bring people into more direct contact with difficulty which, whilst unpleasant, may be therapeutically beneficial. However, supporting people to engage with mindfulness practice early on in therapy is arguably worthwhile if this can avoid treatment dropout. Facilitators of MBCT for OCD may also need to (repeatedly) emphasise further that mind wandering and unpleasant sensations or reactions during mindfulness practice are normal and do not signal personal failure, and indeed are helpful as they allow mindful skill development in relation to such experiences (e.g. (Segal et al., 2002)). As gathering home practice logs proved difficult (a recurrent problem even in well-established MBCT for depression research (Parsons, Jensen, Roepstorff, Fjorback, & Linehan, 2019), the use of technology such as apps (which would automatically log patients accessing mindfulness meditation practices) would aid research into engagement in MBIs for OCD (Parsons et al., 2019). Similarly, it would be beneficial to include post-treatment questionnaires eliciting the extent of home practice. In conclusion, findings suggested that patients with OCD value MBIs in relation to their OCD difficulties but also emphasised the need for further research to understand whether and how their potential to improve OCD symptoms may be enhanced.

Chapter 6: General discussion

6.1 General discussion

The overall aim of this thesis was to contribute to existing knowledge and understanding of what may help to improve outcomes of CBT for OCD. The specific aims of this thesis were two-fold; i) to explore patient engagement in CBT for OCD, and; ii) to explore the potential of mindfulness-based interventions (MBIs) for OCD. To achieve the first aim, a meta-analysis of the magnitude, moderators and reasons for non-adherence to CBT for OCD was conducted along with a qualitative exploration of patients' perspectives on barriers and facilitators to engagement in group ERP. Towards the second aim, the relationship of mindfulness and self-compassion with OCD symptoms was examined, followed by a qualitative evaluation of patients' experiences of MBIs, specifically Mindfulness-based ERP (MB-ERP) and MBCT adapted for OCD (MBCT-OCD).

Several key findings emerged in relation to the first study aim: i) the magnitude of refusal (16%) and dropout (16%) from CBT for OCD was moderate whilst mean session attendance (87%), module completion (76%) and mean patient task engagement were (mostly) at least satisfactory; ii) there was a medium to large effect of adherence to (between-session) ERP tasks on post-treatment OCD symptom reduction for face-to-face CBT and a medium (pooled) effect for remote CBT (r = .39); iii) (single) sociodemographic or clinical client variables, therapist, therapy and/or study design variables did not moderate refusal or dropout, apart from therapy format (individual vs group); iv) (predictors of) patient adherence are relatively under-recorded and researched in treatment studies of CBT and measures of task engagement are varied and of variable quality; v) patient perspectives on engagement in group ERP suggest that client attitudes towards therapy, group processes, personal circumstances, understanding

how to overcome OCD and the personal relevance of ERP are inter-related, dynamic barriers and facilitators to engagement.

Key findings related to the second aim included: i) self-compassion and mindfulness skills negatively predicted OCD symptoms, when depression severity was controlled for; with a small sized effect ($\Delta R^2 = .07$; mindfulness: pr = .20, selfcompassion: pr = -.09) ii) mindfulness and self-compassion skills were lower in treatment-seeking adults with clinically significant OCD symptoms relative to treatment-seeking adults with clinically significant anxiety and/or depression symptoms and compared to healthy controls; ii) self-compassion and mindfulness did not substantively explain OCD symptoms over and above obsessive beliefs and distress tolerance, apart from a small effect of nonreactivity (pr = -.27) and nonjudging (pr = -.27) .15) facets on obsessing symptoms and of self-compassion on washing (pr = -.09) and checking symptoms (pr = -.07), and; iii) patients with OCD mostly perceived MBIs, specifically MB-ERP and MBCT adapted for OCD, as acceptable treatments that brought additional benefits over and above CBT, in line with theorised mechanisms of MBIs for OCD. This final chapter starts with a discussion of the key findings of the thesis and their theoretical, clinical and/or and research implications, followed by a consideration of the strengths and limitations of the thesis and directions for future research.

6.1.1 Magnitude and measurement of patient non-adherence to CBT for OCD

The systematic review and meta-analysis of patient adherence to CBT for OCD (paper 1, Chapter 2) revealed a relatively modest pooled mean rate of refusal and dropout, both at 16%. The dropout rate is consistent with two other meta-analyses of

dropout from CBT for OCD (Öst et al., 2015; Swift & Greenberg, 2012). A reliable refusal rate has not previously been reported for CBT for OCD; therefore, this thesis adds to the existing literature on the magnitude of refusal of CBT for OCD.

Whilst not unsubstantial, the dropout rate for CBT for OCD was lower than often assumed and reported in the wider research literature (e.g. Abramowitz, Taylor, and McKay (2005) report a 25% dropout for ERP). This thesis therefore contributes to the research literature in providing a reliable estimate of dropout that invites more nuanced questions about the apparent aversiveness of CBT for OCD. Similarly, as research has shown that many people with OCD do not seek help, the 16% refusal rate is perhaps not as high as one would assume. However, this finding related to refusal in the context of nonrandomised studies only; furthermore, it can be difficult to capture the full extent of refusal as by definition refusal is calculated for *eligible* patients; patient refusal prior to confirmation of eligibility for therapy (through an in-person assessment to confirm OCD diagnosis) does not contribute to this figure. The risk of early dropout was 2.5 times greater than for late dropout, suggesting most patients who drop out from CBT for OCD are unlikely to have experienced significant benefit, particularly given research has shown early rather than late dropout was associated with poor outcomes (e.g. Aderka et al., 2011). This suggests that whilst dropout may be relatively modest at 16%, it is still important to address. Results furthermore showed that, on average, participants who completed face-to-face CBT received a therapeutic 'dose' of therapy, in accordance with US and UK practice guidelines (APA, 2007; NICE, 2005). Completion rates for remote therapies also appeared at least satisfactory. However, the ways in which this was measured could have been more informative (see below).

The narrative synthesis of between-session task engagement in face-to-face therapies and the meta-analysis of ERP task completion in remote therapies (paper 1, Chapter 2) showed that for most studies, between-session CBT task adherence was at least satisfactory. Furthermore, there was a consistent medium to large association between CBT task adherence and post-treatment OCD symptom reduction, in line with previous research into the association of homework with outcomes for CBT for a range of psychological disorders (e.g. Kazantzis et al., 2016). The positive association of between-session practice and post-treatment CBT outcomes seemed robust. However, as several studies showed that between-session task adherence needed to be high (e.g. a minimum of 75-90% good quality adherence to between-session ERP tasks as assigned and with minimal to no compulsions or safety aids) to achieve recovery (e.g. De Araujo, et al., 1996; Simpson et al., 2011; Wheaton, Galfalvy, et al., 2016), anything less than high levels of patient adherence may not necessarily be adequate to achieve recovery.

The systematic review and meta-analysis highlighted several issues in relation to the (quality of) measurement of adherence: 50% of studies of CBT for OCD were excluded because they did not (clearly) report adherence data. Only a small percentage of the 123 studies included in the paper reported on the magnitude of session attendance (7%) or CBT task-adherence (10%). This was surprising considering the theoretical pertinence of adherence to within- and between-session ERP tasks to therapy outcomes (e.g. Franklin et al., 2005). Different measures were used to assess between-session ERP tasks adherence and some were of questionable quality; this prevented pooling study data for task adherence. Session attendance was rarely reported and the statistics provided (mean percentage and number of sessions attended) did not adequately portray

variable attendance rates among completers (e.g. a breakdown of percentages for number of attended sessions would be more helpful).

6.1.1.1 *Implications and future directions*

The clinical and research implications of results relating to the magnitude of non-adherence are tied in with the implications of findings relating to the quality of measurement of adherence; therefore, these are discussed together. Whilst the meta-analysis included effectiveness studies that were reflective of real-life clinical settings, the impression lingers that refusal and dropout in routine settings may be higher, e.g. two studies of NHS IAPT services that routinely deliver CBT for OCD for common mental health problems, reported a 48% refusal and 23% dropout rate (across disorders) (Di Bona et al., 2014; Richard & Borglin, 2010). Further publication of routine refusal and dropout rates would aid our understanding of the scale of the problem in routine services. Directions for future research also include a further exploration of the magnitude of refusal and session attendance, taking on board the measurement issues raised in the previous discussion.

The findings also suggest that a clinical concern about treatment refusal and dropout needs to be complemented with a strong emphasis on within- and between-session therapy processes. Session attendance may present patients' 'minimum effort' compared to within- and between-session ERP tasks and cognitive strategies, which reflect the active, voluntary participation of patients (Holdsworth et al., 2014).

Therefore, it is key to gain a better understanding of the magnitude of task engagement in CBT for OCD. To achieve this objective, it is important to address the issues relating to measurement of adherence that were laid bare by the first study. Having appropriate measurement tools that are sensitive to both quantity and quality of engagement, specify

the task and the therapist's skill in setting the task, are required. Furthermore, measurements of task engagement are often taken on a sessional basis but combined into one composite score, which does not elucidate the pattern of engagement over the course of therapy. Reporting such information would benefit the understanding of this key aspects of engagement and its potential impact on outcomes of CBT for OCD.

These issues are not restricted to studies of engagement CBT for OCD. A review and meta-analysis of 47 studies that measured engagement with psychological or psychosocial treatment (including CBT) similarly concluded that theoretically sound, clinically meaningful, reliable and validated measures of engagement were relatively absent (Tetley et al., 2011). The findings from the systematic review would concur with their recommendation that both the degree and the quality of task engagement should be closely examined to get a well-informed understanding of a client's engagement (Primakoff et al., 1986). This would require a clear operationalisation of good or poor quality ERP tasks. Furthermore, the first study highlighted that adherence to other therapeutic tasks in CBT for OCD, e.g. cognitive exercises, are rarely measured nor are other aspects of patient participation such as self-disclosure and contributing to insession discussions, which also resonates with the conclusions reached by Tetley et al. (2011). These aspects of patient engagement in CBT for OCD require further investigation.

Whilst the inconsistent reporting of refusal and dropout rates in treatment studies of OCD is perhaps unnecessary given that this information is relatively easy to gather and report, it is more understandable that task engagement data has been lacking as monitoring therapy task engagement can be very difficult. Patients may forget to monitor or return home practice logs or may find it burdensome. Moreover, completing

home practice logs may be difficult for patients with OCD centred around perfectionism and checking mistakes. Those who struggle to complete home practice logs may be the same participants who struggle with engagement in these tasks; their information is perhaps more likely to be absent and this could bias results. Furthermore, within the context of research trials, adding further measures of engagement to what are often already elaborate sets of questionnaires risks over-burdening the research participant. Relying exclusively on therapists' assessments of engagement is unlikely to paint an accurate picture of patient engagement as research shows that therapists are not necessarily able to reliably reflect on this (e.g. Hunsley et al., 1999; Pekarik & Finney-Owen, 1987). Technological developments could help to gauge patient engagement more effectively, e.g. by developing home practice apps that automatically monitor how often and long patients log on for home practice and allow video uploads of home practice sessions.

6.1.2 Predictors of patient engagement in CBT for OCD

Mental health professionals have always understood the importance of engaging the patients they work with; they typically care deeply about achieving the best possible outcomes for their patients. When treatment fails, they might question themselves, the (limitations of the) therapy or the patient. Therefore, mental health professionals naturally grapple with what might hinder or help engagement, using their clinical judgment. Research should provide evidence to help guide practitioners in their efforts to address poor engagement. And yet, at least within the realm of CBT for OCD, there has been little consistent evidence to support clinical practice in this area.

This thesis explored what may contribute to patient engagement in CBT for OCD, first by testing moderators of refusal and dropout (study 1) and subsequently through a qualitative exploration of participant perspectives on facilitators and barriers to engagement in group ERP (study 2). The limited number of individual studies that examined predictors of CBT task adherence precluded meta-analysis and space did not permit a narrative synthesis of these studies in the paper (1).

The moderate to substantial heterogeneity of refusal and dropout rates suggested moderator effects. However, moderator analyses of refusal and dropout from CBT for OCD (study 1) did not reveal any significant moderator/predictor effects of client sociodemographic, clinical, therapy or research design characteristics on refusal or dropout other than a moderator effect of therapy format on dropout: group therapy was associated with lower dropout than individual therapy. However, the latter result was inconclusive as to whether peer support benefits treatment completion as a selection bias could not be ruled out; group CBT participants may have been more motivated or less (socially) anxious (as they opted into research evaluating group therapy), which may have enhanced their engagement.

The lack of significant moderators of refusal and dropout was surprising even though the latter was in line with results from other meta-analyses that tested some of the same moderators of dropout (type of CBT, therapist experience and number of sessions) (Ong et al., 2016; Öst et al., 2015). The lack of significant results raises interesting questions. One possible explanation is theoretical; perhaps single variables do not consistently predict dropout. The meta-analysis could only consider one predictor or moderator at a time, therefore not elucidating possible interactions between them. Furthermore, the meta-analysis did not include psychological variables such as

motivation, readiness to change or treatment expectations as predictors of dropout as too few studies examined this, yet the wider engagement literature suggests that these variables bear a significant relationship with engagement in psychotherapy (Wampold, 2015; Holdsworth et al., 2014). Methodological limitations may also have contributed to the lack of significant results; some of the sub-group analyses may have been underpowered to detect effects (Borenstein et al., 2009). Furthermore, due to a lack of studies providing this information, the meta-analysis regressed between-study differences in moderator variables (e.g. mean depression severity) on dropout, rather than pooling primary within-study data on differences in client characteristics between adherent and nonadherent patients.

Study 1 included a conventional content analysis of patient reasons for nonadherence. Results provided initial support for the notion that a mismatch between patient preference and the treatment on offer, particularly when the treatment was group CBT, affected patients' opt-in to therapy. However, the content analysis was based on a very small number of studies and findings need to be treated with caution. Reasons for dropout, extracted from a relatively small number of studies, suggested that negative perceptions of treatment (modality) credibility, poor motivation and limited therapy progress contributed to dropout, as did life events, practical constraints (e.g. work commitments) and research-related dropout (e.g. change in medication). None of these variables were included in the moderator analyses; their potential as predictors of nonadherence should be explored further.

The absence of significant moderator effects, except for a therapy format effect that suggested peer support may play a role in therapy completion, informed the decision to conduct a qualitative exploration of barriers and facilitators of patient

engagement in group ERP (paper 2). The study identified five main themes that captured participants' perceived facilitators and barriers to engagement in group ERP: 'understanding how to overcome OCD', 'personal relevance', 'group processes', 'patient attitudes towards ERP' and 'personal circumstances'. These themes represented barriers and facilitators at the level of the client, therapist, therapy and social environment that were either specific to (group) ERP or potentially trans-therapeutic and transdiagnostic, such as group processes. Furthermore, the analysis suggested that intrapersonal factors, e.g. treatment expectations, motivations, commitment and perseverance, could fluctuate over the course of therapy rather than representing static entities. Moreover, there appeared to be dynamic relationships between these different barriers and facilitators of engagement. The qualitative analysis highlighted that patient engagement was also reflected in their participation in group discussion and feedback. This is clearly an important part of therapy engagement (e.g. Tetley et al., 2011) but rarely measured in the context of group CBT for OCD. Furthermore, OCD symptom subtypes would need to be considered in understanding what helps or hinders patient engagement. These findings provide a possible explanation for the lack of significant moderator effects as the moderator analyses could not examine these complex interactions between variables.

There was some convergence between findings from the first and second paper.

The meta-analysis (paper 1) showed that dropout from group therapy was lower than for individual therapy. While the second paper did not provide a comparative analysis of participants perceptions of group versus individual therapy, the theme pertaining to the group format (i.e. group processes) suggests that sharing and comparing experiences, and a sense of belonging and accountability to the group were mostly highly valued

aspects of the course and supported patient engagement. This resonates with early theoretical accounts of the potential benefits of group ERP for OCD (Kobak et al., 1995). Conversely, the content analysis in the first paper suggested that ambivalence or anxiety about the group therapy format may contribute to therapy refusal whilst study 2 similarly highlighted that general social anxiety, fears about catching other people's OCD symptoms, lack of personal attention and/or a sense of shame about their OCD symptoms, particularly among participants with taboo thoughts, may potentially hinder (initial) participation in group ERP.

6.1.2.1 *Implications and future directions*

There is clearly a need for further research into predictors of patient engagement. Even though CBT is the gold standard treatment for OCD, there is a relative lack of research into engagement and how this relates to non-response. Whilst the meta-analysis confirmed the important role of between-session task engagement, particularly ERP, in CBT outcomes, there has been relatively little research into what might predict patient engagement in between-session ERP.

The findings from study 1 and 2 also have specific theoretical, clinical and research implications. Most client sociodemographic or clinical variables and therapy characteristics are unlikely to predict engagement in isolation and it may be more fruitful to consider intrapersonal, psychological variables in dynamic interaction with group processes and therapy factors. This goes to the heart of the complexity of engagement research; the engagement process is an oscillating, intricate interplay between different factors not easily captured in questionnaires and certainly not adequately understood through single measurements taken at pre-treatment only (e.g. Bachofen et al., 1999). The qualitive analysis also suggests an interplay between OCD

subtypes and group processes, with a resultant impact on engagement. Specifically, participants with taboo thoughts appeared to feel more anxious about disclosing OCD symptoms in a group setting than patients with reactive obsessions, e.g. about contamination. This suggests that OCD subtype needs to be considered in the examination of patient engagement in CBT for OCD: without this, we might be missing an important factor.

These suggestions resonate with established researchers in the wider field of patient engagement in psychological therapies, who advocate that research should move beyond examining sociodemographic predictors of, e.g., dropout and focus on psychological variables including participants' beliefs about their mental health difficulties, expectations of and motivation for treatment, and the client-therapist relationship (Taylor et al., 2012; Wierzbicki & Pekarik, 1993). Harris (1998) also proposes that research should become more theory-driven, testing out different theoretical models of therapy attrition. For example, Brogan and Prochaska (1999) found that the trans-theoretical stage model of (readiness to) change (Prochaska & DiClemente, 1992) was a good predictor of the dropout status.

Research needs to examine all facets of engagement, including participation in (group) discussion and feedback. Furthermore, study 1 and 2 highlighted (relationships between) several potential predictors, which could now be examined further.

Quantitative studies should measure engagement and outcome variables concurrently and repeatedly over the course of therapy to gain a more informed perspectives of how therapy processes interact with client characteristics and their social environment to influence outcomes (Holdsworth et al., 2014). The extent to which identified barriers and facilitators were specific to ERP also needs further exploration.

Group processes are not the focal point of therapeutic exploration in ERP and are rarely researched; yet clearly the group climate has the potential to help or hinder engagement. Observational assessments and conversational analyses based on audio- or video-taped sessions, may provide fruitful ways of exploring the group climate as a predictor of engagement (Elliott, 2010; Rhodes, 2011). This type of therapy process research is uncommon in CBT for OCD but might have real value given the lack of consistent evidence from quantitative analyses.

There are a few potential clinical implications from studies 1 and 2. Firstly, group CBT (including group ERP) might have the potential to facilitate engagement relative to individual therapy but may be challenging for individuals who experience social anxiety or a lack of social confidence. Also, group CBT may not be indicated for clients who feel their OCD symptoms warrant more individual attention and may be challenging for patients with taboo thoughts who may experience difficulties disclosing OCD symptoms to other participants. Nonetheless, the group can also provide normalisation and opportunities for testing shame-related beliefs about these intrusions (e.g. Fals-Stewart & Lucente, 1994; Kobak et al., 1995). Whilst group therapy is less resource-intensive than individual therapy (NICE, 2005) it is important to take patient preference for either format into account. Initial assessments provide a vital opportunity for the assessor to anticipate and respond to clients' reservations about group therapies.

Patients' attitudes to group ERP, including expectations, motivation, self-efficacy, commitment and perseverance and readiness to change, appear to interact with group dynamics, which therefore provides a target for therapist intervention (Holdsworth et al., 2014). Careful consideration needs to be given to group composition and group cohesion; group processes that may be getting in the way of engagement in

ERP need to be openly addressed. For example, therapists should anticipate and discuss the anxiety that patients may experience when they interact with other patients with OCD. They need to be mindful that non-attendance could impact on remaining participants in both positive and negative ways (Paquin & Kivlighan, 2016). Nonattendance must be addressed proactively, as is good clinical practice, and sensitively discussed within the group to facilitate discussion and expression of doubts and ambivalence. The extent to which participants achieve success with ERP, also influenced by the perceived personal relevance of ERP tasks, is likely to affect morale of the group; this too needs careful consideration and reflection by therapists. Therapist training and supervision would need to foreground the interpersonal and communication skills required to facilitate a positive group climate. Furthermore, therapists would need to create a positive but realistic expectancy of the efficacy of therapy, aided by appropriate psychoeducation, and anticipate that disclosing OCD symptoms in group ERP may be challenging for patients with 'forbidden' thoughts (e.g. Kobak et al., 1995). As the thematic analysis highlighted that within-session ERP was not necessarily experienced as effective by all participants, there should be the possibility for therapists to deliver therapy within the home environment, as required (e.g. Rowa et al., 2007), taking into account the additional resource demands this would have in publicly funded healthcare services.

As the findings from study 2 suggest that comorbid depression may affect between-session ERP task engagement, which might explain the link between comorbid depression and therapy outcomes (e.g. Knopp et al., 2013), patients with comorbid depression may require more between-session support to make the most of therapy, e.g. through between-session phone calls or home visits. It also highlights the importance of

careful assessment to clarify whether the depression is secondary to OCD (and if so, OCD should usually be treated first; NICE (2005)). Finally, practical and logistic considerations are not trivial in enhancing engagement; offering sessions at convenient locations and times are all important in ensuring participants can attend and remain engaged in therapy.

6.1.3 The role of mindfulness and self-compassion in OCD

The role of mindfulness and self-compassion skills in OCD was explored in study 3 (Chapter 4). Key findings include a substantive negative association of mindfulness and self-compassion with OCD symptoms, above and beyond their shared association with depression symptoms. Furthermore, treatment-seeking adults with clinically significant OCD symptoms reported significantly lower trait mindfulness and selfcompassion than healthy controls and treatment-seeking adults with clinically significant depression and/or anxiety symptoms. This provided initial support for the hypothesis that adults with OCD may experience mindfulness and self-compassion deficits relative to adults with other common mental health problems. Mindfulness had a significantly larger association with OCD symptoms than self-compassion, suggesting that mindfulness deficits may be more pertinent to OCD symptoms than selfcompassion deficits. Once the effects of obsessive beliefs and distress tolerance were accounted for, two mindfulness facets independently predicted obsessing symptoms; the ability to bring a nonreactive stance to inner experiences (small-medium effect), and to take a non-evaluative (nonjudging) stance towards distressing thoughts and images (small effect). Self-compassion also continued to independently predict washing and checking symptoms once obsessive beliefs and distress tolerance were accounted for,

but effects were very small. This study found that distress tolerance was not a substantive independent predictor of OCD symptoms, which mirrors research by Blakey et al. (2016) and Fergus and Wu (2011), who conclude that distress tolerance is perhaps best conceived of as a transdiagnostic vulnerability factor.

6.1.3.1 *Implications and future directions*

In recent years, interest in the exploration of the potential of MBIs for OCD has grown. Various adaptations of MBIs, originally intended for other mental health problems, are increasingly being tested for OCD. Whilst studies on MBIs for OCD generally take care to consider the theoretical premise of these interventions for OCD, one of the fundamental assumptions, i.e. that people with OCD lack mindfulness skills, has rarely been investigated.

The clinical implications of the study include that the potential added benefit of MBIs for OCD, e.g. as an augmentation therapy of CBT, may lie in supporting patients to particularly develop their non-reactivity and nonjudging skills in relation to obsessional intrusions. The findings also imply that enhancing self-compassion per se is unlikely to lead to substantive OCD symptom improvement as only very small unique effects on checking and washing symptoms were found. Targeting obsessive beliefs and, to a lesser extent, the mindfulness skills of non-reactivity and non-judging may be more advantageous and an increase in self-compassion may naturally follow on from this (shift in perspective on cognition) (e.g. Kuyken et al., 2010).

The fact that mindfulness skills did not have a large predictive effect on OCD symptoms once obsessive beliefs were accounted for, is perhaps not incompatible with the notion that mindfulness skills and obsessive beliefs have much in common. Didonna

(2009) asserts that mindfulness acts upon the relationship between intrusions and the meanings that are attached to them. Therefore, mindfulness skills influence the interpretation that is given to intrusions, as captured in obsessive beliefs. This relationship can perhaps best be thought of in mediational terms, i.e. mindfulness skills may act upon OCD symptoms through their effect on obsessive beliefs. However, the cross-sectional study design did not allow for this hypothesis to be investigated (see Maxwell and Cole (2007) and O'Laughlin, Martin and Ferrer (2018) for research showing a lack of concordance between cross-sectional and longitudinal mediation analyses). Intervention (or longitudinal observational) research with repeated measurement of all variables over the course of therapy (e.g. Kazdin, 2007) could test whether a change in mindfulness skills predicts OCD symptom improvement through a change in obsessive beliefs.

A broader theoretical point is that mindfulness, self-compassion and obsessive beliefs may be partially overlapping constructs and/or may be better explained by a third variable, such as meta-cognition (e.g. Wells, 2009) or de-centering (e.g. Bernstein et al., 2015; Safran & Segal, 1990). The boundaries between these constructs may well be blurred. For example, a factor analysis of the Meta-Cognitions Questionnaire (MCQ-30) (Wells & Cartwright-Hatton, 2004) and FFMQ by Solem et al. (2015) found that 'nonjudging' and 'acting with awareness' FFMQ facets loaded onto a meta-cognitive factor whilst the 'observe', 'describe' and 'non-reactivity' facets loaded onto a unique mindfulness factor; the metacognition factor but not the mindfulness factor independently predicted OCD symptoms. Furthermore, Myers, Fisher and Wells (2009) and Solem, Myers, Fisher, Vogel and Wells (2010) found that meta-cognitive beliefs were a better independent predictor of OCD symptoms than inflated responsibility and

perfectionist beliefs whilst Solem, Håland, Vogel, Hansen and Wells (2009) and Grotte et al. (2015) found that a change in meta-cognitive beliefs was a better predictor of post-treatment (ERP) OCD symptom reduction than a change in inflated responsibility beliefs and/or perfectionist beliefs. This also taps into the wider debate about the primacy of (specific) obsessive beliefs in the aetiology and maintenance of OCD symptoms (e.g. Abramovitz, 2003; Frost & Steketee, 1997; Holloway et al., 2006; OCCWG, 2003; Taylor et al., 2005). Overall, the (nature of the) relationships between mindfulness, obsessive beliefs and meta-cognition, or decentering, could be explored further. In the first instance, further analysis of the survey data could involve an exploratory factor analysis of items from the OBQ-20, FFMQ-SF-O and SCS-SF to examine the overlap between these constructs.

6.1.4 Acceptability, potential benefits and mechanisms of MBIs for OCD

Study 4 presents the findings from two qualitative studies of MBIs for OCD with a focus on patient perspectives on the acceptability, benefits and potential mechanisms of these interventions. Whilst MB-ERP(study 1) integrated mindfulness with a standard ERP intervention to facilitate engagement in ERP, MBCT-OCD (study 2) was a standalone intervention that did not involve explicit ERP/CBT tasks and focused primarily on mindfulness skills training through mindfulness practice and post-practice group discussion. The thematic analyses were conducted separately but brought together in one paper to allow a comparison of thematic content and facilitate an understanding of common and unique experiences associated with these different MBI for OCD formats, as perceived by participants.

The thematic analyses generated three main themes that were common across both MBCT and MB-ERP: 'satisfaction with course features', 'acceptability of key therapy tasks' and 'using mindfulness to respond differently to OCD'. Most MBCT-OCD and MB-ERP participants were satisfied with their course and considered it an acceptable treatment for OCD that brought valued changes that were not limited to OCD symptom reduction (as evidenced by the content analysis). No harm or disadvantages were noted, but some participants reflected on limitations of these approaches and not all participants experienced mindfulness as accessible or helpful. These findings resonate with the satisfaction expressed by participants in other qualitative studies of MBCT (Hertenstein et al., 2012; Sguazzin et al., 2017) and mindfulness integrated with CBT (Fairfax et al., 2014).

MBIs invite participants to cultivate curiosity and equanimity towards whatever arises during mindfulness practice (and present-moment experiences in general), including difficult feelings, thoughts and sensations, whilst acknowledging and normalising that these experiences can give rise to aversive reactions and impulses to avoid/stop the practice (Segal et al., 2002). Whilst MBCT-OCD participants were invited to engage with longer and more varied within-and between-session mindfulness practices (of up to 45 minutes) than MB-ERP participants, who were set daily 10-15-minute practices, both groups of participants perceived formal mindfulness practice as challenging ('acceptability of key therapeutic tasks' sub-theme). This was reflected in the experiences MBCT-OCD participants had during practice (discomfort, difficulty concentrating, boredom) and in the struggles reported by both MB-ERP and MBCT participants in finding time and space for regular mindfulness practice. Similar struggles

with home practice were raised in other qualitative evaluations of MBIs for OCD (e.g. Hertenstein et al., 2012; Sguazzin et al., 2017).

MBIs attach key importance to regular and sustained mindfulness practice to develop and consolidate mindfulness skills that can be used to relate differently to, thoughts, feelings, and bodily sensations (Crane et al., 2014; Segal et al., 2002). Therefore, significant struggles with sustaining a regular mindfulness practice may affect treatment outcomes; a recent review found a significant, moderate association between the degree of formal meditation practice during MBCT and MBSR and primary psychological outcomes (*r*=.30, 95%CI [.21, .39], k=19) (Parsons et al., 2017). However, the relationship between formal mindfulness practice and treatment outcomes is not straightforward whilst the importance of informal practice is not well understood (Lloyd, White, Eames, & Crane, 2018). This raises some interesting questions that are considered further below (under implications and directions for future research).

MBCT-OCD participants perceived that MBCT and CBT for OCD complemented each other well. They questioned the potency of MBCT in the absence of prior or combined CBT. This may be because a more potent effect of mindfulness on OCD symptoms is likely to depend on whether patients feel able to engage in sustained mindfulness practice (Parsons et al., 2017). Also, (some) participants perceived CBT to be a more direct and targeted approach to challenging intrusions that gave them the tools to challenge the veracity of their appraisals of intrusions, whilst mindfulness taught what one participant called a 'right brain' approach: 'the mindfulness approach is very much like just sit there and observe, the patterns of things, get curious about it [....] you engage a different part of your brain'. In other words, participant accounts appeared to resonate with the notion that MBIs for OCD 'promote[s] direct

metacognitive awareness' whilst CBT focuses on 'changing appraisals in order to modify the impact of intrusions' (Selchen et al., 2018, p.59).

Sub-themes highlighted the following ways in which MB-ERP and/or MBCT participants perceived mindfulness to benefit OCD: i) calm and relaxation, ii) becoming (more) aware (MBCT only) iii) coming back to the present, iv) observing and allowing, v) giving less meaning to intrusions, and vi) kindness to self (MBCT only). Participants appeared to emphasise different potential mechanisms of change and it would be interesting to further explore these potential mechanisms in relation to OCD symptom subtypes. The findings are largely in agreement with theorised ways in which MBIs might benefit OCD (e.g. Hale et al., 2013) and enhance engagement in ERP (Didonna, 2009; Strauss et al., 2015) and mirror results from other recent qualitative studies (Hertenstein et al. 2012; Squazzin et al., 2017). The 'kindness to self' sub-theme for MBCT-OCD suggests that self-compassion skills may target OCD symptoms, particularly those that centre on order, symmetry and perfection and/or self-critical thoughts associated with and unacceptable (sexual or aggressive) intrusions (e.g. Bream et al., 2017; Wetterneck et al., 2013). This has some resonance with findings from study 3 (Chapter 4) that showed a (very) small unique effect of self-compassion on checking and washing compulsions, although overall self-compassion did not substantively add to explaining OCD symptom subtypes over and above depression, obsessive beliefs, distress tolerance and mindfulness. The 'calm and relaxation' subtheme reflected both the physiological effects of mindfulness (experiencing less anxious arousal or stress) and cognitive effects (being less caught up in rumination and worry). From the patients' perspective, this was very helpful in achieving the right frame of mind to apply the skills they had already learnt in CBT. Baer (2003) notes that the aim

of MBIs is not to achieve relaxation per se but rather to nonjudgmentally observe present-moment experiences; therefore, relaxation should not be the primary reason for engaging in mindfulness practice, although it may occur. This sub-theme touches on concerns that patients might use mindfulness to feel calmer or more relaxed at times when their OCD symptoms are triggered; this has the potential to function as a distraction or unhelpful neutralising strategy that avoids immersion and prevents inhibitory learning during ERP (Fairfax, 2008;2014; Treanor, 2011). However, the fact that 'observing and allowing' was an important sub-theme suggests that mindfulness, as theorised, aided exposure to intrusions and associated distress and compulsive urges in ways that benefitted reappraisal of intrusions (as reflected in the 'giving less meaning to thoughts' sub-theme). This is also asserted by other researchers of MBIs for OCD, who argue that mindfulness encourages open, accepting, nonjudging awareness of intrusions and associated distress rather than suppressing, negative thoughts and reducing compulsions, which is compatible with ILT approaches to ERP (Fairfax et al., 2014; Külz et al., 2018; Wahl et al., 2013).

6.1.4.1 *Implications and future directions*

The findings from the fourth paper suggest several possible avenues for the further adaptation of MBIs for OCD to maximise potential benefits: it might be beneficial to extend MBIs beyond 8 weeks to allow sufficient attention to both CBT and mindfulness approaches and to consider lengthening sessions to 2.5 hours, which is already common in standard MBCT (e.g. Crane, 2009). For example, Didonna (*in press*) will shortly publish a treatment manual of an MBCT course for OCD (November 2019), consisting of 11 weekly, 2.5 hour sessions. This would also allow more time for discussion of individual OCD symptoms.

The fact that many participants struggled with formal mindfulness practices goes to the heart of the apparent counter-cultural quality of mindfulness (Kabat-Zinn, 2003). The extent to which these difficulties reflect unique challenges for participants with OCD, e.g. due to the incessant 'mental chatter' that characterises OCD, elevated distress intolerance and/or anxiety sensitivity, needs further exploration. It may be important for course facilitators of MBIs for OCD to emphasise being fully present with intrusions, anxious (and other) arousal and compulsive urges as mindfulness skills could potentially be used to distract from and avoid these experiences. Whilst the consensus among MBI practitioners and teachers is that practice needs to be daily and prolonged for benefits to emerge or to achieve their full potential (Segal et al., 2002; Crane, 2009), research evidence is equivocal about the amount of required practice to achieve benefits and the relationship between home practice and therapy outcomes (Lloyd et al., 2018; Parsons et al., 2017). In any case, given the challenges participants encountered in engaging with formal mindfulness practice between sessions, future studies could possibly investigate ways to make formal home practice more accessible. As informal practice was preferred by most participants, research could also focus on increasing instruction to participants regarding how they should best bring informal mindfulness into daily life. As gathering home practice logs proved exceedingly difficult, the use of technology such as apps (which would automatically log patients accessing mindfulness meditation practices) would aid research into engagement in MBIs for OCD. Similarly, it would be beneficial to include post-treatment questionnaires eliciting the extent of home practice.

Potentially, a more radical departure from the MBCT format may benefit adults with OCD. For example, although there is a well-considered rationale for using the

body scan as the first meditation practice (Segal et al., 2002), most participants found this a very challenging meditation to begin with. A more gradual build-up in length and difficulty of mindfulness practices might help to build distress tolerance and enhance engagement. Increased use of mindful movement practices in the early stages of the course may also benefit engagement as they enable participants to notice physical sensations more readily. Didonna (2009) similarly proposed that for people with severe OCD symptoms, it may be helpful to gradually introduce mindfulness. For example, it might be advisable to progress from walking practices (that generate proprioceptive sensations) to the body scan (interoceptive sensations), from short to long exercises and from informal to formal practice. A case study by Patel (2007) similarly described introducing mindfulness practices gradually and starting with most preferred/least intrusive practices. Offering practices on preference, e.g. depending on OCD symptom presentation, may help enhance mastery and ease people into committing to practise daily. Evidently, a note of caution is that engaging in 'enjoyable' practices could lead to avoidance of practices that bring people into more direct contact with difficulty which, whilst by definition unpleasant, may be therapeutically beneficial.

The interest in MBIs for OCD is growing at a steady pace, reflected in self-help books such as the mindfulness workbook for OCD (e.g. Herschfield & Corboy, 2013) and the imminent publication of a treatment manual for MBCT for OCD (Didonna, *in press*). A specific focus on enhancing self-compassion in (some) patients with OCD has been included in a recent treatment manual of CBT for OCD (Bream et al., 2017), although at present there are no outcome studies of compassion-based approaches for OCD (Ferrari et al., 2019; Wilson, Mackintosh, Power, & Chan, 2019). In the foreseeable future, two further RCTs of MBCT adapted for OCD will likely to

published (Lu et al., 2018; Lopez-Sola, Serra-Balsco, Alonso, Lopez-Sola, & Andrews-Hannah, 2018), both of which have incorporated self-compassion skills training into the treatment. The question is whether this interest is warranted considering research evidence to date, including the findings reported in this thesis. Whilst the qualitative findings from the fourth paper suggest that most participants experienced MB-ERP and MBCT-OCD as acceptable and beneficial treatments for OCD in line with theorised mechanisms, the quantitative analysis of treatment effects, whilst under-powered to detect statistically significant effects, showed that MB-ERP was unlikely to have added benefit beyond ERP (see Strauss et al., 2018). Furthermore, there was no discernible difference between ERP and MB-ERP in patient dropout, attendance and task engagement. For MBCT-OCD, the pre-to post-treatment reduction in OCD symptoms (descriptive statistics) was disappointing as descriptive statistics showed a negligible mean change in Y-BOCS scores from pre- to post-treatment (M= -0.43 (SD =3.29), range: - 6 to +5); % improvement (M = -2% (SD = 17%), range = -33% to +24%) and just one participant achieved a partial response that brought their symptoms into remission. Perusal of OCI-R data suggested a -10% (SD=17%) mean reduction in post-treatment OCD symptoms severity, ranging from +17 to -43%. Post-treatment obsessive beliefs, as measured by the OBQ-20 scores reduced by -15 % overall (SD=7%), ranging from -3% to -23%. Mindfulness (FFMQ) scores increased by -9% (SD =9%), ranging from -3% to +21% and self-compassion scores (SCS-SF) increased by 2% (SD=11%, range= -9% to +22%). Post-treatment distress tolerance (DTS) increased by a mean 17% (SD=29%, range: -19% to 63%). These findings suggest a highly variable degree of improvement or deterioration across participants on these measures of proposed mechanisms.

Possible reasons for these disappointing outcomes and variability on changes on mechanism measures (over and above what has already been discussed above) include that some participants had very longstanding OCD symptoms and had experienced multiple unsuccessful and/or prematurely discontinued CBT treatments. Three participants reported experiencing significant stressful life events over the course of therapy that resulted in a worsening in their OCD symptoms and associated depressive symptoms. Therefore, it is possible that stressful life events, OCD symptom chronicity and poor engagement may have adversely affected OCD symptom improvement in this small sample.

Since the fourth study was conducted, a further RCT of MBCT as an augmentation therapy for OCD (Külz et al, 2018) was published, along with two uncontrolled studies of MCBT adapted for OCD (Didonna, Lanfredi, et al., 2019; Selchen et al, 2018). Selchen et al. (2018) conducted an uncontrolled study that tested MBCT adapted for OCD, both as a stand-alone, first-line intervention (*N*=19) and as an augmentation therapy for CBT, i.e. for participants showing only partial (or no) response to CBT conducted within the past 2 years (*N*=18). Retention was excellent, with only 5% dropout across both conditions. For both courses, pre-to post reductions in OCD symptoms were significant ('pre-CBT' MBCT change in Y-BOCS score: 5.84 (*d*=1.10); 'post-CBT' MBCT Y-BOCS change score: 8 (*d*=1.31). OCD symptom reduction was significantly greater (*p*=.03) for post-CBT MBCT than for pre-CBT MBCT (there were no significant between-group differences on sociodemographic and clinical variables at baseline). Didonna, Lanfredi, et al. (2019) piloted a novel adaptation of MBCT for OCD with 35 patients, which consisted of 11 2.5-hour sessions and incorporated elements from compassion-focussed therapy and partner/family

sessions (Didonna, in press). All participants completed the course and session attendance rates were excellent, suggesting it was a highly acceptable treatment. There was a significant medium to large pre- to post-treatment effect on OCD symptom reduction (-4.3 points on Y-BOCS) (d=-0.72). Furthermore, 37% of participants experienced a partial (9%) or full (28%) response to treatment. An RCT of this approach is now underway (Lu et al., 2018). Külz et al. (2019) compared MBCT adapted for OCD as an augmentation therapy of CBT (N=81) with a psychoeducational (PE) course (N=64). Dropout rates were low (MBCT: 7%, PE: 9%) and mean session attendance was good (MBCT: 6.5, PE: 5.3, both out of 8), suggesting high acceptability. All participants had received CBT of at least 20 sessions within the last 3 years. At posttreatment, there was no discernible difference in OCD symptom reduction on the Y-BOCS (Mean Y-BOCS difference: MBCT=3.6, PE =3) although participants in the MBCT condition reported a greater reduction in OCD symptom on the OCI-R ($\eta_p^2 = .05$, p=.036). These significant differences were not maintained at six-month follow-up. At post-treatment, a significantly greater proportion of MBCT than PE participants achieved a full response (MBCT: 21%, PE: 13%) and partial response (MBCT: 13%, PE: 5%). The significant difference in response rate was not maintained at six-month follow-up. There was a significant difference in obsessive beliefs ($\eta p2 = .05, p=.024$), quality of life ($\eta p2=.06$, p=.01), mindfulness ($\eta p2=.05$, p=.02) and meta-cognition $(\eta p2=.05, p=.06)$, particularly negative beliefs about thoughts concerning uncontrollability and danger, and depression ($\eta p2=.05$, p=.09) in favour of MBCT. No differences were noted in general pathology, self-compassion or distress tolerance either post-treatment or at six-month follow-up. Interestingly, 64% of MBCT and PE participants were in therapy at the time of the study, overwhelmingly or exclusively

consisting of CBT (MBCT: 97%, PE:100%). This figure increased to 71% for MBCT and 69% for PE at post-treatment. Whilst this suggests it did not affect the difference in outcomes between groups, it does beg the question whether the OCD symptom reduction reported by both groups were due to the MBCT or PE programmes or the effect of ongoing CBT treatment. Concurrent treatment predicted outcomes for the PE but not the MBCT group, suggesting MBCT may have provided a complementary form of therapy that accelerated improvement relative to PE. Overall, the authors concluded that MBCT was a highly acceptable treatment associated with moderate self-reported OCD symptom improvement and a significantly larger proportion of (partial) response to treatment compared to the PE condition. However, as the between-group effect on self-reported OCD symptoms was small and no significant differences were found in clinician-rated OCD symptom severity, the authors suggested that it would be worth exploring whether therapies such as meta-cognitive therapy (MCT) (e.g. van der Heiden et al., 2016) and ACT (Bluett et al., 2014) may achieve superior effects to MBCT. Overall, the evidence base to date suggests that MBIs may have potential for OCD but findings are mixed and adequately powered definitive RCTs are needed to firmly ascertain if MBIs for OCD do or do not have substantive benefit for OCD over and above CBT. Research evidence to date does not allow us to conclude that MBIs improve treatment outcomes over and above CBT and given the wealth of evidence for CBT for OCD it is important that high-quality CBT, conducted in line with best practice (e.g. Bream et al., 2017), remains the primary treatment offered to people with OCD.

6.2 Strengths and limitations of the thesis

The strength of this thesis is that it grappled with a complex question of how to improve outcomes of CBT for OCD. Therefore, it challenges complacency which might ensue from the fact that CBT for OCD is the gold standard in the treatment of OCD (NICE, 2005). In relation to the first aim, strengths include that the thesis employed both quantitative and qualitative methodologies to explore patient engagement in CBT for OCD. To the best of our knowledge, the first paper is the first comprehensive systematic review and meta-analysis with a primary focus on patient adherence to CBT for OCD. Similarly, study 2 is a rare qualitative study focused on participant perspectives on the barriers and facilitators to engagement to group ERP. It provides an in-depth, rich account of perceived barriers and facilitators to engagement and highlights there may be a dynamic interplay between these factors.

The potential benefits of MBIs for OCD have increasingly been explored, supported by theoretically plausible mechanisms of MBIs for OCD, yet few studies have examined whether the premise that OCD is characterised by mindfulness and self-compassion deficits is correct. Therefore, in relation to the second aim, strengths of the thesis included the exploration of the (unique) association, and relative importance, of trait mindfulness and self-compassion with OCD symptoms. The study involved a large sample size of treatment-seeking adults, based on a priori power calculations, which ensured group comparisons were sufficiently powered and permitted an examination of mindfulness and self-compassion with OCD symptom subtypes and their unique importance relative to depression severity, obsessive beliefs and distress tolerance. This is important given that the heterogeneity of OCD consistently presents a challenge to research on OCD.

Furthermore, the fourth paper included a qualitative evaluation of mindfulness-based approaches for OCD, with (MB-ERP) and without (MBCT-OCD) the inclusion of ERP tasks. Both forms of MBI were informed by discussions with members of a lived experience advisory panel and mindfulness teaching and supervision experts. MB-ERP was offered to participants as part of a pilot RCT comparing ERP with MB-ERP (Strauss et al., 2018), i.e. participants were willing to be randomised to either treatment. MBCT-OCD was offered to patients with OCD who did not sufficiently benefit from CBT or when they refused CBT for any reason; the study therefore explored MBCT as an alternative psychological therapy within a routine clinical setting for adults with OCD who for any reason did not benefit from CBT. Therefore, the studies were well suited to exploring whether offering MB-ERP or MBCT for OCD to routine patients was viable.

This thesis has several limitations. These will be discussed further below.

Contribution to knowledge

At the time the thesis topic was conceived, there were few studies of MBIs for OCD and no published RCTs. However, since then, further research has emerged including two RCTs (Key et al., 2017; Külz et al, 2018) and two uncontrolled studies (e.g. Didonna, Lanfredi, et al., 2019; Selchen et al, 2018). Nonetheless, study 3 made a novel contribution in exploring the unique association of mindfulness and self-compassion with OCD symptoms in great detail, whilst the qualitative format of study 4 allowed an in-depth exploration of participant perspectives on the acceptability as well as the potential (personally valued) benefits and mechanisms of OCD, which quantitative studies do not necessarily elucidate. Overall, the thesis captured the

zeitgeist of the wider OCD research community and adds to the growing knowledge base of the acceptability and potential benefits of MBIs for OCD.

Methodological limitations: meta-analysis

The meta-analysis was constrained by a lack of primary studies that directly tested differences between treatment completers and dropouts. Also, whilst it was a large meta-analysis, it could only test single moderators, which meant interaction effects could not be examined. The meta-analysis was ambitious in scope yet some of the information could not be extracted from primary studies; there were few studies of CBT task engagement and their varied measurement meant results could not be meta-analysed. This is not a failure of the meta-analysis per se but limits its implications. Other methodological limitations include that the quality of studies was not assessed, as existing quality assessment tools were not pertinent to adherence data, and the coding was conducted by a single coder; given the scope of the meta-analysis it was not feasible to do otherwise.

Generalisability/transferability

A further limitation of the thesis pertains to the generalisability of the findings. The meta-analysis included a large number of studies and the third paper, a correlational study, included a large sample of treatment seeking adults and students (2400+ overall). However, whilst the third study included a large clinical sample of treatment-seeking adults, the OCD sub-sample was not based on a formal diagnosis of OCD but on the clinical cut-off score of the OCI-R, as it was not feasible to confirm diagnosis with such a large sample recruited across 28 study sites. Furthermore, the healthy control group was made up of university students; this is evidently not an ideal control group for a

clinical sample yet the large sample sizes meant the recruitment of a community sample, likely to require financial remuneration, was not feasible. This therefore places some limitations on the generalisability of the findings to adults with a diagnosis of OCD, bearing in mind that there is good evidence that OCD can be studied in analogue samples (see Abramowitz et al., 2014). Secondly, whilst the qualitative studies were conducted with participants with a diagnosis of OCD, findings were based on relatively small samples, recruited through an NHS mental health trust in the South of England. This too limits the transferability of the findings. However, the convergence of results with other qualitative studies suggested that the findings may still have more general applicability in understanding of both patient engagement in CBT for OCD and the potential of MBIs for OCD.

Qualitative analysis

The qualitative analyses employed (reflexive) thematic analysis, which is a flexible, accessible methodology that was well-suited to the exploration of (patterns in) participant experiences of novel therapies (e.g. Braun & Clarke, 2006; Clarke & Braun, 2017). Limitations of this type of analysis include that it does not allow a consideration of the continuity and contradiction within individual accounts, but this was not necessarily problematic within the context of exploring shared and unique aspects of patients experiences across the dataset. The thematic analysis was conducted from a critical realist perspective, which asserts that it is possible to gain an understanding of how people experience, think and feel about the studied phenomenon but that this understanding is influenced by the researchers' subjectivity, i.e. prior knowledge, expectations and beliefs influence the analysis (Willig, 2001; Barker, Pistrang, & Elliott, 2016). The researchers' understanding is therefore partial and needs to be

continually re-assessed and revised, making it paramount that researchers are reflexive about their own point of view (Willig, 2001). When consensus and 'coherence truth' criteria are applied, research should be replicable (Barker et al., 2016).

A key difference in the analysis of MB-ERP and MBCT-OCD data (study 4) was that the first author (TL) coded both sets of data but had no involvement in the delivery of MB-ERP whereas she had been closely involved in the adaptation and delivery of MBCT for OCD. This meant that she knew the MBCT-OCD but not the MB-ERP participants. To minimise the effect this may have had on the interpretation of the data, the coding and interpretation was discussed with CS and/or KC at all stages of the process.

Measures

The qualitative studies (2 and 4) used the Change Interview. This interview asks broad, open-ended questions about participants' perceived changes over the course of therapy and what they attributed these changes to, helpful and problematic aspects of the course and personal and social resources and limitations. This allowed the researcher(s) to gauge the extent to which (barriers and facilitators to) engagement (study 2) and/or mindfulness (study 4) spontaneously featured in participants' experience of the course. However, developing interviews designed expressly to gather participant views on these topics may have generated yet richer participant accounts to benefit the conclusions drawn from these studies.

A further limitation included its reliance on self-report in study 3. It was evidently not feasible to include behavioural assessments of mindfulness or self-compassion in the context of such a large correlational study. However, self-report carries several

limitations, e.g. the consistency effect (answering similar questions in the same way to avoid seeming inconsistent), social desirability (not wanting to give an unfavourable impression of oneself or answering questions in ways researchers may want to hear) and ability to accurately reflect on oneself (Grossman & van Dam, 2011). In addition, several measures (FFMQ, SF, SCS-SF and DTS) used reverse-scoring, which is not necessarily unproblematic (e.g. assuming mind wandering, limited attention span, being on automatic pilot are the opposite of mindfulness) (Grossman, 2008; Grossman & van Dam, 2011).

The findings for study 2 call the recommended clinical cut-off score of the OCI-R (Foa et al., 2002; Huppert et al., 2007) into question; within a clinical population of treatment seeking adults, the prevalence of OCD is highly unlikely to be 50%. In mitigation, the OCI-R is a widely used measure (e.g. Overduin & Furnham, 2012) with good psychometric properties (Foa et al., 2002; Huppert et al., 2007) and multiple studies have applied the recommended clinical cut-off score of 21 for similar purposes (e.g. Abramowitz et al., 2009). Furthermore, all associations between the OCI-R and other variables, e.g. obsessive beliefs, were in the expected direction, whilst the clinical groups based on the OCI-R showed differences in obsessive beliefs in line with anticipated effects. The analyses in study 2 were not limited to a group comparison; a continuum approach to studying OCD was also used (i.e. measuring associations between endorsement of OCD symptoms on the OCI-R and other variables), for which there is good evidence (Abramowitz et al., 2014).

Some studies have called the factor structure of the SCS-SF (the self-compassion measure used in this thesis) into question (Hayes et al., 2016) whilst the fact that the SCS-SF contains negatively and positive worded items and has subscales that overlap

with well-established concepts has also attracted criticism (Muris & Pettrochhi, 2017). Yet, the SCS and SCS-SF are the most established measures of self-compassion to date. A new measure of compassion is now being developed and could be used to further explore the relationship of OCD with self-compassion (Gu, Baer, Cavanagh, Kuyken, & Strauss, *in press*).

Research on mindfulness is complicated by the fact that mindfulness comes from a Buddhist tradition, around 2500 years ago, originally written about in a different language and therefore not a familiar concept to most people (Grossman, 2008). Also, as mindfulness is cultivated through a sustained commitment to mindfulness practice, most people in the general population will be inexperienced in mindfulness. Therefore, Sauer et al. (2013) highlight that the novice may naively answer the questions without clearly grasping the construct and perhaps be unaware of their own 'mindlessness'. This is likely to affect how mindfulness questionnaires are answered and whether they truly reflect mindfulness skills in the way they are conceptualised within the Buddhist and clinical psychology literature. Furthermore, Grossman (2008) critiques the FFMQ facets, including whether the 'acting with awareness' facet simply measures lapses of attention and whether the 'describe' facet reflects the capacity to verbally express oneself or pre-conceptual verbal labelling, neither of which is not synonymous with mindfulness. Finally, Grossman points out that there is no gold standard reference for mindfulness to assess the validity of the FFMQ-SF, or any other measure of mindfulness, against.

Conceptual/Theoretical

In addition to the limitations set out above in relation to the measurement of mindfulness, a potential conceptual limitation of this thesis is that mindfulness was understood as skill and that low self-reported mindfulness was assumed to reflect a lack of mindfulness skills. Whilst the notion of mindfulness as a skill that can be gradually developed through sustained mindfulness meditation practice is firmly embedded in the mindfulness literature and reflects its Buddhist origins, it cannot be definitively concluded that low self-reported mindfulness does indeed reflect a lack of skill or, by extension, that increased self-reported mindfulness following an MBI definitely demonstrates increased mindfulness skills. Alternative explanations, e.g. inclination or motivation towards being mindful, familiarity with the concept per se or participant response bias, are possible and could be explored further. However, results from study 4 (Chapter 5) and other qualitative studies into participant perspectives on MBIs (e.g. Finucane & Mercer, 2006; Mason & Hargreaves, 2001) do appear to suggest that participants who value mindfulness and express the motivation to respond mindfully to their mental health difficulties and in everyday life, nonetheless describe a process of developing their capacity to be mindful over the course of the intervention, through sustained practice. Finally, a potential conceptual limitation reflects a more general critique of mindfulness research. Whilst MBIs are firmly established in the mainstream of mental health service provision and enshrined in NHS guidelines as (one of) the treatment(s) of choice for recurrent depression (NICE, 2009), practitioners from a Buddhist perspective have questioned the secular application of mindfulness practices outside of the broader Buddhist philosophy, ethics and culture (Keng et al. 2011; Marx,

2015). They query whether it runs the risk of becoming just another cognitive behavioural technique or exercise, with the intention of 'fixing' problems, which is antithetical to the Buddhist understanding of suffering (e.g. Kabat-Zinn, 2003). However, Kabat-Zinn (2003) argues that mindfulness practices are universal at heart as they essentially encompass intentionally bringing one's attention to present-moment experiences.

6.3 Future research priorities

Several priorities for future research were identified over the course of this thesis (as discussed in the previous study-based consideration of future research). These will be summarised below.

Research into patient engagement in CBT for OCD should be more ambitious in attempting to answer what predicts patient engagement. This includes taking a more theory-driven approach, e.g. informed by health behaviour models (e.g. Kwasnicka, Dombrowksi, White, & Sniehotta, 2016) and utilising novel research procedures (Elliott et al, 2010, Rhodes, 2011). Research in this area also relies on consistent monitoring and reporting of patient engagement and treatment response data and on the development of suitable measures of engagement.

Research needs to further explore how MBIs achieve their effects on OCD symptom reduction and whether MBIs as augmentation therapies for CBT are potentially more efficacious than further ('booster') CBT or other psychological therapy approaches applied to OCD in recent years, specifically ACT (e.g. Bluett et al., 2014) and meta-cognitive therapy (MCT) (e.g. Fisher & Wells, 2008; van der Heiden, van Rossen, Dekker, Damstra, & Deen, 2016). This includes understanding whether

mindfulness skills enhancement predicts OCD symptoms improvement and the exploration of possible mediators of this relationship. Also, MBIs for OCD need to take account of OCD symptom subtypes and, as with CBT, gauge the role of patient engagement in treatment outcomes.

Adaptations of MBCT (or indeed novel MBIs) might need to be more radical and specifically tailored to OCD before we can decidedly conclude that MBIs do or do not have anything to offer to adults with OCD. Further experimental research into whether exposure is a mechanism of mindfulness may be particularly fruitful in attempting to understand how mindfulness may benefit ERP for OCD (e.g. Wahl et al., 2013; Treanor, 2011). Also, OCD has been reclassified in the latest edition of DSM-V (APA, 2013). Whilst this is not without controversy (Abramowitz & Jacoby, 2015), its classification as a disorder marked by excessive habit formation, in the context of goal-directed behaviour deficits, suggests further research into the potential benefit of mindfulness in targeting these potential mechanisms of OCD is warranted.

6.4 Conclusions

The overall aim of this thesis was to contribute to existing knowledge and understanding of what may help to improve outcomes of CBT for OCD. This thesis explored the role of patient engagement in CBT for OCD and the potential of MBIs for OCD, informed by the fact that CBT for OCD does not appear to benefit all patients. The thesis addressed a gap in the research literature on CBT for OCD through the meta-analysis of the magnitude of patient (non-) adherence to CBT for OCD and the exploration of factors that contribute to (the process of) patient engagement. The thesis highlighted that research into patient engagement in CBT for OCD is surprisingly

limited given the wealth of research exploring the (predictors of) the efficacy of CBT for OCD. Further research in this area is therefore warranted. The qualitative exploration of patient engagement in group ERP confirmed that understanding what aids or hinders patient engagement is a complex undertaking that requires a more indepth, theory-driven exploration of the interaction between various predictive factors. The thesis made a novel contribution to understanding the role of mindfulness and self-compassion skills in OCD and added to the growing evidence base on the potential of MBIs for OCD by exploring whether MBIs for OCD are likely to benefit patients in line with their theorised potential. The thesis provided preliminary evidence that mindfulness and self-compassion skills may contribute to our understanding of some OCD symptom subtypes and this now warrants further exploration. Furthermore, findings suggested that patients with OCD value MBIs to deal with their symptoms but also emphasised the need for further research to understand whether and how their potential to improve OCD symptoms may be enhanced.

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7 APPENDICES CHAPTER 1

APPENDIX A

Table A1
Standard MBCT course structure and content (Segal et al., 2013)

Session no. & theme	Content	Practices
Awareness and automatic pilot	Re-visiting introductions and ground rules; selective attention/hypervigilance in OCD; getting caught up in (worrying about & responding to) intrusive thoughts	raisin exercise; body scan; everyday mindfulness, 2-3- minute breathing practice
Living in our heads	Thoughts and feelings exercise ('walking down the street'); setting up pleasant events calendar practice	body scan, 10-minute sitting meditation
Gathering the scattered mind	Inviting participants to use the 3-minute breathing space (3MBS), setting up unpleasant (mental) events calendar	5 minute 'seeing'/ 'hearing' exercise; 30-minute sitting meditation; 3-minute breathing space (3MBS); Mindful stretching
Recognising aversion	Defining the territory of depression: automatic thoughts questionnaire and diagnostic criteria for depression.	5-minute 'seeing'/'hearing' exercise; 30- to 40- minute sitting meditation; poem, e.g. 'wild geese'; 3MBS; Mindful walking
Allowing, letting be	Session involves meditation practices only (+ sessional home practice feedback, distribution of handouts and planning home practice)	30- to 4- minute sitting meditation; introducing a difficulty within the practice and noting its effects on the body and reactions to it; Breathing space (with added instructions); Rumi's poem 'the guest house'
Thoughts are not facts	Preparation for end of course Moods, thoughts, and alternative viewpoints exercise Discuss breathing space as first step before taking a wider view of thoughts Discuss depression relapse signature	30-to 40- minute sitting meditation, noticing how we relate to thoughts that arise, Breathing space

How can I best take care of myself?	Exercise to explore links between activity and mood; Plan how best to schedule activities for when mood threatens to overwhelm; Rebalancing nourishing and depleting activities; Generating list of pleasure and mastery activities; 3MBS as a first step before choosing whether to take mindful action; Identifying actions to deal with threat of relapse/recurrence	30- to 40- minute sitting meditation – awareness of when difficulties arise within the practice, noting their effects and reactions to them, on the body, 3MBS or mindful walking
Maintaining and extending new learning	Review of the course and what has been learnt; personal reflections; Give out questionnaire for participant to give personal reflections on the program. Discuss how best to keep up momentum developed over the past 7 weeks in both formal and informal practice	Body scan practice, concluding meditation (marble, stone or bead)/participants wishing each other well

Table A2

MBCT course adapted for OCD (MBCT-OCD)

Session no.	Content	Practices
& theme		
Introductory	Introductions; ground rules; introducing the cognitive model of OCD; how MBCT might help people with OCD; what taking part in the course involves	Introductory mindfulness practice (breathing/grounding)
Awareness and automatic pilot	Re-visiting introductions and ground rules; selective attention/hypervigilance in OCD; getting caught up in (worrying about & responding to) intrusive thoughts	Marble exercise; body scan; everyday mindfulness, 2-3 minute breathing practice
Living in our heads	Normalising intrusive thoughts; setting up pleasant events calendar practice	body scan, 10-minute sitting meditation
Gathering the scattered mind	Inviting participants to use the 3-minute breathing space (3MBS) when OCD symptoms emerge, setting up unpleasant (mental) events calendar	5 minute 'seeing'/ 'hearing' exercise; 30-minute sitting meditation; 3-minute breathing space (3MBS); Mindful stretching
Recognising aversion	Defining the territory of OCD (revisiting the cognitive model); the role of (aversion to) anxiety;	5-minute 'seeing'/'hearing' exercise; 30- to 40- minute sitting meditation; poem, e.g. 'wild geese'; 3MBS; Mindful walking
Allowing, letting be	Exploring the meaning we give to intrusive thoughts (i.e. obsessive beliefs) using the OBQ-20 The role of thought suppression, avoidance and compulsions in maintaining OCD	30- to 4- minute sitting meditation; introducing a difficulty within the practice and noting its effects on the body and reactions to it; Breathing space (with added instructions); Rumi's poem 'the guest house'
Thoughts are not facts	Preparation for end of course; discuss breaking the OCD vicious cycle; Introduce the notion of	30-to 40- minute sitting meditation, noticing how we

	'Theory A vs Theory B'; discuss distress/anxiety tolerance and building up confidence that one can tolerate distress/anxiety	relate to thoughts that arise, Breathing space
How can I best take care of myself?	Using the 3MBS as a first step before choosing how best to respond to OCD; self-compassion vs immediate relief in overcoming OCD; keeping up the good work	30- to 40- minute sitting meditation – awareness of when difficulties arise within the practice, noting their effects and reactions to them, on the body, 3MBS or mindful walking
Maintaining and extending new learning	Review of the course and what has been learnt; personal reflections; how to keep up momentum	Body scan practice, concluding meditation (marble, stone or bead)/participants wishing each other well

APPENDIX B

 Table B1

 Overview of three common transdiagnostic models of mindfulness

Baer (2003)	 exposure relaxation self-management cognitive change acceptance
Brown, Ryan and Creswell (2007)	 exposure enhancement of body-mind functioning insight non-attachment integrated functioning
Shapiro et al. (2006)	 re-perceiving (meta-cognitive shift) exposure self-regulation, self-management behavioural, cognitive and emotional flexibility values clarification

8 APPENDICES STUDY 1 (CHAPTER 2)

APPENDIX A

Table A.1Coding of Clinical Representativeness of patients (based on Hans & Hiller, 2013)

Referrals	Patients were referred through usual clinical routes (referred by general practitioner, self-referral). At least some of the patients under study were actively recruited (from the community or from patient samples).
Patients	 If patients meet criteria for disorder under study, there are no exclusion criteria besides acute suicidality, acute psychosis, organic brain disease, substance dependence, or disorders potentially interfering with treatment engagement. Exclusion criteria beyond those above, including comorbidity and medication.
Allowance of medication	 Medication is allowed. Code 1 if no specific mention in exclusion criteria. Patients are forced to stop medication or are excluded from the study due to medication. Code 1 if medication is discontinued for therapeutic reasons (e.g., benzodiazepines in the case of exposure therapy).

APPENDIX B

Study references

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APPENDIX C

Study	Mean refusal rate	Reasons for refusal	Mean Dropout rate	Reasons for dropout	Risk Ratio early vs late dropout	Mean (No/%) session attendance	Mean (No%) module completion	Mean CBT task adheren-	Association CBT task adherence & Y-BOCS symptom reduction
1. Abramowitz et al. (2013)	7	7	7	>					
2. Abramowitz, Foa, & Franklin (2003)			Ņ		٨				
3. Abramowitz, Franklin, Zoellner, & DiBernardo (2002)								<u> </u>	^
	>		7						
5. Aderka et al. (2011)						<u> </u>			
6. Alonso et al. (2001)	ļ	٨	ļ						
7. Anderson & Rees (2007)			Y						
8. Andersson et al. (2012)			>	7	ļ		7		
9. Andersson et al. (2011)	٨		V		V		Ņ		
10. Bachofen et al. (1999)	^		ļ		ļ				1
11. Belotto-Silva et al. (2012)			V	Ą					
12. Bhar, Kyrios, & Hordern (2015)	٨								
13. Cabedo et al. (2010)	٨		V						
14. Castle et al. (1994)			V						
15. Challacombe et al. (2017)			V						
16. Chambless & Steketee (1999)			ļ						
17. Collins & Coles (2017)	٨		V						
18. Cordioli et al. (2002)			٧	٧	V				
19. Cordioli et al. (2003)			V	1	V				
20. Cottraux et al. (1990)	*		V	Ą				٨	
21. Cottraux et al. (2001)			7						
22. De Araujo, Ito, & Marks (1996)									٨
23. De Araujo, Ito, Marks, & Deale (1995)			7		٨				
24. De Leeuw, van Megen, Kahn, & Westenberg (2017)			γ						
25. Demal, Zitterl, Lenz, Zapotoczky, & Zitterl-Eglseer (1996)			٨	٨					

Table C1 Overview of studies included under each adherence variable

	Mean refusal rate	Reasons for refusal	Mean Dropout rate	Reasons for dropout	RR - Early vs late dropout	Mean (No/%) session attendance	Mean (No/%) module completion	Mean CBT task adheren-	Association CBT task adherence & Y-BOCS symptom reduction
 Diefenbach, Wootton, Bragdon, Moshier, & Tolin (2015) 	7	7	٧	٦			V		
27. Enright (1991)			V	Λ					
28. Espie (1986)	٨		٨			√ (Mean % only)			
29. Fals-Stewart & Lucente (1993)	١							ļ	
30. Fals-Stewart, Marks, & Schafer (1993)			^						
31. Fineberg, Hughes, Gale, & Roberts (2005)			1						
32. Foa et al. (2005)			>	>					
Foa, Steketee, & Grayson (1985)			Ņ						
			>						
35. Freeston et al. (1997)			7	>					
36. Freeston, Leger, & Ladouceur (2001)			V						
37. Fritzler, Hecker, & Losee (1997)			٨						
38. Fullana et al. (2014)	٨		V		V				
39. Goetter, Herbert, Forman, Yuen, & Thomas (2014)			7					7	
40. Greist et al. (2002)			>		٧				>
41. Greist et al. (1998)			٨						>
42. Hagen et al. (2016)			>						
43. Haland, Vogel, Lie, Launes, Pripp, & Himle (2010)	7	7	>	>				-	
44. Havnen, Hansen, Haug, Prescott, & Kvale (2013)	>		^						
45. Herbst et al. (2014)			>						
46. Himle et al. (2006)			>						
47. Hoogduin & Hoogduin (1984)	>		٨						
48. Houghton, Saxon, Bradburn, Ricketts, & Hardy (2010)	٨	٨	7			√ (Mean No. only)			
49. Jones & Menzies (1998)			٨						
50. Jonsson, Hougaard, & Bennedsen (2011)			٨	<u>^</u>		1			
51. Kampman, Keijsers, Hoogduin, & Verbraak (2002)			٧		٧				
52. Kearns, Tone, Rush, & Lucey (2010)	ļ	ļ	٨						
53. Kellner, Nowack, Wortmann, Yassouridis, & Wiedemann (2016)			٧		V				

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Study	Mean refusal rate	Reasons for refusal	Mean Dropout rate	Reasons for dropout	RR - Early vs late dropout	Mean (No/%) session attendance	Mean (No/%) module completion	Mean CBT task adheren-	Association CBT task adherence & Y-BOCS symptom reduction
54. Kenwright, Marks, Graham, Franses & Mataix-Cols (2005)			7						7
55. Kobak, Greist, Jacobi, Levy-Mack, & Greist (2015).									7
56. Krochmalik, Jones, & Menzies (2001)			^						
57. Krochmalik, Jones, Menzies, & Kirkby (2004)			Ŋ						
			V						
59. Kushner et al. (2007)			٨						
60. Kyrios, Hordern, & Fassnacht (2015)			٨						
			٨						
62. Lovell et al. (2017)).		
63. Lovell et al. (2006)			١						
64. Lovell, Ekers, Fulford, Baguley, & Bradshaw (2004)			Ŋ		١/				
65. Lovell, Fullalove, Garvey, & Brooker (2000)	٨		٨						
66. Mahoney, Mackenzie, Williams, Smith, & Andrews (2014)							٨		
67. Mancebo, Steketee, Muroff, Rasmussen, & Zlotnick (2017)			>	>	<i>\</i>				
68. Marsden, Lovell, Blore, Ali & Delgadillo (2017)			Ņ						
69. McLean et al. (2001)			^	7					
70. McLean et al. (2015)			V						
71. Morgieve et al. (2014)			7						
72. Nakatani et al. (2005)			V	V					
73. Nedeljkovic, Kyrios, Moulding, & Doron (2011)			1						
O'Connor et al.			7						
75. O'Connor et al. (2005)			>						
76. Polman, Bouman, van Geert, de Jong, & den Boer (2011)			>						
77. Rosqvist et al. (2001)			7					į	
78. Rowa et al. (2007)				3				1	
79. Safak et al. (2014)			7	7		Ņ			
- 1	>		>	>					
81. Saxena et al. (2009)			>		>				

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Study	Mean refusal rate	Reasons for refusal	Mean Dropout rate	Reasons for dropout	RR - Early vs late dropout	Mean (No/%) session attendance	Mean (No/%) module completion	Mean CBT task adheren-	Association CBT task adherence & Y-BOCS symptom reduction
82. Seol, Kwon, Kim, Kim, & Shin (2016)			١						
83. Shinmei et al. (2017)			1	ħ.					
84. Simpson, et al. (2013)			ļ	36				r	^
85. Simpson et al. (2008)			ļ	^					
86. Simpson, Gorfinkle, & Liebowitz (1999)	>	7	٨	>	>				
87. Simpson et al. (2011)						.00			٨
88. Simpson et al. (2010)			ļ	ħ.	7	ļ		1	
89. Sousa, Isolan, Oliveira, Manfro, & Cordioli (2006)			٦	/\	N				
90. Storch et al. (2007)			ļ	36					
91. Storch et al. (2008)			ļ	/\					
92. Taylor et al. (2003)			٦						
93. Tenneij, van Megen, Denys, & Westenberg (2005)			٦	<u>/</u>					
94. Tolin, Diefenbach, & Gilliam (2011)			٧	\				٨	
95. Tolin, Diefenbach, Maltby, & Hannan (2005)			Ý						
96. Tolin et al. (2007)			√	- 70				Ņ	ļ
97. Tolin, Maltby, Diefenbach, Hannan, & Worhunsky (2004)			ァ	>				7	>
98. Tundo, Salvati, Busto, Di Spigno, & Falcini (2007)			>	^					
99. Van Balkom et al. (1998)			١	>					
100. Van Balkom et al. (2012)			٦						
101. Van NoppenSteketee, McCorkle, & Pato (1997)			√	r					
102. Van Oppen et al. (1995)			Ŋ	^					
103. Van Oppen et al. (2010)			√						
104. Vandborg, Hartmann, Bennedsen, Pedersen, &			>	Λ		>			
105 Visser et al. (2015)			7	7					
106. Vogel et al. (2012)	>	7	7						
107. Vogel et al. (2014)			7						
108. Vogel, Stiles, & Gotestam (2004)			Ņ	3				7	
109. Vos, Huibers, & Arntz (2012)			Ņ	٨					
110. Vyskocilova, Prasko, & Sipek (2016)			>	>					

Study	Mean refusal	Reasons for	Mean Dropout	Reasons	RR - Early vs late	Mean (No/%)	Mean (No/%)	Mean CBT	Association CBT task
	rate	refusal	rate	dropout	dropout	session	module	task adheren-	adherence & Y-BOCS
								93	symptom reduction
111.Warren & Thomas (2001)			>			√ (mean No. only)			
112. Wheaton et al. (2016)								~	
113. Wheaton, Huppert, Foa, & Simpson (2016)								7	
114. Whittal, Woody, McLean, Rachman, & Robichaud (2010)			>					>	
115. Whittal, Thordarson, & McLean (2005)			7			7		7	7
116.Wilhelm et al. (2009)			٨	٨	٨				
117. Wilhelm et al. (2005)			Λ	V	Ą				
118. Wilson & Chambless (2005)			٨						
119. Wootton, Dear, Johnston, Terides, & Titov (2013)	90		٨	Ņ			Ą		
120. Wootton, Dear, Johnston, Terides, & Titov (2014)	^		Ą	٨			٨		
121. Wootton et al. (2011)	ļ		À	À			\^		
122. Wroe & Wise (2012)	٨	٨	٨						
123. Yang et al.(2015)			Ą						
TOTAL	79	8	111	41	24	8	8	14	13

12.93

15.27 17.20 28.50 17.50

18.00

Mean total BDI 15.06

15.20

18.20

Mean total YBOCS 28.10 25.75 25.65 23.30 23.99 24.08 28.55 23.80 24.50 20.00 25.00 25.89 25.70 24.70 21.11 24.85 Mean % prior CBT 0 28 26 26 54 0 Mean % medicat ion 25 45 39 19 62 22 17 30 55 56 45 28 51 Mean % axis II 82 0 Mean % Axis 1 50 37 33 Mean % Comorbi 45 52 65 Mean duratio 13.70 13.00 17.45 11.40 11.90 18.00 10.00 15.00 23.60 21.10 12.00 14.30 8.96 13.37 09.9 Table C2 Sociodemographic characteristics of included studies (N=117)* Mean % Female 33 65 43 58 70 55 30 52 64 75 50 65 69 51 4 36.05 Mean age 37.45 29.00 33.73 34.00 39.00 31.00 34.04 34.00 36.50 35.90 33.00 35.15 34.40 37.08 32.10 33.13 33.79 32.30 39.50 35.80 30.20 158 219 Z 16 09 54 101 23 62 42 47 44 62 46 39 70 26 27 9 17 9 27 32 Sample ** C ITT ITT III III ITT ITT III CILL III III ILL III U U U Year 2013 2003 2002 2001 2007 2012 2011 2012 2015 2010 1994 2017 2017 2002 2003 1990 2001 1995 1996 2015 1999 1991 OCD only Collins & Coles Abramovitz Abramovitz -Belotto-Silva Challacombe Abramovitz Chambless -De Aurojo Diefenbach Andersson Andersson Anderson Bachofen Cottraux De Leeuw Cordioli Cottraux Cordioli Cabedo Enright Alonso Castle Demal Study Pilot Bhar A 13 20 22 23 10 12 15 16 18 19 17 21 9

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e	Study	Year	Sample **	N	Mean	Mean % Female	Mean duratio n	Mean % Comorbi d	Mean % Axis 1	Mean % axis II	Mean % medicat	Mean % prior CBT	Mean total YBOCS	Mean total BDI
28	Espie	1986	III	5	28.80	09	4.60				09	100		
23	Fals-Stewart & Lucente	1993	LLI	137	30.50	85	15.50		63					
30	Fals-Stewart	1993	ט	93	30.50	55	12.70				ď		20.73	12.17
31	Fineberg	2005	III	41	39.45	9/	13.75			6	34		23.30	
32	Foa	2005	III	122	34.80	48	16.40						25.40	
33	Foa	1985	υ	19	34.10		12.00					0	6	17.90
34	Franklin	2000	ILI	110	34.20	47		54		17	٥		26.79	18.44
35	Freeston	1997	III	29	35.80	45	9.40				35		23.50	20.65
36	Freeston	2001	III	9	30.17	19	12.33						23.17	18.50
37	Fritzler	1997	III	12	37.17	33					19		22.90	19.37
38	Fullana	2014	บ	74	34.09	62							22.20	
39	Goetter	2014	ITI	15	32.20	87					13			
40	Greist	2002	III	218	39.00	42	22.00	24					25.00	
41	Greist	1998	III	40	34.90	48						0	23.60	
42	Hagen	2016	υ	44	33.25	99		ñ-		.0			24.41	
43	Haland	2010	υ	50	35.90	74	16,10		64			14	23.70	16.80
44	Havnen	2013	III	9	38.80	19	21.30				33	29	23.50	15.60
45	Herbst	2013	III	34	35.71	65	14.06			6	ž.	0	20.13	13.49
46	Himle	2006	ITI	3	29.00	100	10.33	19			19		30.17	
47	Hoogduin	1984	ITI	25	33.50	09	5.50				3		e e	
48	Houghton	2010	ITI	37	36.80	49	16.00	98				in .	24.20	
49	Jones	1998	ပ	21	38.50	16				y-		.25		13.43
50	Jonsson	2011	III	93	32.70	99			40	30	81	501	26.46	22.10
51	Kampman	2002	ຍ	6	28.60	100			44			0	28.10	
52	Keams	2010	ITI	24	43.00	58	21.60					S	24.70	21.90
53	Kellner	2016	บ	16	33.35	99	15.45	64			64		26.75	21.75

a	Study	Year	Sample **	>	Mean age	Mean % Female	Mean duratio n	Mean % Comorbi d	Mean % Axis 1	Mean % axis II	Mean % medicat	Mean % prior CBT	Mean total YBOCS	Mean total BDI
54	Kenwright	2005	III	44	40.00	52	16.00				50	64	26.00	
55	Kobak	2015	Ш	87	38.34	63	5.40	7.2					22.43	
99	Krochmalik	2001	III	5	42.00	08	26.40							10.40
23	Krochmalik	2004	บ	18	37.07	81							25.70	
88	Krone	1991	υ	36	38.00		19.00	47			45		21.20	15.60
59	Kushner	2007	III	32							62		27.65	
09	Kyrios	2015	ŭ	59	36.00	61							23.19	19.35
19	Lindsay	1997	III	6	31.60	44	00'6						28.70	21.33
62	Lovell	2017	III	473	32.70	09							25.13	
63	Lovell	2006	III	72	31.90	59	15.10				51	35	25.70	17.95
59	Lovell	2004	III	7	29.14	17	6.79						25.57	15.00
65	Lovell	2000	ITI	4	35.00	75							26.25	22.50
99	Mahoney	2014	ITI	29	39.07	09					34			
19	Mancebo	2017	III	∞	45.00	88			88	88		0	30.38	
89	Marsden	2017	III	55	32.04	62							25.82	
69	Mclean	2001	Ü	63	35.00	48			51		48		21.85	17.40
70	Mclean	2015	III	32	31.41	90					100		25.84	
17	Morgieve	2014	III	35	32.43	51	17.17				49		22.46	
72	Nakatani	2005	ນ	28	33.80	89	12.80			82			29.60	
73	Nedeljkovic	2011	ນ	26	38.11	53							26.38	22.27
74	O'Connor	2012	ບ	37	47.93	89	A				23		25.24	17.02
75	O'Connor	2005	ນ	36	40.00	42							20.75	16.70
9/	Polman	2011	III	7	25.71	100	6.19				43		22.14	
11	Rosqvist	2001	III	11	40.00	45		27					22.45	
78	Rowa	2007	ນ	28	33.83	75					82		26.00	
61	Safak	2014	ITI	37	32.13	92	8.89	57			54			

≘	Study	Year	Sample **	2	Mean age	Mean % Female	Mean duratio n	Mean % Comorbi d	Mean % Axis 1	Mean % axis II	Mean % medicat ion	Mean % prior CBT	Mean total YBOCS	Mean total BDI
08	Sampaio	2016	III	30	39.50	57	24.60							
81	Saxena	2009	ວ	10	40.60	40			0				25.20	
82	Seol	2016	ນ	27	29.22	30	9.47				4		23.70	14.89
83	Shinmei	2017	ITI	37	35.70	54	13.30						26.92	22
84	Simpson	2013	III	100	33.90	48	16.10		48		87	7	26.40	
85	Simpson	2008	III	108	39.20	43	22.00		44		100	12	25.80	
98	Simpson	1999	III	9	35.00	17		100				0	23.80	
88	Simpson	2010	III	30	39.90	47	18.50		90			13	28.10	
68	Sousa	2006	III	99	38.50	11	23.50					0	25.60C	22.10C
90	Storch	2007	ຍ	24	29.00	50							30.35	16.05
16	Storch	2008	υ	62	31.80	47							26.75	16.05
92	Taylor	2003	III	33	38.00	9/	23.00						19.00C	
93	Tenneij	2005	III	96	36.70	92	15.50					36	14.35	
94	Tolin	2011	III	34	33.64	28		89			47	0	24.91	
95	Tolin	2005	III	11	40.50	55		46					23.91	13.27
96	Tolin	2007	III	4	38.18	37				34	99	0	23.33	21.31
26	Tolin	2004	III	20	39.35	50	ě.		75	30			25.20	19.28
86	Tundo	2007	III	36	31.00	37	13.40		58		68		28.20	
66	Van Balkom (- Van Oppen)	1998	บ	32	36.90	59	13.95				88		25.80	17.33
100	Van Balkom	2012	ILI	48	36.80	59	19.10	09					23.00	
101	Van Noppen	1997	υ	36	33.00	19							23.90	
102	Van Oppen	1995	υ	57	34.70	53	12.90						24.75	16.45
103	Van Oppen	2010	LLL	118	35.00	09	17.00						26.00	
104	Vandborg	2015	၁	39	30.26		7.75				59		25.64	
105	Visser	2015	ITI	06	34.80	99					39		26.05	16.70

≘	Study	Year	Sample	N	Mean	Mean	Mean	Mean %	Mean	Mean	Mean	Mean	Mean	Mean
			« «		age	% Female	duratio n	comorbid ity	% Axis 1	% axis II	% medicat ion	% prior CBT	total	total BDI
106	Vogel	2012	III	9	31.50	17						17	24.70	
107	Vogel	2014	Ш	30	33.10	09							23.90	11.23
108	Vogel	2004	III	27	35.35	70			30				24.30	15.90
109	Vos	2012	ITI	78	30.64	62	6.35				21			
110	Vyskocilova	2016	ITI	57	31.74	58	16.23		95	54	100		24.30	18.43
111	Warren	2001	ŭ	19	30.10	37	5.28	32			89		23.00	
114	Whittal	2010	III	73	31.50	47			75		52	0	18.18C ***	17.26C
115	Whittal	2002	υ	65	34.91	63	13.23		55				22.58	17.68
116	Wilhelm	2009	III	29	33.40	52		41			48	0	25.60	
117	Wilhelm	2005	III	15	33.50	33						33	23.30	12.40
118	Wilson	2005	ITI	9	33.16	90							21.50	21.00
119	Wootton	2013	III	52	38.00	75					81		22.13	
120	Wootton	2014	III	44	34.26	78					31		21.30	
121	Wootton	2011	III	22	35.18	65					27		20.90	
122	Wroe	2012	III	17	35.64	24	14.40						24.53	17.59
123	Yang	2015	III	22	30.95	55	8.22					0	24.43	
I	Information provided by (N) st	d by (N) sa	tudies:		114	107	99	19	19	6	52	31	102	53
	Mean	u			34.86	58	14.10	57	51	46	53	18	24.49	17.58
	Total	_		5627										

*Six studies that use CBT task adherence data from outcome studies already included in the meta-analysis are not listed here. ** Indicates whether sociodemographic data is based on intention-to-treat/treatment starter or completer samples. *** C= based on completer sample.

Table C.3 Overview of design and treatment characteristics of included studies (N=117)*

€	Study	Vear	Design	Treatment conditions**	Theranist contact	Session fred
- [A1	2012	TI11-1	(-1) HCE	-101-	M-4
-	Abramovitz	2013	Uncontrolled	CB1 (couple)	>IO nrs	Mod
7	Abramovitz	2003	Controlled	ERP (High freq.), ERP (Mod freq.)	>10 hrs	High vs mod
4	Abramovitz - pilot	2002	Uncontrolled	CBI	>10 hrs	Mod to low
9	Alonso	2001	Uncontrolled	ЕКР	>10 hrs	Low
7	Anderson	2007	Controlled	CBT (Gtp), CBT, WLC	$\leq 10 \mathrm{hrs}$	Low
8	Andersson	2012	Controlled	CBT (remote, therapist-assisted), Psych Pla	≤10 hrs	
6	Andersson	2011	Uncontrolled	CBT (remote, therapist-assisted)	<10 hrs	
10	Bachofen	1999	Uncontrolled	ERP (self-help)	<10 hrs	
111	Belotto-Silva	2012	Controlled	CBT (Grp), Med	>10 hrs	Low
12	Bhar	2015	Uncontrolled	LED	>10 hrs	Low
13	Cabedo	2010	Controlled	CBT, CBT (Gtp)	>10 hrs	Low
14	Castle	1994	Uncontrolled	ERP		
15	Challacombe	2017	Uncontrolled	LED	>10 hrs	Mod
16	Chambless - OCD only	1999	Uncontrolled	ERP	>10 hrs	Mod to low
17	Collins & Coles	2017	Uncontrolled	ERP	>10 hrs	
18	Cordioli	2002	Uncontrolled	CBT (Grp)	>10 hrs	Low
19	Cordioli	2003	Controlled	CBT (Grp), WLC	>10 hrs	Low
20	Cottraux	1990	Controlled	ERP + Med, ERP + Pla, Anti-ERP + Med	>10 hrs	Low
21	Cottraux	2001	Controlled	CT, ERP	>10 hrs	Mod (ERP), Mod to low (CT)
23	De Aurojo	1995	Controlled	ERP (In vivo), ERP (In vivo + imaginal)	>10 hrs	Low
24	De leeuw	2017	Controlled	ERP + Pla, ERP + Med (DCS)	<10 hrs	Low
25	Demal	9661	Uncontrolled	CBT + Med	>10 hrs	Low
26	Diefenbach	2015	Uncontrolled	ERP (remote - therapist assisted)	≤10 hrs	
27	Enright	1991	Uncontrolled	CBT (Gtp)	>10 hrs	Low
28	Espie	1986	Uncontrolled	CBT (Gtp)	>10 hrs	Low
29	Fals-Stewart & Lucente	1993	Uncontrolled	ERP	>10 hrs	Mod

E	Study	Vear	Design	Treatment conditions*	Therapist confact	Session fred
30	Fals-stewart	1993	Controlled	ERP, ERP (Grp)	>10 hrs	Low (grp), Mod
31	Fineberg	2005	Controlled	CBT (Gtp), Psych Pla	>10 hrs	Low
32	Foa	2005	Controlled	ERP, ERP + Med, Med, Pla	>10 hrs	High
33	Foa	1985	Controlled	ERP in vivo, ERP imaginal	>10 hrs	High
34	Franklin	2000	Uncontrolled	ERP	>10 hrs	High
35	Freeston	1997	Controlled	CBT, WLC	>10 hrs	Mod
36	Freeston	2001	Uncontrolled	CT	>10 hrs	Low
37	Fritzler	1997	Controlled	ERP, WLC	≤10 hrs	Low
38	Fullana	2014	Uncontrolled	ERP	>10 hrs	Low
39	Goetter	2014	Uncontrolled	ERP (remote, assisted (video-conference))	>10 hrs	
40	Greist	2002	Controlled	ERP, ERP (self-help), Psych Pla	<pre>≤ 10 hrs (remote), >10 hrs (face-to-face)</pre>	Low (ERP)
41	Greist	1998	Uncontrolled	ERP (self-help)	<10 hrs	
42	Hagen	2016	Uncontrolled	ERP		
43	Haland	2010	Uncontrolled	ERP (Grp)	>10 hrs	Low
44	Havnen	2013	Uncontrolled	ERP (Grp)	>10 hrs	High
45	Herbst	2013	Controlled	CBT (remote, therapist-assisted), WLC	≤10 hrs	
46	Himle	2006	Uncontrolled	CBT (remote, therapist-assisted (videoconference))	>10 hrs	
47	Hoogduin	1984	Uncontrolled	ERP		
48	Houghton	2010	Uncontrolled	CBT		
49	Jones	8661	Controlled	CI (Grp), WLC	≤10 hrs	Low
50	Jonsson	2011	Controlled	CBT, CBT (Grp)	>10 hrs	Low
51	Kampman	2002	Uncontrolled	CBT	≤10 hrs	Low
52	Kearns	2010	Uncontrolled	CBT (Grp)	>10 hrs	Low
53	Kellner	2016	Controlled	ERP + Med, ERP + Pla		
54	Kenwright	2005	Controlled	ERP (remote, assistance requested), ERP (remote, assistance scheduled)	≤10 hrs	
55	Kobak	2015	Controlled	ERP self-help, ERP (remote, lay coaching) ERP (remote, therapist coaching)	<10 hrs	

А	Study	Year	Design	Treatment conditions*	Therapist contact	Session freq.
99	Krochmalik	2001	Uncontrolled	CT	<10 hrs	Low
57	Krochmalik	2004	Controlled	ERP, CT (DIRT)	>10 hrs	
28	Krone	1661	Uncontrolled	ERP (Grp)	>10 hrs	Low
59	Kushner	2007	Controlled	ERP + Med (DCS), ERP + Pla	≤10 hrs	Mod
09	Kyrios	2015	Uncontrolled	CBT	>10 hrs	Low
61	Lindsay	1997	Controlled	ERP	>10 hrs	High
62	Lovell	2017	Controlled	(remote, therapist-assisted)	<10 hrs	
63	Lovell	2006	Controlled	ERP, ERP (remote, assisted (phone))	<10 hrs	
64	Lovell	2004	Uncontrolled	CBT	≤10 hrs	Low
65	Lovell	2000	Uncontrolled	ERP (remote, therapist assisted)	≤10 hrs	
99	Mahoney	2014	Controlled	ICBT (remote self-help), TAU	$\leq 10 \mathrm{hrs}$	
<i>L</i> 9	Mancebo	2017	Uncontrolled	ERP (Grp)	>10 hrs	Low
89	Marsden	2017	Controlled	ERP	>10 hrs	
69	McLean	2001	Controlled	CT (Grp), ERP (Grp)	>10 hrs	Low
70	McLean	2015	Uncontrolled	ERP	>10 hrs	Mod
71	Morgieve	2014	Controlled	CBT, CBT + CAPT (computer-assisted psychopedagogic tool)	>10 hrs	Low
72	Nakatani	2005	Controlled	ERP + Pla, Psych Pla + Med, Psych Pla + Pill Pla	$\leq 10 \mathrm{hrs}$	Low
73	Nedeljkovic	2011	Uncontrolled	CBT	>10 hrs	Low
74	O'Connor	2012	Controlled	CBT (overt), CBT (overt + covert)	>10 hrs	Mod
75	O'Connor	2005	Controlled	CBT (Grp), CBT (Ind)	>10 hrs	Low
76	Polman	2011	Uncontrolled	CBT	>10 hrs	Low
11	Rosqvist	2001	Uncontrolled	ERP	>10 hrs	Mod
78	Rowa	2007	Controlled	ERP (office), ERP (home)	>10 hrs	Mod
62	Safak	2014	Uncontrolled	CBT (Grp)	>10 hrs	Low
08	Sampaio	2016	Uncontrolled	ERP	>10 hrs	Mod
81	Saxena	2009	Uncontrolled	CBT	>10 hrs	High
82	Seol	2016	Uncontrolled	CBT (self-help)	<10 hrs	
83	Shinmei	2017	Uncontrolled	ERP	>10 hrs	Low

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n	Study	Year	Design	Treatment conditions*	Therapist contact	Session freq.
84	Simpson	2013	Controlled	ERP + Med, Med, Pla	>10 hrs	Mod
85	Simpson	2008	Controlled	ERP + Med, Psych Pla + Med	>10 hrs	Mod
98	Simpson	6661	Uncontrolled	ERP + Med	>10 hrs	Mod
88	Simpson	2010	Controlled	ERP, ERP +MI	>10 hrs	Mod
68	Sousa	2006	Controlled	CBT (Grp), Med	>10 hrs	Low
06	Storch	2007	Controlled	ERP + Med (DCS), ERP + Pla	>10 hrs	Low
91	Storch	2008	Controlled	CBT (high), CBT (low)	>10 hrs	High vs Low
92	Taylor	2003	Controlled	CBT (remote, therapist-assisted)	<10 hrs	
63	Tenneij	2002	Controlled	ERP + Med (3 months), ERP + Med (9 months)	>10 hrs	
94	Tolin	2011	Controlled	ERP, ERP (stepped: ERP (remote-therapist assisted), ERP)	≤10 hrs (remote) >10 hrs (ERP)	Mod (face-to-face)
95	Tolin	2005	Uncontrolled	ERP (stepped: ERP (self-help), ERP (remote, therapist-assisted), ERP)	≤10 hrs (remote) >10 hrs (ERP)	Mod (face-to-face)
96	Tolin	2007	Controlled	ERP, ERP (stepped: ERP (self-help), ERP)	<10 hrs (remote) >10 hrs (ERP)	Mod (ERP)
16	Tolin	2004	Uncontrolled	ERP	>10 hrs	High to low
86	Tundo	2007	Uncontrolled	CBT		Low
66	Van Balkom (- Van Oppen data)	8661	Controlled	CT + Med, $ERP + Med$	<10 hrs	Mod
100	Van balkom	2012	Controlled	CT, Med	$\leq 10 \text{ hrs}$	Low
101	Van Noppen	1661	Controlled	ERP (family), ERP (Grp)	>10 hrs	Low
102	Van Oppen	5661	Controlled	CI, ERP	>10 hrs	Low
103	Van Oppen	2010	Controlled	ERP (self-controlled/student therapist), ERP (self-controlled/qualified therapist), ERP (therapist-controlled/student), ERP (therapist-controlled/qualified therapist)	>10 hrs	Low
104	Vandborg	2015	Uncontrolled	CBT	>10 hrs	Low
105	Visser	2015	Controlled	CBT, IBA	>10 hrs	Low
106	Vogel	2012	Uncontrolled	ERP (remote, assisted (video-conference))	>10 hrs	

А	Study	Year	Design	Treatment conditions*	Therapist contact	Session freq.
107	Voge1	2014	Controlled	ERP (remote, assisted (video-conference)), ERP (self-help), WLC	>10 hrs	
108	Vogel	2004	Controlled	CBT (CT + ERP), ERP + Psych Pla	>10 hrs	Mod
109	Vos	2012	Controlled	CT (danger), CT (responsibility)	>10 hrs	Low
110	Vyskocilova	2016	Uncontrolled	CBT + Med (Grp + Ind)	>10 hrs	High
111	Warren	2001	Uncontrolled	CBT		Low
114	Whittal	2010	Controlled	CT, Psych Pla	>10 hrs	Low
115	Whittal	2005	Controlled	CT, ERP	>10 hrs	Low
116	Wilhelm	2009	Controlled	CI, WLC	>10 hrs	Low
117	Wilhelm	2005	Uncontrolled	CI	>10 hrs	Low
118	Wilson	2005	Uncontrolled	L	>10 hrs	Low
119	Wootton	2013	Controlled	CBT (remote, assisted), CBT (remote, assisted), WLC	$\leq 10 \text{ hrs}$	
120	Wootton	2014	Uncontrolled	CBT (self-help)	$\leq 10 \mathrm{hrs}$	
121	Wootton	2011	Uncontrolled	CBT (remote, therapist-assisted)	$\leq 10 \mathrm{hrs}$	
122	Wroe	2012	Uncontrolled	CBT (Grp)	>10 hrs	Low
123	Yang	2015	Uncontrolled	CBT	>10 hrs	Low
*Six	*Six studies that use data previous		in other studies incl	v renorted in other studies included in the meta-analysis for the mirrose of examinino CRT task adherence are not listed here **Individual	T task adherence are not	listed here **Individual

*Six studies that use data previously reported in other studies included in the meta-analysis for the purpose of examining CBT task adherence are not listed here **Individual face-to-face treatment unless otherwise specified. WLC = wait-list control, Grp= Group, Med = medication, Pla = pill placebo, Psych Pla = Psychological placebo, Self-help = remote, unassisted treatment. Remote, assisted = remote therapy with therapist assistance, High =>2*wkly, Mod = 2*wkly, Low = <1*wkly

APPENDIX D

Measure	10				Anchors			
	0	1	2	3	4	S	9	7
Homework Compliance Scale (Primakoff, Epstein, & Covi, 1986; Leung & Heimberg, 1996)	No homework assigned	The patient did not attempt the AHW*	The patient attempted the AHW but was unable to execute it for reasons such as lack of ability or extenuating circumstances	The patient did homework that was different from AHW, but that would be considered "relevant" to cognitive therapy and the patient's patient's particular target problems	The patient did a portion of the AHW	The patient did	The patient did more of the AHW than was requested	
Patient exposure adherence scale (PEAS) (Simpson et al., 2010) Item a) quantity of exposure: what % of exposures assigned did the patient attempt since last visit? (#attempted/#assigned = % attempted)	Ŧ.	None (0%)	Minimal (< 10%)	Very few (~ 25%)	About half (~50%)	Many (~75%)	Most (> 90%)	All that were assigned (100%)
PEAS Item b) quality of exposure: how well did	1	Refused	Attempted exposures with no intent or attempt to	Attempted exposures with intention of refraining from	Made a good effort to conduct the exposures as	Good = completed the exposures as assigned by the	Very good = exposures performed as assigned by the	Excellent = all of the exposures attempted were performed as assigned by the

Table D.1 Summary of Likert-scale measures of adherence to between-session CBT tasks.

were attempted?			compulsions (e.g. few or minimal exposures conducted with full intent to ritualize after)	computations but with obvious reluctance (e.g. spent little time on exposures, did compulsions during the exposures without making real effort to refrain)	assigned by the therapist but gave into compulsions during or after the exposure	therapust (e.g. appropriate exposure, correct amount of time), with minimal compulsions or safety aids during or afterwards)	therapist (e.g. appropriate level exposure, correct amount of time, no compulsions during or afterwards, no safety aids	therapist (e.g. appropriate level exposure, correct amount of time, no compulsions during or afterwards, no safety aids), the patient facilitated the process (e.g. made modifications to the assignment that increased the exposure) and the patient looked for opportunities to extent the exposure homework into their lifestyle)
PEAS	ı	None (0%)	Minimal (<10%)	Sporadically (~25%)	About half (~-50%)	Many (~75%)	Most (>90%)	(Most (>90%) and re- exposed themselves if
Item c) degree of ritual prevention: what % of								they slipped and did rituals or no urges
urges to ritualise did								because symptoms
patient successfully								are so minimal or
resist since the last visit?								100% response prevention
Clinician Rated Effort Scale (Tolin, Maltby,	Made no effort to	Minimal effort	Some effort	Much effort	Put their best effort into			
Diefenbach, Hannan, & Worhunsky, 2004) Degree of patient effort.	do EX/RP				EX/RP			
For bibliotherapy, clinician considers								
amount of the book read,								
frequency/ duration of								

EKP, degree of effort to inhibit compulsions							
Homework Compliance Rating	No effort	Minimal effort	Some effort	Average	Alot	Best effort	
Form (HCRE) (Tolm, Diefenbach, & Gilliam, 2011)							
Item 1. Amount of							
effort put into ERP							
assignments							
HRCF	None	30	1 hour	1.5 hours	2 hours	More than 2	
		minutes				hours	
Item 2. Time spent on							
exposure each day							
outside of the treatment							
session							
HRCF	None	(Not	(Not defined)	Half	Most	All	
		defined)					
Item 3. Reading - how							
much of the assigned							
reading they completed							

Note: *AHW = assigned homework

APPENDIX E

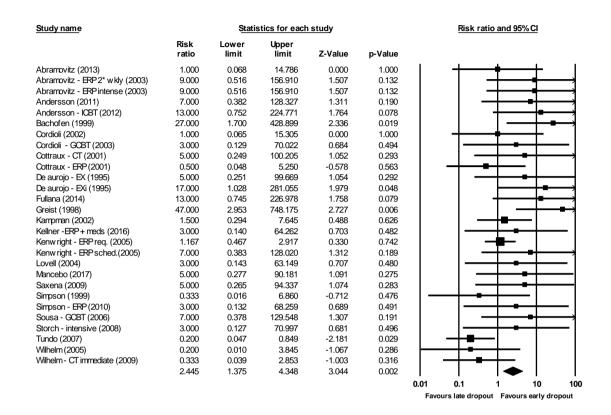


Fig. E.1: Forest plot risk ratio early vs late dropout

APPENDIX F

Table F.1Results from subgroup analyses of the overall refusal rate.

Moderator (k)	Mean % refusal	95% CI	I^2	Q	p
Therapy type				0.808	.37
ERP (12)	13.6	8.7, 20.5	61.76	28.77	.002
CBT (13)	17.4	12.3, 24.1	46.34	22.37	.034
Format				1.509	.22
Face-to-face (18)	14.3	10.1, 19.9	60.59	43.14	<.001
Remote (8)	19.3	13.6, 26.6	9.51	7.74	.36
Format *				0.739	.39
Group (7)	17.8	8.5, 33.5	71.97	21.41	.002
Individual (10)	12.5	8.5, 17.9	47.87	17.26	.045
Therapist contact		•	•	0.32	.57
>10 hours (17)	15.5	10.7, 21.9	64.08	44.55	<.001
≤10 hours (7)	17.9	12.7, 24.7	0.00	5.03	.54
Session frequency*				0.077	.78
Twice-weekly (4)	14.8	10.3, 20.8	3.93	3.12	.37
\leq once weekly (9)	13.4	7, 24.1	77.15	35.01	<.001
Recruitment				1.00	.32
Routine (16)	17.1	11.6, 24.4	63.3	40.87	<.001
Active (8)	13.1	9, 18.6	0	5.10	<.648
Patients				1.22	.27
Non-routine (14)	12.4	9, 17	23.57	17.01	.2
Routine (10)	16.7	10.9, 24.6	56	20.45	.015

Note: ERP=Exposure and response prevention, CBT = cognitive-behavioural therapy (including ERP), remote = therapy conducted online, by phone or videoconference, * face-to-face therapies only

(Method of Moments) Meta-regression analysis showed that therapy duration (in weeks) was not a significant predictor of treatment refusal (B=-.0499, 95% CI [-.1685,.0686], z=-.83, p=.41, k=15).

 Table F2

 Results from subgroup analyses of the overall dropout rate.

Moderator (k)	Mean % dropout	95% CI	I^2	Q	р
Treatment format*			_	4.28	.039
Individual (99)	17.3	15.4,19.4	38.36	158.99	<.001
Group (23)	12.9	10.0,16.6	18.36	28.17	.17
Session frequency*	•	•	*	3.32	.19
>twice-weekly (11)	14	8.2, 22.7	59.78	24.86	.006
Twice-weekly (25)	19	14.9, 23.9	34.56	36.68	.047
\leq once weekly (73)	14.8	12.9, 16.9	27.30	99.04	.019
Therapy type				3.41	.49
ERP (62)	16.6	13.7, 20	60.84	155.77	<.001
CBT (53)	15.2	12.8, 18	30.01	74.35	.028
CT (16)	14.1	10.7, 18.4	0	11.12	.75
ERP + Meds (12)	20.4	14, 28.7	54.17	24.00	.013
ERP + Pill Pla (6)	19.5	10.8, 32.5	26.54	6.81	.24
Treatment format				0.182	.67
Face-to-face (125)	16.1	14.5,18	38.26	200.85	<.001
Remote (28)	14.7	9.5,22	72.51	98.23	<.001
Therapist assistance				0.57	.45
Remote - self-help (8)	19.3	8.3,38.7	83.44	42.28	<.001
Remote - assisted (20)	13.5	8.8,20.4	50.97	38.75	.005
Therapist contact				0.001	.94
>10 hours (103)	15.6	13.9, 17.6	34.62	156.01	<.001
\leq 10 hours (42)	15.8	11.6, 21.1	67.48	126.07	.<.001
Study design				0.002	.97
Controlled (94)	16	13.9, 18.3	43.41	164.33	<.001
Uncontrolled (59)	15.9	13, 19.4	59.81	144.31	<.001
Recruitment				0.001	.97
Active (40)	15	12, 18.6	47.30	74.01	.001
Routine (70)	15.1	12.8,17.7	38.18	111.61	.001
Patients				1.889	.169
Non-routine (122)	15.2	13.4, 17.3	48.21	233.64	<.001
routine (24)	18.7	14.3, 24.1	54.09	50.09	.001
Medication				0.614	.43
Not allowed (28)	14.5	10.8, 19.1	57.20	63.09	<.001
Allowed (119)	16.4	14.5, 18.5	46.78	221.72	<.001
Therapist experience*				3.27	.20
Pre-degree attainment (7)	19.7	16,24	0.00	3.99	0.68
Post-degree attainment (72)	16.6	14.2,19.2	42.70	123.91	<.001
Mixed (25)	15.1	12.1,18.7	17.38	29.05	0.22

Note: ERP=Exposure and response prevention, CBT = cognitive-behavioural therapy (including ERP), CT = cognitive therapy, ERP + Meds = ERP with medication, $ERP + Pill\ Pla = ERP$ with pill placebo, remote = therapy conducted online, by phone or videoconference, * face-to-face therapies only.

 Table F3

 Results from (Method of Moments) meta-regression analyses of treatment-level dropout rates

Variable (k)	Point estimate	95% CI	z	p
Baseline mean total Y-BOCS (83)	0059	0779,.0661	16	.87
Baseline mean total BDI (41)	.0011	0681,.0659	03	.97
Baseline mean total HAMD (21)	.0847	0418,.2213	1.31	.19
Mean % Axis 1 comorbidity (16)	.0079	0192,.0350	.57	.57
Mean % comorbid major depression (22)	.0217	0015,.0449	1.83	.07
Mean % concurrent medication (51)	0025	0151,.0064	56	.58
Mean % prior CBT (48)	0001	0121,.0119	02	.99
Mean Age (90)	0010	0547,.0555	03	.97
Mean % Female (78)	0068	0203,.0066	99	.32
Mean % work (28)	0007	0146,.0133	09	.93
Mean % married or living together (38)	0025	0181,.0132	31	.76
Mean % Caucasian (18)	0009	0386,.0368	05	.96
Mean Years Education (18)	0097	0372, .0178	69	.49
Mean Duration of OCD (51)	0101	0594, .0391	40	.69
Treatment duration in weeks (106)*	.0048	0206, .0302	.37	.71

Note: Pre-Y-BOCS = Pre-treatment mean total Yale-Brown Obsessive-Compulsive Scale score, BDI = Pre-treatment mean total Becks Depression Inventory, HAMD = Pre-treatment mean total Hamilton rating scale for depression* face-to-face therapies.

APPENDIX G

Study name		Statis	tics for each st	udy			Correla	ition and	95% CI	
	Correlation	Lower limit	Upper limit	Z-Value	p-Value					
Bachofen (1999)	0.650	0.303	0.845	3.289	0.001	- 1		1	-	-
Greist (2002)	0.270	0.005	0.500	1.996	0.046			-		
Greist (1998)	0.570	0.310	0.751	3.885	0.000				-	.
Kenwright (2005)	0.270	-0.029	0.525	1.773	0.076			- ├	■→	
Kobak (2015)	0.310	0.106	0.489	2.938	0.003			_ ⊣	■	
	0.390	0.234	0.526	4.662	0.000					
						-1.00	-0.50	0.00	0.50	1.00

Fig. G.1: Forest plot of correlation between ERP task adherence and post-treatment Y-BOCS change scores

9 APPENDICES STUDY 2 (CHAPTER 3)

APPENDIX A



NRES Committee South East Coast - Surrey
HRA
Bristol Research Ethics Committee Centre
Whitefriars
Level 3, Block B
Lewins Mead
Bristol
BS1 2NT

Telephone: 01173421328 Facsimile: 01173420445

20 December 2013

Dr. Clara Strauss Clinical Research Fellow Sussex Partnership NHS Foundation Trust R&D Department, Sussex Education Centre, Mill View Hospital, Hove, BN3 7HZ

Dear Dr. Strauss

A comparison to two types of group behaviour therapy for obsessive compulsive disorder. A pilot randomised Study title:

controlled trial of behaviour therapy and mindfulness-based behaviour therapy for OCD

REC reference: 13/LO/1768

IRAS project ID: 131285

Thank you for your letter of 20 December 2013. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 05 December 2013

Documents received

The documents received were as follows:

Document	Version	Date
Participant Consent Form: Consent Form	2	20 December 2013
Participant Information Sheet: Participant Information Sheet	3	20 December 2013

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	Version	Date
GP/Consultant Information Sheets	GP Letter 1	31 October 2013
Interview Schedules/Topic Guides	Change Interview Schedule (Protocol Appendix)	
Investigator CV	Clara Strauss	31 October 2013
Participant Consent Form: Consent Form	2	20 December 2013
Participant Information Sheet: Participant Information Sheet	3	20 December 2013
Protocol	3	31 October 2013
Questionnaire: YBOCS-II, BDI-II, FFMQ, OBQ-44, SWEMWS	(Protocol Appendix)	ć.
Questionnaire: Mini International Neuropsychiatrist Interview	(MINI 6.0.0)	Î.
REC application		01 November 2013
Referees or other scientific critique report	RfPB Offer Letter, peer reviews and response letter	
Summary/Synopsis	Gantt Chart 1 and Flow Chart a	31 October 2013

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

13/LO/1768

Please quote this number on all correspondence

Yours sincerely

Miss Stephanie Macpherson REC Manager

E-mail: nrescommittee.secoast-surrey@nhs.net

Copy to: Ms Tanya Telling, Sussex NHS Trust tanya.telling@sussexpartnership.nhs.uk

Ms. Gina Declemente, Sussex Partnership gina.declemente@sussexpartnership.nhs.uk



Research and Development

Sussex Education Centre Mill View Hospital Nevill Avenue Hove BN3 7HZ

> Tel: 01273 265928 Fax: 01273 242182

www.sussexpartnership.nhs.uk

13th January 2013

Dr Clara Strauss Research and Development Sussex Education Centre Mill View Hospital Nevill Avenue Hove BN3 7HZ

Dear Dr Strauss,

Study title: A comparison to two types of group behaviour therapy for obsessive compulsive disorder: A pilot randomised controlled trial of behaviour therapy and mindfulness based behaviour therapy for OCD

Ref: CSP 121385

Thank you for your application to Sussex Partnership Trust for research governance approval of the above named study.

I am pleased to inform you that you have all the necessary internal and external regulatory approvals to proceed. Details of your research project and any associated supporting documentation will be stored on an electronic database administered by the R&D Department.

This approval is valid in the following sites:

- Sussex Partnership NHS Foundation Trust Assessment and Treatment Centre's
- Sussex Partnership NHS Foundation Trust Wellbeing Services

The documents reviewed for this approval were:

Document	Version	Date
Participant Consent Form: Consent Form	2	20 December 2013
Participant Information Sheet: Participant Information Sheet	3	20 December 2013
GP/Consultant Information Sheets	1	31 October 2013
Interview Schedules/Topic Guides	Change Interview Schedule (Protocol appendix)	
Protocol	3	31 October 2013
Questionnaire: YBOCS-II, BDI-II, FFMQ, OBQ-44, SWEMWS	Protocol appendix	
Questionnaire: Mini International Neuropsychiatrist Interview	Mini (6.0.0)	



Investigator CV: Dr Clara Strauss		31 October 2013
Investigator CV: Emily Ironmonger		
Investigator CV: Dr Liz Forrester		
Investigator CV: Dr Lyn Ellett		
Investigator CV: Laura Lea		
NRES Committee South East Coast		20 December 2013
Surrey Favourable Opinion Letter		
Signed Research Contract	SPFT & Secretary of State for Health	18 December 2013
Locked and Signed R&D Form: 131285/544355/14/418		20 December 2013
Locked and Signed SSI Form: 131285/546716/6/809/229454/288667		20 December 2013
RfPB funding award email		

Conditions of approval

The approval covers the period stated in the Research Ethics Committee (REC) application and will be extended in line with any amendments agreed by the REC. Research must commence within 12 months of the issue date of this letter. Any delay beyond this may require a new review of the project resources.

Please alert the Research and Development Office if significant developments occur as the study progresses, whether in relation to the safety of individuals or to scientific direction.

Please ensure that you comply fully with the Department of Health Research Governance Framework, in particular that you are aware of and fully discharge your responsibilities in respect to Data Protection, Health and Safety, financial probity, ethics and scientific quality. You should refer in particular to Sections 3.5 and 3.6 of the Research Governance Framework.

Please ensure that all information regarding patients or staff remains secure and strictly confidential at all times. Ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice, Data Protection Act and Human Rights Act. Unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

Amendments

Project amendment details dated after the issue of this approval letter should be emailed to the Research and Development Office for formal approval.

NIHR Adoption

This project has been adopted by the NIHR and as Principal Investigator for this site you are responsible for ensuring accrual numbers are submitted to the co-ordinating centre for study. If you need any support to manage this please contact me.

ICH-GCP Monitoring

The Trust has a duty to ensure that all research is conducted in accordance with the Research Governance Framework and to ICH-GCP standards. In order to ensure compliance the Trust undertakes random audits. If your project is selected you will be given 4 weeks notice to prepare all documentation for inspection. The trust undertakes annual monitoring of all research studies, please respond to any requests for information. Failure to do this will result in the suspension of research governance approval.



I wish you luck with your project and would be grateful if you could inform me when the project is complete or due to be closed on this site.

Yours sincerely,

andelling

Tanya Telling Research and Development Manager

CC: Lead CLRN / Sponsor: WSHNT.CLRNSurreySussex@nhs.net

10 APPENDICES STUDY 3 (CHAPTER 4)

APPENDIX A

Table A1Descriptive statistics for sociodemographic variables in the total (N=2411), clinical (n=1871) and student (n=540) samples.

Variable		Total	Clinical	Student
		(N, %)	(<i>n</i> , %)	(n, %)
Age	18-24	864 (35.8)	338 (18.1)	526 (97.4)
	25-34	394 (16.3)	386 (20.6)	8 (1.5)
	35-44	306 (12.7)	303 (16.2)	3(.6)
	45-54	330 (13.7)	329 (17.6)	1 (.2)
	55-64	304 (12.6)	303 (16.2)	1 (.2)
	65+	190(7.9)	190 (10.2)	0
	Prefer not to say	11(.5)	11 (.6)	0
	missing	12 (.5)	11 (.6)	1 (.2)
Gender	Female	1774	1332	442(81.9)
		(73.6)	(71.2)	
	Male	600 (24.9)	508 (27.2)	92 (17)
	Other	7 (.3)	7 (.3)	1(.2)
	Prefer not to say	9 (.4)	6 (.4)	2(.4)
	missing	21 (.9)	18 (1)	3 (.6)
Highest education	Secondary	1421	1019	402 (74.4)
		(58.9)	(54.5)	
	Higher	897 (37.2)	764 (40.8)	133 (24.6)
	Prefer not to say	73(3)	69 (3.7)	4 (.7)
	missing	20 (.8)	19 (1)	1 (.2)
Employment status	(Self-)employed	1072	1050	22 (4.1)
		(44.5)	(56.1)	
	Looking for work	134 (5.6)	126 (6.7)	8 (1.5)
	Not looking for work	92 (3.8)	88 (4.7)	12 (.7)
	Unable to work	174 (7.2)	174 (9.3)	0
	Student	630 (26.1)	127 (6.8)	503 (93.1)
	Retired	243(10.1)	243 (13)	0
	Prefer not to say	46 (1.9)	44 (2.4)	2 (.4)
	Missing	20 (.8)	19 (1)	1 (.2)
Ethnicity	White background	2201	1748	453 (83.9)
		(91.3)	(93.4)	
	Other background	173 (7.2)	95 (5.1)	78 (14.4)
	Prefer not to say	27 (1.1)	19 (1)	8 (1.5)
	Missing	10(.4)	9 (.5)	1 (.2)
Treatment status	Not yet started tx	n/a	1442(77.1	n/a
)	
	Received at least	n/a	353 (18.9)	n/a
	some tx			
	Prefer not to say	n/a	48 (2.6)	n/a
	missing	n/a	28 (1.5)	n/a

Previous mindfulness	Yes	386 (16)	337 (18)	49 (9.1)
experience	No	1908(79.1	1437	471 (87.2)
)	(76.8)	
	Prefer not to say	84(3.5)	65 (3.5)	19 (3.5)
	Missing	33(1.4)	32 (1.7)	1(.2)

Note: tx=treatment, n/a=not applicable

Table A2Summary of Chi-Square tests with sociodemographic variables of OC (n=833), AD (n=738) and HC (n=231) samples.

Variable	Category	OC	AD	НС	X^2
		(<i>n</i> , %)	(<i>n</i> , %)	(<i>n</i> , %)	
Age	18-24	205 (24.7)	111	223(96.5)	618.10*
			(115.1)		
	25-34	209 (25.2)	136 (18.5)	4 (1.7)	
	35-44	135 (16.3)	115 (15.6)	3 (1.3)	
	45-54	119 (14.3)	147 (20)	1 (.4)	
	55-64	97 (11.7)	145 (19.7)	0	
	65+	57 (6.9)	79 (10.7)	0	
	Prefer not to say	8 (1)	2 (.3)	0	
Gender**	Female	580(702)	537 (73.3)	187 (81.3)	11.93 ns
	Male	238 (28.8)	192 (26.2)	43 (18.7)	
	Other	4 (.5)	2 (.3)	0	
	Prefer not to say	4 (.5)	2 (.3)	1 (.4)	
Highest	Secondary	490 (59)	367 (50.3)	177 (76.6)	58.3*
education	Higher	302 (36.3)	339 (46.4)	53 (22.9)	
	Prefer not to say	39 (4.7)	24 (3.3)	1 (.4)	
Employment	(Self-)employed	458 (55.2)	424 (57.9)	7 (3)	1021.48*
status	Looking for	59 (7.1)	54 (7.4)	4 (1.7)	
	work				
	Not looking for	46 (5.5)	32 (4.4)	1 (.4)	
	work				
	Unable to work	105 (12.7)	49 (6.7)	0	
	Student	71 (8.6)	50 (6.8)	218 (94.4)	
	Retired	69 (8.3)	108 (14.8)	0	
	Prefer not to say	22 (2.7)	15 (2)	1 (.4)	
Ethnicity	White	776 (93.3)	685 (94.6)	207 (89.6)	9.71 ns
	Other	46 (5.5)	37 (5)	22 (9.5)	
	Prefer not to say	10(1.2)	3 (.4)	2 (.9)	
Treatment	Not yet started tx	651(78.5)	589 (81.5)	Na	3.54 ns
status	Received at least	151 (18.2)	120 (16.6)	Na	
	some tx				
	Prefer not to say	27 (3.3)	14 (1.9)	Na	
Mindfulness	Yes	145 (17.6)	115 (15.8)	14 (6.1)	18.88*
experience	No	652 (78.9)	583(80.3)	209 (90.5)	
	Prefer not to say	29 (3.9)	28 (3.9)	8 (3.5)	

Note: OC = obsessive compulsive group; AD = anxious/depressed group, HC=healthy control group, tx=treatment, X^2 = Chi-square, ns=non-significant, *p<.001 ** Fisher's exact test was used as expected counts of less than 5 exceeded 20% and/or the minimum expected count was less than 1

APPENDIX B

Table B1

One-way ANOVA testing group (OC, AD and HC) effect on OBQ-20 and DTS.

Scale	Group	N	Mean	SD	df	Welch's F
OBQ-20	НС	230	54.54	17.70		
ODQ-20	AD	702	76.89	23.79	698.59	562.40*
	OCD	796	99.45	21.07		
	НС	230	3.49	.70		
DTS	AD	704	2.48	.87	669.66	382.59. *
	OCD	799	2.02	.75		

Note: HC= healthy controls, AD=anxious/depressed group, OC= obsessive-compulsive group, OBQ-20 = Obsessive Beliefs Questionnaire -20, DTS = Distress Tolerance Scale, * bootstrap p<.001

Table B2Contrast tests for OBQ-20 and DTS. Contrast 1 = OC vs HC, contrast 2 = OC vs AD.

Scale	contrast	df	t	Hedges' g [95%	Conclusion
				CI]	
OBQ-20	1	434.20	32.42*	2.20 [2.03, 2.38]	OC>HC
	2	1297.574	19.88*	1.02 [0.99, 1.11]	OC>AD
DTS	1	393.17	-27.58*	-2.22 [-2.40, -2.05]	OC <hc< td=""></hc<>
	2	1399.38	-10.83*	-0.63 [-0.74, -0. 53]	OC <ad< td=""></ad<>

Note: OBQ-20 = Obsessive Beliefs Questionnaire – 20, DTS = Distress Tolerance Scale, *bootstrap $p \le .001$

APPENDIX C

Table C1Clinical sample Pearson zero-order correlation coefficients [BCa 95% CI, 1000 samples] between OCI-R and FFMQ-SF-O full- and sub-scales and SCS-SF full scale

OCI-R	FFMQ-SF-	O				SCS-SF
	Total	Describe	Act	Nonjudge	Nonreact	
Total	44*	29*	30*	27*	27*	35*
	[47,40]	[33,25]	[33,26]	[31,22]	[32,22]	[39,31]
Washing	21*	18*	14*	12*	12*	14*
	[26,17]	[23,13]	[18,08]	[16,07]	[17,07]	[18,10]
Checking	27*	19*	20*	17*	15*	20*
	[31,23]	[23,15]	[24,15]	[22,12]	[20,11]	[23,16]
Ordering	26*	16*	19*	16*	17*	24*
	[30,21]	[21,11]	[24,14]	[20,11]	[21,12]	[28,19]
Obsessing	52*	27*	31*	37*	44*	44*
	[56,49]	[32,23]	[36,27]	[41,33]	[48,40]	[48,40]
Neutralising	22*	17*	17*	14*	11*	16*
	[27,18]	[22,12]	[22,12]	[18,09]	[.16,05]	[20,12]

Note: OCI-R=Obsessive-Compulsive Inventory-Revised, FFMQ-SF-O= Five Facet Mindfulness Questionnaire - Short Form minus observe facet, SCS-SF = Self-Compassion Scale - Short Form, * p<.001

Table C2Clinical sample Pearson zero-order correlation coefficients [BCa 95% CI, 1000 samples] between OBQ-20 and FFMQ-SF-O full- and sub-scales and SCS-SF full scale.

OBQ	FFMQ-SF-	SCS-SF				
	Total	Describe	Act	Nonjudge	Nonreact	•
Total	57*	35*	35*	43*	36*	58*
	[54,60]	[31,39]	[30,39]	[39,47]	[32,41]	[54,61]
Threat	52*	36*	33*	35*	32*	51*
	[49,56]	[31,40]	[29,38]	[30,40]	[28,36]	[48, 55]
Perfection	50*	29*	33*	38*	32*	60*
	[46,53]	[24, 33]	[29,37]	[33,42]	[27,36]	[- 57,63]
Responsibi-	34*	19*	19*	30*	22*	31*
lity	[30,38]	[14,23]	[14,24]	[25,34]	[17,27]	[26,36]
Control	57*	37*	31*	44*	36*	52*
	[54,60]	[33,41]	[27,35]	[40,48]	[31,40]	[49,56]

Note: OBQ-20 = Obsessive-Beliefs Questionnaire-20, FFMQ-SF-O = Five Facet Mindfulness Questionnaire - Short Form minus observe facet. SCS-SF = Self-Compassion Scale- - Short Form. * p<.001

Table C3Clinical sample (N=1730) Pearson zero-order correlations between FFMQ-SF-O subscales.

		Describe	Act	Nonjudge	Nonreact
Act		.35*			
BCa 95% CI	Lower	.31			
	upper	.39			
Nonjudge		.18*	.30*		
BCa 95% CI	Lower	.13	.25		
	upper	.22	.35		
Nonreact		.21*	.18*	.17*	
BCa 95% CI	Lower	.16	.13	.11	
	upper	.25	.23	.23	
Total - Observe		.70*	.71*	.63*	.56*
BCa 95% CI	Lower	.68	.68	.59	.52
	upper	.72	.74	.66	.60

Note: * *p*<.001

Table C4Clinical sample (N=1780) Pearson zero-order correlations between OCI-R sub-scales.

		Total	Washing	Checking	Ordering	Obsessing	Hoarding
Washing		.69*					
	Lower	.67					
BCa 95% CI	Upper	.72					
Checking		.76*	.45*				
	Lower	.74	.40				
BCa 95% CI	Upper	.79	.49				
Ordering		.77*	.47*	.54*			
	Lower	.75	.43	.50			
BCa 95% CI	Upper	.79	.51	.58			
Obsessing		.68*	.37*	.38*	.36*		
	Lower	.66	.33	.34	.32		
BCa 95% CI	Upper	.70	.40	.41	.40		
Hoarding		.60*	.24*	.36*	.33*	.34*	
	Lower	.57	.19	.31	.28	.29	
BCa 95% CI	Upper	.64	.29	.41	.37	.39	
Neutralising		.74*	.51*	.50*	.54*	.36*	.29*
BCa 95% CI	Lower	.71	.46	.46	.51	.32	.24
	Upper	.76	.56	.55	.58	.40	.34

Note: * *p*<.001

Table C5Clinical Sample (N=1748) Pearson zero-order correlations between OBQ-20 subscales.

		Threat	Perfectionism	Responsibility	Importance
			Terrectionism	Responsibility	Importance
Perfectionism		.68*			
BCa 95% CI	Lower	.65			
	Upper	.71			
Responsibility		.59*	.54*		
BCa 95% CI	Lower	.56	.51		
	Upper	.62	.58		
Importance		.74*	.65*	.60*	
BCa 95% CI	Lower	.72	.62	.57	
	Upper	.76	.68	.63	
Total		.89*	.84*	.80*	.88**
BCa 95% CI	Lower	.88	.83	.78	.87
	Upper	.90	.86	.82	.89

Note: * *p*<.001

Table C6Clinical sample (N=1777) Pearson zero-order correlations between DTS sub-scales.

		Total	Tolerance	Appraisal	Regulation
Tolerance		.89*			'
BCa 95% CI	Lower	.88			
	Upper	.90			
Appraisal		.87*	.70*		
BCa 95% CI	Lower	.886	.66		
	Upper	.89	.73		
Regulation		.80*	.60*	.60*	
BCa 95% CI	Lower	.78	.56	.57	
	Upper	.82	.63	.63	
Absorption		.89*	.78*	.76*	.56*
BCa 95% CI	Lower	.88	.76	.73	.52
	Upper	.90	.80	.78	.60

Note: ** *p*<.001

APPENDIX D

Table D1Hierarchical regression of PHQ-9, FFMQ-SF-O subscales and SCS-SF on OCI-R subscales. BCa 95 % CI, SE and p-values based on 1000 bootstrap samples.

Outcome		Predictor	$\frac{a \cdot p}{B}$		upper		$\frac{\beta}{\beta}$		ΔR^{2*}		sr^2
Washing	1	PHQ	0.09	0.07	0.11	0.01	.21	.001			
N=1655	2	PHQ	0.06	0.04	0.09	0.01	.15	.001	.02	.13	.015
		Describe	-0.07	-0.10	-0.03	0.02	10	.001		10	.009
		Act aware	0.00	-0.04	0.05	0.02	.00	.988		.00	.000
		Nonjudge	-0.04	-0.08	0.00	0.02	05	.060		05	.002
		Nonreact	-0.05	-0.10	0.00	0.03	06	.037		06	.003
		SCS-SF	0.00	-0.02	0.02	0.01	.00	.874		.00	.000
Checking	1	PHQ	0.13	0.11	0.16	0.01	.26	.001	.07		
<i>N</i> =1661	2	PHQ	0.09	0.06	0.12	0.01	.17	.001	.03	.15	.020
		Describe	-0.06	-0.10	-0.02	0.02	08	.002		07	.005
		Act aware	-0.04	-0.08	0.01	0.03	04	.141		04	.001
		Nonjudge	-0.06	-0.10	-0.02	0.02	08	.002		07	.005
		Nonreact	-0.05	-0.11	-0.01	0.03	06	.056		05	.002
		SCS-SF	-0.01	-0.04	0.02	0.01	03	.325		02	.001
Ordering	1	PHQ	0.15	0.13	0.17	0.01	.27	.001	.08		
<i>N</i> =1658	2	PHQ	0.10	0.07	0.13	0.02	.18	.001	.03	.16	.023
		Describe	-0.03	-0.07	0.01	0.02	04	.160		04	.001
		Act aware	-0.03	-0.08	0.03	0.03	03	.342		03	.001
		Nonjudge	-0.05	-0.10	0.00	0.02	06	.020		05	.003
		Nonreact	-0.05	-0.10	0.01	0.03	05	.118		04	.001
		SCS-SF	-0.05	-0.07	-0.02	0.01	10	.003		08	.006
Obsessing	1	PHQ	0.28	0.26	0.30	0.01	.49	.001	.24		
<i>N</i> =1655	2	PHQ	0.19	0.16	0.21	0.01	.33	.001	.16	.33	.075
		Describe	-0.04	-0.07	0.00	0.02	05	.026		05	.002
		Act aware	-0.01	-0.06	0.04	0.02	01	.595		02	.000
		Nonjudge	-0.20	-0.24	-0.16	0.02	22	.001		25	.039
		Nonreact	-0.29	-0.35	-0.24	0.03	28	.001		29	.055
		SCS-SF	-0.03	-0.05	0.00	0.01	06	.049		05	.002
Neutralising	<u>g1</u>	PHQ	0.11	0.09	0.12	0.01	.24	.001	.06		
<i>N</i> =1650	2	PHQ	0.07	0.05	0.10	0.01		.001		.15	.020
		Describe		-0.08	-0.01	0.02				07	.004
		Act aware Nonjudge			0.03	0.02 0.02				01 05	.000 .002
		Nonreact		-0.06	0.04	0.02				02	.002
		SCS-SF		-0.04	0.00	0.01				04	.002

Note: OCI-R=Obsessive Compulsive Inventory-Revised, PHQ-9=Patient Health Questionnaire-9, FFMQ-SF-O= Five-Facet Mindfulness Questionnaire-Short Form full scale minus observe subscale, SCS-SF= Self-Compassion Scale-Short Form * F-change statistic significant at p<.001 unless otherwise stated, ΔR^2 =(change) explained variance, ns= non-significant, pr=partial correlation, sr^2 = semi-partial correlation squared.

Table D2Hierarchical regression of PHQ-9, OBQ-20, DTS, FFMQ-SF-O subscales and SCS-SF on OCI-R subscales. BCa 95 % CI, SE and p-values based on 1000 bootstrap samples.

Outcome		Predictor	В		upper	SE	β	p	ΔR^{2*}		sr^2
Washing	1	PHQ	0.09	0.07	0.11	0.01	.21	.001	.05	.21	.045
<i>N</i> =1531	2	PHQ	0.03	0.01	0.06	0.01	.08	.010	.07	.07	.005
		OBQ-20	0.03	0.02	0.04	0.00	.29	.001		.24	.052
		DTS	0.00	-0.18	0.17	0.092	.00	.951		.00	.000
	3	PHQ	0.04	0.01	0.06	0.01	.08	.006	.01	.07	.005
		OBQ-20	0.03	0.02	0.04	0.00	.31	.001		.23	.047
		DTS	027	-0.03	0.14	0.10	01	.793		01	.000
		Describe	-0.04	-0.08	0.00	0.02	06	.030		06	.003
		Act aware	0.01	-0.03	0.06	0.02	.02	.615		.01	.000
		Nonjudge	0.00	-0.04	0.05	0.02	.01	.899		.00	.000
		Nonreact	-0.04	-0.08	0.01	0.03	04	.190		04	.001
		SCS-SF	0.03	0.01	0.06	0.01	.09	.006		.07	.004
Checking	1	PHQ	0.13	0.10	0.15	0.01	.25	.001	.07	.25	.065
<i>N</i> =1533	2	PHQ	0.04	0.01	0.06	0.01	.08	.005	.12	.08	.005
		OBQ-20	0.04	0.04	0.05	0.00	.37	.001		.30	.083
		DTS	-0.13	-0.36	0.62	0.1	09	.188		04	.001
	3	PHQ	0.04	0.01	0.07	0.01	.08	.009	.01	.07	.004
		OBQ-20	0.05	0.04	0.06	0.00	.40	.001		.30	.080
		DTS	-0.21	-0.42	0.12	0.1	06	.039			.002
		Describe	-0.03	-0.06	0.01	0.02	04	.150			.001
		Act aware	-0.03	-0.07	0.02	0.02	03	.270		03	.001
		Nonjudge	0.02	-0.02	0.06	0.02	.02	.319		.02	.000
		Nonreact	-0.01	-0.07	0.04	0.03	01	.620		01	.000
		SCS-SF	0.05	0.02	0.07	0.01	.11	.002		.09	.008
Ordering	1	PHQ	0.15	0.12	0.18	0.01	.28	.001	.08	.28	.076
<i>N</i> =1534	2	PHQ	0.00	0.03	0.09	0.02	.11	.001	.10	.11	.010
		OBQ-20	0.05	0.04	0.05	0.00	.35	.001		.29	.074
		DTS	-0.12	-0.35	0.12	0.01	02	.3290		03	.001
	3	PHQ	0.06	0.03	0.10	0.02	.11	.001	.001	.10	.009
		OBQ-20	0.05	0.04	0.06	0.00	.36	.001	ns	.27	.066
		DTS	-0.14	-0.39	0.11	0.12	03	.322		03	.001
		Describe	0.00	-0.04	0.05	0.02	.01	.845		.01	.000
		Act aware	-0.01	-0.06	0.05	0.03	01	.725		01	.000
		Nonjudge	0.03	-0.02	0.07	0.02	.03	.246		.03	.001
		Nonreact	-0.02	-0.07	0.03	0.03	02	.609		01	.000
		SCS-SF	0.01	-0.02	0.04	0.01	.02	.491		.02	.000
Obsessing	1	PHQ	0.28	0.25	0.30	0.01	.49	.001	.24	.49	.239
<i>N</i> =1531	2	PHQ	0.15	0.13	0.18	0.01	.27	.001	.18	.30	.057
		OBQ-20	0.05	0.04	0.06	0.00	.36	.001		.34	.078

		DTS	-0.64	-0.83	-0.45	0.01	16	.001		17	.020
3	3	PHQ	0.14	0.12	0.17	0.01	.26	.001	.05	.27	.043
		OBQ-20	0.04	0.03	0.05	0.00	.28	.001		.27	.041
		DTS	-0.41	-0.59	-0.24	0.01	11	.001		11	.007
		Describe	-0.01	-0.04	0.02	0.02	01	.526		02	.000
		Act aware	-0.01	-0.05	0.04	0.02	01	.785		01	.000
		Nonjudge	-0.12	-0.17	-0.08	0.02	13	.001		16	.013
		Nonreact	-0.25	-0.30	-0.21	0.02	24	.001		27	.040
		SCS-SF	0.03	0.01	0.06	0.01	.07	.015		.06	.002
Neutralising	1	PHQ	0.10	0.08	0.12	0.01	.24	.000	.06		
<i>N</i> =1530	2	PHQ	0.04	0.02	0.06	0.01	.10	.000	.09	.09	.007
		OBQ-20	0.03	0.03	0.04	0.00	.33	.000		.26	.066
<u> </u>		DTS	0.07	-0.01	0.23	0.01	.02	.455		.02	.000
	3	PHQ	0.04	0.02	0.07	0.01	.10	.001	.003	.08	.006
		OBQ-20	0.04	0.03	0.04	0.00	.35	.000	ns	.25	.060
		DTS	0.02	-0.15	0.20	0.01	.01	.822		.00	.000
		Describe	-0.02	-0.05	0.02	0.02	03	.314			.001
		Act aware	-0.01	-0.06	0.03	0.02	02	.580			.000
		Nonjudge	0.01	-0.03	0.06	0.02	.02	.526		.02	.000
		Nonreact	0.00	-0.04	0.05	0.02	.01	.854		.01	.000
		SCS-SF	0.02	0.00	0.04	0.01	.06	.081		.04	.002

Note: OCI-R=Obsessive Compulsive Inventory-Revised, PHQ-9=Patient Health Questionnaire-9, OBQ-20 = Obsessive Beliefs Questionnaire-20, DTS = Distress Tolerance Scale, FFMQ-SF-O= Five-Facet Mindfulness Questionnaire-Short Form full scale minus observe subscale, SCS-SF= Self-Compassion Scale-Short Form * F-change statistic significant at p<.001 unless otherwise stated, ΔR^2 =(change) explained variance, ns= non-significant, pr=partial correlation, sr^2 = semi-partial correlation squared.

APPENDIX E

Antony Walsh
Research Governance Officer
Research and Enterprise
Tel: 01273 8722748 antony.walsh@sussex.ac.uk
General enquiries: rgoffice@sussex.ac.uk



13 September 2016

Research and Enterprise University of Sussex Falmer Brighton BN1 9QF

Dr Tamara Leuweerik School of Psychology Pevensey 1 University of Sussex BN1 9HR

Dear Tamara

Full Study Title: An anonymous survey of mindfulness and self-compassion in adults

offered psychological therapies in the NHS

Ref No.: 016 LEE

IRAS Ref: tbc

I am writing to confirm that the University of Sussex has assessed your application and on our recommendation the University is willing to take on the role of **Research Sponsor** for your study.

Your project has been allocated the following reference: 016 LEE please quote this on all correspondence.

Conditions of Approval

Please note that you cannot commence this study until you have been given a favourable opinion from the Health Research Authority (HRA) by an appropriate and recognised Research Ethics Committee (REC) (e.g. NHS or Social Care research ethics committee). The approval will cover the period stated in your application to that committee, and will be extended in line with any amendments agreed by the REC.

A favourable opinion must be gained from the appropriate REC within 6 months of the issue date of this letter. Any delay beyond this may require a new review of the project.

If your project receives an unfavourable ethical opinion from a REC and subsequently you re-submit your application please share the revised documents with the University as your sponsor.

Insurance

The study will be indemnified by the University of Sussex. The Public Liability Certificate, Employers Liability Certificate and Professional Negligence Certificate are available from the University of Sussex insurance webpage: http://www.sussex.ac.uk/finance/services/corporateaccounting/insurance.

Amendments

Any amendments to the project dated after the issue of this approval letter must be submitted to your sponsor for approval in order for sponsorship to be valid. Please email your amendments to rgoffice@sussex.ac.uk

Amendments

Any amendments to the project dated after the issue of a favourable ethical opinion must be submitted to the Sponsor in order for Sponsorship to be valid. Please submit your application for an amendment to rgoffice@sussex.ac.uk using the 'Request for an Amendment Form'.

Please note that as of 1 April 2016 all amendments will require submission via the HRA Approval review system, in line with the guidance available on the HRA website: http://www.hra.nhs.uk/about-the-hra/our-plans-and-projects/assessment-approval/amendments-nhs-england-studies/.

Monitoring

The University as Sponsor may undertake audits and inspections. If your project is selected for audit or inspection you will be given notice to prepare all documentation for inspection.

It is your responsibility to inform your sponsor in the event of early termination of the project or if you fail to complete the work.

I wish you luck with your project.

Yours sincerely

Antony Walsh

A. Ward

Research Governance Officer Research and Enterprise Services

The University of Sussex



East of England - Cambridge East Research Ethics Committee

The Old Chapel Royal Standard Place Nottingham NG1 6FS

Please note: This is an acknowledgement letter from the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

01 November 2016

Dr Tamara Leeuwerik School of Psychology Pevensey 1, 2C4 University of Sussex BN1 9HR

Dear Dr Leeuwerik

Study title:	An anonymous survey of mindfulness and self-compassion in adults offered psychological therapies in the NHS
REC reference:	16/EE/0438
Protocol number:	016 LEE
IRAS project ID:	203776

Thank you for your letter of 1 November 2016, I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 01 November 2016

Documents received

The documents received were as follows:

Document	Version	Date
Copies of advertisement materials for research participants [advertisement on online research participant system (control group)]	3	01 November 2016

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	Version	Date
Copies of advertisement materials for research participants [poster (control group)]	2	26 October 2016
Copies of advertisement materials for research participants [flyer (control group)]	2	26 October 2016
Copies of advertisement materials for research participants [advertisement on intranet (control group)]	2	26 October 2016
Copies of advertisement materials for research participants [University of Sussex internal email (control group)]	2	26 October 2016
Copies of advertisement materials for research participants [advertisement on online research participant system (control group)]	3	01 November 2016
Covering letter on headed paper [Covering letter]	1	20 September 2016
IRAS Application Form [IRAS_Form_21092016]		21 September 2016
IRAS Application Form XML file [IRAS_Form_21092016]		21 September 2016
IRAS Checklist XML [Checklist_21092016]		21 September 2016
Letter from funder [ESRC award]	1	15 April 2015
Letter from sponsor [Sponsorship approval letter LEE016 130916]	1	13 September 2016
Letters of invitation to participant [letter of invitation to participant]	1	08 September 2016
Other [Thank you page (debriefing)]	1	08 September 2016
Other [Public liability certificate]	1	11 October 2016
Other [Professional negligence research certificate]	1	11 October 2016
Other [covering letter - response to EE-CEREC]	1	11 October 2016
Participant information sheet (PIS) [Online participant information sheet]	1	08 September 2016
Participant information sheet (PIS) [Participant information sheet (paper version)]	1	08 September 2016
Research protocol or project proposal [Research protocol]	1	08 September 2016
Response to Request for Further Information		01 November 2016
Summary CV for Chief Investigator (CI) [CV Tamara Leeuwerik]	1	08 September 2016
Summary CV for student [CV Tamara Leeuwerik]	1	08 September 2016
Summary CV for supervisor (student research) [CV Dr Clara Strauss]	Version 1	08 September 2016
Summary CV for supervisor (student research) [CV Dr Kate Cavanagh]	Version 1	08 September 2016
Validated questionnaire [Five Facet Mindfulness Questionnaire - Short Form]	1	08 September 2016
Validated questionnaire [Self-compassion scale - short form]	1	08 September 2016
Validated questionnaire [Patient Health Questionnaire - 9]	1	08 September 2016
Validated questionnaire [Obsessive-Compulsive Inventory - Revised]	1	08 September 2016
Validated questionnaire [Obsessive beliefs questionnaire]	1	08 September 2016
Validated questionnaire [Generalised anxiety disorder - 7]	1	08 September 2016
Validated questionnaire [Distress tolerance scale]	1	08 September 2016
Validated questionnaire [Short Warwick-Edinburgh mental wellbeing scale]	1	08 September 2016

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

16/EE/0438

Please quote this number on all correspondence

Yours sincerely

Joanne O'Neil REC Assistant

E-mail: NRESCommittee.EastofEngland-CambridgeEast@nhs.net

Copy to: Dr Antony Walsh

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Ms Taffy Bakasa, Sussex Partnership NHS Foundation Trust



Dr Tamara Leeuwerik School of Psychology University of Sussex BN1 9HR

Email: hra.approval@nhs.net

21 December 2016

Dear Dr Leeuwerik

Letter of HRA Approval

Study title: An anonymous survey of mindfulness and self-compassion

in adults offered psychological therapies in the NHS

IRAS project ID: 203776
Protocol number: 016 LEE
REC reference: 16/EE/0438

Sponsor University of Sussex

I am pleased to confirm that <u>HRA Approval</u> has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. Please read Appendix B carefully, in particular the following sections:

- Participating NHS organisations in England this clarifies the types of participating
 organisations in the study and whether or not all organisations will be undertaking the same
 activities
- Confirmation of capacity and capability this confirms whether or not each type of participating
 NHS organisation in England is expected to give formal confirmation of capacity and capability.
 Where formal confirmation is not expected, the section also provides details on the time limit
 given to participating organisations to opt out of the study, or request additional time, before
 their participation is assumed.
- Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria) - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details

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and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A List of documents reviewed during HRA assessment
- B Summary of HRA assessment

After HRA Approval

The document "After Ethical Review – guidance for sponsors and investigators", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- · Notifying amendments
- · Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as
 detailed in the After Ethical Review document. Non-substantial amendments should be
 submitted for review by the HRA using the form provided on the <u>HRA website</u>, and emailed to
 hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation
 of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please email the HRA at https://hra.approval@nhs.net. Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

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HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is 203776. Please quote this on all correspondence.

Yours sincerely

Natalie Wilson

Assessor

Email: hra.approval@nhs.net

Copy to: Dr Antony Walsh, University of Sussex, Sponsor contact

Ms Taffy Bakasa, Sussex Partnership NHS Foundation Trust, Lead NHS R&D

contact

NIHR CRN Portfolio Applications Team

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Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	Version	Date
Copies of advertisement materials for research participants	2	26 October 2016
[University of Sussex internal email (control group)]		0.4.1
Copies of advertisement materials for research participants [Advertisement on intranet (control group) - version 3 24.11.16]	3	24 November 2016
Copies of advertisement materials for research participants	4	24 November 2016
[Advertisement on online research participant system - version 4		
24.11.2016]		
Copies of advertisement materials for research participants [Flyer (control group) - version 3 24.11.2016]	3	24 November 2016
Copies of advertisement materials for research participants [Poster (control group) version 3 24.11.2016]	3	24 November 2016
Covering letter on headed paper [Covering letter]	1	20 September 2016
IRAS Application Form [IRAS_Form_21092016]		21 September 2016
IRAS Application Form XML file [IRAS_Form_21092016]		21 September 2016
IRAS Checklist XML [Checklist 21092016]		21 September 2016
Letter from funder [ESRC award]	1	15 April 2015
Letter from sponsor [Sponsorship approval letter LEE016 130916]	1	13 September 2016
Letters of invitation to participant [email of invitation to participant	2	24 November 2016
(clinical sample) - version 2 24.11.2016]	-	2 1110101111101 2010
Letters of invitation to participant [Letter of invitation to participant (clinical sample) -version 2]	2	24 November 2016
Letters of invitation to participant [letter of invitation to participant]	1	08 September 2016
Notice of Substantial Amendment (non-CTIMP) [Amendment REC REF 16EE0438 IRAS ID 203776]	1	24 November 2016
Other [Statement of Activities]	2	28 November 2016
Other [Scedule of Events]	2	28 November 2016
Other [Thank you page (debriefing)]	1	08 September 2016
Other [Public liability certificate]	1	11 October 2016
Other [Professional negligence research certificate]	1	11 October 2016
Other [covering letter - response to EE-CEREC]	1	11 October 2016
Other [Sponsorship Approved amendments letter LEE016 241116]		24 November 2016
Other [Thank you page (community sample) version 1 24.11.2016]	1	24 November 2016
Other [UoS internal email (control group) version 3 24.11.2016]	3	24 November 2016
Participant information sheet (PIS) [Paper Participant information sheet (clinical sample) version 2]	2	24 November 2016
Participant information sheet (PIS) [Online participant information sheet (Olinical sample) version 2]	2	24 November 2016
Participant information sheet (PIS) [Online Participant information sheet (Online Participant information sh	1	24 November 2016
Research protocol or project proposal [Research protocol Version 2 24.11.2016]	2	24 November 2016
Response to Request for Further Information		01 November 2016
Summary CV for Chief Investigator (CI) [CV Tamara Leeuwerik]	1	08 September 2016
Summary CV for student [CV Tamara Leeuwerik]	1	08 September 2016
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Summary CV for supervisor (student research) [CV Dr Clara Strauss]	Version 1	08 September 2016
Summary CV for supervisor (student research) [CV Dr Kate Cavanagh]	Version 1	08 September 2016
Validated questionnaire [Five Facet Mindfulness Questionnaire - Short Form]	1	08 September 2016
Validated questionnaire [Self-compassion scale - short form]	1	08 September 2016
Validated questionnaire [Patient Health Questionnaire - 9]	1	08 September 2016
Validated questionnaire [Obsessive-Compulsive Inventory - Revised]	1	08 September 2016
Validated questionnaire [Obsessive beliefs questionnaire]	1	08 September 2016
Validated questionnaire [Generalised anxiety disorder - 7]	1	08 September 2016
Validated questionnaire [Distress tolerance scale]	1	08 September 2016
Validated questionnaire [Short Warwick-Edinburgh mental wellbeing scale]	1	08 September 2016

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Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, participating NHS organisations, capacity and capability and Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria) sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name: Tamara Leeuwerik Email: tl279@sussex.ac.uk

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	This a non-commercial, multicentre study taking place in the NHS. A Statement of Activities has been submitted. This will act as the agreement between Sponsor and participating NHS organisations. Therefore no other agreements are expected.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional

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Section	HRA Assessment Criteria	Compliant with Standards	Comments
			indemnity provided by their medical defence organisation covers the activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	Sponsor is not providing funding to participating NHS organisations.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	
6.3	Devices – MHRA notice of no objection received	Not Applicable	
6.4	Other regulatory approvals and authorisations received	Not Applicable	

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

This is a non-commercial, multicentre study. There is only one site-type involved in this research. Participating NHS organisations will aid in the identification of participants by performing database searches, eligibility checks and mailing out relevant study documents to participants. Research activity will include the completion of online (or paper if applicable) questionnaires.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents

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Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.

The applicant has indicated that they <u>intend</u> to apply for inclusion on the NIHR CRN Portfolio.

APPENDIX F

Five Facet Mindfulness Questionnaire Short-Form (FFMQ-SF)

Below is a collection of statements about your everyday experience. Please indicate, by circling the number in the box to the right of each statement, how frequently or infrequently you have each experience **in general**. Please answer according to what really reflects your experience rather than what you think your experience should be. **Please provide an answer for each statement**.

		Never or very rarely true	Not often true	Sometimes true, sometimes not true	Often true	Very often or always true
1.	I'm good at finding the words to describe my feelings	1	2	3	4	5
2.	I can easily put my beliefs, opinions, and expectations into words	1	2	3	4	5
3.	I watch my feelings without getting carried away by them	1	2	3	4	5
4.	I tell myself that I shouldn't be feeling the way I'm feeling	1	2	3	4	5
5.	it's hard for me to find the words to describe what I'm thinking	1	2	3	4	5
6.	I pay attention to physical experiences, such as the wind in my hair or sun on my face	1	2	3	4	5
7.	I make judgments about whether my thoughts are good or bad.	1	2	3	4	5
8.	I find it difficult to stay focused on what's happening in the present moment	1	2	3	4	5
9.	when I have distressing thoughts or images, I don't let myself be carried away by them	1	2	3	4	5
10.	generally, I pay attention to sounds, such as clocks ticking, birds chirping, or cars passing	1	2	3	4	5
11.	when I feel something in my body, it's hard for me to find the right words to describe it	1	2	3	4	5
12.	it seems I am "running on automatic" without much awareness of what I'm doing	1	2	3	4	5

	Never or very rarely true	Not often true	Sometimes true, sometimes not true	Often true	Very often or always true
13. when I have distressing thoughts or images, I feel calm soon after	1	2	3	4	5
14. I tell myself I shouldn't be thinking the way I'm thinking	1	2	3	4	5
15. I notice the smells and aromas of things	1	2	3	4	5
16. even when I'm feeling terribly upset, I can find a way to put it into words	1	2	3	4	5
17. I rush through activities without being really attentive to them	1	2	3	4	5
18. usually when I have distressing thoughts or images I can just notice them without reacting	1	2	3	4	5
19. I think some of my emotions are bad or inappropriate and I shouldn't feel them	1	2	3	4	5
20. I notice visual elements in art or nature, such as colours, shapes, textures, or patterns of light and shadow	1	2	3	4	5
21. when I have distressing thoughts or images, I just notice them and let them go	1	2	3	4	5
22. I do jobs or tasks automatically without being aware of what I'm doing	1	2	3	4	5
23. I find myself doing things without paying attention	1	2	3	4	5
24. I disapprove of myself when I have illogical ideas	1	2	3	4	5

Self-Compassion Scale - SF

Please indicate the extent to which each item is generally true for you on a scale of 1 (almost never) to 5 (almost always), by writing a number to the right of each item. Please read each statement carefully before answering. **Please provide an answer for each statement.**

almost never almost always

1 2 3 4 5

1	when I fail at something important to me I become consumed by feelings of inadequacy	
2	I try to be understanding and patient towards those aspects of my personality I don't like	
3	when something painful happens, I try to take a balanced view of the situation	
4	when I'm feeling down, I tend to feel like most other people are probably happier than I am	
5	I try to see my failings as part of the human condition	
6	when I'm going through a very hard time, I give myself the caring and tenderness I need	
7	when something upsets me, I try to keep my emotions in balance	
8	when I fail at something that's important to me, I tend to feel alone in my failure	
9	when I'm feeling down I tend to obsess and fixate on everything that's wrong	
10	when I feel inadequate in some way, I try to remind myself that feelings of inadequacy are shared by most people	
11	I'm disapproving and judgmental about my own flaws and inadequacies	
12	I'm intolerant and impatient towards those aspects of my personality I don't like	

Patient Health Questionnaire - 9

Over the last 2 weeks, on how many days have you been bothered by any of the following problems?

		Not at all	Several days	More than half the days	Nearly every day
1	Little interest or pleasure in doing things	0	1	2	3
2	Feeling down, depressed or hopeless				
3	Trouble falling or staying asleep, or sleeping too much				
4	Feeling tired or having little energy				
5	Poor appetite or overeating				
6	Feeling bad about yourself – or that you are a failure or have let yourself or your family down				
7	Trouble concentrating on things, such as reading the newspaper or watching television				
8	Moving or speaking so slowly that other people could have noticed, or the opposite – being so fidgety or restless that you have been moving around a lot more than usual				
9	Thoughts that you would be better off dead or of hurting yourself in some way				

Obsessive-Compulsive Inventory - Revised (OCI-R)

The following statements refer to experiences that many people have in their everyday lives. Circle the number that best describes **HOW MUCH** that experience has **DISTRESSED or BOTHERED you during the PAST MONTH.** The numbers refer to the following verbal labels:

0 1 2 3 4

Not at all A little Moderately A lot Extremely

	Not at all	A little	Moderately	A lot	Extremely
1. I have saved up so many things that they	0	1	2	3	4
get in the way.					
2. I check things more often than necessary.	0	1	2	3	4
3. I get upset if objects are not arranged	0	1	2	3	4
properly.					
4. I feel compelled to count while I am doing	0	1	2	3	4
things					
5. I find it difficult to touch an object when I	0	1	2	3	4
know it has been touched by strangers or					
certain people.					
6. I find it difficult to control my own	0	1	2	3	4
thoughts.					
7. I collect things I don't need.	0	1	2	3	4
8. I repeatedly check doors, windows,	0	1	2	3	4
drawers, etc.					
9. I get upset if others change the way I have	0	1	2	3	4
arranged things.					
10. I feel I have to repeat certain numbers.	0	1	2	3	4
11. I sometimes have to wash or clean	0	1	2	3	4
myself simply because I feel contaminated.					
12. I am upset by unpleasant thoughts that	0	1	2	3	4
come into my mind against my will.					
13. I avoid throwing things away because I	0	1	2	3	4
am afraid I might need them later.					
14. I repeatedly check gas and water taps	0	1	2	3	4
and light switches after turning them off					
15. I need things to be arranged in a	0	1	2	3	4
particular way					
16. I feel that there are good and bad	0	1	2	3	4
numbers.					
17. I wash my hands more often and longer	0	1	2	3	4
than necessary.					
18. I frequently get nasty thoughts and have	0	1	2	3	4
difficulty in getting rid of them.		<u> </u>			

Obsessive Beliefs Questionnaire (OBQ-20)

This inventory lists different attitudes or beliefs that people sometimes hold. Read each statement carefully and decide how much you agree or disagree with it. For each statement, choose the number matching the answer that best describes how you think. Because people are different, there are no right or wrong answers. To decide whether a given statement is typical of your way of looking at things, simple keep in mind what you are like most of the time. Use the following scale.

1	2	3	4	5	6	7
Disagree	Disagree	Disagree a	Neither agree	Agree a	Agree	Agree
Very Much	Moderately	little	nor disagree	little	moderately	very much

1.	If I'm not absolutely sure, I'm bound to make a mistake.	1	2	3	4	5	6	7
2.	To be a worthwhile person, I must be perfect at everything I do.	1	2	3	4	5	6	7
3.	Even if harm is very unlikely, I should try to prevent it at any cost.	1	2	3	4	5	6	7
4.	For me, having bad urges is as bad as actually carrying them out.	1	2	3	4	5	6	7
5.	If I don't act when I foresee danger, then I am to blame for consequences.	1	2	3	4	5	6	7
6.	In all kinds of daily situations, failing to prevent harm is just as bad as deliberately causing it.	1	2	3	4	5	6	7
7.	For me, not preventing harm is as bad as causing harm.	1	2	3	4	5	6	7
8.	I should be upset if I make a mistake.	1	2	3	4	5	6	7

9.	For me, things are not right if they are not perfect.	1	2	3	4	5	6	7
10.	Having nasty thoughts means I'm a terrible person.	1	2	3	4	5	6	7
11.	If I do not take extra precautions, I am more likely than others to have or cause a serious disaster.	1	2	3	4	5	6	7
12.	I am more likely than other people to accidentally cause harm to myself or to others.	1	2	3	4	5	6	7
13.	Having bad thoughts means I am weird or abnormal.	1	2	3	4	5	6	7
14.	Even when I am careful, I often think bad things will happen	1	2	3	4	5	6	7
15.	Having intrusive thoughts means I'm out of control.	1	2	3	4	5	6	7
16.	Harmful events will happen unless I'm careful.	1	2	3	4	5	6	7
17.	I must keep working until it's done exactly right.	1	2	3	4	5	6	7
18.	To me, failing to prevent disaster is as bad as causing it.	1	2	3	4	5	6	7
19.	Having a bad thought is morally no different than doing a bad deed.	1	2	3	4	5	6	7
20.	No matter what I do, it won't be good enough.	1	2	3	4	5	6	7

Generalised Anxiety Disorder – 7 (GAD -7)

Over the last 2 weeks, on how many days have you been bothered by any of the following problems? Please circle the number in the relevant box.

		Not at all	Several days	More than half the days	Nearly every day
1	Feeling nervous, anxious or on edge	0	1	2	3
2	Not being able to stop or control worrying	0	1	2	3
3	Worrying too much about different things	0	1	2	3
4	Trouble relaxing	0	1	2	3
5	Being so restless it is hard to sit still	0	1	2	3
6	Becoming easily annoyed or irritable	0	1	2	3
7	Feeling afraid as if something awful might happen	0	1	2	3

Distress Tolerance Scale (DTS)

Think of times that you feel distressed or upset. Select the item from the menu that best describes your beliefs about feeling distressed or upset.

best describes your beliefs about 18	Strongly	Mildly	Agree	Mildly	Strongly
	agree	agree	and	disagree	disagree
		46.00	disagree	u.oug. 00	undug. dd
			equally		
1. Feeling distressed or upset is	1	2	3	4	5
unbearable to me					
2. When I feel distressed or	1	2	3	4	5
upset, all I can think about is					
how bad I feel.					
3. I can't handle feeling	1	2	3	4	5
distressed or upset.					
4. My feelings of distress are so	1	2	3	4	5
intense that they completely					
take over.					
5. There's nothing worse than	1	2	3	4	5
feeling distressed					
6. I can tolerate being	1	2	3	4	5
distressed or upset as well as					
most people.					
7. My feelings of distress or	1	2	3	4	5
being upset are not acceptable.					
8. I'll do anything to avoid	1	2	3	4	5
feeling distressed or upset.					
9. Other people seem to be able	1	2	3	4	5
to tolerate feeling distressed or					
upset better than I can.					
10. Being distressed or upset is	1	2	3	4	5
always a major ordeal for me.					
11. I am ashamed of myself	1	2	3	4	5
when I feel distressed or upset.					
12. My feelings of distress or	1	2	3	4	5
being upset scare me.					
13. I'll do anything to stop	1	2	3	4	5
feeling distressed or upset.					
14. When I feel distressed or	1	2	3	4	5
upset, I must do something					
about it immediately.					
15. When I feel distressed or	1	2	3	4	5
upset, I cannot help but					
concentrate on how bad the					
distress actually feels.					

11 APPENDICES STUDY 4 (CHAPTER 5)

APPENDIX A



NRES Committee South East Coast - Surrey

HRÂ Bristol Research Ethics Committee Centre Whitefriars Level 3, Block B Lewins Mead Bristol BS1 2NT

> Telephone: 01173421328 Facsimile: 01173420445

20 December 2013

Dr. Clara Strauss Clinical Research Fellow Sussex Partnership NHS Foundation Trust R&D Department, Sussex Education Centre, Mill View Hospital, Hove, BN3 7HZ

Dear Dr. Strauss

Study title: A comparison to two types of group behaviour therapy

for obsessive compulsive disorder. A pilot randomised

controlled trial of behaviour therapy and mindfulness-based behaviour therapy for OCD

REC reference: 13/LO/1768 IRAS project ID: 131285

Thank you for your letter of 20 December 2013. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 05 December 2013

Documents received

The documents received were as follows:

Document	Version	Date
Participant Consent Form: Consent Form	2	20 December 2013
Participant Information Sheet: Participant Information Sheet	3	20 December 2013

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	Version	Date
GP/Consultant Information Sheets	GP Letter 1	31 October 2013
Interview Schedules/Topic Guides	Change Interview Schedule (Protocol Appendix)	
Investigator CV	Clara Strauss	31 October 2013
Participant Consent Form: Consent Form	2	20 December 2013
Participant Information Sheet: Participant Information Sheet	3	20 December 2013
Protocol	3	31 October 2013
Questionnaire: YBOCS-II, BDI-II, FFMQ, OBQ-44, SWEMWS	(Protocol Appendix)	6
Questionnaire: Mini International Neuropsychiatrist Interview	(MINI 6.0.0)	Tr.
REC application		01 November 2013
Referees or other scientific critique report	RfPB Offer Letter, peer reviews and response letter	
Summary/Synopsis	Gantt Chart 1 and Flow Chart a	31 October 2013

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

13/LO/1768

Please quote this number on all correspondence

Yours sincerely

Miss Stephanie Macpherson REC Manager

E-mail: nrescommittee.secoast-surrey@nhs.net

Copy to: Ms Tanya Telling, Sussex NHS Trust

tanya.telling@sussexpartnership.nhs.uk

Ms. Gina Declemente, Sussex Partnership gina.declemente@sussexpartnership.nhs.uk



Research and Development

Sussex Education Centre Mill View Hospital Nevill Avenue Hove BN3 7HZ

> Tel: 01273 265928 Fax: 01273 242182

www.sussexpartnership.nhs.uk

13th January 2013

Dr Clara Strauss Research and Development Sussex Education Centre Mill View Hospital Nevill Avenue Hove BN3 7HZ

Dear Dr Strauss,

Study title: A comparison to two types of group behaviour therapy for obsessive compulsive disorder: A pilot randomised controlled trial of behaviour therapy and mindfulness based behaviour therapy for OCD

Ref: CSP 121385

Thank you for your application to Sussex Partnership Trust for research governance approval of the above named study.

I am pleased to inform you that you have all the necessary internal and external regulatory approvals to proceed. Details of your research project and any associated supporting documentation will be stored on an electronic database administered by the R&D Department.

This approval is valid in the following sites:

- Sussex Partnership NHS Foundation Trust Assessment and Treatment Centre's
- Sussex Partnership NHS Foundation Trust Wellbeing Services

The documents reviewed for this approval were:

Document	Version	Date
Participant Consent Form: Consent Form	2	20 December 2013
Participant Information Sheet: Participant Information Sheet	3	20 December 2013
GP/Consultant Information Sheets	1	31 October 2013
Interview Schedules/Topic Guides	Change Interview Schedule (Protocol appendix)	
Protocol	3	31 October 2013
Questionnaire: YBOCS-II, BDI-II, FFMQ, OBQ-44, SWEMWS	Protocol appendix	
Questionnaire: Mini International Neuropsychiatrist Interview	Mini (6.0.0)	



Investigator CV: Dr Clara Strauss		31 October 2013
Investigator CV: Emily Ironmonger		
Investigator CV: Dr Liz Forrester		
Investigator CV: Dr Lyn Ellett		
Investigator CV: Laura Lea		
NRES Committee South East Coast		20 December 2013
Surrey Favourable Opinion Letter		I
Signed Research Contract	SPFT & Secretary of State for Health	18 December 2013
Locked and Signed R&D Form: 131285/544355/14/418		20 December 2013
Locked and Signed SSI Form: 131285/546716/6/809/229454/288667		20 December 2013
RfPB funding award email		

Conditions of approval

The approval covers the period stated in the Research Ethics Committee (REC) application and will be extended in line with any amendments agreed by the REC. Research must commence within 12 months of the issue date of this letter. Any delay beyond this may require a new review of the project resources.

Please alert the Research and Development Office if significant developments occur as the study progresses, whether in relation to the safety of individuals or to scientific direction.

Please ensure that you comply fully with the Department of Health Research Governance Framework, in particular that you are aware of and fully discharge your responsibilities in respect to Data Protection, Health and Safety, financial probity, ethics and scientific quality. You should refer in particular to Sections 3.5 and 3.6 of the Research Governance Framework.

Please ensure that all information regarding patients or staff remains secure and strictly confidential at all times. Ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice, Data Protection Act and Human Rights Act. Unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

Amendments

Project amendment details dated after the issue of this approval letter should be emailed to the Research and Development Office for formal approval.

NIHR Adoption

This project has been adopted by the NIHR and as Principal Investigator for this site you are responsible for ensuring accrual numbers are submitted to the co-ordinating centre for study. If you need any support to manage this please contact me.

ICH-GCP Monitoring

The Trust has a duty to ensure that all research is conducted in accordance with the Research Governance Framework and to ICH-GCP standards. In order to ensure compliance the Trust undertakes random audits. If your project is selected you will be given 4 weeks notice to prepare all documentation for inspection. The trust undertakes annual monitoring of all research studies, please respond to any requests for information. Failure to do this will result in the suspension of research governance approval.



I wish you luck with your project and would be grateful if you could inform me when the project is complete or due to be closed on this site.

Yours sincerely,

andelling

Tanya Telling Research and Development Manager

CC: Lead CLRN / Sponsor: WSHNT.CLRNSurreySussex@nhs.net

APPENDIX B

Change Interview

(Adapted from Elliott, 2001)

Interview Strategy: This interview works best as a relatively unstructured empathic exploration of the client's experience of the course. Think of yourself as primarily trying to help the client tell you the story of his or her the course so far. It is best if you adopt an attitude of curiosity about the topics raised in the interview, using the suggested open-ended questions plus empathic understanding responses to help the client elaborate on his/her experiences. Thus, for each question, start out in a relatively unstructured manner and only impose structure as needed. For each question, a number of alternative wordings have been suggested, but keep in mind that these may not be needed.

- Ask client to provide as many details as possible
- Use the "anything else" probe (e.g., "Are there any other changes that you have noticed?"): inquire in a non-demanding way until the client runs out of things to say

Introduction given to clients: After the course, clients are asked to come in for a semi-structured interview that can take up to one hour. The major topics of this interview are any changes you have noticed since the course began, what you believe may have brought about these changes, and helpful and unhelpful aspects of the course. The main purpose of this interview is to allow you to tell us about the course and the research in your own words. This information will help us to understand better how the course works; it will also help us to improve the course. This interview is audio-recorded for later transcription. Please provide as much detail as possible.

Interview Schedule:

1.	Chan	ges:	[about	10	min]
				~	

1a. What changes, if any, have you noticed in yourself since the course started? (Interviewer: Reflect back change to client and write down brief versions of the changes for later. If it is helpful, you can use some of these follow-up questions: For example, Are you doing, feeling, or thinking differently from the way you did before? What specific ideas, if any, have you gotten from the course so far, including ideas about yourself or other people? Have any changes been brought to your attention by other people?)

	1b. Has anything changed for the worse for you since the course started?
i.	

ii.	
iii.	
iv.	
v.	
	1c. Is there anything that you wanted to change that hasn't since the course started?
i.	
ii.	
iii.	
iv.	
v.	
	2. <i>Change Ratings</i> : [about 10 min] (Go through each change and rate it on the following three scales:) 2a. For each change, please rate how much you expected it vs. were surprised by it? (Use this rating scale:)
	 (1) Very much expected it (2) Somewhat expected it (3) Neither expected nor surprised by the change (4) Somewhat surprised by it (5) Very much surprised by it
	2b. For each change, please rate how likely you think it would have been if you hadn't done the course? (Use this rating scale:)
	 (1) Very unlikely without the course (clearly would not have happened) (2) Somewhat unlikely without the course (probably would not have happened) (3) Neither likely nor unlikely (no way of telling) (4) Somewhat likely without the course (probably would have happened) (5) Very likely without the course (clearly would have happened anyway)

2c. How important or significant to you personally do you consider this change to be?

(Use this rating scale:)

- (1) Not at all important
- (2) Slightly important
- (3) Moderately important
- (4) Very important
- (5) Extremely important

	Expected it?	Likely?	Importance?
	(1-5)	(1-5)	(1-5)
Change 1:			
Change 2:			
Change 3:			
Change 4:			
Change 5:			

- 3. *Attributions*: [about 5 min] In general, what do you think has caused the various changes you described? In other words, what do you think might have brought them about? (Including things both outside of the course and in the course)
- 4. *Helpful Aspects*: [about 10 min] Can you sum up what has been helpful about the course so far? Please give examples. (For example, general aspects, specific events)
- 5. **Resources**: [about 5 min]
- 5a. What personal strengths do you think have helped you make use of the course to deal with your problems? (what you're good at, personal qualities)
- 5b. What things in your current life situation have helped you make use of the course to deal with your problems? (family, job, relationships, living arrangements)
- 6. **Problematic Aspects**: [about 5 min]
- 6a. What kinds of things about the course have been hindering, unhelpful, negative or disappointing for you? (For example, general aspects. specific events)
- 6b. Were there things in the course which were difficult or painful but still OK or perhaps helpful? What were they?

6c. Has anything been missing from your treatment? (What would make/have made the course more effective or helpful?)

7. *Limitations*: [about 5 min]

- 7a. What personal limitations do you think have made it harder for you to use the course to deal with your problems? (things about you as a person)
- 7b. What things in your life situation have made it harder for you to use the course to deal with your problems? (family, job, relationships, living arrangements)
- 8. *Suggestions*. [about 5 min] Do you have any suggestions for us, regarding the research or the course? Do you have anything else that you want to tell me?
- 9. *Final reflections* [about 5-10 minutes] on the course (**MBCT course only**):
- 9a) What were the main issues or difficulties you were experiencing *before* you started the course?
- 9b) To what extent have these issues or difficulties changed since undertaking and completing the course?
- 9c) How do you live with these issues or difficulties now? Have you noticed any differences in how you live with these issues or difficulties since completing the course?

Rating Scales:

1	2	3	4	5
Very much expected the change to happen	Somewhat expected the change to happen	Neither expected the change to happen nor was surprised by it	Somewhat surprised by the change	Very much surprised by the change

1	2	3	4	5
Very unlikely without the	Somewhat unlikely	Neither likely nor unlikely	Somewhat likely without	Very likely without the
course (clearly	without the course		the course (probably	course (clearly would have

would not have	(probably	(no way of	would have	happened
happened)	would not have	telling)	happened)	anyway)
	happened)			

1	2	3	4	5
Not at all important	Slightly important	Moderately important	Very important	Extremely important

APPENDIX C

Antony Walsh
Research Governance Officer
Research and Enterprise
Tel: 01273 8722748 antony.walsh@sussex.ac.uk
General enquiries: rgoffice@sussex.ac.uk

US UNIVERSITY OF SUSSEX

Research and Enterprise University of Sussex Falmer Brighton BN1 9QF

Dr Tamara Leuweerik School of Psychology Pevensey 1 University of Sussex BN1 9HR

18 July 2017

Dear Tamara

Full Study Title: MIND4OCD: A feasibility study of Mindfulness-Based Cognitive

Therapy adapted for adults with obsessive-compulsive disorder

Ref No.: 023 LEE

I am writing to inform you that your application for University Sponsorship has now been assessed and that the University is willing to take on the role of Research Sponsor for the duration of the study.

Your project has been allocated the following reference: 023 LEE. Please quote this on all correspondence.

Health Research Authority (HRA) Approval

From 1st April 2016, all applications to conduct research in the NHS in England will come under 'Health Research Authority (HRA) Approval' - a single approval incorporating the assessment of governance and legal compliance with the independent Research Ethics Committee opinion provided via the UK research ethics service. See: http://www.hra.nhs.uk/about-the-hra/our-plans-and-projects/assessment-approval/ for further information.

Please note research activity cannot commence until a favourable ethical opinion from a Research Ethics Committee and HRA Approval have been confirmed. Favourable ethical opinion must be gained within 6 months of the issue date of this letter. University Sponsorship will cover the period stated in the Research Ethics Committee application and if required to be extended will necessitate a project amendment to be submitted to the Sponsor and notified to the HRA.

Please ensure any project documentation revised as a result of Research Ethics Committee review is also submitted to the Sponsor (via regoffice@sussex.ac.uk) for the Sponsor's records.

Indemnity

The study will be indemnified by the University of Sussex. The Public Liability, Employers Liability and Professional Negligence Certificates are available from the University of Sussex insurance webpage: http://www.sussex.ac.uk/finance/services/corporateaccounting/insurance

Amendments

Any amendments to the project dated after the issue of a favourable ethical opinion must be submitted to the Sponsor in order for Sponsorship to be valid. Please submit your application for an amendment to rgoffice@sussex.ac.uk

Please note, from 1st April 2016 all amendments will require submission via the HRA Approval review system, in line with the guidance available on the HRA website: http://www.hra.nhs.uk/about-the-hra/our-plans-and-projects/assessment-approval/amendments-nhs-england-studies/

Monitoring and Auditing

The University of Sussex is committed to upholding the highest quality ethical standards and has a duty to ensure all research is conducted in accordance with the University Research Governance Framework, and has arrangements in place to monitor and audit studies which are deemed eligible.

It is your responsibility to inform me in the event of early termination of the project or if you fail to complete the work.

I wish you luck with your project.

Antony Walsh

A. Ward

Research Governance Officer

Information about University Sponsorship processes (including CI responsibilities) can be found at: http://www.sussex.ac.uk/staff/research/governance/sponsorship



Whitefriars Level 3 Block B Lewins Mead Bristol BS1 2NT

Telephone: 0207 104 8028

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

25 September 2017

Dr Tamara Leeuwerik Pevensey 1, 2C4 University of Sussex Falmer, Brighton BN1 9RH

Dear Dr Leeuwerik

Study title: MIND4OCD: A Feasibility Study of Mindfulness-Based

Cognitive Therapy adapted for Obsessive-Compulsive

Disorder.

REC reference: 17/SW/0172
Protocol number: 023 LEE
IRAS project ID: 224619

Thank you for your letter of 12 September 2017, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further

information, or wish to make a request to postpone publication, please contact https://hrs.net/brastudyregistration@nhs.net/ outlining the reasons for your request.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hrs.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Copies of advertisement materials for research participants [MIND4OCD advertisement text]	1	18 July 2017
Covering letter on headed paper [Covering letter]	1	19 July 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Public Liability Certificate]	1	18 July 2017
GP/consultant information sheets or letters [MIND4OCD Letter to GP]	1	18 July 2017
Interview schedules or topic guides for participants [MIND4OCD Change Interview]	1	18 July 2017
IRAS Application Form [IRAS_Form_19072017]		19 July 2017
IRAS Checklist XML [Checklist_19072017]		19 July 2017
IRAS Checklist XML [Checklist_20072017]		20 July 2017
IRAS Checklist XML [Checklist_12092017]		12 September 2017
Letter from funder [ESRC award Tamara Leeuwerik]	1	18 July 2017
Letter from sponsor [Sponsorship approval letter]	1	18 July 2017
Non-validated questionnaire [MIND4OCD Sociodemographic and additional questions]	1	18 July 2017
Non-validated questionnaire [MIND4OCD Mindfulness home practice record]	1	18 July 2017
Other [Sponsor Professional Negligence Research Certificate]	1	18 July 2017
Other [Sponsor Employers Liability Certificate]	1	18 July 2017
Other [Honorary research contract T.Leeuwerik]	1	18 July 2017
Other [Honorary research contract T Leeuwerik - signatures]	1	18 July 2017
Other [Sponsor Professional Negligence Research Certificate 2017/2018]		12 September 2017
Other [Sponsor Public Liability Certificate 2017/2018]		12 September 2017
Other [Sponsor Employers Liability 2017/2018]		12 September 2017

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Other [Covering letter - response to prov op ltr 14.8.17]	1	12 September 2017
Participant consent form [MIND4OCD Consent form - tracked changes]	2.0	12 September 2017
Participant consent form [MIND4OCD Consent Form]	2.0	12 September 2017
Participant information sheet (PIS) [MIND4OCD Participant Information Sheet - tracked changes]	2.0	12 September 2017
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Summary CV for supervisor (student research) [CV Clara Strauss]	1	18 July 2017
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Summary, synopsis or diagram (flowchart) of protocol in non technical language [Summary of Study (A6.1 IRAS form)]	2.0	12 September 2017
Summary, synopsis or diagram (flowchart) of protocol in non technical language [MIND4OCD Pre-course information about MBCT]	1	12 September 2017
Validated questionnaire [MINI 6.0.0.]	1	18 July 2017
Validated questionnaire [Y-BOCS severity Scale]	1	18 July 2017
Validated questionnaire [Obsessive Beliefs Questionnaire (OBQ-20)]	1	18 July 2017
Validated questionnaire [Patient Health Questionnaire (PHQ-9)]	1	18 July 2017
Validated questionnaire [Generalised Anxiety Disorder (GAD-7)]	1	18 July 2017
Validated questionnaire [Five-Facet Mindfulness Questionnaire (FFMQ-SF)]	1	
Validated questionnaire [Self-compassion Scale]	1	
Validated questionnaire [Distress Tolerance Scale]	1	18 July 2017
Validated questionnaire [Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS)]	1	18 July 2017
Validated questionnaire [Work and Social Adjustment Scale (WSAS)]	1	
Validated questionnaire [Obsessive-Compulsive Inventory (OCI)]	1	20 July 2017
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Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- · Adding new sites and investigators
- · Notification of serious breaches of the protocol
- · Progress and safety reports
- · Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

17/SW/0172

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

pp. Dr Denise Sheehan

Chair

Email:nrescommittee.southwest-exeter@nhs.net

Enclosures: "After ethical review – guidance for researchers" [SL-AR2]

Copy to: Dr Antony Walsh

Ms Taffy Bakasha, R&D Dept. Sussex Education Centre



Email: hra.approval@nhs.net

Dr Tamara Leeuwerik Pevensey 1, 2C4 University of Sussex Falmer, Brighton BN1 9RH

25 October 2017

Dear Dr Leeuwerik

Letter of HRA Approval

Study title: MIND4OCD: A Feasibility Study of Mindfulness-Based

Cognitive Therapy adapted for Obsessive-Compulsive

Disorder.

IRAS project ID:224619Protocol number:023 LEEREC reference:17/SW/0172

Sponsor University of Sussex

I am pleased to confirm that <u>HRA Approval</u> has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. Please read Appendix B carefully, in particular the following sections:

- Participating NHS organisations in England this clarifies the types of participating
 organisations in the study and whether or not all organisations will be undertaking the same
 activities
- Confirmation of capacity and capability this confirms whether or not each type of participating
 NHS organisation in England is expected to give formal confirmation of capacity and capability.
 Where formal confirmation is not expected, the section also provides details on the time limit
 given to participating organisations to opt out of the study, or request additional time, before
 their participation is assumed.
- Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria) - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

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It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- · A List of documents reviewed during HRA assessment
- . B Summary of HRA assessment

After HRA Approval

The document "After Ethical Review – guidance for sponsors and investigators", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- · Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as
 detailed in the After Ethical Review document. Non-substantial amendments should be
 submitted for review by the HRA using the form provided on the HRA website, and emailed to
 hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation
 of continued HRA Approval. Further details can be found on the <a href="https://hrx.ncbi.nlm.ncb

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application

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procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is 224619. Please quote this on all correspondence.

Yours sincerely

Sharon Northey Senior Assessor

Email: hra.approval@nhs.net

Copy to: Dr Antony Walsh - Sponsor contact

Ms Taffy Bakasha, R&D Dept. Sussex Education Centre - R&D contact

IRAS project ID	224619
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Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	Version	Date
Copies of advertisement materials for research participants [MIND4OCD advertisement text]	1	18 July 2017
Covering letter on headed paper [Covering letter]	1	19 July 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Public Liability Certificate]	1	18 July 2017
GP/consultant information sheets or letters [MIND4OCD Letter to GP]	1	18 July 2017
HRA Schedule of Events [HRA Assessed Schedule of Events]	1.0	14 August 2017
HRA Statement of Activities [HRA Assessed Statement of Activities]	1.0	14 August 2017
Interview schedules or topic guides for participants [MIND4OCD Change Interview]	1	18 July 2017
IRAS Application Form [IRAS_Form_19072017]		19 July 2017
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Participant information sheet (PIS) [MIND4OCD Participant Information Sheet - tracked]	2.1	04 October 2017
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Summary CV for student [CV Tamara Leeuwerik]		18 July 2017
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Validated questionnaire [Five-Facet Mindfulness Questionnaire (FFMQ-SF)]	1	
Validated questionnaire [Self-compassion Scale]	1	
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Validated questionnaire [Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS)]	1	18 July 2017
Validated questionnaire [Work and Social Adjustment Scale (WSAS)]	1	
Validated questionnaire [Obsessive-Compulsive Inventory (OCI)]	1	20 July 2017

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Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, participating NHS organisations, capacity and capability and Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria) sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name: Dr Antony Walsh Tel: 01273872748

Email: Antony.Walsh@sussex.ac.uk

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	The applicant has confirmed that Participant Identification Centres are not being used.
2.1	Participant information/consent documents and consent process	Yes	Following REC favourable opinion the Participant Information Sheet has had a minor amendment to bring it in line with HRA standards. The current version is approved as part of the HRA approval. No further approvals are expected.
3.1	Protocol assessment	Yes	Following REC favourable opinion the Protocol has had a minor amendment. The current version is approved as part of the HRA approval. No further approvals are expected.
4.1	Allocation of responsibilities and rights are agreed and	Yes	The statement of activities will act as the research agreement between the

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Section	HRA Assessment Criteria	Compliant with Standards	Comments
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	Funding has been secured from the Economic and Social Research Council Doctoral Programme Grant. The Statement of Activities shows that there is no funding for the NHS organisations.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

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Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

There is one NHS participating organisation; therefore there is one site type.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website.

If Chief Investigators, sponsors or Principal Investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the Chief Investigator, sponsor or Principal Investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.

Participating NHS organisations in England will be expected to formally confirm their capacity and capability to host this research.

- The sponsor should ensure that participating NHS organisations are provided with a copy of
 this letter and all relevant study documentation, and work jointly with NHS organisations to
 arrange capacity and capability whilst the HRA assessment is ongoing.
- Further detail on how capacity and capability will be confirmed by participating NHS
 organisations, following issue of the Letter of HRA Approval, is provided in the Participating
 NHS Organisations and Allocation of responsibilities and rights are agreed and documented
 (4.1 of HRA assessment criteria) sections of this appendix.
- The <u>Assessing, Arranging, and Confirming</u> document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

Principal Investigator Suitability

This confirms whether the sponsor's position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England, and the minimum expectations for education, training and experience that PIs should meet (where applicable).

This is a single site study and the study Chief Investigator (CI) will, in addition, act as Principal Investigator (PI). Therefore no additional PI or Local Collaborator (LC) is required.

GCP training is <u>not</u> a generic training expectation, in line with the <u>HRA statement on training expectations</u>.

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HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken.

The CI has a contractual relationship with the one NHS Trust taking part in the study. Where arrangements are not already in place, research staff not employed by the NHS host organisation undertaking any of the research activities listed in the research application would be expected to obtain an honorary research contract. This would be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm enhanced DBS checks, including appropriate barred list checks, and occupational health clearance.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England in study set-up.

The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.

APPENDIX D

Table D1Overview of MBCT adapted for OCD

Session no. &	Content	Practices
theme		
Introductory	Introductions; ground rules;	Introductory mindfulness
	introducing the cognitive model	practice (breathing/grounding)
	of OCD; how MBCT might help	
	people with OCD; what taking	
	part in the course involves	
1.Awareness	Re-visiting introductions and	Marble exercise; body scan;
and automatic	ground rules; selective	everyday mindfulness, 2-3
pilot	attention/hypervigilance in OCD;	minute breathing practice
	getting caught up in (worrying	
	about & responding to) intrusive	
	thoughts	
2.Living in our	Normalising intrusive thoughts;	body scan, 10-minute sitting
heads	setting up pleasant events	meditation
	calendar practice	
3.Gathering the	Inviting participants to use the 3-	5 minute 'seeing'/ 'hearing'
scattered mind	minute breathing space (3MBS)	exercise; 30-minute sitting
	when OCD symptoms emerge,	meditation; 3-minute breathing
	setting up unpleasant (mental)	space (3MBS); Mindful
	events calendar	stretching
4.Recognising	Defining the territory of OCD	5-minute 'seeing'/'hearing'
aversion	(revisiting the cognitive model);	exercise; 30- to 40- minute
	the role of (aversion to) anxiety;	sitting meditation; poem, e.g.
		'wild geese'; 3MBS; Mindful
		walking
5.Allowing,	Exploring the meaning we give to	30- to 4- minute sitting
letting be	intrusive thoughts (i.e. obsessive	meditation; introducing a
	beliefs) using the OBQ-20	difficulty within the practice
	The role of thought suppression,	and noting its effects on the
	avoidance and compulsions in	body and reactions to it;
	maintaining OCD	Breathing space (with added
		instructions); Rumi's poem
		'the guest house'
6.Thoughts are	Preparation for end of course;	30-to 40- minute sitting
not facts	discuss breaking the OCD vicious	meditation, noticing how we

	cycle; Introduce the notion of	relate to thoughts that arise,
	'Theory A vs Theory B'; discuss	Breathing space
	distress/anxiety tolerance and	
	building up confidence that one	
	can tolerate distress/anxiety	
7.How can I	Using the 3MBS as a first step	30- to 40- minute sitting
best take care	before choosing how best to	meditation – awareness of
of myself?	respond to OCD; self-compassion	when difficulties arise within
	vs immediate relief in	the practice, noting their
	overcoming OCD; keeping up the	effects and reactions to them,
	good work	on the body, 3MBS or mindful
		walking
8.Maintaining	Review of the course and what	Body scan practice, concluding
and extending	has been learnt; personal	meditation (marble, stone or
new learning	reflections; how to keep up	bead)/participants wishing
	momentum	each other well