

# The Safety of Mindfulness-Based Interventions: a Systematic Review of Randomized Controlled Trials

Samuel Y. S. Wong<sup>1,2</sup> · Joyce Y. C. Chan<sup>3</sup> · Dexing Zhang<sup>1</sup> · Eric K. P. Lee<sup>1</sup> · Kelvin K. F. Tsoi<sup>1,4</sup>

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## Abstract

The rapid growth of mindfulness-based interventions (MBIs) has raised questions regarding their safety. This review aimed to quantify the adverse events of mindfulness-based stress reduction (MBSR) and mindfulness-based cognitive therapy (MBCT) reported in randomized control trials (RCTs) which included a statement of monitoring of adverse events. Literature was searched from the OVID databases until August 2017. A total of 36 RCTs were identified from 7931 search records, with 25 trials using MBSR and 11 trials using MBCT. A total of 19 (1%) and 19 (0.9%) adverse events were reported in the mindfulness intervention group and control group, respectively. In the MBSR group, none of them reported serious adverse event, and only three (12.0%) studies reported six (0.49%) intervention-related adverse events from among 1231 participants. No significant difference between the MBSR intervention and control groups was observed (6/1231 vs. 2/1244; risk difference (95% CI) = 0.0033 (−0.01 to 0.01)). In the MBCT group, no intervention-related adverse events were reported, and only one trial reported ten (1.5%) cases of intervention-unrelated adverse events from 768 participants. No statistically significant difference in terms of the reported adverse events between the intervention and control groups was observed in the MBCT trials. Only a small proportion of trials reported monitoring of adverse events. Very few adverse events were reported in RCTs that used MBSR/MBCT. The MBSR/MBCT is regarded as relatively safe interventions. However, future studies are highly encouraged to report adverse events in mindfulness interventions for more affirmative conclusions.

**Keywords** Mindfulness · Stress reduction · Cognitive therapy · Adverse effects

## Introduction

In about four decades, mindfulness-based interventions (MBIs) have become not only a popular therapeutic inter-

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✉ Samuel Y. S. Wong  
yeungshanwong@cuhk.edu.hk

<sup>1</sup> Jockey Club School of Public Health and Primary Care, The Chinese University of Hong Kong, Sha Tin, Hong Kong

<sup>2</sup> Jockey Club School of Public Health and Primary Care, Prince of Wales Hospital, 4/F, Shatin, N.T., Hong Kong

<sup>3</sup> Department of Medicine and Therapeutics, The Chinese University of Hong Kong, Sha Tin, Hong Kong

<sup>4</sup> Stanley Ho Big Data Decision Analytics Research Centre, The Chinese University of Hong Kong, Sha Tin, Hong Kong

vention for improving psychological and physical conditions (Allen et al. 2006; Goyal et al. 2014; Khoury et al. 2013; Mental Health Foundation 2010) but also a non-therapeutic intervention for promoting mental well-being (Galante et al. 2014; Khoury et al. 2015). Among various MBIs, mindfulness-based stress reduction (MBSR) and mindfulness-based cognitive therapy (MBCT) are two of the most often studied interventions. MBSR is a structured mindfulness training program that facilitates participants to cultivate mindfulness by learning various meditation skills such as mindful breathing, body scan, and mindful movement and walking (Kabat-Zinn 1982; Kabat-Zinn 1990; Kabat-Zinn et al. 1992). MBSR was later integrated with cognitive behavioral techniques and become mindfulness-based cognitive therapy (Segal et al. 2002; Teasdale 2004), which has been shown to be effective for the prevention of recurrent depression among people who suffer from multiple episodes of depression. MBCT is now recommended by both the National Institute for Health and Care Excellence and the American Psychiatric Association for

treating people with recurrent depression (Shonin et al. 2013).

Over the past 15 years, the number of scientific publications on MBIs has increased from fewer than 50 in 2003 to over 900 in 2014 (Pagnini and Philips 2015). Although the positive effects of mindfulness interventions are increasingly well recorded (e.g., in reducing anxiety, depression, and stress; cultivating compassion; and helping the management of chronic illness and pain), questions have been raised regarding the safety of using MBIs for various clinical and non-clinical problems in both academic (Farias and Wikholm 2015; Farias and Wikholm 2016; Shonin et al. 2014) and non-academic (Foster 2016; Rocha 2014) fields. Some anecdotal stories, case studies, and qualitative interviews found that mindfulness practices may include depression and anxiety, panic, mania, seizures, psychotic symptoms, or other negative feelings such as fear, anger, despair, dissociation, grandiosity, feelings of depersonalization, defenselessness, guilt, and religious delusions, or somatic discomfort such as neurological problems (e.g., increased epileptogenesis), loss of appetite, reduced food intake, and difficulty sleeping (Castillo 1990; Dobkin et al. 2012; Irving et al. 2009; Jaseja 2005; Kuijpers et al. 2007; Lustyk et al. 2009; Perez-De-Albeniz and Holmes 2000; Sethi and Bhargava 2003; Shonin et al. 2014; Yorston 2001). An earlier study on 27 long-term meditators (average meditation experience, 4.27 years) found that 62.9% reported at least one adverse effect in intrapersonal (e.g., increased awareness of negative emotions, increased disorientation, confused mind, addiction to meditation, less motivation in life, boredom, and pain), interpersonal (worsened relationships), or societal (e.g., increased alienation from the society) aspects and 7.4% had profound adverse effects which led to withdrawal from mediation or hospitalization (Shapiro 1992). More recently and comprehensively, the Varieties of Contemplative Experience (VCE) study published in 2016 interviewed 60 Western Buddhist meditation practitioners and experts of Theravāda, Zen, and Tibetan traditions about their meditation-related experiences with a focus on their experiences that have been described as challenging, difficult, distressing, functionally impairing, and/or requiring additional support. They found that all of them had negative experiences after practicing meditation for 1 day to more than 25 years (mean = 7.1 years; standard deviation = 8.0 years) and the experiences were summarized to 59 meditation-related experiences across seven domains: cognitive, perceptual, affective, somatic, conative, sense of self, and social (Lindahl et al. 2017).

Despite its long history, it is clear that mindfulness is not a practice that is free of adverse effects. Although anecdotal stories, case reports, and qualitative interviews that documented and discussed potential adverse effects associated with meditation have been published previously, no review has been systematically conducted to assess the frequency of adverse events in meditation- or mindfulness-related

intervention studies, which are being applied to wide populations. There is a need to conduct research systematically in order to evaluate the potential adverse effects and safety when using MBIs as both therapeutic and non-therapeutic interventions. Therefore, to raise the awareness regarding safety issues when providing MBIs and also prevent potential mindfulness-related problems in future practices, the primary objective of the current study was to review the published randomized controlled trials (RCTs) systematically that can provide more solid evidence through a comparison group, on two major structured MBIs—MBSR and MBCT which are widely used and usually designed for beginners, to document the frequency and nature of any reported adverse effects associated with MBSR/MBCT.

## Method

This systematic review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Moher et al. 2009).

### Search Strategy

Literature searches were performed in MEDLINE, EMBASE, and PsycINFO from their inception to 12 August 2017 in order to include all potentially eligible studies. Search terms including “mindful,” “mindfulness-based,” “MBSR”, “MBCT,” “effect,” “trial,” “study,” and “random” were used (Appendix 1). Randomized controlled trials of MBSR or MBCT that mentioned adverse events were manually identified after previewing the titles or abstracts of all the search records. The selection was limited to peer-reviewed articles. We also used WorldCat and Google Scholar (first ten pages) to search for gray literature. Manual searches were extended to the bibliographies of the review articles and included research studies.

### Inclusion and Exclusion Criteria

Studies were included if they met the following inclusion criteria: (i) randomized controlled trial that investigated MBSR or MBCT in any kind of population and (ii) having a statement about the adverse events of the study at any place of the report, regardless of the occurrence or type of adverse events; i.e., studies which mentioned that there were or were no adverse events were both included. Given that we cannot assume if the RCTs did or did not have adverse events without an explicit statement regarding it, RCTs without any statement on the adverse event were not included. No restrictions were applied regarding the control group; i.e., studies with waitlist control, no intervention, usual care, or active control groups with non-mindfulness

interventions were all included. Papers were excluded if they were not written in English.

## Data Extraction

Two investigators (J.Y.C.C. and D.Z.) independently assessed the relevance of the search results and extracted the data into an Excel spreadsheet. The data included the year of publication, study location, the number of participants, participants' mean age, the percentage of males, information on mindfulness intervention, the type of participants, and the type and number of adverse events. Furthermore, information on drop-out rates and compliance rates in the intervention and control groups, journals' impact factor in the year when the trial was published (from *Journal Citation Reports*, <https://jcr.thomsonreuters.com/>), the mention of Consolidated Standards of Reporting Trials (CONSORT) (yes, no), funding source (commercial, non-commercial, or none), and disclosure of conflict of interest (yes, no) was collected. When discrepancies regarding study eligibility or data extraction were identified, a third investigator (K.K.F.T.) was invited to assess the results and a discussion with the other two investigators was held until a consensus was reached.

## Adverse Events as Outcomes

The primary outcomes were adverse events including (1) death, (2) life-threatening situations, (3) hospitalization, (4) disability or permanent damage, (5) congenital anomaly/birth defect, (6) need for medical or surgical intervention to prevent the outcomes, (7) significant adverse episodes during or shortly after the treatment (e.g., suicide, suicide attempts, psychosis, mental health-related hospital admissions), (8) clinically significant deterioration (a worsened mental state after completion of the therapy), which can include the emergence of new symptoms (e.g., emotional and physical discomfort, including feeling of anger, anxiety, or pain), or (9) participants' negative experience of therapy which can be described as patient-experienced harm (Parry et al. 2016). The adverse events were also classified as related or unrelated to the intervention, if they were clearly judged and stated by the authors in their original reports. For example, Williams et al. (2014) reported five adverse events in the intervention group and ten in the control group and stated that only one (an episode of serious suicidal ideation) of them was potentially due to the cognitive psychological education treatment in the control group. Dropout rates were regarded as being due to the adverse events only if the authors provided explicit reasons that the dropout rates were due to adverse events in the original study.

## Study Quality

The quality of each eligible trial was also assessed by referring to the methodology section of the CONSORT statement for RCTs (Moher et al. 2001). Study quality was assessed by the following parameters: (1) method of subject allocation, (2) randomization procedures with concealed allocation, (3) eligibility criteria for subjects and settings for data collection, (4) sufficient details of interventions for each group with sufficient details, (5) appropriate description of the method of blinding, (6) pre-specified primary and secondary outcome measures, (7) estimation of the required sample size, and (8) all adverse events reported in each group. The maximum quality score was 8. The Cochrane risk of bias assessment was not included in this review as this assessment was designed to evaluate the underestimation or overestimation of the true treatment effect of interventions by looking into study procedures such as randomization, concealment, blindness, and selective reporting. As this review only focused on the adverse events instead of treatment effects, the assessment of the Cochrane risk of bias was not considered suitable here.

## Data Analyses

Risk difference (RD) was used for comparing the absolute difference between the intervention group and control groups. Therefore, RD with 95% confidence interval (CI) was used to compare the reported number of adverse events. Meta-analyses were performed to combine the RD of individual studies using Review Manager version 5.3 (2014). Statistical heterogeneity among the trials was assessed, and  $p$  value  $< 0.1$  was considered as significant heterogeneity (Fleiss 1986). The level of heterogeneity was further assessed by  $I^2$ , which describes the percentage of the total variation across studies due to heterogeneity rather than chance alone. The DerSimonian and Laird procedure for random-effects model was used for trials with statistically significant heterogeneity; otherwise, in trials with no significant heterogeneity, the Mantel-Haenszel fixed-effects model was applied (DerSimonian and Laird 1986). Forest plots were used to present the compiled results graphically. Subgroup analyses were performed according to (i) types of mindfulness interventions (stress reduction, cognitive therapy, or others), (ii) diseases of participants (including cancer, hypertension or other cardiovascular problems, mental illness, pain management, or healthy subjects), and (iii) types of control groups (usual care, waitlist or no intervention, or education program). Furthermore, the following factors were also tested to see if they were associated with adverse events in the intervention or control group when there was or was no nexus between the adverse events and interventions: mean age, percentage of males, sample size, duration of intervention period, duration of follow-up period, drop-out rate in the intervention group, drop-out rate in the control

group, compliance rate of the intervention, quality score of the trial, year of publication, and impact factor of the journal in the year when the trial was published (*t*-tests were used), and location (Europe, the rest), recruitment site (clinical, non-clinical, or both), study results (positive, negative), mention of the CONSORT (yes, no), funding source (commercial, non-commercial, or none), and disclosure of conflict of interest (yes, no) (chi-square tests were used).

## Results

### Literature Search and Study Selection

A total of 7931 records were identified with 90 of them being extracted from the bibliographies of the included records. All titles and abstracts of the records were screened, and 499 articles out of 535 relevant articles were subsequently excluded for the following reasons: 51 studies were systematic reviews, 241 studies were not randomized controlled trials, 195 trials did not mention or report any adverse events, 10 studies were not based on MBCT or MBSR, 1 study used MBCT in both intervention and control groups, and 1 study was a follow-up study and with the same group of participants. Finally, 36 RCTs (15.6% of 231 trials) with a statement on the adverse events being monitored during the study were included (Fig. 1).

### Characteristics of the Included Studies

This study included 36 RCTs with a total of 4031 participants. The sample sizes of the included studies ranged from 31 to 424 participants. A total of 19 (1%) and 19 (0.9%) adverse events were reported in the mindfulness intervention group and control group, respectively. The studies were conducted in the USA ( $n = 19$  studies), the UK ( $n = 7$ ), Norway ( $n = 2$ ), Denmark ( $n = 2$ ), Australia ( $n = 2$ ), Switzerland ( $n = 1$ ), Canada ( $n = 1$ ), Hong Kong ( $n = 1$ ), and India ( $n = 1$ ). All included trials were published in 2007 or after; studies that reported having adverse events in either the intervention or control group were published in 2011 or after. Different types of participants were recruited from various study sites, such as students from high school/university, adults from hospital clinics, and elderly from the community. The mean age of the participants ranged from 12.5 to 74.9 years in the included studies. The percentage of male participants in each study ranged from 0 to 100% with a mean of 34% (standard deviation (SD) = 25%). The duration of the interventions was 8 weeks on average and ranged from 4 to 24 weeks. The follow-up period ranged from 1 to 24 months, but 10 studies did not conduct a follow-up after the intervention. Twenty-five studies used the MBSR; 11 studies used the MBCT. Twelve studies were conducted among people with mental

health problems including depression, anxiety, social stress, substance use disorders, or sleep-related problems. Nine studies were conducted among healthy populations. The others were among people with cancer ( $n = 5$ ), hypertension/heart disease ( $n = 2$ ), pain ( $n = 2$ ), or other diseases ( $n = 4$ ). The dropout rates ranged from 0 to 36.8% with a mean of 14.3% (SD = 9.4%) for the MBI groups, and for the control groups, the dropout rates ranged from 0 to 66.7% with a mean of 16.5% (SD = 14.4%). The compliance rates for the MBI groups ranged from 52.1 to 100% with a mean of 85.5% (SD = 10.9%), and for the control groups, the rates ranged from 68.1 to 100% with a mean of 85.8% (SD = 11.0%). The details of the included studies are shown in Tables 1 and 2 and Appendix 2. The study quality of the included trials was good, with the quality score ranging from 6 to 8.

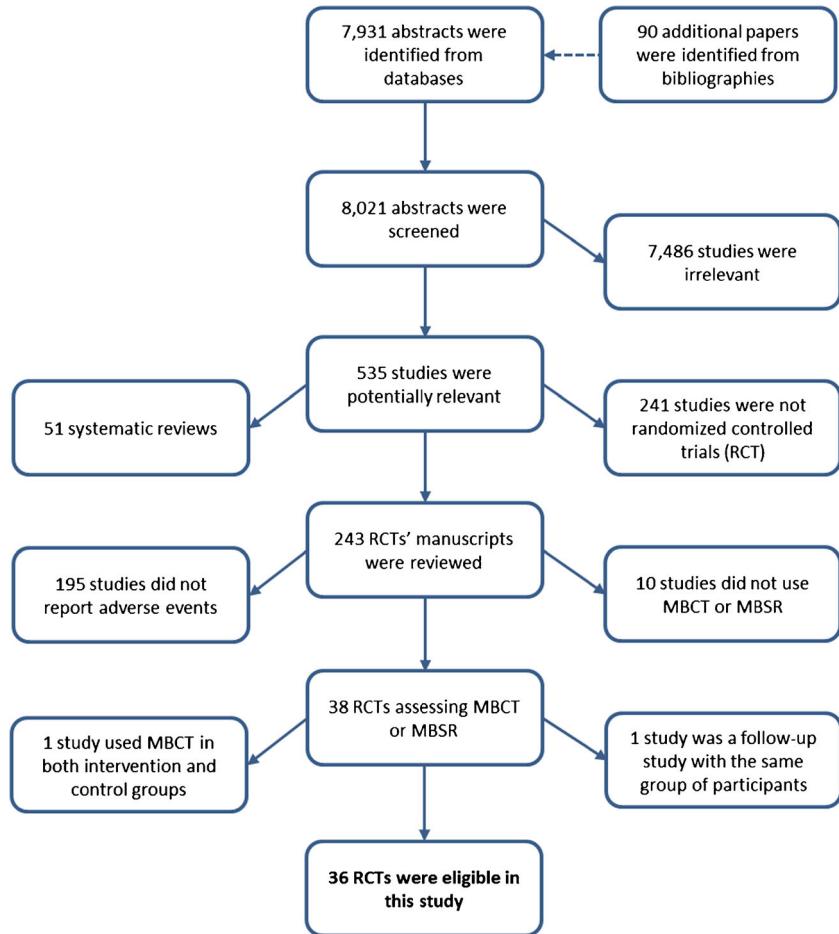
### Mindfulness-Based Stress Reduction

Among the 25 MBSR trials, none of them reported serious adverse event. Only three trials (12.0%) reported at least one intervention-related adverse event, including four cases of anger or anxiety in a pain trial (La Cour and Petersen 2015), one case of soreness reported in an anxiety disorder trial (Hoge et al. 2013), and one case of strained neck in a family caregiver study (Hou et al. 2014) (Table 3). A meta-analysis was performed to compare the adverse events in intervention and control groups. We separately analyzed the intervention-related adverse events and intervention-unrelated adverse events using two forest plots. For intervention-related adverse events, heterogeneity was not found across the trials, and a fixed-effect model showed comparable adverse events (6/1231 vs. 2/1244; RD (95% CI) = 0.0033 (-0.01 to 0.01)) (Fig. 2, Table 3). Regarding intervention-unrelated adverse events, a trial reported three cases of intervention-unrelated adverse events, i.e., fighting incidence among three participants. A meta-analysis was performed, and all intervention-unrelated adverse events were compared. No significant difference between the intervention and control groups was observed (3/1231 vs. 1/1244; RD (95% CI) = 0.0016 (-0.01 to 0.01)) (Fig. 2).

### Mindfulness-Based Cognitive Therapy

Among the 11 MBCT trials, two of them reported serious adverse events which were intervention-unrelated. One study reported four cases of hospitalizations due to physical health problem and one case of hospitalization due to overdose (Table 3) as well as nine cases of hospitalizations in the control group (Williams et al. 2014). Another study that compared the effectiveness of MBCT with maintenance antidepressant treatment for the prevention of depressive relapse or recurrence reported ten serious adverse events (three non-fatal cases and two fatal cases in each group), but the authors reported

**Fig. 1** Flowchart of literature search



that there was no reason to believe that any of these events were related to the trial based on the assessment of the Trial Steering and Data Monitoring Committees (Kuyken et al. 2015). A meta-analysis was performed to compare the overall intervention-related adverse events. Heterogeneity was not found across trials, and a fixed-effect model showed comparable adverse events (0/768 vs. 2/788; RD (95% CI) = −0.0014 (−0.01 to 0.01)) (Fig. 3). For intervention-unrelated adverse events, no statistically significant difference between the intervention and control groups was observed (10/768 vs. 14/788; RD (95% CI) = −0.005 (−0.02 to 0.01)) (Fig. 3).

## Subgroup Analyses

Mindfulness interventions were applied to a spectrum of patients, including those with mental illness (12 studies), cancer (6 studies), and healthy (8 studies) subjects. Subgroup analyses did not show any significant difference in the reported adverse events among different types of participants (Appendix 3). In the control groups, usual care (17 studies) and waitlist (12 studies) were the most used approaches for comparison among the trials. Subgroup analyses did not show a significant difference in the reported adverse events between

studies with usual care control or waitlist control (Appendix 3), except one study with education program as control (Williams et al. 2014); it was shown that MBCT had less intervention-unrelated adverse events than cognitive psychological education program (RD (95% CI) = −0.09 (−0.15 to −0.04)). Furthermore, trials were more likely to report having adverse events in the MBI groups, regardless of the association with the intervention, if they had larger sample size (174 (47) vs. 93 (14),  $t = -2.232$ ,  $p = 0.032$ ) or if they were conducted in Europe (UK, Denmark, Norway, and Switzerland) instead of other countries (USA, Canada, Australia, Hong Kong, and India) (75 vs. 22%,  $\chi^2 = 7.630$ ,  $p = 0.006$ ). However, the sample size or country was not associated with the likelihood of having mindfulness-related adverse events. The following factors were related to the existence of adverse events in the control group, regardless of its relationship with the intervention in the control group: larger sample sizes (177 (57) vs. 89 (12),  $t = -2.381$ ,  $p = 0.023$ ), publication in journals with higher-impact factors (13.7 (6.9) vs. 4.6 (0.7),  $t = -2.662$ ,  $p = 0.0124$ ), or longer follow-up period (9 (3.5) vs. 4.2 (0.8) months,  $t = -2.072$ ,  $p = 0.046$ ). Trials were more likely to report intervention-related adverse events in the control group if they had negative results (50 vs.

**Table 1** Characteristics of included study for mindfulness-based stress reduction (MBSR)

Study (year)	Country	Study period	Recruitment site	Type of subjects	Type of control	Sample size	Mean age	Age range	Male (%)	Duration of intervention (weeks)	Follow-up period (months)	Quality score (max = 8)
Blom et al. (2013)	Canada	NA	Community, hospital	Hypertension	Waitlist	101	56	20–75	37	12	6	8
Björnström et al. (2010) <sup>1</sup>	USA	2007–2008	Community	Cancer	Waitlist	71	51.8	NA	1	8	3	7
Brewer et al. (2011)	USA	NA	Community	Smokers	No intervention	88	46	NA	63	4 (twice/week)	4	8
Britton et al. (2010)	USA	NA	Clinics	Substance abuse	No intervention	55	16.4	13–19	50	6	12	5
Daubenhimer et al. (2016) <sup>1</sup>	USA	2009–2012	Clinic	Adolescents with obesity	Education program	194	47.5	18+	18	24	12.5	6
de Vibe et al. (2013)	Norway	2009–2010	University	Students	Usual care	288	23	NA	24	7	0	6
Gross et al. (2011)	USA	2007–2008	Community	Chronic insomnia	Others	30	50.7	18–65	27	8	3	6
Grossman et al. (2010)	Switzerland	2007–2009	Hospital	Multiple sclerosis	Usual care	150	47.3	NA	21	8	6	8
Hoffman et al. (2012)	UK	2005–2006	Day care centers	Breast cancer	Waitlist	229	49	18+	0	8	3	8
Hoge et al. (2013)	USA	2008–2011	Community	Generalized anxiety disorder	Education program	89	39.2	18+	49	8	0	6
Hou et al. (2014)	Hong Kong	2010–2012	Clinic, community	Family caregiver	Others	141	57.5	18–61	17	8	3	8
Jain et al. (2007)	USA	NA	University	Students	Education program	51	15	18–61	19	4	0	7
Jedel et al. (2014)	USA	2008–2010	University clinic	Inactive ulcerative colitis	No intervention	27	42.8	18–70	49	8	12	8
Jee et al. (2015)	USA	2012–2013	Foster/kinship care services	Traumatized youth	Usual care	42	16.8	14–21	55	10	4	7
Johns et al. (2015)	USA	2010	Clinic, cancer registry	Cancer survivors	Waitlist	35	57.3	18+	6	7	6	7
La Cour and Petersen (2015)	Denmark	2010–2012	Pain center	Chronic pain	Usual care	109	47.7	NA	15	8	6	7
McClintock et al. (2015) <sup>2</sup>	USA	2014–2015	University	Maladaptive interpersonal dependency	No intervention	48	19	NA	15	4	1	6
Morone et al. (2008)	USA	NA	Clinic, community	Older adults with low back pain	Waitlist	37	74.9	65+	43	8	3	7
Ong et al. (2014)	USA	2008–2012	Community Clinic	Chronic insomnia	Others	38	42.9	21+	26	8	6	7
Parswanji et al. (2013)	India	NA	Clinic	Coronary heart disease	Usual care	31	47	30–65	100	8	0	6
Possennato et al. (2016)	USA	2012–2013	Clinic	Posttraumatic stress disorder	Usual care	62	46.4	NA	87	4	2	7
Pradhan et al. (2007)	USA	2004–2005	Community	Rheumatoid arthritis	Usual care	63	54	18+	13	8	4	7
Sibinga et al. (2013)	USA	2009	School	Youth	Education program	41	12.5	11–14	100	12	0	8
Vollestad et al. (2011)	Norway	NA	Community	Anxiety disorder	Waitlist	76	42.5	18–65	33	8	6	7
Würzen et al. (2015)	Denmark	2007–2009	Surgery departments	Breast cancer	Usual care	336	54.1	18–75	0	8	12	7

NA not available (or no report)

<sup>1</sup> The MBSR is combined with exercise<sup>2</sup> The MBSR is combined with dialectical behavior therapy

7%,  $\chi^2 = 7.236, p = 0.007$ ) or had reported any conflict of interests (50 vs. 11%,  $\chi^2 = 4.126, p = 0.042$ ). Other factors were not found to be associated with reporting intervention-related or unrelated adverse events, in the intervention or control group.

## Discussion

This systematic review evaluated the adverse effects of MBSR and MBCT in published RCTs. The review covered a variety of RCTs among diverse participants with different age, gender, and health conditions. Very few adverse events were found in these studies, and even fewer were attributed to mindfulness-based interventions. MBSR and MBCT are regarded to be relatively safe interventions. However, attention should be paid to temporary negative emotions and increased depression and anxiety, which could be possible when one explores their inner experiences. Attention should also be paid to muscle soreness during mindfulness practice (e.g., stretching exercise).

This study has several implications. First, we found that only fewer than one in five trials have mentioned the monitoring of adverse effects, which was lower than the reporting rate of 21% found in psychological interventions trials for mental and behavioral disorders (Jonsson et al. 2014). Furthermore, very few of these trials provided a description of adverse events as well as the methods used for collecting data. It is unknown whether there were indeed no adverse events or whether those adverse events were not explicitly documented unlike for drug trials in which adverse events are reported regularly. It is suggested that a rate of 5% is typical in psychological treatments (Boisvert and Faust 2003). A recent national survey in England and Wales reported that 5.2% out of 14,587 respondents experienced adverse effects from psychological treatments and that those younger than 65 years, sexual and ethnic minorities, and people who were unsure of the type of therapy they were receiving were more likely to report negative effects (Crawford et al. 2016). Besides adverse events commonly documented in drug trials such as death and hospitalization, the adverse events of mindfulness intervention may also include mental-, physical-, and spiritual-related problems (Lustyk et al. 2009). Researchers in future trials on mindfulness-based intervention should consider reporting the potential adverse events found in this review, as well as those reported in previous case or empirical studies. The reporting of these adverse events should be a standard requirement shown in CONSORT. In this review, trials conducted in Europe or published in journals with higher-impact factors were more likely to report having adverse events, which might be due to the fact that these journals and European

countries might have more stringent guidelines or requirements/procedures, such as the presence of a data monitoring committee in guiding the reporting of adverse events to facilitate better reporting or safety guarantee. It is also worth noting that among the trials that reported mindfulness-related adverse events, they were more likely to be published in high-impact journals, such as *Lancet*, *Psychotherapy* and *Psychosomatics*, and the *Journal of Clinical Psychiatry*. It seems that there is no pressure not to report or underreport adverse events, but journals with higher-impact factors in fact tend to accept studies with more stringent reporting of adverse events. Meanwhile, the development of a specific reporting tool for recording adverse effects for all mindfulness-based interventions may be needed to make such reporting more systematic and easier for comparison. Second, though only few adverse events were observed in this review, researchers should continue to take necessary safety precautions to screen for and take care of vulnerable individuals in future mindfulness studies. Although screening or safety procedures are currently not standardized in mindfulness research, researchers may take their own study aim and population into consideration in doing so. For example, based on the suggested sample screener schematic by Lustyk et al. (2009), researchers may screen for PTSD, seizure disorder/epilepsy, acute psychosis, mania, suicidality, or other health problems of concern in their studies. Clinical professionals, besides experienced mindfulness instructors, should be included in the study to monitor and provide support in case any potential adverse events occur during the intervention. Third, more studies covering a longer follow-up period are needed to understand the potential adverse effects on long-term practitioners of mindfulness after intervention, as well as the effects from intensive retreats as the “dosage” of mindfulness may be related to the occurrence of adverse events (Baer and Kuyken 2016; Crane and Segal 2016) and studies included in our current review were structured intervention lasting for weeks with each session lasting only for 2–3 h. Fourth, more studies are needed to examine the characteristics of participants who may be more vulnerable to adverse effects or more likely to quit mindfulness practices, though our analyses did not find dropout, compliance rate, or other factors associated with the reporting of adverse events caused by mindfulness interventions in the included trials. Fifth, not all included trials reported the connection between the interventions and adverse events. Future trials are encouraged to include such information for better understanding. Ethical and data monitoring committees are expected to take an active role in evaluating the connection between adverse events and interventions. Sixth, trials with negative results or with any conflict of interests were more likely to report

Study (year)	Country	Study period	Recruitment site	Type of subjects	Type of control	Sample size	Mean age	Age range	Male (%)	Duration of intervention (weeks)	Follow-up period (months)	Quality score (max = 8)
Barnhofer et al. (2009)	UK	2007	Clinic, community	Chronic recurrent depression	Usual care	31	42	18–65	32	8	0	7
Britton et al. (2012)	USA	2004	Community	Recurrent depression	Waitlist	52	47	NA	17	8	0	7
Chambers et al. (2016)	Australia	NA	Medical center	Cancer	Enhance usual care	189	70.7	NA	100	8	9	7
Foley et al. (2010)	Australia	2006–2007	Clinic	Cancer	Waitlist	115	55	24–78	23	8	3	7
Kuyken et al. (2008)	UK	NA	Clinic	Depression	Usual care	123	49	21–72	24	8	15	6
Kuyken et al. (2015)	UK	2010–2011	Clinic	Depression	Usual care	424	49.5	20–79	23	8	24	6
Taylor et al. (2014)	UK	NA	University	Students	Waitlist	79	28.6	NA	19	8	0	8
Rimes and Wingrove (2013)	UK	NA	National health service unit	Chronic fatigue syndrome	Waitlist	37	43.5	NA	16	8	6	6
Williams et al. (2014)	UK	2009–2010	Clinic, community	Depression	Education program	230	43	18–68	28	8	12	8
Witkiewitz and Bowen (2010)	USA	2007	Non-profit public service agency	Substance use disorders	Usual care	168	40.5	18–70	64	8	4	6
Van Vugt et al. (2012)	USA	2004–2005	Clinic, community	Depression	Waitlist	52	46.9	NA	23	8	0	6

NA not available (or no report)

**Table 3** Adverse events in mindfulness study

	Mindfulness-based interventions <sup>1</sup>	
	MBSR	MBCT
No. of studies reported no adverse event	19 (76.0%)	9 (81.8%)
No. of studies reported Intervention-related adverse events	4 (16.0%)	2 (18.2%)
Reported serious adverse events		
Study (reported number in mindfulness-based intervention vs. control)		
Serious suicidal ideation after cognitive psychological class (control)	0	Williams (0 vs. 1)
Reported other adverse events		
Study (reported number in mindfulness-based intervention vs. control)		
Anger	La Cour and Petersen (2015) (2 vs. 0)	0
Anxiety	La Cour and Petersen (2015) (2 vs. 0)	0
Distressing	0	Chambers et al. (2017) (0 vs. 1)
Excessive sleepiness, headache, and dizziness	Gross et al. (2011) (0 vs. 1) <sup>2</sup>	0
Sleep disruption	Hoge et al. (2013) (0 vs. 1)	0
Soreness	Hoge et al. (2013) (1 vs. 0)	0
Neck strain after yoga	Hou et al. (2014) (1 vs. 0)	0
No. of studies reported Intervention-unrelated adverse events	2 (8.0%)	3 (20.0%)
Reported serious adverse events		
Study (reported number in mindfulness-based intervention vs. control)		
Fatal <sup>3</sup>	Blom et al. (2013) (0 vs. 1)	Kuyken et al. (2015) (2 vs. 2)
Over dose	0	Williams et al. (2014) (1 vs. 0)
Hospitalization due to physical health problems	0	Williams et al. (2014) (4 vs. 9)
Reported other adverse events		
Study (reported number in mindfulness-based intervention vs. control)		
Fatigue, dizziness, shortness of breath, pain due to pre-existing conditions	0	0
Fight among the youth participants	Jee et al. (2015) (3 vs. 0)	0
Non-fatal <sup>3</sup>	0	Kuyken et al. (2015) (3 vs. 3)

<sup>1</sup> Mindfulness-based interventions: mindfulness-based stress reduction (MBSR) and mindfulness-based cognitive therapy (MBCT)<sup>2</sup> At least one adverse event was reported in the control group<sup>3</sup> Definitions on the fatal and non-fatal adverse events were not described

intervention-related adverse events in the control group; future studies should take a closer look at these relationships. Furthermore, most studies are from the Western countries and more studies on different populations are needed to increase external validity.

## Limitations

The review has a number of limitations. First, only RCTs were included in this study. Adverse events may also be reported in cohort studies and single-arm trials, apart from case or qualitative study (Castillo 1990; Chan-Ob and Boonyanarunthee 1999; Jaseja 2005; Kennedy 1976;

Kuijpers et al. 2007). Adverse events may be underreported or not systematically reported in current randomized controlled trials. Adverse events may not have garnered clinical attention in these randomized controlled trials or there might not have been enough time to observe potential adverse effects as previously reported in long-term mediators (Shapiro 1992). However, comparing MBIs with the control group in a randomized controlled setting may reduce potential placebo effects. Furthermore, large population-based prospective surveys can estimate incidence rates of adverse events associated with mindfulness. Future studies may consider such surveys.

Second, many trials did not report any adverse event. As we cannot guarantee that the trials were run without adverse

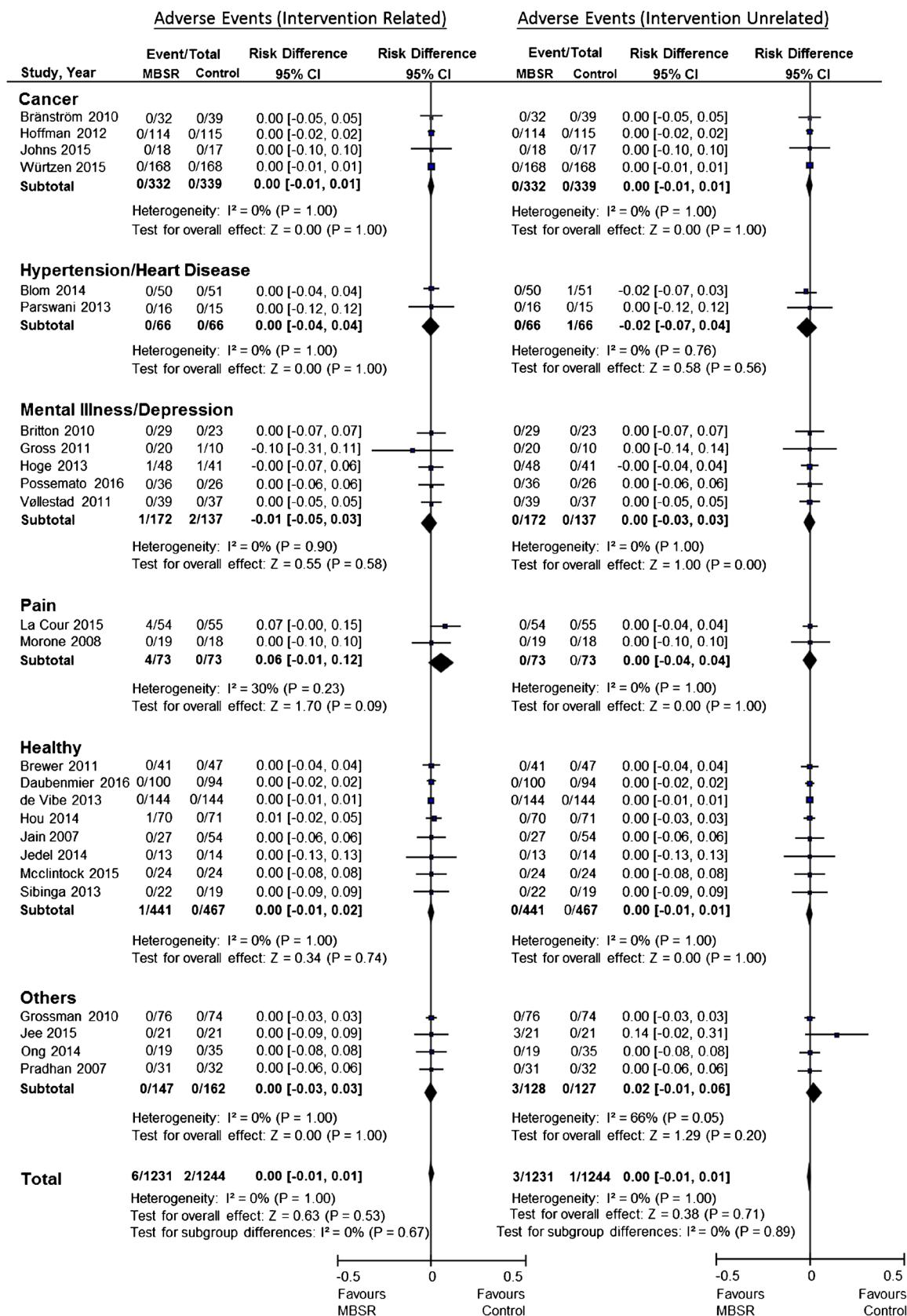
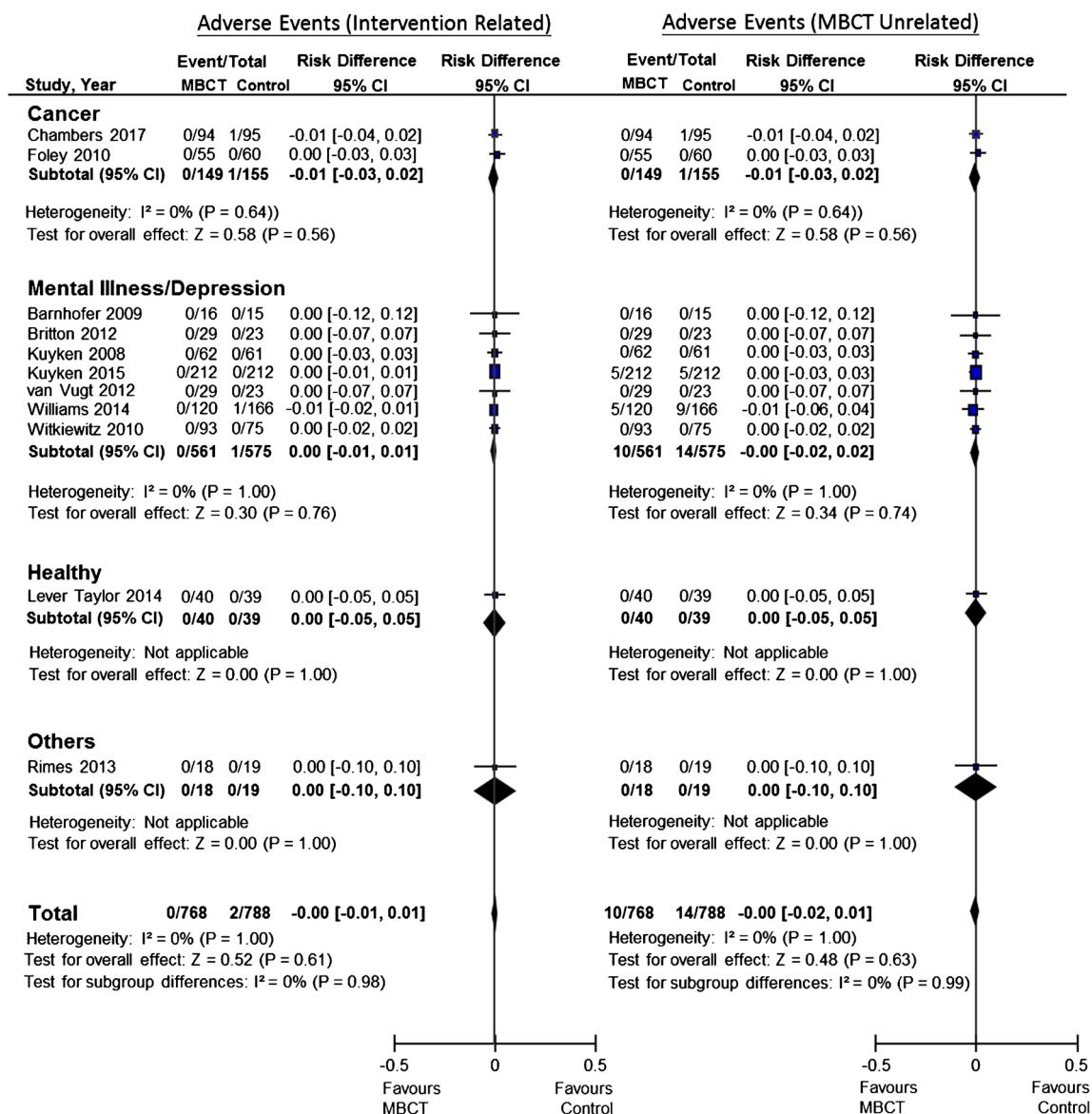


Fig. 2 Forest plots to compare adverse events between mindfulness-based stress reduction (MBSR) and control



**Fig. 3** Forest plots to compare adverse events between mindfulness-based cognitive therapy (MBCT) and control

events or that the authors simply did not report adverse events, all trials with unclear reporting on adverse events were excluded from this review. Furthermore, a review showed that trials published in journals with higher-impact factors were more likely to include harm-related information (Jonsson et al. 2014), which further suggests that journals can play an important role in standardizing the reporting of adverse events in future trials. Third, there were substantial heterogeneities across the study design and recruitment settings. Although we attempted to run subgroup analyses to include similar studies for analyses, we were unable to determine clear definitions on the study groupings and the groupings were based on empirical judgments by academics and healthcare professionals. Fourth, as we have included only randomized controlled trials

and the included studies used structured mindfulness-based interventions and employed mindfulness instructors who have received structured training, our findings may not be applied to mindfulness interventions conducted by instructors with a lower or variable degree of training or recipients with long-term mindfulness practices. Finally, as with most other systematic reviews, we may have missed some unpublished trials during the literature search and trial reports not written in English were not included.

## Compliance with Ethical Standards

**Ethical Standard** The manuscript does not contain clinical studies or patient data.

**Conflict of Interest** The authors declare that they have no conflict of interest.

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