Should mindfulness-based cognitive therapy be used for psychosis? A systematic review of the literature and meta-analysis

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Summary. Background. In England, psychosis incidence is $31.7 \times 100,000$ persons per year. Mindfulness-based interventions for psychosis (MBIp) might reduce its symptoms; however, the research outcomes on its effect size (ES) vary considerably. This project aims to ascertain the existing evidence. **Methods.** Eight publications from a pool of over 260 studies were extracted and analysed at meta-analysis for ES as satisfying the inclusion criteria. **Results.** MBIp has a moderate ES (r=0.34; p<.001) on psychosis with a 95% confidence interval (CI) of 0.26-0.42 (small to high). **Discussion.** MBIp improves psychosis symptoms. However, the studies analysed show heterogeneity in ES. Hence only conditional recommendations can be made for MBIp.

Key words. Meta-analysis, mindfulness, psychosis, systematic review, therapy.

Introduction

CONTEXT

In England, psychosis incidence is 31.7×100,000 persons per year and 54% of them receive combined therapy consisting of psychotropic medication and psychological interventions, including cognitive behavioural therapy (CBT) and mindfulness-based interventions for psychosis (MBIp), which appear to be effective in reducing severe and lasting psychotic symptoms and are endorsed by the National Institute for Health and Care Excellence (NICE)1-5. A previous meta-analysis, a multicentric study with 101 patients with psychosis (PWP) and a randomised controlled trial (RCT) with 138 PWP, found a moderate effect size (ES) of MBIp in pre-post studies and a smallto-moderate effect when compared with treatment as usual (TAU)⁵⁻⁷. The authors work for the mental health services in England, where it is felt that MBIp could help PWP deal with distressing delusions and hallucinations.

La terapia cognitiva basata sulla mindfulness dovrebbe essere usata per la psicosi? Una revisione sistematica della letteratura e meta-analisi.

Riassunto. Background. In Inghilterra, l'incidenza di psicosi è di 31,7×100.000 persone all'anno. Gli interventi basati sulla terapia cognitiva fondata sulla mindfulness per la psicosi (MBIp) potrebbero ridurre i suoi sintomi; tuttavia, i risultati della ricerca sulla dimensione del suo effetto (ES) variano considerevolmente. Questo progetto mira ad accertare le prove esistenti. Metodi. Da un pool di oltre 260 studi solo otto pubblicazioni soddisfacenti i requisiti di inclusione sono state estratte e analizzate in meta-analisi per ES. Risultati. MBIp ha un ES moderato (r=0,34; p<0,001) sulla psicosi con un intervallo di confidenza del 95% (CI) di 0.26-0.42 (da piccolo ad alto). **Discussione.** MBIp migliora i sintomi della psicosi. Tuttavia, gli studi analizzati mostrano eterogeneità in ES. Quindi solo raccomandazioni condizionali possono essere fatte per la MBIp.

Parole chiave. Meta-analisi, mindfulness, psicosi, revisione sistematica, terapia.

DEFINITION OF TERMS

Mindfulness, originating from Buddhist meditation, is a practice that leads to awareness of the essence of the mind in an insightful and non-judgemental experience while dealing with reality as it is, empowering self-awareness, reducing anxiety and depression, decreasing rumination and obsessive worrying about things and lowering the evasion, repression and denial of ideas, perceptions and memories^{2,8-13}.

MBIp is psychotherapy usually conducted in groups in meetings of 40 minutes, with no silences and with instructions every 30-60 seconds to help PWP disengage from distressing hallucinations and delusions without the need to examine and challenge them¹⁴. MBIp can be delivered in the following fashions:

- Mindfulness-based-Stress-Reduction (MBSR) is an eight-week group therapy improving self-efficacy and acceptance during losses and limitations¹⁵.
- Mindfulness-based-Cognitive-Therapy (MBCT) is an eight-week group therapy teaching mindfulness skills¹⁶.

- Mindfulness-based-Psychoeducation-Program me (MBPP) helps PWP, especially those suffering from hallucinations, improve mindfulness and reduce rumination, stress and disruption¹⁷.
- Acceptance-and-Commitment-Therapy (ACT) helps PWP contact the present moment and their values and not take their thoughts literally¹⁸.
- Individual-Mindfulness-Therapy-for-Voices (iM-TV) helps PWP who suffer from auditory hallucinations¹⁹.
- Mindfulness-Based-Crisis-Intervention (MBCI) reinforces PWP's mindfulness during crises and goals setting²⁰.

According to DSM-5, psychosis is a pathology of mind, such as schizophrenia, schizoaffective disorder or drug-induced psychosis, presenting one or more of the following symptoms for one month or more²¹⁻²³:

- delusions or positive symptoms, as fixed and false beliefs held in the face of evidence to the contrary;
- perceptual hallucinations (auditory, visual, olfactory, tactile, taste and smell), as perceptions without an object;
- passivity experiences, as thoughts believed not to be originating from the self;
- thought (speech) disturbances, as disorganised and tangential thoughts with loose associations and neologisms or derailment;
- disorder of expression of emotions or negative symptoms with depression, flat affect, apathy, anhedonia, scarcity of speech and blunting:
- disorganised behaviour, including unusual, eccentric, aimless and restless activity or catatonia;
- psychomotor disturbances, including mutism, arousal, stupor, negativism, stiff posturing or flexibility.

AIM OF THE STUDY

Previous research on psychotherapy overestimates its efficacy, while MBIp studies have some methodological issues and are based on few randomised controlled trials (RCT)^{6,14,24}. The British Association for Counselling and Psychotherapy recommends using evidence-based practice (EBP) for intervention

evaluation and new psychotherapy policies²⁵. Therefore, the current systematic review (SR) will help endorse or reject the efficacy of MBIp and promote EBP by using an approach placed at the vertex of the evidence pyramid (SR, meta-analysis; figure 1) and apply statistically-based, bias-free, valid and verifiable methods to suggest conclusions and avoid procedures of little or uncertain efficacy for patients^{5,6,25-31}.

Methods

LITERATURE SEARCH

The Boolean search terms for secondary data were 'mindfulness,' 'psychosis,' 'patient*,' 'inpatient*,' 'psychiatry,' 'outcome*,' 'randomised controlled trial/RCT' and 'psychotherapy' (table 1). The search engines queried were PubMed, Google Scholar, Medline, Embase, PsycInfo, CINAHL and Cochrane Central Register of Controlled Trials. The inclusion criteria were quantitative, qualitative and mixed-method peer-reviewed research on outcomes, RCT, studies no older than five

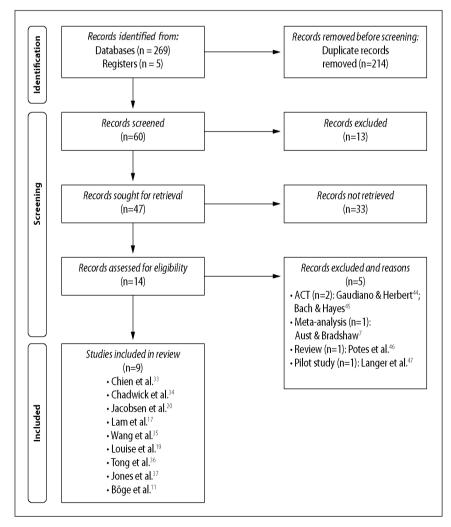


Figure 1. Identification of studies via databases and registers.

Table 1. A Boolean literature search of titles and abstracts.							
Search Engine	Keywords	Number of titles ^a					
PubMed-Embase-PsycInfo	#1'mindfulness'	98,609					
Medline-CINAHL-EMCARE:	#2'psychosis'	248,890					
	#3'patient*'	26,066,981					
	#4'inpatient*'	604,843					
	#5'psychiatry'	884,125					
	#6'outcome*'	2,617,046					
	#7'randomised controlled trial/RCT'	128,258					
	#8'psychotherapy'	578,180					
Combined:	(1-AND-2)-AND-3	209					
	(1-AND-2)-AND-4	25					
	(1-AND-2-AND-4)-AND-5	10					
	(1-AND-2-AND-4)-AND-6	20					
	(1-AND-2-AND-4)-AND-7	5					

^aThe combined number included duplicates.

years old, studies with statistical analysis, MBIp and English articles or abstracts (table 2a). The exclusion criteria were other systematic reviews, meta-analyses of other studies, studies with no outcomes or statistics, pilot studies, studies older than five years old and ACT (table 2b). The PRISMA³² flowchart summarises the search stages for the 260 studies found (figure 1). The research retrieved respected the higher levels of EBP

Table 2a. Summary of included studies with the author's extracted ES from every study.							
Reference	Population (Size N)	Intervention	Methods and Study Design	Comparison	Outcomes	ES	
Chien et al. ³³	124 PWP	Group-MBPP	Quantitative/RCT	Functioning at baseline, 12- and 24-month follow-up	Improved observing and acting with awareness	0.24	
Chadwick et al. ³⁴	54 PWP: MBCT+TAU 54 PWP: TAU	12-week- group-MBCT	Quantitative/RCT	Baseline and 10-month follow-up MBCT+TAU vs. TAU	PSYRATS: reduced distress at auditory hallucinations	0.10	
Jacobsen et al. ²⁰	50 PWP	1-5-sessions- group-MBCI	Quantitative/RCT	6- and 12-month follow-up: MBCI vs. social activity therapy	After 12 months, the readmission rate was lower in the mindfulness group	0.19	
Lam et al. ¹⁷	46 PWP	8-week-MBPP	Quantitative/RCT	8-week MBPP vs. TAU	After 3 months, the MBPP group showed improvement and reduction in rumination	0.31	
Wang et al. ³⁵	131 PWP	Group-MBCT	Quantitative/RCT	6-month follow-up MBCT vs TAU vs psychoeducation	PANSS: Reduction of psychotic symptoms	0.80	
Louise et al. ¹⁹	14 PWP	4-week- individual-iMTV	Quantitative/ Non-randomised	Functioning at baseline and 2-month follow-up	SMQ: treated patients show an absence of aversion and non- judgment	0.39	
Tong et al. ³⁶	11 PWP	Group-MBCT	Mixed-method, longitudinal study	Assessment at baseline and post-intervention	PANSS: improved general psychopathology and mindfulness of feelings	0.70	
Jones et al. ³⁷	40 PWP 50 PSP	15-sessions- group-MBCT	Quantitative	PWP vs. PSP	PWP had a higher subjective recovery rate	0.31	
Böge et al. ¹¹	27 PWP	Individual- MBCT	Qualitative/ Thematic analysis	4-sessions-MBCT	Improvement in emotion, cognition and symptoms changes	-	

Legend: PWP= patients with psychosis; PSP= patients without psychosis.

Table 2b. Summary of excluded studies with reasons.							
Reference	Population (Size N)	Intervention	Methods and Study Design	Comparison	Outcomes	Reasons for exclusion	
Gaudiano and Herbert ⁴⁴	40 PWP	ACT	Quantitative Randomised	ACT+TAU vs. TAU-only	Reduced scores in psychiatric tests	Pilot study/ACT	
Bach and Hayes ⁴⁵	80 PWP	ACT	Quantitative	ACT+TAU vs. TAU-only	At 4-month follow-up, reduced readmission of ACT group	Old study/ACT	
Aust and Bradshaw ⁷	549 PWP	MBIp	Meta-analysis	TAU vs. MBIp	MBI improves the quality of life and negative symptoms	SR	
Potes et al. ⁴⁶	-	-	Review	Comparison between studies	MBI improves functioning, recovery, mindful awareness, cognition, depression	SR	
Langer et al. ⁴⁷	-	MBIp-project	Mixed method	-	-	Pilot study	

(figure 1) with five RCT^{17,20,33-35}, one controlled trial without randomisation¹⁹, two cohort studies^{36,37} and one qualitative and rigorous group study¹¹.

OUTCOME MEASURES

The outcome measures in the studies were as follows:

- Southampton-Mindfulness-Questionnaire (SMQ): a 16-item-self-report scale measuring the degree of the subject's mindfulness during upsetting thoughts and hallucinations³⁸;
- Positive-and-Negative-Symptoms-of-Schizophrenia (PANSS): a 30-item questionnaire assessing positive and negative symptoms of schizophrenia³⁹;
- Psychotic-Symptom-Rating-Scale (PSYRATS): a 17-item scale assessing hallucinations and delusions over a range of 'absent' to 'marked'⁴⁰.

METHODS OF DATA SUMMARISATION

The PICO(s) (Population, Intervention, Comparison, Outcome and Study Design) summarised the articles⁴¹. An SR analyses the relevant research thoroughly to address a specific question and determine the validity of each study considered when stating conclusions⁴². Here, the intervention (I) is the independent variable – MBIp – while the outcome (O) represents the dependent variable – the effect of MBIp⁴³. RCT are experimental studies that answer therapy questions and compare patients receiving the intervention or experimental group (e.g., MBIp) with a control group that does not receive the intervention or receives TAU or has no psychosis; through randomisation, the experimenter assigns partici-

pants on a random basis to a control or experimental group; outcomes are usually assessed at baseline/pre-test and post-test³⁰. The author extracted the ES from each study (table 2a).

STATISTICAL ANALYSIS

Effect Size (ES). Pearson's *r* transformed the outcomes of the individual studies into ES measures to estimate the magnitude of the intervention (MBIp) on the outcomes³⁰. ES is expressed as an interval scale from 0 to 1, with 0.20 or less representing a small effect, 0.24 to 0.33 an intermediate effect, 0.37 to 0.45 a large effect, and >0.80 a very large effect^{48,49}. Online Campbell⁵⁰ and Lenhard and Lenhard⁴⁸ software calculated the ES.

A random-effect meta-analysis (M-A) performed by Medcalc Statistical Software (www. medcalc.org) merged the global ES from the individual studies, extracted the heterogeneity factor I^2 , and the risks of publication bias Egger's and Begg's test^{42,43,51,52}.

Research hypothesis and alpha error. The Level I or alpha α error defines the statistical probability of committing a mistake by rejecting the null hypothesis H_o – no relationship between the dependent, independent and other variables – when it is instead true. It is here set at p=.05, indicating that the authors were willing to accept no more than a 5% chance of committing that error^{49,53}.

The Kolmogorov-Smirnov (K-S) test verified the normality distribution of the ES of all studies to justify a parametric test and meta-analysis^{43,54}.

Split-half Pearson's r calculated internal reliability on the extracted ES^{55} .

RESEARCH HYPOTHESES

Hypothesis 1 H_o 1: MBIp has no effect on PWP. Hypothesis 2 H_o 2: there is no difference between studies in terms of ES.

ASSESSMENT OF RISK OF BIASES (ROB)

Cochrane GRADE software assessed the RoB for the RCT, while ROB-2 software assessed the RoB for non-RCT 56,59 .

Results

MAJOR FINDINGS

The K-S test (D=.24; p=.63) reported a normality distribution for all ES, hence justifying the meta-analysis, while the split-half indicated significant reliability in the findings (r=0.65).

The authors rejected $\rm H_o 1$, as MBIp shows an intermediate effect on PWP when assessed at immediate follow-up and for a median period of two months after its discontinuation (r=0.34; 95%CI=0.26–0.42; p<.001). The authors also rejected $\rm H_o 2$ due to the significant heterogeneity of ES between studies ($\rm I^2$ =68.94%; p=.002) (figure 2).

CHARACTERISTICS OF SELECTED POPULATION

The global population comprised 170 PWP and 165 PSP.

Type of mindfulness intervention

MBIp included MBPP 17,33 , iMTV 19 , MBCI 20 , individual MBCT 11 , and group MBCT $^{34-37}$.

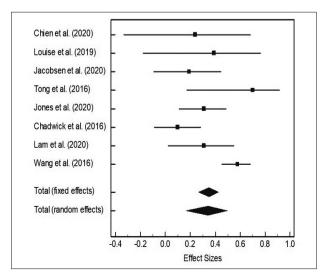


Figure 2. Forest plot of meta-analysis.

QUANTITATIVE OUTCOMES

MBIp produced the following ES on PWP's psychotic symptoms:

- large effect on the absence of aversion and nonjudgment at 2-month follow-up (r=0.39)¹⁹;
- large effect in reduction of positive and negative symptoms at 6-month follow-up $(r=0.70-0.80)^{35,36}$;
- intermediate effect in observing and acting with awareness at 24-month follow-up $(r=0.24)^{35}$;
- intermediate effect on subjective recovery rate at immediate follow-up (r=0.31)³⁷;
- intermediate effect on reduced rumination at 3-month follow-up $(r=0.31)^{17}$;
- small effect in reducing distress and disturbance from auditory hallucinations at 10-month followup (r=0.10)³⁴;
- small effect on the readmission rate at 12-month follow-up $(r=0.19)^{20}$.

OUALITATIVE OUTCOMES

CASP Checklist⁶⁰ evaluated Böge et al.¹¹. After a 4-week MBIp intervention, a thematic analysis extracted the effects of MBIp on 27 PWP with three major themes, such as emotions – higher acceptance of psychotic symptoms –, cognition – increased self-awareness and empowerment –, and symptoms changes – reduction of anxiety, depression, and PANSS¹¹. However, the authors did not explain MBIp to participants, although they triangulated their impressions for the conclusions; research design, recruitment strategies, data collection were clearly stated¹¹.

FOLLOW-UP ASSESSMENT

The median follow-up period was two months, while the mode was zero months, mostly occurring in post-treatment immediately after completing the MBIp in all studies.

ROB ASSESSMENT

RoB in RCTs was assessed by GRADE in five RCTs^{17,20,33-35}, yielding moderate certainty in the results; the authors are convinced that the study's ES is close to the actual effect⁶¹ (figure 3). The certainty of the evidence for the SR relates to how confident the author is that effect size represents the actual effect, which is usually high for RCTs⁶². The results of the GRADE subcategories for RoB were as follows^{57,58,62}:

- no RoB in design and implementation, as the RCTs had allocation concealment, blindness and followup, although studies mainly were single-blinded (therapist aware); exclusion criteria were reported;
- RoB in inconsistency and heterogeneity in ES and I2;
- no RoB in indirectness, as PICO was implemented;

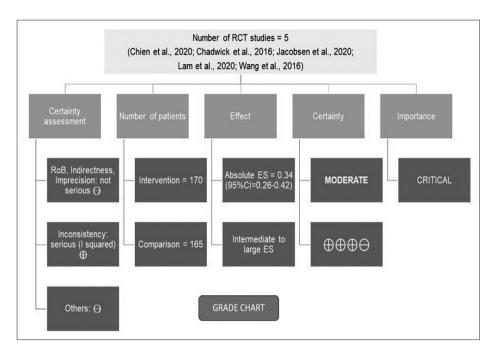


Figure 3. GRADE RoB assessment for RCT studies.

- no RoB in imprecision, as MBIp had a moderate effect, while an adequate sample of patients was allocated to the experimental-intervention and control groups;
- RoB in publication bias as seen in the funnel plot (figure 4), although publication biases tested in M-A were not statistically significant (Egger's test: p=.99; Begg's test: p=.25).

ROB-2⁵⁶ assessed RoB for four non-RCTs^{11,19,36,37}. The tool yielded an 80% low risk in supporting MBIp and a 20% of some concern linked to the absence of randomisation in these studies. No RoB was found in studies' deviation from intents, missing outcome data or measurement, or selection results (figure 5).

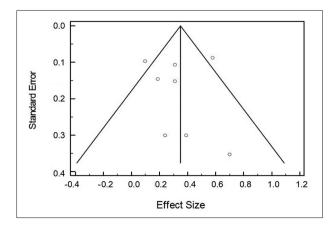


Figure 4. Funnel plot for publication biases showing heterogeneity of ES.

RESEARCH OBJECTIVITY

The current study improved its objectivity by using recent research with measurable outcomes and statistical analysis that was bias-free, predictable, transparent and verifiable^{29,63}.

EXTERNAL VALIDITY

Cochrane AMSTAR-2 yielded a low quality for external validity for the current review because it ignored the RoB in the individual studies^{63,64}. The points respected were: comprehensive literature search, list and description of included and excluded studies, PICO method, RoB assessment, RoB valua-

tion in the meta-analysis (funnel plot; Egger's and Begg's test), meta-analysis and methods explaining studies' heterogeneity and publication biases (GRA-DE and ROB-2)⁶⁴.

Discussion and conclusions

The current review reports a moderate effect size of MBIp on psychosis with moderate certainty in the results. There is also an 80% low risk in supporting MBIp, although the current study has a low quality for external validity. In PWP's psychotic symptoms, MBIp produced observing and acting with awareness, absence of aversion and non-judgment, reduction of positive and negative symptoms, increased subjective recovery rate, reduced distress and disturbance from auditory hallucinations. Qualitatively, MBIp increased acceptance of psychotic symptoms, self-awareness and empowerment with reduced anxiety and depression.

Limitations emerge from threats to external and population validity. The findings refer to PWP in the adult population and cannot be generalised to other PWP cohorts, while assessment scales and MBIp interventions differed for all studies^{65,66}. However, a clinical validity can be claimed for the results regarding MBIp⁴³.

The GRADEpro⁶⁷ scale endorses a conditional recommendation for the suggestion of MBIp, mainly linked to the threats to validity and the risk of biases in outcome-based studies. Nonetheless, GRADEpro extracted a large desirable effect of MBIp, which has trivial undesirable effects, low costs of implementation, high impact on health equity, amounting to the

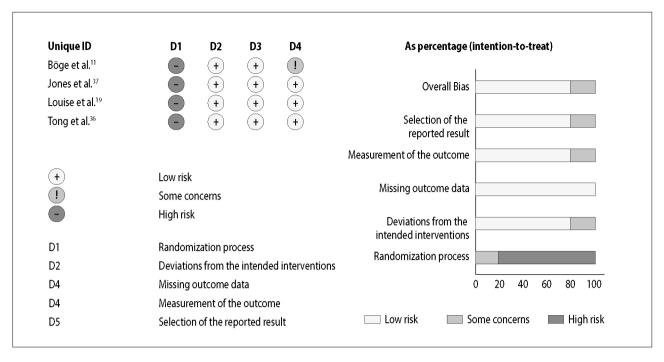


Figure 5. ROB-2 for non-randomised studies included in the analysis.

acceptability of the intervention's feasibility for major stakeholders 67 .

Future research shall standardise and control MBIp procedures and outcome measures, specify the required length and amount of MBIp needed, and identify required follow-up periods to stabilise PWP's presentation¹⁴.

Conflict of interests: the authors have no conflict of interests to declare.

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