Efficacy of Internet-Based Cognitive Behavioral Therapy for Adults with Obsessive-Compulsive Disorder: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

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Abstract:

Introduction: The COVID-19 pandemic has brought tremendous impact to mental health management in patients with obsessive compulsive disorder (OCD). Internet-based cognitive behavior therapy (I-CBT) has been demonstrated to be efficacious on alleviating symptoms among adult patients with OCD.

Purpose of study: This systematic review and meta-analysis aims to evaluate the efficacy of Internet-Based Cognitive Behavioral Therapy for adult OCD patient.

Methods: This review selects randomized controlled trials found in multiple databases searching for studies implementing I-CBT for OCD up to September 7th, 20212021, using determined inclusion criteria, such as OCD patient with study population only adults age population, assess obsessive compulsive score and assess depression, and exclusion criteria such as unsuitable study design, studies with incomplete outcome data, and studies in languages other than English. This review was arranged based on PRISMA guideline. **Results and Discussion:** Our review includes 6 RCTs with a total of 590 participants. Quantitative analysis of mean differences was performed using Review Manager 5.4 in continuous, random-effects model. I-CBT demonstrates promising efficacy in reducing adverse psychosocial conditions in OCD patients including obsessive compulsive symptoms (pooled MD: -4.49 [95%CI: -6.78 – (-2.19)]; p=0.0001) and depression (pooled MD: -1.97 [95%CI: -3.61-(-0.34)]; p=0.02). **Conclusion:** I-CBT presents a promising solution for alleviating symptoms in OCD patients. We also recommend further studies to be done especially in developing countries to evaluate the cost effectiveness and feasibility of I-CBT.

Keywords: Obsessive compulsive disorder, Internet-based, Cognitive behavioral therapy, Adults, Efficacy

Introduction:

With the prevalence of 2-3% worldwide and its early development in life, obsessive compulsive disorder or OCD is a mental health condition that has tremendous effect on public health.[1] Obsessive compulsive disorder (OCD) is a condition where intrusive thoughts and compulsive action are present when trigger(s), such as behavior or specific conditions, are met. The obsession can arise from common fears, such as contamination, unacceptability, aggression, hoarding, or symmetry concerns. Obsessive thoughts that are present can bring out many implications to action and mostly on their mental distress, anxiety, and excessive worries which occurs more frequently than we thought it would be.[2]

The COVID-19 pandemic has also badly affected this condition. With the condition, people with OCD are constantly intruded with distress from virus related thoughts and hand washing behavior.[3] With frequent triggers and inconsistent flow of information, people with OCD, especially contamination fear, has shown to have more severe and frequent symptoms. This condition has also pushed people with OCD to have personal coping mechanisms as physical therapy is restricted.[4,5] Other than that, the high distress caused by the pandemic has also badly impacted people with no signs of OCD to have symptoms too.[3]

Current study shows that cognitive behavioral therapy (CBT), especially exposure and response prevention (ERP) which is done by face-to-face meeting, is more favorable to be alleviate OCD symptoms than pharmacological treatment.[6,7] However, with the present condition, I-CBT or internet-based cognitive behavioral therapy has gained more popularity with the ease of use and effective implementation. With the advancement in technology, this adaptation of CBT in the internet has found its place to be one of the alternative strategies to alleviate the condition. Many other symptoms such as anxiety, stress, and depression, have been proven to be decreased and controlled by I-CBT proven by the growing amount of research right now.[4,8]

However, to our knowledge, there has not been any review or

meta-analysis done to conclude the findings. Therefore, we conducted a systematic review and meta-analysis to further promote the use of I-CBT in Indonesia, especially for OCD patients.

Material and Methods:

This systematic review and meta-analysis were conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist which can be accessed through http://www.prisma-statement.org/

Search strategy

A comprehensive literature search was performed in multiple databases including PubMed, Scopus, Cochrane, ProQuest, Science Direct, and EBSCOhost, searching for studies implementing internet-based cognitive behavioral therapy for obsessive compulsive disorder from inception up to September 7th, 2021 with the following keywords: ("internet" [MeSH Terms] OR internet[Text Word] OR online) AND ("cognitive behavioral therapy"[MeSH Terms] OR cognitive behavioral therapy [Text Word]) AND (obsessive[All Fields] AND compulsive[All Fields]) AND efficacy). The detailed keywords for each database are attached in **Appendix 1**.

Study eligibility criteria

Along with study screening, the authors predetermined the following inclusion criteria: (1) type of study, clinical randomized controlled trials; (2) study population, only adults age

population; (3) intervention, internet-based cognitive behavioral therapy; (4) outcomes, which include obsessive compulsive score, depression, quality of life, and other secondary parameters reported. Meanwhile, the exclusion criteria are set to: (1) unsuitable study design, including cohort studies, preclinical studies, commentaries, conference abstracts, and letters to the editor; (2) studies with incomplete outcome data; (3) studies which are not completed yet at the time of retrieval; (4) studies with irretrievable full-text articles; (5) studies without a control group; and (6) studies in languages other than English. Furthermore, duplicate removal was performed using EndNote X9 software. Screening of titles and abstracts of studies was carried out according to criteria of accessibility by three independent reviewers. Any disagreements were discussed into consensus. The detailed planned procedure is illustrated in **Figure 1**.

Data extraction

We predetermined the outcome sheet in tabular form to include the following data to be extracted: (1) author and year of publication; (2) study characteristics, including study design and location of study; (3) study population, including sample size, mean age, and other related

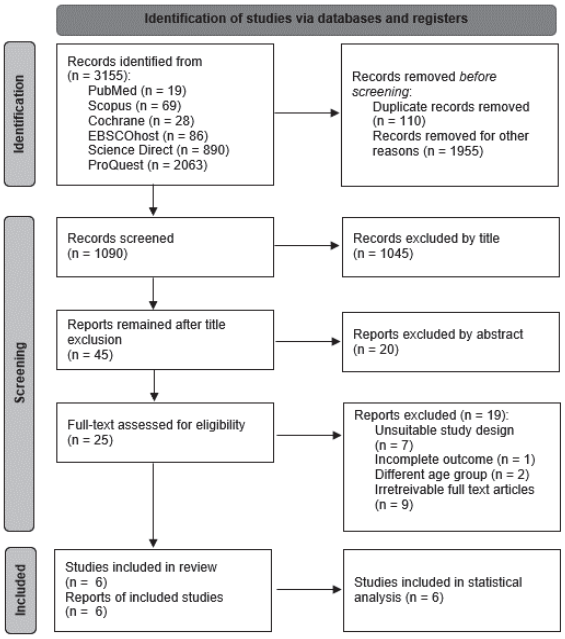

Figure 1. Diagram flow of literature search strategy

characteristics; (4) intervention, type of internet-based cognitive behavioral therapy used and duration of follow-up; and (5) study outcomes, including comparative indicators, values pre- and post-intervention, as well as effect size in Cohen's d and significance (p) values. Qualitative characteristics were extracted by two reviewers, and an independent third author rechecked accuracy of extracted data meanwhile performing statistical analysis. Moreover, we present the extracted data in detail in **Table 1**.

Quality assessment

Quality of each study was accessed using the Cochrane Risk of Bias 2.0,[9] which evaluates 5 domains including randomisation bias, bias due to deviations from intended interventions, missing outcome data, outcome measurement, and bias in reporting results. The overall quality of study is then converted based on the Agency for Healthcare Research and Quality (AHRQ) standards. This assessment was performed by three independent reviewers and if there is any disagreement, resolution would be made based on consensus by the three reviewers.

Statistical analysis

We performed statistical analysis using Review Manager ver. 5.4 (The Nordic Cochrane Center, The Cochrane Collaboration, Copenhagen). The mean differences and standard deviations (SDs) were extracted from studies, and we interpreted the pooled effects. We utilized continuous, DerSimonian-Laird random effects

model as proposed by Riley et al, since we considered that indecipherable heterogeneity could be discovered from studies.[10] Heterogeneity was further evaluated using I^2 statistics, with cut-off limits of 0%, 25%, 50%, and 75% as insignificant, low, moderate, and high heterogeneity, respectively.[11] Additionally, we performed sensitivity analysis following the Duval and Tweedie's trim-and-fill method to identify any outlier study.

Results and Discussion:

Search results and study selection

Initial search is conducted using previously mentioned strategies from PubMed, Scopus, Cochrane, ProQuest, EBSCOhost, and ScienceDirect resulted in a total of 3,155 studies (**Figure 1**). Before the screening process, we exclude 110 studies which are either deduplicated, 1,955 studies which are marked as ineligible by automation tools and other reasons, such as ineligible language. Furthermore, 1045 studies and 20 studies were excluded after title screening and abstract screening, respectively. Studies which are not related to our main topics are excluded in this phase. In addition, 19 studies were further excluded since 7 studies have unsuitable study design, 6 studies use inappropriate intervention type, and 9 studies were not available in full text version. The final search yielded in a final nine studies, consisting of mostly randomized controlled trials to be included in further analysis.

Publication bias

Critical appraisal was conducted using Cochrane Risk of Bias 2.0 for randomized controlled trials criteria which is then categorized into low-risk bias, some concerns, or high-risk bias. Detailed descriptions of each domain are available on **Appendix 2**. We found no study with high risk of bias. We only found one study by Schroder et al which considers the need of some concerns. However, the reported need of concerns is only due to no information about the randomization process or bias in deviations from intended interventions because the participants are aware of their assigned interventions which is relatively unavoidable as in this study, unguided I-CBT were given. Nevertheless, the other studies are evaluated as having low risk of bias, thus, may be concluded that our study included overall good quality of studies.

Mechanisms of I-CBT for OCD patients

Current available gold standard treatment for OCD is cognitive behavioral therapy which is given face-to-face with the patient at the healthcare facilities.[6] Ironically, a lot of patients are late or cannot get CBT because of the barrier of the cost, time, and stigmatization.[12–15] Yet, the COVID-19 pandemic also adds even

Table 1. Study Characteristics

			Study characteristics				Study Outcomes				
Studies, year	**Location**	**Study Design**	**Sample size; mean age**	**Sample characteristics**	**Interventions**	**Follow-up duration**	**Measured Parameters**	**Intervention Group (Mean; S.D)**	**Control Group (Mean; S.D)**	**Effect Size (Cohen's d)**	**P-value**
Andersson et al, 2012	Sweden	RCT	101 patients ICBT : 33 y (19-62 y) ; Control : 35 y (18-67 y)	Patients with primary diagnosis of OCD, without co-morbidity as primary condition, use of psychotropic was allowed (stable for 2 months), without having CBT for past 2 years, other psychological treatment, alcoholalcohol, or drug abuse, minimal or extreme OCD, hoarding association, suicidal ideation, axis 2 diagnosis, or any	OCD patients given either 10 weeks of ICBT (n=50) or attention control condition (n=51)	4 months	YBOCS OCI-R MADRS-S GAF	12.94 (6.26) 12.50 (10.15) 8.90 (6.67) 65.78 (8.65)	18.88 (4.18) 19.22 (11.52) 10.16 (6.94) 60.18 (10.94)	1.12 (0.69-1.53) 0.62 (0.21-1.02) 0.89 (0.47-1.29) 1.20 (0.76-1.61)	<0.001 <0.001 <0.05 <0.01

				physical illness that could interfere							
Andersson et al, 2014	Sweden	RCT	101 patients Booster: 36.39 y; Control: 37.32 y	Patient with principal diagnosis of OCD with use of psychotropic medication was allowed (stable for 2 months), without minimal or extreme OCD, hoarding symptoms, and No. co-morbidity	Patients were randomized to a booster program (n=47) or no booster program (n=46)	4 months	YBOCS GAF MADRS-S	11.37 (6.61) 73.15 (12.46) 8.35 (6.75)	12.05 (6.63) 72.37 (13.43) 7.55 (5.67)	1.72 1.36	<0.05 <0.05
Mahoney et al, 2014	Australia	RCT	86 patients I-CBT : 37.69 y; TAU : 40.46 y	Patient with clinically significant symptoms of OCD without psychosis, significant alcohol dependence, suicidal ideation, or significant cognitive deficits	Patients were randomized to immediate I-CBT group (n=44) or treatment as usual group (n=42)	3 months	DOCS OBQ-20 K10 PHQ-9	19.83 (12.71) 70.71 (25.53) 19.75 (5.87) 7.21 (4.24)	29.11 (12.21) 92.31 (26.07) 26.97 (6.72) 11.23 (5.11)	0.78 (.29-1.26) 0.82 (.33-1.30) 1.12 (.63-1.60) 0.84 (.35-1.32)	<0.001 0.001 <0.001 <0.001

Herbst et al, 2014	Germany	RCT	34 patients ISG : 38.19±8.80 y (28-59 y) WLCG : 33.22±9.50 y (19-55 y)	Patient with OCD as their primary disorder according to DSM-IV and doesn't have another relevant current or past mental disorder.	Patients were randomized to 14 sessions of ICBT (n=16) or waiting-list control group (n=18)	8 weeks and 6 months	Y-BOCS SR Y-BOCS SR obsession Y-BOCS SR compulsions OCI-R BDI-II	14.44±5.90 7.25±2.95 7.19±3.65 15.56±8.93 7.62±7.54	19.33±6.46 8.50±3.91 10.83±3.73 24.11±10.84 12.44±8.61	0.82 0.34 0.95 0.87 0.56	<0.001 0.007 <0.001 <0.001 <0.001
Schroder et al, 2020	Germany	RCT	128 patients Intervention = 41.45 (SD 12.15) Control = 38.98 (SD 11.55)	Patient with clinically significant symptoms of OCD without psychosis, significant alcohol dependence, suicidal ideation, or significant cognitive deficits	Patients with self-reported OCD are randomly allocated to unguided I-CBT (n=64) or care-as-usual (n=64) for 8 weeks	8 Weeks	Y-BOCS WHO-QoL PHQ-9 I-8 RSES IQ-24	17.38 (7.35) 76.87 (13.48) 9.87 (5.62) 24.64 (3.17) 28.32 (7.53) 62.70 (14.74)	18.98 (6.17) 76.47 (11.10) 10.33 (5.84) 23.80 (3.25) 26.51 (7.08) 63.69 (13.69)	0.3 0.1 0.2 0.1 0.3 0.1	0.176 0.758 0.445 0.265 0.017 0.485
Wootton et al, 2019	Australia	RCT	140 patients ICBT = 34.03 (18-64) WLC = 33.30 (19-59)	Patients with OCD scored at least 7 on DOCS, scored 14 on YBOCS and did not have suicidal plans or history of self-harm, no	Patients with OCD are assessed then randomly allocated to five lesson intervention delivered over 8 weeks to ICBT	8 Weeks and 3 Months	YBOCS-SR PHQ-9 DOCS (Total) DOCS (Main)	15.42 (13.67-17.17) 8.24 (6.27-10.21) 20.11 (16.97-23.24) 8.56 (7.39-9.73)	21.61 (20.31-22.91) 11.43 (10.06-12.79) 31.11 (27.2-35.02) 12.42 (11.43-13.4)	1.05 (0.89-1.21) 0.58 (0.43-0.73) 0.84 (0.69-1.00) 1.02 (0.86-1.17)	<0.001 <0.01 <0.005 <0.001

				severe symptoms, no reported psychotic illness, and no regular use of drinking alcohol.	group (n=65) or WLC group (n=75)						

Note: NR = Not reported; YBOCS : Yale–Brown Obsessive Compulsive Scale; OCI-R : Obsessive Compulsive Inventory - Revised; GAF : Global Assessment of Functioning; MADRS-S: self-rated Montgomery–Åsberg Depression Rating Scale; DOCS : Dimensional Obsessive-Compulsive Scale; OBQ-20 : Obsessional Beliefs Questionnaire-20 items; PHQ-9 : The Patient Health Questionnaire-9; K-10 : Kessler 10-item Psychological Distress Scale; OCI-R : Obsessive-Compulsive Inventory-Revised; BDI-II: The Beck Depression Inventory-II; Y-BOCS SR: Yale-Brown Obsessive Compulsive Scale Sel Reported; WHO-QoL: World Health Organization Quality-of-Life Scale; I-8: Impulsivity-8; RSES: Rosenberg's Self-Esteem Scale; IQ-24: Insecure-Questionnaire-24; SD : standard deviation.

more urgency to make haste and find a solution that breaks the barrier.

I-CBT is a program that is delivered online and structured from treatment rationale, psychoeducation, cognitive treatment, and in vivo exposure and response prevention (ERP). The therapist is present to give support, assess the intervention, and giving feedback for the mental exercises. homework exercises.[12–16] By using I-CBT, it will save therapist's time and also gives the chance of getting feedback within 24 hours. According to study by Andersson et al, conventional face-to-face CBT spent an average of 540-900 minutes over a 10 week10-week period. Much lower than face-face CBT, patients only spent an average of 129 minutes over a 10 week period. [15,16] This treatment also removes the barriers from face-to-face CBT such as inconvenience, stigma, and personal embarrassment because I-CBT gives patients more privacy and anonymity. I-CBT is also cost-effective because I-CBT reduces travel cost because it is delivered online.[12,15]

Efficacy of I-CBT for obsessive compulsive symptoms

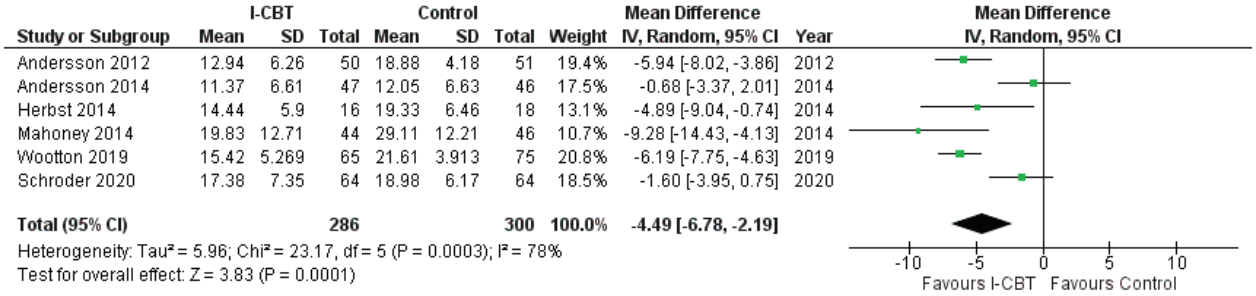

Figure 2A. Forest Plot of I-CBT Effectiveness for Obsessive Compulsive Symptoms

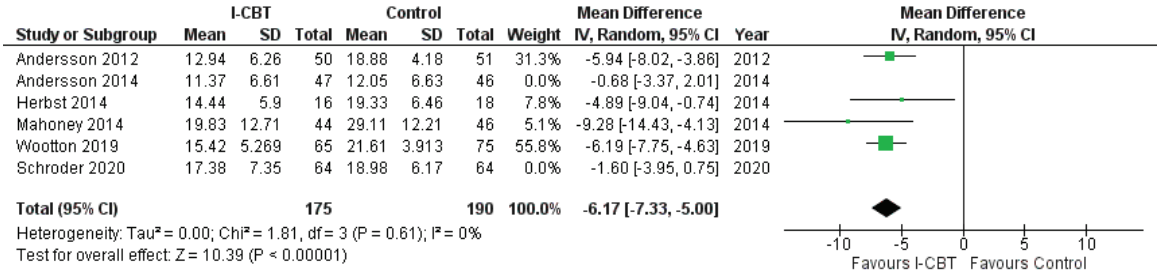

Figure 2B. Sensitivity Analysis of Studies Evaluating I-CBT for Obsessive Compulsive Symptoms

Patients with OCD are characterized by obsession and compulsion. Obsession is an unwanted intrusive thoughts, image, or impulses that are recurrent, persistent and lead to distress. In OCD, obsession is followed by compulsion which is a ritualized, repetitive, and intentional behaviour that aims to reduce and neutralize the distress from the obsessive content. Without any intervention OCD symptoms will worsen and affect the patient's social and work life.[12–18]

Six studies are included in our quantitative synthesis which demonstrated I-CBT as an effective treatment method for reducing obsessive and compulsive symptoms in adults with OCD, yielding a pooled mean difference (MD) value of -4.49 [p=0.0001; 95%CI: -6.78 – (-2.19)] (**Figure 2A and 2B**). Although relatively high heterogeneity has been found, with an I^2 value of 78%, our sensitivity analysis identified Andersson et al (2014) and Schroder et al's study as an outlier, and with its removal the heterogeneity has decreased to much lower value of 0%. When these studies are removed, the pooled MD is -6.17 [p=<0.0001, 95%CI: -7.33 – (-5.00)].[16,18] Andersson et al's study (2014) has shown inferior results compared to the other studies, which might be due to the type of the intervention, which compare between booster and no booster group, in opposition to other studies which compare I-CBT and treatment as usual (TAU) group.[16] On the other hand, Schroder et al's study has also shown inferior results which might be due to the use of unguided type of I-CBT. In this study, participants are given I-CBT without any guidance from the healthcare providers which might resulted in significantly less effective result compared to the other studies. Therefore, the guided type of I-CBT areis found to be more effective than the unguided type. The limited period of the intervention in the study was also concerned to affect the result.[18] However, we do not perform further subgroup analysis which aims to explore further the heterogeneity as there is lack of similarities between the two outlier studies in term of obsessive and compulsive symptoms.

Efficacy of I-CBT for depressive symptoms

Depression is a mood disorder that causes depressive episodes which make the person feel depressed, lose interest, and don't have energy to do activities. To be diagnosed with depression, at least five of nine depressive symptoms listed in the DSM-5 must be present. Which are sleep disturbance; interest/pleasure

reduction; guilt feelings or thoughts of worthlessness; energy changes/fatigue; concentration/ attention impairment; appetite/weight changes; psychomotor disturbances; suicidal thoughts; and depressed mood.[19,20]

Figure 3A shows the forest plot of I-CBT in reducing the occurrence of depression in adult patients with OCD. The pooled MD yields a value of -1.97 [p=0.02, 95%CI: -3.61-(-0.34)], with moderate heterogeneity (I^2=64%). Different type of assessment were used (i.e., MADRS-S, PHQ-9, BDI-II) but all of them are validated and have already been established.[12–16,18] Furthermore, as we performed sensitivity analysis in **Figure 3B**, we found that Andersson et al's (2014) and Schroder et al's study are again identified as an outlier studies with inferior results as explained in the outcomes of obsessive compulsive symptoms before. The most logical explanation would be due to different type of interventions given in those studies.[16,18] Recent meta-analyses by Karyotaki et al., also concluded that guided I-CBT is more effective than unguided I-CBT to reduce depression score for the patient which align with Schroder et al's study that show less effective result in reducing depressive symptoms.[18,21] Once removed, the heterogeneity is negligible (I^2=3%) w

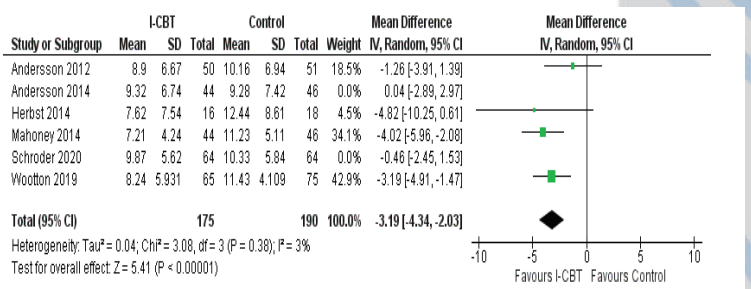

Figure 3B. Sensitivity Analysis of Studies Evaluating I-CBT For Depressive Symptoms

ith pooled MD yielding a value of -3.19 [p=<0.00001, 95%CI: -4.34-(-2.03)]. Nevertheless, subgroup analysis is not performed due to lack of similarities between the outlier studies in terms of depressive symptoms.

Other outcomes

Besides the efficacy of I-CBT to reduce obsessive compulsive and depressive symptoms, Schroder et al's study has also proven its positive impact to patient's quality of life, although not statistically significant.[18] Study by Wootton, et al., also shows that I-CBT has a high acceptability with 82% participants were either very satisfied or satisfied with the program and 96% participants would recommend it to their friends.[14] It also aligned with other study that prove acceptability of I-CBT is high (Herbst, et al., 2014; Schroder, et al., 2021).[13,18]

Applicability in Indonesia

All in all, there are at least three main reasons why this innovation might be suitable to tackle current problems in Indonesia. Firstly, the internet users in Indonesia have reached 73,7% of the total population that has increased around 8,9% last year due to the pandemic and the advancement of Palapa Ring. Therefore, the internet base is suitable and viable to be used to help OCD patients in Indonesia.[22]

Secondly, inadequate knowledge and misperception due to several cultural beliefs have worsened the situation. People with mental disorders are likely to be outcasted or locked in another place by their own family rather than being brought to healthcare facilities. Moreover, the lack of transportation facilities in rural areas might also make it more difficult for patients to reach healthcare facilities.[23]

Lastly, the number of mental health professionals in Indonesia is still limited. According to the WHO Mental Atlas (2017), Indonesia has only 3 mental health professionals for every 100,000 people which is much lower than the global median, 9 per 100,000 people. It makes the accessibility to reach mental health treatment more exclusive. By using I-CBT the treatment for mental health, especially OCD will be more effective and inclusive for everyone, including people in rural areas and low socio-economic backgrounds.[24,25]

Strengths and limitations

There are strengths and limitations of this meta-analysis. From our knowledge, this is the first meta-analysis of I-CBT efficacy on adult OCD patients. The result of the meta-analysis shows a promising and significant pooled MD results for I-CBT efficacy on adult OCD patients. The risk of bias assessment results for the studies are also low.

Some limitations should be considered even though our findings are promising. The heterogeneity is high because the I-CBT intervention and period for each study is different. The limited access to full text studies should be considered. The language barrier should also be considered as we only include English studies.

Conclusion

The COVID-19 pandemic has increased OCD symptoms occurrence and burden the therapy management of patients. Therefore, this increased the urgency of a solution for alleviating the symptoms and decreased its depression level. Our study has proven that I-CBT as a novel treatment for OCD has significantly reduce obsessive

compulsive symptoms and depression levels with high acceptability rate. Yet, it also increases a patient's quality of life and general health. The internet base in Indonesia can also boost I-CBT applicability in Indonesia, relieve the high burden of mental health workers, and reduce misperception and the lack of knowledge of mental health disorder in Indonesia. As a recommendation, we suggest further clinical studies assessing I-CBT use in Indonesian OCD patients as well as the advancement of internet quality and widen its scope especially in rural areas.

Declarations

Ethics approval and consent to participate

Not applicable.

Availability of data and material

Not applicable.

Conflict of interests

Authors declare no competing intention for completing this review.

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Not applicable.

Authors' contributions

Nathaniel Gilbert Dyson, Josh Nathaniel Jowono, Cokorda Istri Agung Dewinta Adnyani: All authors have contributed equally

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Appendices

Appendix 1. Search keywords and databases

Database	Search Keywords
PubMed	("internet"[MeSH Terms] OR internet[Text Word] OR online) AND ("cognitive behavioral therapy"[MeSH Terms] OR cognitive behavioral therapy[Text Word]) AND (obsessive[All Fields] AND compulsive[All Fields]) AND efficacy
Scopus	TITLE-ABS-KEY ((internet OR online) AND ("cognitive behavioral therapy" OR CBT) AND (obsessive OR compulsive OR OCD OR "obsessive compulsive disorder") AND efficacy)
Cochrane	(Internet AND Cognitive Behavior Therapy AND Obsessive Compulsive Disorder AND efficacy)
ProQuest	(Internet AND Cognitive Behavior Therapy AND Obsessive Compulsive Disorder AND efficacy)
ScienceDirect	(Internet or online) AND (Cognitive Behavior Therapy or CBT) AND (Obsessive OR Compulsive OR OCD OR Obsessive Compulsive Disorder) AND Efficacy
EBSCOhost	(Internet OR online) AND ("cognitive behavioral therapy" OR CBT) AND (obsessive OR compulsive OR OCD OR "obsessive compulsive disorder") AND efficacy

Appendix 2. Risk of Bias Assessment

Bias domain	Signalling questions	Response options	Authors; year of publication					
			Andersson et al; 2012	**Anderrson et al; 2014**	**Mahoney et al; 2014**	**Herbst et al; 2014**	**Schroder et al; 2020**	**Wootton et al; 2019**
Bias arising from the randomization process	1.1 Was the allocation sequence random?	Y / PY / PN / N / NI	Y	Y	Y	Y	Y	Y
	1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	Y / PY / PN / N / NI	Y	Y	Y	Y	N	Y
	1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	Y / PY / PN / N / NI	N	N	N	N	N	N
	Risk of bias judgement	**- / + / ?**	**- (low risk)**	**- (low risk)**	**- (low risk)**	**- (low risk)**	**? (some concerns)**	**- (low risk)**
Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	2.1. Were participants aware of their assigned intervention during the trial?	Y / PY / PN / N / NI	N	N	N	N	PY	N
	2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	Y / PY / PN / N / NI	N	N	N	N	N	N
	2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context?	NA / Y / PY / PN / N / NI	NA	NA	NA	NA	N	NA
	2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups?	NA / Y / PY / PN / N / NI	NA	NA	NA	NA	NA	NA
	2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?	NA / Y / PY / PN / N / NI	NA	NA	NA	NA	NA	NA
	2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Y / PY / PN / N / NI	Y	Y	Y	Y	Y	Y
	2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	NA / Y / PY / PN / N / NI	NA	NA	NA	NA	NA	NA
	Risk of bias judgement	**- / + / ?**	**- (low risk)**	**- (low risk)**	**- (low risk)**	**- (low risk)**	**? (some concerns)**	**- (low risk)**
Domain 2: Risk of bias due to deviations from	2.1. Were participants aware of their assigned intervention during the trial?	Y / PY / PN / N / NI	N	N	N	N	N	N