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Internet-delivered cognitive-behaviour therapy (ICBT) for obsessive-compulsive disorder when delivered as routine clinical care: A phase IV clinical trial

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ABSTRACT

Cognitive-behaviour therapy (CBT) is an effective treatment for obsessive-compulsive disorder (OCD), but many patients experience difficulty accessing this treatment. Internet-delivered CBT (ICBT) enhances access to CBT for individuals with OCD and has been shown to be efficacious in Phase I, II, and III clinical trials. However, there are fewer studies investigating ICBT for OCD in Phase IV clinical trials, which demonstrate the *effectiveness* of the intervention when provided as part of routine care. The aim of the present study was to report on the effectiveness of ICBT for OCD, using data from Australia's MindSpot Clinic, a federally funded treatment service that provides free ICBT to Australian adults with anxiety, depression, and pain conditions. A total of 225 MindSpot users (68 % female; *M*age = 34.82; SD = 11.02) were included in the study. Within-group effect sizes at post-treatment on the Yale-Brown Obsessive-Compulsive Scale, indicated medium effect sizes (g = 0.6; 95 % CI: 0.5−0.7), increasing to large effects at three-month follow up (g = 0.9; 95 % CI: 0.8–1.0). Effects on secondary outcome measures including measures of depression, generalized anxiety, and psychological distress ranged from (g = 0.5–0.6) at post-treatment and (g = 0.5–0.7) at three-month follow up. Results from benchmarking analyses indicated that the results from routine care were significantly smaller than those found in a recent clinical trial using the same treatment protocol. The results indicate that ICBT delivered in real world settings is associated with meaningful improvements in OCD symptoms, however future research may wish to examine which patients respond best to this treatment approach and how to enhance outcomes.

1. Introduction

Obsessive-compulsive disorder (OCD) is a relatively common mental health condition, with a lifetime prevalence estimated to be as high as 3% (Kessler, Petukhova, Sampson, Zaslavsky, & Wittchen, 2012). Individuals with OCD experience intrusive and unwanted thoughts, urges, images and/or doubts (i.e., obsessions), and repetitive and time-consuming behaviours (i.e., compulsions), which serve to decrease the distress caused by the obsessions (American Psychiatric Association, 2013). Symptoms for the disorder respond to both pharmacological and psychological interventions (Skapinakis et al., 2016), however cognitive-behaviour therapy (CBT), incorporating exposure and response prevention (ERP), is recommended as the first-line psychological treatment for OCD (American Psychiatric Association, 2007; National Institute for Health & Care Excellence, 2005). ERP involves gradual exposure to feared stimuli while refraining from the engagement in compulsions (i.e., response prevention).

Despite the demonstrated efficacy of CBT for OCD less than one in five patients receive this treatment when they seek care in the community (Stobie, Taylor, Quigley, Ewing, & Salkovskis, 2007). There are also considerable barriers to accessing expert treatment for individuals with OCD including stigma, the direct and indirect costs of treatment, geographical isolation, or lack of access to a suitably qualified clinician (Gentle, Harris, & Jones, 2014; Marques et al., 2010). Internet-delivered

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CBT (ICBT) has the potential to reduce barriers and improve access to evidence-based treatment for OCD.

ICBT for OCD has been demonstrated to be effective in Phase I (i.e., feasibility) clinical trials (Andersson et al., 2011; Diefenbach, Wootton, Bragdon, Moshier, & Tolin, 2015; Patel et al., 2018; Seol, Kwon, Kim, Kim, & Shin, 2016; Wootton et al., 2011). For instance, Wootton et al. (2011) examined the feasibility of an eight lesson program, delivered over 8 weeks in a small sample (N = 22) of individuals diagnosed with OCD. The results indicated large treatment effects (d = 1.53) on the Yale-Brown Obsessive Compulsive Scale (YBOCS; Goodman et al., 1989) and 71 % of participants no longer met diagnostic criteria for OCD at post-treatment (Wootton et al., 2011). Similarly, Andersson et al. (2011) examined the feasibility of a 15-module program, delivered over 15 weeks in another small sample (N = 23) of individuals diagnosed with OCD. The results from this study indicated large treatment effects on the Y-BOCS (d = 1.56) with 41 % of participants no longer meeting diagnostic criteria for OCD at post-treatment (Andersson et al., 2011).

The efficacy of ICBT for OCD has also been supported by Phase II clinical trials (i.e., efficacy trials) (Mahoney, Mackenzie, Williams, Smith, & Andrews, 2014; Wootton, Karin, Titov, & Dear, 2019) using two different ICBT programs. For instance, Wootton et al. (2019) compared the efficacy of a self-guided ICBT intervention compared with a waitlist control group and found large within-group (d =1.25) and between-group (d = 1.05) effect sizes on the self-report YBOCS at post-treatment. Similarly, Mahoney et al. (2014) compared a guided ICBT intervention for OCD against a waitlist control group and also found a large within-group (g = 0.87) and between-group effect size (g = 0.78) on the Dimensional Obsessive-Compulsive Scale (DOCS; Abramowitz et al., 2010) at post-treatment.

Several Phase III clinical trials (i.e., comparisons to other interventions) have also supported the efficacy of ICBT for OCD (Andersson et al., 2012; Kyrios et al., 2018; Wootton, Dear, Johnston, Terides, & Titov, 2013). For instance, Andersson et al. (2012) compared ICBT to online supportive therapy and found large between-group effect sizes at post-treatment (d = 1.12) favouring the ICBT condition. Kyrios et al. (2018) compared ICBT to a progressive muscle relaxation condition and found a medium between-group effect size (d = 0.55) favouring the ICBT condition. Finally, Wootton et al. (2013) compared ICBT for OCD with bibliotherapy-delivered CBT (BCBT) and found that ICBT for OCD is similarly effective to BCBT for OCD with a small between-group effect size (d = 0.17).

To date there have been fewer Phase IV clinical trials investigating ICBT for OCD. Phase IV clinical trials allow investigators to examine whether an intervention that has already been demonstrated to be efficacious is clinically useful when delivered as part of routine care. Such trials have important implications for the delivery of health care services. Luu et al. (2020) investigated the effectiveness of an ICBT intervention for OCD when delivered as part of routine care. In this study 309 patients with symptoms of OCD completed a 6-lesson guided ICBT intervention, which was previously examined in a Phase II clinical trial (Mahoney et al., 2014). Despite low rates of treatment completion (i.e., 39 % of participants completed all lessons) the treatment resulted in medium effects sizes from pre-treatment to post-treatment (g = 0.61) on the DOCS, however no follow-up data was available (Luu et al., 2020).

MindSpot (www.mindspot.org.au) was launched in 2012 as part of the Australian Government e-Mental Health Strategy (Australian Government, 2012), and provides free internet-delivered treatments for mental health conditions to the Australian population. In the first 30-months of operation the service demonstrated large treatment effects (Cohen's d range 0.7–2.4) across all treatment programs from assessment to three-month follow-up, including transdiagnostic programs for anxiety and depressive disorders, post-traumatic stress disorder, and OCD (Titov et al., 2017). Results from a more recent study of the effectiveness of MindSpot's treatment programs, which included more than 20,000 patients over seven years of operation indicate that patients obtain significant benefits from the treatments with effect sizes (Cohen's d) $\geq$ 1.30 and average symptom reductions between 45 % and 54 % (Titov et al., 2020).

MindSpot disseminates an ICBT intervention for OCD (*The OCD Course*), which has previously shown to be efficacious in Phase I, Phase II, and Phase III clinical trials (Wootton et al., 2011, 2013; Wootton, Dear, Johnston, Terides, & Titov, 2014, 2019). Results from the first 30 months of the MindSpot clinic, indicated that individuals who completed *The OCD Course* (n = 69) obtained large effects sizes on measures of OCD symptomatology at post-treatment (d = 0.9) and at three-month follow up (d = 1.1). Similar results were also seen on measures of distress and anxiety (Titov et al., 2017).

Given the small literature on the *effectiveness* of ICBT when delivered as part of routine care, the aim of the present study was to report on the effectiveness of the MindSpot's OCD Course in a larger clinical sample. It was hypothesised that 1) participants completing *The OCD Course* as part of routine-care through MindSpot would report clinically significant improvements in their OCD symptoms from pre-treatment to post-treatment (with large within-group effect sizes); 2) that symptom improvements would be durable over a three-month time-frame; and 3) that results obtained would be similar to those seen in ICBT for OCD efficacy trials. Understanding the *effectiveness* of ICBT for OCD using a Phase IV clinical trial methodology has important implications for understanding how to best deliver ICBT to consumers with OCD in the community.

2. Method

2.1. Design

The study was a Phase IV clinical trial comprising an open trial design. Data was obtained from registered MindSpot users who completed the *OCD Course* between February 2013-July 2019 and who provided consent for their data to be included in service evaluations. Macquarie University Human Research Ethics Committee provided ethical approval for the study.

2.2. Participants

Two hundred and twenty-five MindSpot patients were included in the current study (68 % female; *M*age = 34.82; SD = 11.02). The demographic characteristics of the sample are outlined in Table 1. OCD Course patients were required to be 1) aged at least 18 years; 2) an Australian resident eligible for Medicare services; 3) self-report symptoms of OCD on the 10 item YBOCS severity scale, confirmed with a pre-treatment clarifying interview; and 4) requested to be enrolled in the OCD course. Patients were not included in the OCD Course if they were 1) acutely suicidal; 2) already engaged in regular treatment with a clinician; or 3) required a comprehensive face-to-face assessment due to the complexity of their symptoms.

2.3. Assessment

Participants initially completed an online battery of self-report questionnaires (including the YBOCS) to assess psychological symptoms. Following this, participants were assessed by a MindSpot clinician via telephone to assess risk and ascertain whether the OCD Course was suitable for the patient. More detailed information about the assessment, treatment, and risk management processes at MindSpot can be found in other publications (Nielssen et al., 2015; Titov, Dear, Staples, Bennett-Levy et al., 2015; Titov, Dear, Staples, Terides et al., 2015; Titov et al., 2017, 2018, 2019).

2.4. Treatment

The OCD Course delivered at MindSpot was initially developed and

Table 1
Demographic Characteristics of Patients (N = 225).

Age	
Mean (SD)	34.82 (11.02)
Range	18–79
Gender (% female)	68.4 %
State	
New South Wales	44.9 %
Victoria	23.1 %
Queensland	16.9 %
South Australia	4.9 %
Western Australia	3.6 %
Australian Capital Territory	3.1 %
Tasmania	2.2 %
Northern Territory	1.3 %
Marital Status (%)[a]	
Single/separated/divorced/widowed	47.8 %
Married/defacto	52.2 %
Education (%)[b]	
High school	22.0 %
Trade/vocational certificate	31.8 %
Tertiary education	46.2 %
Employment status (%)[b]	
Working	61.7 %
Unemployed	7.9 %
At home parent	11.7 %
Retired	1.4 %
Registered sick/disabled	5.6 %
Student	11.7 %
Ethnicity	
Born in Australia (% Yes)[c]	78.4 %
Identifies as Aboriginal and/or Torres Strait Islander (% Yes)[d]	3.5 %
Taking psychotropic medication for OCD (% yes)[e]	45.4 %
Lesson completion (% complete)	
Lesson 1	98.2%
Lesson 2	91.5%
Lesson 3	79.1%
Lesson 4 [f]	68.8 %
Lesson 5	54.6%

Note. [a] $N = 207$. [b] $N = 214$. [c] $N = 194$. [d] $N = 173$. [e] $N = 216$. [f] indicates patients who completed lesson 4 or 5 of the 6-lesson program.

evaluated through the Macquarie University eCentreClinic (www.ecentreclinic.org). When the OCD course was launched at MindSpot it was a 6-lesson course that was delivered over 8 weeks, after approximately 90 patients, the service commenced using the 5-lesson course, also delivered over 8 weeks for pragmatic reasons (i.e., all other MindSpot ICBT interventions are 5 lesson programs). The content was the same in both courses, however in the 6-lesson course Lesson 4 was divided in to two sections, whereas in the 5-lesson course the content was delivered in one lesson. Further information on the intervention can be found in existing publications (Wootton et al., 2011, 2013, 2014, 2019). MindSpot is funded by the Australian government and treatment is provided at no charge to patients. Patients are able to complete the treatment in either a self-guided or clinician-guided format, based on their preferences, however, proportions of patients undertaking each modality are unknown for this sample. For those who opt to complete the treatment in a guided format, clinician guidance is offered either by telephone, or secure messaging system, again depending on patient preference.

2.5. Measures

2.5.1. Yale-Brown Obsessive Compulsive Scale (YBOCS) (Goodman et al., 1989) (self-report version; YBOCS-SR)

The YBOCS-SR is a 10-item scale, with five items measuring the severity of obsessions, and five items measuring the severity of compulsions. Total scores range from 0–40. The scale measures OCD symptom severity independently of symptom subtype and higher scores indicate more severe OCD symptoms. The scale has demonstrated adequate validity and reliability in clinical research (Goodman et al., 1989), the self-report version correlates highly with the clinician-administered version of the scale (Steketee, Frost, & Bogart, 1996), and the YBOCS-SR has demonstrated excellent reliability in previous ICBT studies (Wootton et al., 2019).

2.5.2. Kessler Psychological Distress Scale - 10 item (K-10) (Kessler et al., 2002)

The K-10 is a widely used ten-item measure of psychological distress. The scale has also been shown to have adequate validity and reliability in previous studies (Kessler et al., 2002; Titov et al., 2011), including ICBT studies (Lu, Dear, Johnston, Wootton, & Titov, 2014). Total scores range from 10 to 50 with higher scores indicating greater levels of psychological distress, which was converted to a range of 0–40 to analyse symptom change.

2.5.3. Patient Health Questionnaire 9 item (PHQ-9) (Kroenke, Spitzer, & Williams, 2001)

The PHQ-9 is a nine-item measure of depressive symptoms. Total scores range from 0 to 27, with higher scores indicating more severe depressive symptoms. A cut score of 10 is generally used to indicate patients with major depressive disorder (Kroenke et al., 2001). The PHQ-9 has been shown to have excellent reliability and validity in previous studies (Kroenke et al., 2001; Titov et al., 2011), including ICBT studies (Wootton et al., 2019).

2.5.4. Generalised Anxiety Disorder Scale 7 item (GAD-7) (Spitzer, Kroenke, Williams, & löwe, 2006)

The GAD-7 is a seven-item measure of generalised anxiety. Total scores range from 0 to 21, with higher scores indicating more severe symptoms of anxiety. A cut score of 10 is generally used to indicate the presence of generalised anxiety (Spitzer et al., 2006). The GAD-7 has also been found to have excellent reliability and validity in previous studies (Johnson, Ulvenes, Øktedalen, & Hoffart, 2019; Spitzer et al., 2006), including ICBT studies (Wootton et al., 2011).

The primary outcome measure was the YBOCS-SR, and the secondary outcome measures were the K-10, PHQ-9 and GAD-7. The measures were administered online using the MindSpot secure platform, and were administered at baseline, post-treatment, and at three-month follow-up.

2.6. Statistical analyses

The effectiveness of the MindSpot OCD Course was evaluated in three ways. Firstly, an analysis of symptom change over time was conducted, estimating and testing the overall rate of symptom change from pre-treatment to post-treatment and pre-treatment to three-month follow up. The longitudinal estimate of symptom change was considered as the main metric of treatment efficacy. Change over time was estimated and tested through a series of generalised estimated equation models (GEE; (Liang & Zeger, 1986). These models specified a gamma scale and a log link function to test the rate of change from baseline (exp (β); 95 % confidence intervals). Estimated marginal means and percentage change metrics from these models were used to represent the sample average rate of change within each of the symptom outcomes (Karin, Dear, Heller, Crane, & Titov, 2018; Karin, Dear, Heller, Gandy, & Titov, 2018). Hedges *g* effect sizes were also included for convention (with 95 % confidence intervals).

Secondly, the measurement of symptom change was broken into categories that convey the occurrence of discrete events, such as a clinically significant symptom improvement, or symptom deterioration. The categories of symptom improvement, non-response or deterioration were created with use of the reliable change index (Jacobson & Truax, 1991). Consistent with the recommendations of Farris, McLean, Van Meter, Simpson, and Foa (2013) the proportion of individuals meeting treatment response based on a $\geq$ 35 % reduction on the YBOCS-SR were also calculated. The proportion of individuals who experienced non-response, improvement and deterioration based on the reliable

change index (Jacobson & Truax, 1991), as well as treatment response based on a ≥ 35 % reduction on the YBOCS-SR (Farris et al., 2013) were estimated with a series of logistic regression models using the full sample.

Thirdly, the magnitude of symptom change, observed in the routine care sample, was contrasted against a benchmark taken from a recent clinical trial in order to gauge the translation of the program into the routine care environment. The benchmark was taken from a recent clinical trial that included the same treatment protocol and some of the same symptom outcome measures (Wootton et al., 2019). Participants in the benchmarking trial completed the treatment in a self-guided format (Wootton et al., 2019). The statistical comparison of the routine care and clinical trial effects followed the methodology outlines by Minami and colleagues (Minami, Serlin, Wampold, Kircher, & Brown, 2008), where differences in the rate of change between the groups are considered substantive if they exceed, or fall short of a margin of ±0.2 of standardised mean difference (one fifth of a standard deviation).

All analyses were conducted under the intention to treat (ITT) principle, where post treatment missing data was replaced with a multiple imputation procedure that made a conservative prediction of outcomes of individuals through their rate of treatment adherence and baseline symptoms (Karin, Dear, Heller, Crane et al., 2018; Karin et al., 2021). The analysis, with the multiple imputation procedure, was conducted with SPSS version 26. A post-hoc longitudinal power analysis was also conducted to gauge the maximum sensitivity the current sample achieved for refuting false negatives (non-significant tests for genuine phenomena). Statistical power was estimated with a dedicated software package for longitudinal models (longpower; Donohue & Edland, 2016) taking into consideration the scale of primary outcome (YBOCS) variance, rate of change, and within subjects' clustering.

3. Results

3.1. Missing cases and power analysis

145/225 (65 %) completed outcome measures at post-treatment and 80/225 (35 %) completed outcome measures at three month follow up. Missing data patterns were explored for evidence of systematic dropout and non-ignorable mechanisms of missing data, consistent with clinical missing data guidelines (Little et al., 2012) and dedicated psychotherapy missing data research (Karin, Dear, Heller, Crane et al., 2018; Karin, Dear, Heller, Gandy et al., 2018). An exploration of the range of available variables (the list of variables considered are described with detail in Table 1) identified lesson completion as a single large predictor of missing data at post-treatment (*Wald's* $\chi^2 = 12.145$, $p < 0.001$, *Nagelkerke R Square* = 46 %). These outcomes imply that a MAR assumption would be suitable pending replacement of missing cases adjusted (stratified) by an individual's lesson completion. The impact of missing cases replacement was explored with sensitivity analyses that contrast the analyses with the imputation of missing cases outcomes (main analyses) against analyses that overlook missing cases (sensitivity analyses).

A post-hoc power analysis on the rate of symptom change demonstrate that the sample could adequately refute null differences that were as small as 6% on the primary outcome (YBOCS-SR). This result implied that the sample was adequately powered to refute true null differences (genuine non-significant results) from null differences that may result from insufficient power (false non-significant results). In addition, the sample was large enough to refute standardised means differences that were as a small as 0.14 which is smaller than the margin of ±0.2 standardised mean difference used for the benchmarking analyses.

3.2. Participant characteristics

On average participants were aged in their mid-thirties (M_{age} = 34.82; *SD* = 11.02; range = 18−79) and were primarily female (68 %) and born in Australia (78 %). Participants were located in every Australian State and Territory, and 45 % reported taking psychotropic medication for OCD symptoms. The demographic characteristics of the sample are outlined in Table 1.

3.3. Treatment adherence

Of the 225 participants who commenced the treatment, 155 (68.9 %) were classified as treatment completers (i.e., completed four or more lessons). We examined differences on key demographic and symptom severity characteristics for those who did ($n = 155$) and did not ($n = 70$) complete the treatment. These analyses indicated that there were no significant differences between the groups on age, gender, state of residence, medication use, ethnicity, employment status or marital status. However, there was a significant difference between the groups on educational attainment, as those who had not completed high school were less likely to complete the treatment, whereas those with a post-graduate degree were more likely to complete the treatment ($OR_{exp\beta} = 4.532$, $Wald\chi^2 = 8.50$, $p = .03$). There were no significant differences between completers and non-completers on any of the outcome measures at baseline.

3.4. Symptom change and clinical effectiveness

Estimated marginal means, confidence intervals and test statistics for each of the symptom measure for the total sample are outlined in Table 2, and within-group effect sizes (Hedges *g*) are shown in Table 3. Quartile dispersion plots, illustrating the rate of YBOCS-SR percentage change, are presented in Fig. 1. Analyses of pre-treatment to post-treatment change for the total sample indicated statistically significant symptom reductions for the YBOCS-SR (18 %; $p_{pooled} < 0.001$), and each of the secondary measures including the PHQ-9 (27 %; $p_{pooled} < 0.001$), K-10 (17 %; $p_{pooled} < 0.001$), and GAD-7 (28 %; $p_{pooled} < 0.001$). The rate of change from post-treatment to three-month follow-up increased significantly by an additional margin for the YBOCS-SR (10 %), but no additional increases were observed for the secondary outcomes. The rate of change on the YBOCS-SR was not affected by time since implementation (2013–2014, $\exp(\beta)_{2014} = .973$ (0.813–1.165); to 2013–2019, $\exp(\beta)_{2019} = .948$ (0.827–1.089), $Wald\chi^2 = 21.98$, $p = .263$).

Effect sizes were moderate on the primary outcome measure (YBOCS-SR) at post-treatment ($g = .57$) and large at 3-month follow up ($g = .90$). A series of sensitivity analyses that did not include a missing cases replacement procedure resulted in comparable estimates of change, and statistical test conclusions. The results of these sensitivity analyses are presented in Tables 4 and 5.

3.5. Remission and adverse events

The spectrum of YBOCS-SR symptom change was dichotomised into clinically meaningful categories of improvement, non-response and deterioration for the full sample. Following the RCI formula, a threshold of 9 points or more was used to classify improvement and deterioration events. At post treatment 16 % [11%–21%] of the sample was classified as having made significant improvement, and 2.1 % were classified as deteriorated in their symptoms. At three-month follow-up, improvement increased to 24 % [16%–33%] and deterioration was not observed. Using the Farris et al. (2013) criteria, 22 % [16%–28%] of the full sample met the criteria for treatment response at post-treatment and 36 % [26%–45%] met the criteria for treatment response at follow up.

3.6. Benchmarking analyses

The estimates of symptom change from the routine care sample was contrasted with a benchmark in Tables 2 and 3. As outlined in Table 2, the YBOCS-SR pre-treatment to post-treatment percentage change in

Table 2
Estimated Marginal Means, Percentage Reduction in Symptoms and Test Statistics for Total Sample (ITT).

Routine Care (Effectiveness) Data							
	Estimated Marginal Means (95 % CI)			Change over time			
				Pre-treatment to post-treatment		Pre-treatment to 3-month follow-up	
	Pre-treatment	Post-treatment	3-month follow up	Δ%	*p* value	Δ%	*p* value
YBOCS-SR	21.69 (20.01–23.36)	17.77 (15.77–19.77)	15.72 (13.44–18.00)	18 % (13–23)	< .001	28 % (22–33)	< .001
PHQ-9	10.80 (9.04–12.55)	7.88 (5.93–9.83)	7.91 (5.00–10.82)	27 % (18–36)	< .001	27 % (13–41)	< .001
K-10	17.58 (15.35–19.82)	12.80 (10.05–15.55)	12.94 (10.01–15.87)	17 % (12–22)	< .001	17 % (11–22)	< .001
GAD-7	12.37 (10.82–13.92)	8.90 (6.11–11.69)	8.71 (7.14–10.28)	28 % (17–40)	< .001	30% (23–36)	< .001
Benchmarking (Efficacy) Data (Wootton et al., 2019)							
	Estimated Marginal Means (95 % CI)			Change over time			
				Pre-treatment to post-treatment		Pre-treatment to 3-month follow-up	
	Pre-treatment	Post-treatment	3-month follow up	Δ%	*p* value	Δ%	*p* value
YBOCS-SR	22.52 (21.34–23.71)	15.42 (13.67–17.17)	14.74 (12.49–16.99)	32 % (24–39)	.01	35 % (25–45)	< .001
PHQ-9	11.12 (9.78–12.46)	8.24 (6.27–10.21)	9.43 (6.78–12.07)	26 % (8–44)	< .001	15 % (−9 to 39)	.20

Note. YBOCS-SR – Yale-Brown Obsessive Compulsive Scale, ten item scale; PHQ-9 - Patient health questionnaire, nine-item scale; GAD-7 – Generalised anxiety disorder scale, seven-item scale. K-10 - The Kessler Psychological Distress Sclae. Longitudinal GEE models for quantifying change over time specified $Y_{ij} \sim \log(\mu_{ij}) = \beta 0 + \beta 1 t_j + \in_{ij}$; with *mi* × *mi* working correlation matrix for each $Y_{ij,}$ $Var(Y_{ij}) = \Phi v(\mu_{ij})$ y; where Φ is a scale parameter and v(·) is a gamma variance function $Gamma(\mu_{ij}, \alpha); \in_{ij} \sim N(0, \sigma^2)$. All model estimates were derived from a conditional (missing at random; MAR) multiple imputation procedure (pooling iterations) under the intention to treat principle.

Table 3
Effect Sizes (Hedges g with 95 % CI) for Total Sample.

Measure	Sample	Pre-treatment to post-treatment	Pre-treatment to 3-month follow-up	Post-treatment to 3-month follow-up
YBOCS-SR	Routine care sample	0.57 (0.49 to 0.65)	0.90 (0.82 to 0.98)	0.30 (0.22 to 0.38)
	Benchmark (Efficacy) Data (Wootton et al., 2019)	*1.25 (1.08–1.42)*	*1.23 (0.79–1.68)*	*−0.14 (−0.18 to 0.45)*
PHQ-9	Routine care sample	0.49 (0.41 to 0.57)	0.50 (0.42 to 0.58)	0.00 (-0.08 to 0.08)
	Benchmark (Efficacy) Data (Wootton et al., 2019)	*0.53 (0.38–0.69)*	*0.42 (0.01–0.84)*	*−0.07 (−0.42 to 0.28)*
K-10	Routine care sample	0.55 (0.47 to 0.63)	0.57 (0.49 to 0.65)	0.00 (-0.08 to 0.08)
GAD-7	Routine care sample	0.63 (0.44 to 0.82)	0.68 (0.48 to 0.87)	0.03 (-0.15 to 0.22)

Note. YBOCS-SR – Yale-Brown Obsessive Compulsive Scale, ten item scale; PHQ-9 - Patient health questionnaire, nine-item scale; GAD-7 – Generalised anxiety disorder scale, seven-item scale. K-10 - The Kessler Psychological Distress Scale.

routine care (18 %) was lower than the symptom change benchmark observed in the clinical trial setting (Wootton et al., 2019; 32 %). At three-month follow-up, the rate of YBOCS-SR change remained lower (28 %), but more comparable to the clinical trials benchmark (Wootton et al., 2019; 35 %). Given the statistical power of the sample (margin of 6%), the difference between the groups can be considered as slight, but statistically significant. For depressive symptoms (PHQ-9) comparable rates of change at post treatment were found between the clinical trial (Wootton et al., 2019) and ICBT provided as part of routine care (27 % in the current study vs. 26 % in the benchmark study), with superior results at follow up in the routine care sample (27 %) compared with the clinical trial (15 %).

A comparison of the measure of standardised mean differences (effect sizes) also reflected slightly lower clinical symptom reduction within the routine care sample; on the YBOCS-SR but not the PHQ9 outcomes. The YBOCS-SR pre-post change of the clinical trial significantly exceeded the margin of 0.2 difference for both pre-treatment to post-treatment and pre-treatment to follow-up time points. On the secondary outcomes however, the changes on the PHQ-9 were comparable to the benchmark pre-treatment to post-treatment effect size, and even superior to the benchmark on the pre-treatment to follow-up effect.

4. Discussion

The aim of the present study was to report on the effectiveness of the Australian MindSpot Clinic OCD Course in a large clinical sample treated as part of routine care in a Phase IV clinical trial. It was hypothesised that 1) participants completing the MindSpot OCD Course as part of routine-care would report clinically significant improvements in their OCD symptoms from pre-treatment to post-treatment (with large within-group effect sizes); 2) that symptom improvements would be durable over a three-month time frame; and 3) that results obtained would be similar to those seen in ICBT for OCD efficacy trials. Our hypotheses were partially supported.

We hypothesised that participants would experience a significant reduction in OCD symptoms, with large within-group effect sizes. At post-treatment participants experienced a significant reduction in OCD symptoms, however effect sizes were medium in size. We hypothesised that any improvements in symptoms would be maintained at three-month follow up. Our results indicated that symptoms further reduced at three-month follow up, with effect sizes in the large range seen from pre-treatment to three-month follow up. There was also a significant improvement in symptoms on the secondary outcome measures (PHQ-9, K-10, and GAD-7), resulting in medium effect sizes at post-treatment and three-month follow-up.

We hypothesised that outcomes from routine practice would be equivalent to those seen in ICBT efficacy studies, however, benchmarking analyses indicated that at post-treatment the percentage change in routine care was lower than symptom change observed in a recent clinical trial using the same ICBT program (Wootton et al., 2019). While at three-month follow up the percentage change in the effectiveness study was more similar to the symptom change seen in the clinical trial, the difference between the groups was still considered to be outside of the 'good enough principle' (Minami et al., 2008). It is also important to note that the within-group effect sizes at post-treatment are also below those seen in the face-to-face CBT for OCD efficacy ($d = 1.52$; Eddy, Dutra, Bradley, & Westen, 2004) and effectiveness studies ($d = 1.32$; Stewart & Chambless, 2009), however the three-month follow up effect sizes in the routine care ICBT sample were more similar to these estimates. In order to compare ICBT to traditional face-to-face treatment, controlled trials comparing the two approaches are needed.

Benchmarking for the secondary outcome measures could only be applied for the PHQ-9 as the other outcome measures were not used in the clinical trial. These analyses indicated that the effects found in the effectiveness trial were consistent with the clinical trial at post-treatment (Wootton et al., 2019), and were superior to the clinical trial at follow-up using the 'good enough principle' (Minami et al.,

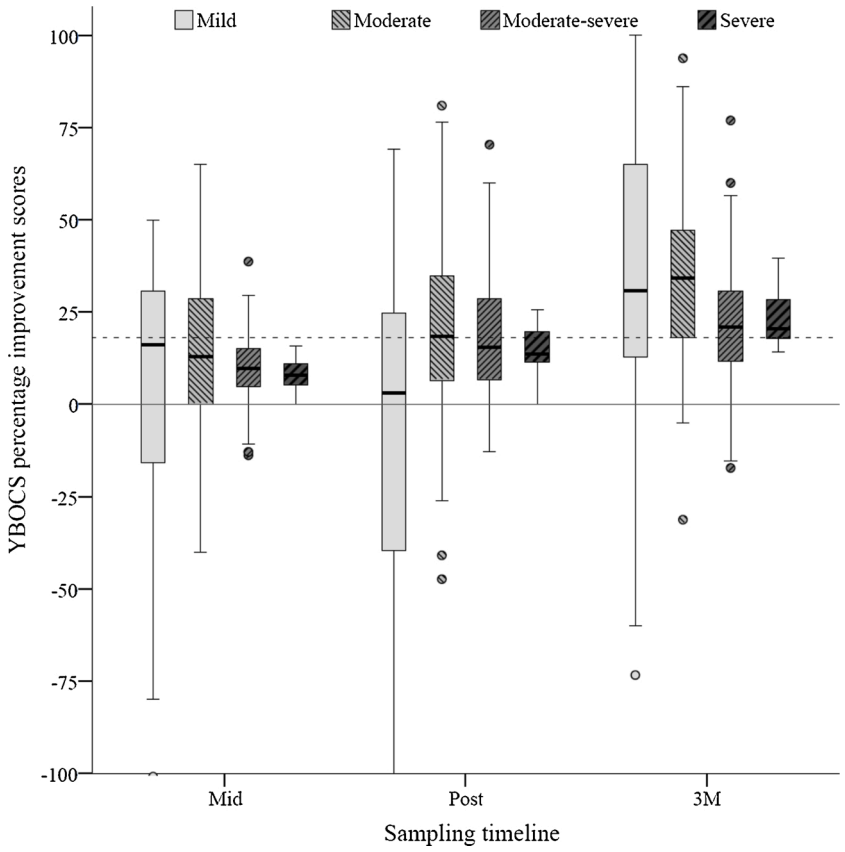

Fig. 1. Change Score Dispersion Plot.

Table 4
Means, Percentage Reduction in Symptoms and Test Statistics for Completers of Post-treatment and Follow-up Questionnaires (N = 145).

	Means (95 % CI)			Change over time			
	Pre-treatment	Post-treatment	3-month follow up	Δ% pre-treatment to post-treatment	Δ% Pre-treatment to 3-month follow-up	*p* value	*p* value
YBOCS-SR	21.69 (20.01–23.36)	17.21 (15.11–19.31)	16.81 (13.04–20.58)	21 % (16–26)	22 % (14–31)	< .001	< .001
PHQ-9	11.02 (9.26–12.79)	7.63 (5.85–9.42)	7.25 (4.94–9.56)	31 % (22–39)	34 % (24–45)	< .001	< .001
K-10	17.63 (15.39–19.87)	13.12 (10.46–15.77)	12.53 (9.28–15.78)	16 % (11–21)	18 % (12–24)	< .001	< .001
GAD-7	12.43 (10.89–13.96)	8.57 (6.85–10.29)	7.66 (5.15–10.17)	31 % (24–38)	38 % (28–49)	< .001	< .001

YBOCS-SR – Yale-Brown Obsessive Compulsive Scale, ten item scale; PHQ-9 - Patient health questionnaire, nine-item scale; GAD-7 – Generalised anxiety disorder scale, seven-item scale. K-10 - The Kessler Psychological Distress Scale. Longitudonal GEE models for quantifying change over time specified $Y_{ij} \sim \log(\mu_{ij}) = \beta 0 + \beta 1 t_j + \in_{ij}$; with *mi* ×*mi* working correlation matrix for each Y_{ij}, $Var(Y_{ij}) = \Phi v(\mu_{ij})$ y; where Φ is a scale parameter and v(·) is a gamma variance function $Gamma(\mu_{ij}, \alpha); \in_{ij} \sim N(0, \sigma^2)$. All model estimates were derived from the observed data only, with missing cases patterns overlooked under the MCAR (missing completely at random) assumption.

Table 5
Effect Sizes (Hedges g with 95 % CI) for Completers of Post-treatment and Follow-up Questionnaires (N = 145).

Measure	Pre-treatment to post-treatment	Pre-treatment to 3-month follow-up	Post-treatment to 3-month follow-up
YBOCS-SR	0.57 (0.49 to 0.65)	0.9 (0.82 to 0.98)	0.3 (0.22 to 0.38)
PHQ-9	0.49 (0.41 to 0.57)	0.5 (0.42 to 0.58)	0.1 (-0.09 to 0.29)
K-10	0.47 (0.28 to 0.67)	0.61 (0.42 to 0.8)	0.09 (-0.1 to 0.28)
GAD-7	0.62 (0.42 to 0.81)	0.83 (0.63–1.02)	0.2 (0.01 to 0.38)

YBOCS-SR – Yale-Brown Obsessive Compulsive Scale, ten item scale; PHQ-9 - Patient health questionnaire, nine-item scale; GAD-7 – Generalised anxiety disorder scale, seven-item scale. K-10 - The Kessler Psychological Distress Scale.

2008). The improvement in symptoms of depression may reflect a reduction in overall levels of distress associated with OCD symptoms. Utilising a transdiagnostic treatment approach which targets OCD and depressive symptoms simultaneously may improve treatment outcomes for depression and future research may wish to compare disorder specific and transdiagnostic ICBT treatment for OCD in the future.

Although patients in the routine care sample did not do as well as the participants in the efficacy trial, there was nevertheless a good overall response to treatment. Studies comparing the outcomes of ICBT in clinical trials and routine care in other patient groups found smaller differences. For example, Staples et al. (2019) used a similar methodology to compare the results of young adults completing a transdiagnostic anxiety and depression ICBT intervention in a clinical trial compared with routine care and found that both samples obtained

equivalent outcomes on the primary outcome measures. Similar results were found when investigating a transdiagnostic ICBT intervention for older adults (Staples, Fogliati, Dear, Nielssen, & Titov, 2016). A possible explanation for the comparatively good results in routine care, where participants may not have been as motivated or as closely followed up as in the trials, was that the symptom ranges in the routine care samples were higher and hence there was greater room for improvement from what was known to be an effective treatment. However, the sample of OCD patients in routine care was more heterogenous than the clinical trial sample, which was specifically recruited because of the presence of OCD symptoms, whereas the routine care sample may have included participants with a range of anxiety disorders. Given the large body of evidence now demonstrating the efficacy of ICBT for a variety of diagnostic groups (Carlbring, Andersson, Cuijpers, Riper, & Hedman-Lagerlöf, 2018) it is important that future research continue to explore whether there are any differences in outcomes when these interventions are widely disseminated as part of clinical practice and, if so, the reasons for these discrepancies. Thus, future Phase IV clinical trials are needed to improve our understanding of the effectiveness of ICBT interventions for OCD when delivered as part of routine care.

Despite the clinical trial and routine care samples using the same intervention there are a number of important differences between patients participating in these studies that should be highlighted. Firstly, individuals who were considered 'high risk' (i.e., a score of $\geq$ 20 on the PHQ-9, reporting suicide plans or intention, or a recent history of suicide attempts or deliberate self-harm behaviours) were screened out of the clinical trial (Wootton et al., 2019), whereas those in the effectiveness trial may have had elevated levels of risk (excluding suicide ideation with intent and plan) and may have had any level of depressive symptoms. Higher pre-treatment depressive symptoms have been demonstrated to negatively affect treatment outcome in face-to-face CBT for OCD (Abramowitz & Foa, 2000; Steketee, Eisen, Dyck, Warshaw, & Rasmussen, 1999), and this may explain some of the differences in outcomes between the groups in the current study.

Secondly, it is also important to highlight that the assessment process, as well as the treatment delivered in previous ICBT studies using the treatment protocol (Wootton et al., 2011, 2013, 2014, 2019) were conducted by clinical psychologists with considerable experience in the assessment and treatment of obsessive compulsive and related disorders, whereas the clinicians managing patients at MindSpot are more generalist in nature (Titov et al., 2020) and more consistent with the experience of clinicians seen in the community. Future research may wish to investigate whether therapist experience with OCD is related to patient outcomes and/or whether targeted training and supervision can enhance outcomes for patients with OCD who complete ICBT as part of routine care.

Thirdly, participants in the routine care sample may have completed the treatment in either a guided or self-guided fashion, whereas individuals in the clinical trial (Wootton et al., 2019) completed the treatment in a self-guided fashion. Unfortunately, in this sample the data was not available to do subgroup analyses and future Phase IV clinical trials of ICBT for OCD may wish to examine such differences. This is especially important given the discrepant findings on whether guided or self-guided ICBT treatments are most effective. For instance, while some meta-analyses have indicated that guided treatments are more effective than self-guided treatments (Spek et al., 2007) more recent research has demonstrated that self-guided and clinician-guided ICBT interventions are equally efficacious as long as the program is supported by regular prompts and reminders (Dear et al., 2015; Titov, Dear, Staples, Bennett-Levy et al., 2015; Titov, Dear, Staples, Terides et al., 2015). Future research may wish to examine whether self-guided ICBT interventions are less effective than clinician-guided ICBT interventions in a controlled trial.

It is also important to highlight that best-practice face-to-face treatment for OCD is considerably time intensive, often utilising 20−40 hours of clinician time (Cottraux et al., 2001; Foa et al., 2005). The treatment protocol used in the current study requires much less clinician time (approximately 90 min per patient when provided in a guided format) (Wootton et al., 2013) and is delivered in 8 weeks. Thus it is unsurprising that the effects of routine ICBT treatments after 8 weeks are only medium in size, which extend to large effects once patients have the chance to implement and practice all of the skills from the intervention (i.e., at treatment follow up). In order to ascertain how to best provide treatment for individuals with OCD in the most cost efficient way it is important for future research to investigate the efficacy of ICBT versus face-to-face treatment for OCD in controlled trials, and also to investigate whether adding a higher intensity treatment, such as face-to-face CBT for those who do not respond to ICBT yields any additional treatment benefit (i.e., stepped-care interventions). Future research may also investigate whether extending the ICBT timeframe results in improved outcomes at post-treatment.

In the current study 16 % of patients met criterion for reliable improvement at post-treatment and 24 % met this criterion at follow-up. At post-treatment only 2% of patients experienced reliable deterioration, which reduced to 0% at follow-up. These results highlight that the MindSpot OCD course is a safe intervention for wide scale dissemination in Australia. The deterioration rates seen in the current study for individuals completing the OCD Course are lower than those seen in the ICBT literature more generally (Karyotaki et al., 2018).

While the current study highlights the effectiveness of the OCD Course in a treatment as usual sample it is also important to acknowledge the limitations of the present study. Firstly, this was a Phase IV clinical trial designed to examine the effectiveness of an intervention that has previously been demonstrated to be efficacious in randomized controlled trials (Wootton et al., 2013; Wootton et al., 2019). Consistent with this the trial does not contain a control group. While the lack of a controlled design does not control for spontaneous remission it is important to highlight that many previous RCTs in OCD have demonstrated that symptoms do not spontaneously remit, with no change in symptoms for waitlist controls (Wootton et al., 2013). Future research in this area may wish to compare the findings of ICBT for OCD with outcomes from those patients who are treated face-to-face in the community.

Secondly, participants in the current study completed an assessment with a generalist clinician, however this was not a structured diagnostic interview and thus it is possible that not all individuals included in the study met criteria for OCD. Similarly, OCD symptoms in the present study were examined with the self-report version of the YBOCS and while concordance between self-report and clinician-administered versions of the YBOCS is acceptable (Steketee et al., 1996), future research may wish to assess OCD symptoms using the clinician-administered YBOCS. It is also important to highlight that there was significant attrition related to study questionnaires, for instance 35 % of participants did not complete post-treatment questionnaires and 65 % did not complete 3-month follow-up questionnaires. While this level of attrition is problematic in an efficacy trial, it is consistent with response rates in other similar Phase IV clinical trials (Dear et al., 2019), where there are generally lower levels of commitment from consumers to complete questionnaires.

Finally, individuals in the routine care group and clinical trial group differed in important pre-treatment clinical variables (e.g., medication use), thus future research should aim to replicate our findings. Additionally, consistent with the Phase IV clinical trial approach, treatment outside of the MindSpot program (pharmacological and psychological) was not monitored and it is possible that patients were engaged with another care provider at the same time. Future research may wish to investigate the incidence of such additional treatment and account for such treatment in analyses.

In summary, the results of this Phase IV clinical trial demonstrate that ICBT for OCD is promising for patients seeking treatment for their symptoms in routine care. The results of routine care were lower than clinical trials at post-treatment, but become more similar at follow-up,

perhaps owing to the continual practice of skills during the follow-up period, and indicating that longer treatment periods may be warranted. Future research may wish to examine how to improve outcomes at MindSpot to ensure patients with OCD achieve optimal outcomes and also to examine improvement in other measures, such as improvement in disability. A replication of the study would also be welcomed as the number of patients completing the MindSpot treatment continue to grow. An examination of the predictors of outcome in future studies would also elucidate who responds best to ICBT for OCD in routine care and enhance our ability to match patients to the most clinically- and cost-effective treatment.

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