Cochrane Library

Cochrane Database of Systematic Reviews

Mindfulness-based stress reduction for family carers of people with dementia (Review)

Liu Z, Sun YY, Zhong BL

Liu Z, Sun YY, Zhong BL.
Mindfulness-based stress reduction for family carers of people with dementia.
Cochrane Database of Systematic Reviews 2018, Issue 8. Art. No.: CD012791.
DOI: 10.1002/14651858.CD012791.pub2.

www.cochranelibrary.com

WILEY

TABLE OF CONTENTS

[Intervention Review]

Mindfulness-based stress reduction for family carers of people with dementia

Zheng Liu[1], Yu-Ying Sun[2], Bao-liang Zhong[3]

[1]Department of Maternal and Child Health, School of Public Health, Peking University, Beijing, China. [2]Public Health, The Chinese University of Hong Kong, Hong Kong, China. [3]Psychiatry, The Chinese University of Hong Kong, Hong Kong, China

Contact address: Zheng Liu, Department of Maternal and Child Health, School of Public Health, Peking University, 38 Xueyuan Road, Beijing, 100191, China. liuzheng@bjmu.edu.cn, follow.lzheart@gmail.com.

Editorial group: Cochrane Dementia and Cognitive Improvement Group.
Publication status and date: New, published in Issue 8, 2018.

Citation: Liu Z, Sun YY, Zhong BL. Mindfulness-based stress reduction for family carers of people with dementia. *Cochrane Database of Systematic Reviews* 2018, Issue 8. Art. No.: CD012791. DOI: 10.1002/14651858.CD012791.pub2.

ABSTRACT

Background

Caring for people with dementia is highly challenging, and family carers are recognised as being at increased risk of physical and mental ill-health. Most current interventions have limited success in reducing stress among carers of people with dementia. Mindfulness-based stress reduction (MBSR) draws on a range of practices and may be a promising approach to helping carers of people with dementia.

Objectives

To assess the effectiveness of MBSR in reducing the stress of family carers of people with dementia.

Search methods

We searched ALOIS - the Cochrane Dementia and Cognitive Improvement Group's Specialized Register, the Cochrane Central Register of Controlled Trials (CENTRAL) (all years to Issue 9 of 12, 2017), MEDLINE (Ovid SP 1950 to September 2017), Embase (Ovid SP 1974 to Sepetmber 2017), Web of Science (ISI Web of Science 1945 to September 2017), PsycINFO (Ovid SP 1806 to September 2017), CINAHL (all dates to September 2017), LILACS (all dates to September 2017), World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP), ClinicalTrials.gov, and Dissertation Abstracts International (DAI) up to 6 September 2017, with no language restrictions.

Selection criteria

Randomised controlled trials (RCTs) of MBSR for family carers of people with dementia.

Data collection and analysis

Two review authors independently screened references for inclusion criteria, extracted data, assessed the risk of bias of trials with the Cochrane 'Risk of bias' tool, and evaluated the quality of the evidence using the GRADE instrument. We contacted study authors for additional information, then conducted meta-analyses, or reported results narratively in the case of insufficient data. We used standard methodological procedures expected by Cochrane.

Main results

We included five RCTs involving 201 carers assessing the effectiveness of MBSR. Controls used in included studies varied in structure and content. Mindfulness-based stress reduction programmes were compared with either active controls (those matched for time and attention with MBSR, i.e. education, social support, or progressive muscle relaxation), or inactive controls (those not matched for time and attention with MBSR, i.e. self help education or respite care). One trial used both active and inactive comparisons with MBSR. All studies

were at high risk of bias in terms of blinding of outcome assessment. Most studies provided no information about selective reporting, incomplete outcome data, or allocation concealment.

1. Compared with active controls, MBSR may reduce depressive symptoms of carers at the end of the intervention (3 trials, 135 participants; standardised mean difference (SMD) -0.63, 95% confidence interval (CI) -0.98 to -0.28; P<0.001; low-quality evidence). We could not be certain of any effect on clinically significant depressive symptoms (very low-quality evidence).

Mindfulness-based stress reduction compared with active control may decrease carer anxiety at the end of the intervention (1 trial, 78 participants; mean difference (MD) -7.50, 95% CI -13.11 to -1.89; P<0.001; low-quality evidence) and may slightly increase carer burden (3 trials, 135 participants; SMD 0.24, 95% CI -0.11 to 0.58; P=0.18; low-quality evidence), although both results were imprecise, and we could not exclude little or no effect. Due to the very low quality of the evidence, we could not be sure of any effect on carers' coping style, nor could we determine whether carers were more or less likely to drop out of treatment.

2. Compared with inactive controls, MBSR showed no clear evidence of any effect on depressive symptoms (2 trials, 50 participants; MD -1.97, 95% CI -6.89 to 2.95; P=0.43; low-quality evidence). We could not be certain of any effect on clinically significant depressive symptoms (very low-quality evidence).

In this comparison, MBSR may also reduce carer anxiety at the end of the intervention (1 trial, 33 participants; MD -7.27, 95% CI -14.92 to 0.38; P=0.06; low-quality evidence), although we were unable to exclude little or no effect. Due to the very low quality of the evidence, we could not be certain of any effects of MBSR on carer burden, the use of positive coping strategies, or dropout rates.

We found no studies that looked at quality of life of carers or care-recipients, or institutionalisation.

Only one included study reported on adverse events, noting a single adverse event related to yoga practices at home

Authors' conclusions

After accounting for non-specific effects of the intervention (i.e. comparing it with an active control), low-quality evidence suggests that MBSR may reduce carers' depressive symptoms and anxiety, at least in the short term.

There are significant limitations to the evidence base on MBSR in this population. Our GRADE assessment of the evidence was low to very low quality. We downgraded the quality of the evidence primarily because of high risk of detection or performance bias, and imprecision.

In conclusion, MBSR has the potential to meet some important needs of the carer, but more high-quality studies in this field are needed to confirm its efficacy.

PLAIN LANGUAGE SUMMARY

Mindfulness-based stress reduction for family carers of people with dementia

Review question

How effective is mindfulness-based stress reduction (MBSR) in reducing stress-related problems of family carers of people with dementia?

Background

Dementia has become a public health burden worldwide. Caring for people with dementia is highly stressful, thus carers are more likely to suffer from psychological problems, such as depression and anxiety, than general population. Mindfulness-based stress reduction is a potentially promising intervention to target these issues. More information is needed about whether MBSR can help family carers of people with dementia.

Study characteristics

We searched for evidence up to September 2017 and found five randomised controlled trials (clinical trials where people are randomly assigned to one of two or more treatment groups) comparing MBSR to a variety of other interventions. We reported the effects of MBSR programmes compared with active controls (interventions in which participants received a similar amount of attention to those in the MBSR group, such as social support or progressive muscle relaxation) or inactive controls (interventions in which participants received less attention than those in the MBSR group, such as self help education).

Key results

We were able to analyse study data from five randomised controlled trials involving a total of 201 carers. Findings from three studies (135 carers) showed that carers receiving MBSR may have a lower level of depressive symptoms at the end of treatment than those receiving an active control treatment. However, we found no clear evidence of any effect on depression when MBSR was compared with an inactive control treatment. Mindfulness-based stress reduction may also lead to a reduction in carers' anxiety symptoms at the end of treatment. Mindfulness-based stress reduction may slightly increase carers' feelings of burden. However, the results on anxiety and burden were very

uncertain. We were unable to draw conclusions about carers' coping strategies and the risk of dropping out of treatment due to the very low quality of the evidence.

None of the studies measured quality of life of carers or people with dementia, or the rate of admission of people with dementia to care homes or hospitals.

Only one included study reported on adverse events, noting one minor adverse event (neck strain in one participant practising yoga at home)

Quality of the evidence

We considered the quality of the evidence to be low or very low, mainly because the studies were small and the way they were designed or conducted put them at risk of giving biased results. Consequently, we have limited confidence in the results.

Conclusion

To summarise, the review provides preliminary evidence on the effect of MBSR in treating some stress-related problems of family carers of people with dementia. More good-quality studies are needed before we can confirm whether or not MBSR is beneficial for family carers of people with dementia.

Summary of findings for the main comparison. MBSR compared to active control for family carers of people with dementia

MBSR (mindfulness-based stress reduction) compared to active control for family carers of people with dementia

Patient or population: family carers of people with dementia
Setting: community
Intervention: MBSR
Comparison: active control

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with active control	Risk with MBSR				
Depressive symptoms assessed with: CESD, POMS-depression subscale Scale from 0 to 60 follow-up: range 7 weeks to 8 weeks	-	SMD 0.63 SD lower (0.98 lower to 0.28 lower)	-	135 (3 RCTs)	⊕⊕⊖⊖ LOW [a b]	Moderate effect size;[c] lower score represents lower depressive symptoms
Anxiety assessed with: STAI-state anxiety subscale Scale from 20 to 80 follow-up: 8 weeks	The mean anxiety was 47.4 score.	MD 7.5 score lower (13.11 lower to 1.89 lower)	-	78 (1 RCT)	⊕⊕⊖⊖ LOW [a b]	Moderate effect size;[c] lower score represents lower level of anxiety
Carer burden assessed with: MBCBS-subjective stress burden, RMBPC-reaction, ZBI Scale from 0 to 100 follow-up: range 7 weeks to 8 weeks	-	SMD 0.24 SD higher (0.11 lower to 0.58 higher)	-	135 (3 RCTs)	⊕⊕⊖⊖ LOW [a b]	Small effect size;[c] lower score represents lower level of carer burden
Dropout rates follow-up: range 7 weeks to 8 weeks	Study population		RR 1.39 (0.32 to 5.99)	166 (4 RCTs)	⊕⊖⊖⊖ VERY LOW [a d]	Important effect size[e]
	88 per 1000	122 per 1000 (28 to 524)				

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

CESD: Center for Epidemiological Studies Depression Scale; **CI:** confidence interval; **MBCBS:** Montgomery Borgatta Caregiver Burden Scale; **MD:** mean difference; **POMS:** Profile of Mood States: **RCT:** randomised controlled trial; **RMBPC:** Revised Memory and Behavior Problems Checklist; **RR:** risk ratio; **SD:** standard deviation; **SMD:** standardised mean difference; **STAI:** State-Trait Anxiety Inventory; **ZBI:** Zarit Burden Interview

GRADE Working Group grades of evidence
High quality: We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate quality: We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low quality: Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low quality: We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[a]We downgraded the quality of evidence by one level due to serious concern about high risk of bias in blinding of participants and personnel.
[b]As suggested by Ryan 2016a, we downgraded the quality of evidence by one level due to serious concern about imprecision.
[c]To assess the magnitude of effect for continuous outcomes, we used the criteria suggested by Cohen 1988: 0.2 represents a small effect, 0.5 a moderate effect, and 0.8 a large effect.
[d]As suggested by Ryan 2016a, we downgraded the quality of evidence by two levels due to very serious concern about imprecision.
[e]As suggested by Ryan 2016b, we considered an RR < 0.75 or RR > 1.25 an important effect size for dichotomous outcomes.

Summary of findings 2. MBSR compared to inactive control for family carers of people with dementia

MBSR (mindfulness-based stress reduction) compared to inactive control for family carers of people with dementia

Patient or population: family carers of people with dementia
Setting: community
Intervention: MBSR
Comparison: inactive control

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with inactive control	Risk with MBSR				
Depressive symptoms assessed with: CESD Scale from 0 to 60 follow-up: range 7 weeks to 8 weeks	The mean depressive symptoms was 14.2 score.	MD 1.97 score lower (6.89 lower to 2.95 higher)	-	50 (2 RCTs)	⊕⊕⊖⊖ LOW [a b]	Small effect size;[c] lower score represents lower depressive symptoms
Anxiety assessed with: STAI-state anxiety Scale from 20 to 80 follow-up: 8 weeks	The mean anxiety was 47.8 score.	MD 7.27 score lower (14.92 lower to 0.38 higher)	-	33 (1 RCT)	⊕⊕⊖⊖ LOW [a b]	Moderate effect size;[c] lower score represents lower level of anxiety

Carer burden assessed with: RMBPC-reaction Scale from 0 to 96 follow-up: 7 weeks	The mean carer burden was 26.4 score.	MD 1.6 score lower (19.48 lower to 16.28 higher)	-	17 (1 RCT)	⊕⊕⊖⊖ VERY LOW [b d]	Small effect size;[c] lower score represents lower level of carer burden
Dropout rates follow-up: 7 weeks	Study population		RR 2.00 (0.21 to 18.69)	20 (1 RCT)	⊕⊖⊖⊖ VERY LOW [b d]	Important effect size[e]
	100 per 1000	200 per 1000 (21 to 1000)				

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

CESD: Center for Epidemiological Studies Depression Scale; **CI:** confidence interval; **MD:** mean difference; **RCT:** randomised controlled trial; **RMBPC:** Revised Memory and Behavior Problems Checklist; **RR:** risk ratio; **STAI:** State-Trait Anxiety Inventory

GRADE Working Group grades of evidence
High quality: We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate quality: We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low quality: Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low quality: We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[a]As suggested by Ryan 2016a, we downgraded the quality of evidence by one level due to serious concern about imprecision.
[b]We downgraded the quality of evidence by one level due to serious concern about high risk of bias in blinding of participants and personnel.
[c]To assess the magnitude of effect for continuous outcomes, we used the criteria suggested by Cohen 1988: 0.2 represents a small effect, 0.5 a moderate effect, and 0.8 a large effect.
[d]As suggested by Ryan 2016a, we downgraded the quality of evidence by two levels due to very serious concern about imprecision.
[e]As suggested by Ryan 2016b, we considered an RR < 0.75 or RR > 1.25 an important effect size for dichotomous outcomes.

BACKGROUND

Description of the condition

Dementia has become a public health priority due to the ageing population. Approximately 46.8 million people are estimated to live with dementia globally, in low- and high-income regions, and the figure increases by 9.9 million annually (Prince 2015). Dementia leads to progressive cognitive deficits, functional impairment, and behavioural changes. Over time, people with dementia become unable to function independently and require increasing amounts of care from others. Such care lasts for a median of 6.5 years and is most often provided by family members of the person with dementia (Haley 1997).

Caring for relatives with dementia is highly challenging. Indeed, family carers of people with dementia are vulnerable to a range of physical and psychological morbidities, including cardiovascular diseases (Mausbach 2007), depression, anxiety (Cooper 2007; Cuijpers 2005), and even early mortality (Schulz 1999). These and other issues may negatively influence carers' quality of life (Thomas 2006). Carers who feel overburdened are likely to institutionalise people with dementia at an earlier stage, putting pressure on the public healthcare budget (Spijker 2008). Consequently, there is a great need to help family carers of people with dementia to cope with the stress they encounter.

Various psychosocial interventions have been developed for family carers of people with dementia (Acton 2001; Peacock 2003; Pinquart 2006; Selwood 2007; Sörensen 2002). These interventions often include a number of components and aim variously to provide knowledge, practical skills (e.g. behaviour management or communication skills), social support and stress reduction. Their efficacy in reducing the distress felt by family carers is generally mild to moderate (Acton 2001; Peacock 2003; Pinquart 2006; Selwood 2007; Sörensen 2002). Furthermore, no matter how skilful or competent carers are, they are highly likely to experience stress and to feel overwhelmed at times in real-life situations. This is where the skills of mindfulness may come in, allowing carers to relate to the challenges they face in new ways (Kabat-Zinn 2013).

Description of the intervention

Mindfulness is described as "the awareness that emerges through paying attention on purpose, in the present moment, and non-judgmentally to the unfolding of experience" (Kabat-Zinn 2013). Mindfulness-based stress reduction (MBSR) is a widely used programme that involves a range of practices with a focus on stress reduction, such as gentle mindful movement (awareness of the body), a body scan (to nurture awareness of the body region by region), and meditation (awareness of the breath) (Cullen 2011).

How the intervention might work

It is common for people caring for a relative with dementia to worry and ruminate over past events or over an uncontrollable future related to the progression of the illness. Worry and rumination are closely related to the distress felt by carers of people with dementia. With a relatively intensive mindfulness training in MBSR, the carers of people with dementia can learn to be present with the difficulties they face, and to accept unconditionally their own emotions and thoughts (which may be distressing or dysfunctional). This process of present-moment awareness and non-judgmental acceptance has been reported to reduce worry and rumination (Borders 2010; Jain 2007).

Mindfulness-based stress reduction has shown promising benefits in clinical and non-clinical populations, including people facing chronic pain, coping with cancer, or parenting children with autism, among others (Baer 2003; Grossman 2004; Keng 2011). The positive effects across various samples indicate that mindfulness training might enhance the ability to cope with stress even in extraordinary circumstances, such as dementia caring (Oken 2010; Whitebird 2013).

Why it is important to do this review

The amount of research on MBSR for carers of people with dementia has increased in recent years (Brown 2016; Oken 2010; Whitebird 2013). It is important to conduct a systematic review and meta-analysis to synthesise the evidence. Previous reviews on a similar topic did not use a systematic search strategy (Hurley 2014); did not provide a quantitative synthesis by using meta-analytic techniques (Hurley 2014; Jaffray 2015; Li 2016); or did not focus specifically on the population of family carers of people with dementia (Dharmawardene 2016; Jaffray 2015; Li 2016). In this review we have comprehensively searched the published and unpublished literature, and quantitatively evaluated the evidence for MBSR for family carers of people with dementia.

OBJECTIVES

To assess the effectiveness of MBSR in reducing the stress of family carers of people with dementia.

METHODS

Criteria for considering studies for this review

Types of studies

We included individually randomised, parallel-group controlled trials. We did not consider cluster-randomised or cross-over trials.

Types of participants

The participants were family carers of people with any type of dementia living in the community. The relationship of family carers to people with dementia could be spouses, children, other family members, friends, or neighbours. We did not consider care workers who were paid to provide care to people with dementia.

Types of interventions

We included studies of MBSR, which was developed by Jon Kabat-Zinn in 1979 (Kabat-Zinn 2013). The standard MBSR programme might be slightly adapted for the study population to accommodate their physical limitations or time commitment, or both. We applied no restrictions to the 'dosage' (i.e. the number or length of individual sessions or the duration of the trials), units of delivery (i.e. groups, individuals, or a mixture of them), or mode of delivery (i.e. face-to-face, telephone-based, Internet-based, or others).

Acceptable comparators were active-control interventions, waiting list, or usual care. Specifically, 'active-control interventions' refers to interventions matched in time and attention with MBSR, with the aim to control for the non-specific effects of MBSR programmes (such as contact with researchers or social support from other participants). Participants in waiting-list controls had

the opportunity to receive MBSR after a waiting period. Participants in usual care controls could receive the support which was usually available in their community.

Types of outcome measures

We included outcomes measured at the end of the intervention period and at later follow-ups.

Primary outcomes

- Depressive symptoms. If the study specified a cut-off score to identify clinically significant depressive symptoms,we also reported the presence of clinically significant depressive symptoms as an outcome.

Secondary outcomes

For carers:

- anxiety;
- carer burden;
- coping style;
- quality of life;
- dropout rates.

For people with dementia:

- quality of life;
- institutionalisation.

Search methods for identification of studies

We identified trials for inclusion by searching electronic databases and other resources.

Electronic searches

We searched ALOIS (www.medicine.ox.ac.uk/alois), the Cochrane Dementia and Cognitive Improvement Group Specialized Register, on 6 September 2017. The search terms used were: mindfulness OR meditation.

ALOIS is a study-based register and is maintained by the Information Specialists for the Cochrane Dementia and Cognitive Improvement Group (CDCIG). It contains studies in the areas of dementia prevention, dementia treatment, and cognitive enhancement in healthy people.

We identified studies for inclusion from the following sources.

- Monthly searches of a number of major healthcare databases: MEDLINE, Embase, CINAHL (Cumulative Index to Nursing and Allied Health Literature), PsycINFO, and LILACS (Latin American and Caribbean Health Science Information Database).
- Monthly searches of a number of trial registers: ISRCTN; UMIN (Japan's Trial Register); the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) Search Portal (which covers ClinicalTrials.gov; ISRCTN; the Chinese Clinical Trials Register; the German Clinical Trials Register; the Iranian Registry of Clinical Trials; and the Netherlands National Trials Register, as well as others).
- Quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL) (the Cochrane Library).
- Six-monthly searches of a number of grey literature sources: ISI Web of Science Conference Proceedings; Index to Theses; Australasian Digital Theses.

Details of the search strategies used for the retrieval of reports of trials from the healthcare databases, CENTRAL, and conference proceedings can be viewed on the Dementia and Cognitive Improvement website (dementia.cochrane.org/searches).

We performed additional searches in many of the sources listed above to cover the time frame from the last searches performed for ALOIS to ensure that the review search was as up-to-date and comprehensive as possible. The search strategies used are presented in Appendix 1.

Searching other resources

We checked the reference lists of all relevant reviews to identify more trials (Dharmawardene 2016; Hurley 2014; Jaffray 2015; Li 2016). We sought unpublished data by contacting researchers and other people with an interest in the field. Where possible, we also contacted the corresponding authors of identified randomised controlled trials for additional information about other relevant studies. There were no language restrictions.

Data collection and analysis

We used Review Manager 5 for Mac to conduct data entry and calculation of effect sizes (RevMan 2014), and Stata/SE version 14.1 for Mac (StataCorp LP) to conduct our investigation of heterogeneity and publication bias, and subgroup, meta-regression, and sensitivity analyses.

Selection of studies

Two review authors (ZL, YYS) independently selected studies in two stages. First, we screened the titles and abstracts of citations obtained by the searches. Second, we obtained the full texts of potentially eligible studies to identify whether studies fulfilled the inclusion criteria. Any disagreements were resolved by discussion or by consulting a third review author (BLZ). We listed the studies that we excluded at the full-text stage with detailed reasons for their exclusion in the Characteristics of excluded studies table.

Data extraction and management

Two review authors (ZL, YYS) independently extracted data based on the recommendations in Section 7.3.1 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a). The collected information included the authors; publication date; country; funding source; study design; eligibility criteria; characteristics of the study population (including age, gender, and relationship to person with dementia); characteristics of interventions (sessions, dosage, duration, mode of delivery); types and contents of comparators; outcomes and results. For results, we collected outcome measures used, time of assessment, and statistics (numbers of participants, means, standard deviations or other summary statistics). Any disagreements were resolved by discussion or by consulting a third review author (BLZ). If important information was unreported, we contacted the original investigators for the missing information. We presented the information in the Characteristics of included studies table.

Assessment of risk of bias in included studies

Two review authors (ZL, YYS) independently assessed the risk of bias of included studies using the Cochrane 'Risk of bias' tool (Higgins 2011b). The sources of bias included the following.

- Selection bias. We assessed random sequence generation and allocation concealment.
- Performance bias. Although it is not possible to blind personnel or participants (or both) to psychosocial interventions of this nature, we nevertheless made judgements about the potential influence of performance bias on treatment effects. For instance, performance bias may be less of a concern for interventions delivered via the Internet than for those delivered face-to-face.
- Detection bias. We judged whether outcome assessors were blinded to allocation.
- Attrition bias. We appraised the comparability of carer characteristics between the completers and the dropouts and the methods used by the study to deal with missing data, including whether or not there was an intention-to-treat analysis.
- Reporting bias. We searched for protocols of included trials, and then determined if all of the outcomes listed in the protocols were reported in the trials.
- Other bias. We mainly described inexplicable baseline imbalances (presumably if these occurred despite a low risk of bias in the domains mentioned) on the variables known to impact carer stress (including gender, age, relationship to individuals with dementia, and baseline assessment of depression or anxiety) under this domain.

We rated the risk of bias in each domain as 'high risk', 'unclear risk', or 'low risk' according to the Cochrane 'Risk of bias' tool (Higgins 2011b). Any disagreements were resolved by discussion or by consulting a third review author (BLZ). We requested missing information related to the 'Risk of bias' assessment from the original investigators.

We included all studies in the initial analyses. We excluded studies assessed as being at high risk of selection, detection, or attrition bias in sensitivity analyses (see Sensitivity analysis).

Measures of treatment effect

For dichotomous data, we used the risk ratio (RR) as the measure of treatment effect with its 95% confidence interval (CI). For continuous data, we calculated the standardised mean difference (SMD) if trials used different psychometric scales, or the mean difference (MD) if trials used the same scale, with 95% CIs. If possible, we used immediate postintervention values to calculate the main treatment effect.

Unit of analysis issues

The participant allocated to a comparison group in the included trials was the unit of analysis.

Dealing with missing data

We evaluated the missing data and dropout rates for each included trial, and we displayed the results in this full review. If necessary, we requested the missing data from the original investigators. We preferred intention-to-treat analyses from the included studies for meta-analysis. We reported any imputation methods used in the original studies.

Assessment of heterogeneity

We assessed clinical or methodological variation across studies by comparing important characteristics of interventions (e.g. duration, intensity), participants (e.g. age, gender), and the comparisons (whether the control groups were active or inactive). We assessed statistical heterogeneity by visual inspection of forest plots, test of significant level (P value), and the I^2 statistic. We rated the level of heterogeneity across studies as low (I^2 = 25%), moderate (I^2 = 50%), or high (I^2 = 75%) (Higgins 2003). The methods we employed to investigate heterogeneity included sensitivity, subgroup, and meta-regression analyses (a detailed description is given in Subgroup analysis and investigation of heterogeneity).

Assessment of reporting biases

We did not assess reporting biases, as a minimum of 10 studies is required for the meaningful interpretation of funnel plots (Egger 1997; Sterne 2011).

Data synthesis

We undertook a meta-analysis only if we judged elements of trials (including participants, interventions, comparisons, and outcomes) to be sufficiently similar and essential data were available. Due to a considerable amount of clinical heterogeneity across included studies, we used the random-effects model to pool the results by inverse variance methods. When meta-analysis was not appropriate, we presented the findings of these studies narratively. Our main analyses were effects of MBSR at the end of treatment. If studies assessed the persistence of intervention effects with post-treatment follow-ups, we conducted separate analyses for outcomes measured within three months, three to six months, and six months to one year from the end of treatment.

Subgroup analysis and investigation of heterogeneity

If we identified moderate or high levels of heterogeneity in the meta-analyses, we carefully considered the following characteristics as potential effect modifiers:

- nature and dose of the active intervention;
- nature of the control intervention;
- levels of carers' depressive symptoms at baseline;
- levels of carer burden at baseline.

If there were sufficient studies, we considered conducting subgroup analyses based on these potential effect modifiers.

Sensitivity analysis

We conducted sensitivity analyses for the following considerations.

- To investigate heterogeneity, we excluded any individual studies for which the 95% CI of the treatment effect did not overlap with others.
- We compared the pooled results by excluding individual studies at high risk of selection, detection, or attrition bias, as described in Assessment of risk of bias in included studies.
- We compared the pooled results of the effects of MBSR on the reduction of levels of carer burden that was measured by different scales in the same study.

Presentation of results: GRADE and 'Summary of findings' tables

We used GRADE methods to rate the quality of the evidence (high, moderate, low, or very low) behind each effect estimate in the review (Guyatt 2011). This rating refers to our level of confidence that the estimate reflects the true effect, taking into account the risk of bias in the included studies, inconsistency between studies, imprecision in the effect estimate, indirectness in addressing our review question, and the risk of publication bias. We produced 'Summary of findings' tables for the comparisons MBSR versus active or inactive controls for family carers of people with dementia, including the following outcomes:

- depressive symptoms of carers;
- anxiety of carers;
- carer burden;
- dropout rates of carers.

RESULTS

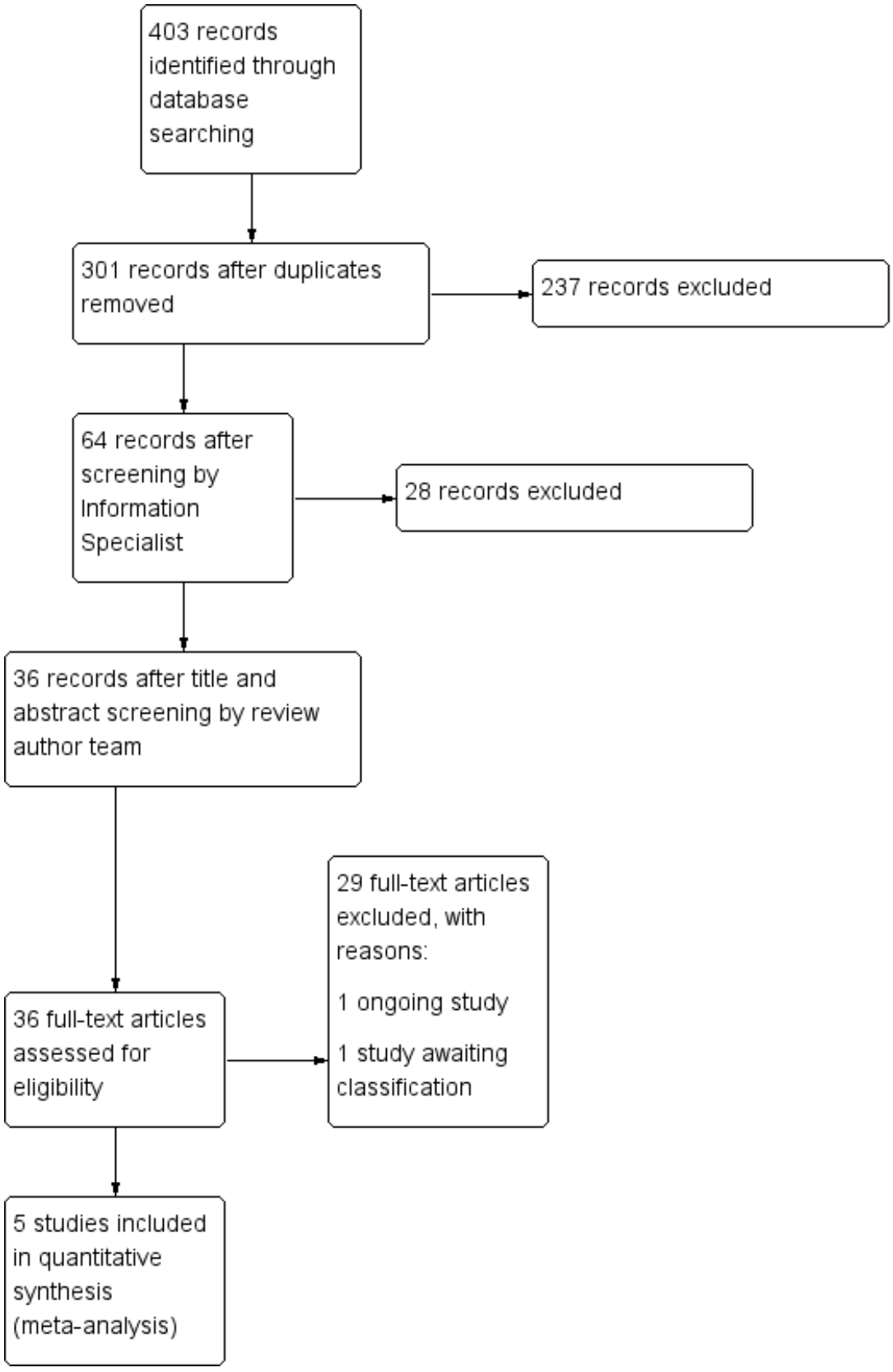
Description of studies

For a detailed description of trials, see: Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies; and Characteristics of studies awaiting classification sections.

Results of the search

Our comprehensive literature searches identified 403 records, of which 301 were left after duplicates were removed. We excluded 265 records based on screening of title/abstract. We obtained the full-text articles for the remaining 36 records, which we screened for inclusion or exclusion (see Figure 1 for the PRISMA flow diagram). We included five trials in the review. We also identified one relevant study awaiting classification (see Characteristics of studies awaiting classification) and one relevant ongoing study (see Characteristics of ongoing studies).

Figure 1. Study flow diagram.



Included studies

A detailed description of the characteristics of the five included trials is provided in Characteristics of included studies. The following is a succinct overview.

Study populations

Three of the included trials recruited only family carers of people with dementia (Brown 2016; Oken 2010; Whitebird 2013); the remaining two studies recruited carers of people with dementia and other neurocognitive disorders, O'Donnell 2013, or chronic disease (Hou 2014). We included only the subsample of carers of people with dementia from Hou 2014 in this review. Sample sizes in the final analyses ranged from 24 in O'Donnell 2013 to 141 in Hou 2014. The mean age of the carers ranged from 57.5 in Hou 2014 to 71.3 in O'Donnell 2013, reflecting the carers' varied relationships to the people with dementia. The proportion of spousal carers ranged from 26% in Whitebird 2013 to 86% in O'Donnell 2013; other carers were adult offspring, other relatives, or friends. More than 80% of carers in all the included studies were women. Two of the included trials specified levels of carer burden or stress as an inclusion criterion (Hou 2014; Whitebird 2013).

Interventions

The included interventions were modelled on original MBSR in Kabat-Zinn 2013, with six to eight weekly sessions covering body scan, mindful hatha yoga, sitting meditation, and other mindfulness practices. One trial also employed a cognitive theoretical framework in addition to MBSR (Oken 2010).

Comparisons

The Oken 2010 study used two comparison arms (group education (active) and respite only (inactive)). The other trials each had one comparison arm. These were education and social support (active) (Brown 2016; Whitebird 2013), progressive muscle relaxation (active) (O'Donnell 2013), and self help (inactive) (Hou 2014).

Outcomes

The most commonly defined primary outcome was depressive symptoms of carers. Studies reported measuring depressive symptoms of carers using the Center for Epidemiological Studies Depression Scale (CESD; Radloff 1977), the Geriatric Depression Scale (GDS; Yesavage 1983), or the depressive symptoms subscale of the Profile of Mood States (POMS; McNair 1971). Two included studies also identified clinically significant depressive symptoms, defined as a score of 4 or more on the GDS (O'Donnell 2013), or a score of 16 or more on the CESD (Hou 2014). Two included studies assessed carers' levels of anxiety using the State-Trait Anxiety Inventory (STAI; Spielberger 1983). Two trials measured carer burden with the Zarit Burden Interview (ZBI; Zarit 1980); one trial used the subjective stress burden subscale of the Montgomery Borgatta Caregiver Burden Scale (MBCBS; Montgomery 2002); another trial used both the Revised Memory and Behavior Problems Checklist (RMBPC; Teri 1992), which was specifically designed for dementia studies, and the Caregiver Appraisal Tool (CAT; Lawton 1989), which was more general to carer studies. One included trial measured coping style using the Coping Responses Inventory (CRI; Moos 1988). No included studies reported on quality of life of carers or people with dementia, or on institutionalisation.

The MBSR programme included in two of the studies had been modified to accommodate the physical limitations of carers (Brown 2016; O'Donnell 2013). Only one study, Hou 2014, reported adverse events occurring when practicing yoga at home (it was unclear whether any adverse events occurred in the other studies). Reports of dropout rates in the MBSR group ranged from 2.6% in Whitebird 2013 to 20% in O'Donnell 2013 and Oken 2010.

Excluded studies

We excluded 28 studies (29 articles) after full-text screening with detailed reasons (see Characteristics of excluded studies). The main reason for exclusion was that the intervention was not MBSR.

Risk of bias in included studies

For an overview of our judgements about each 'Risk of bias' item for individual trials and across all trials, see Figure 2 and Figure 3. For details on the risk of bias of the included trials, see Characteristics of included studies.

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

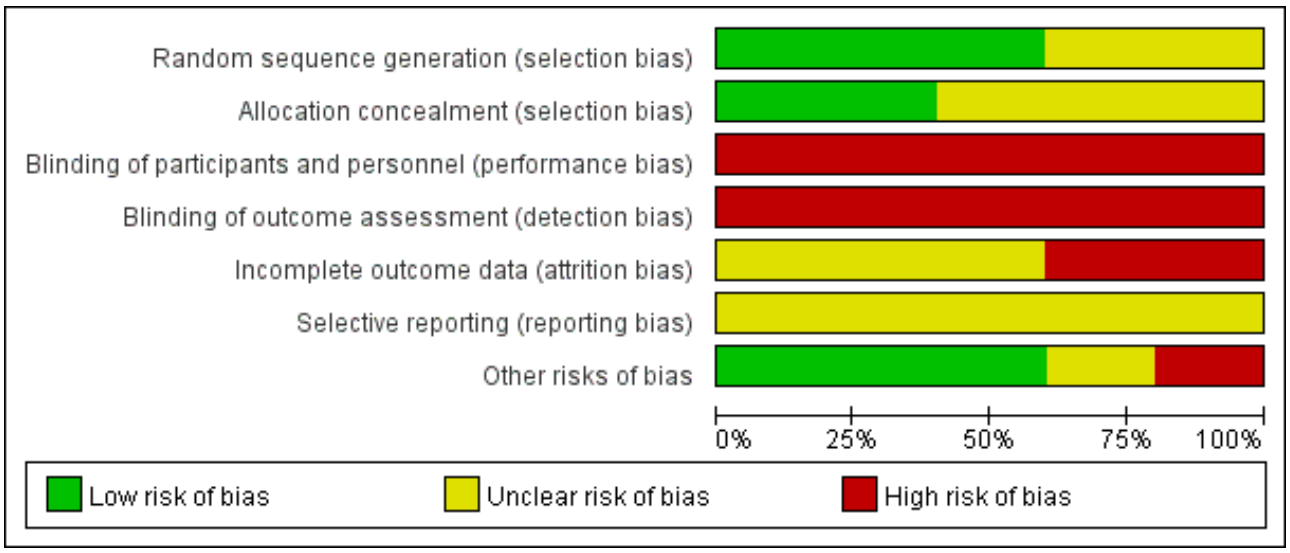
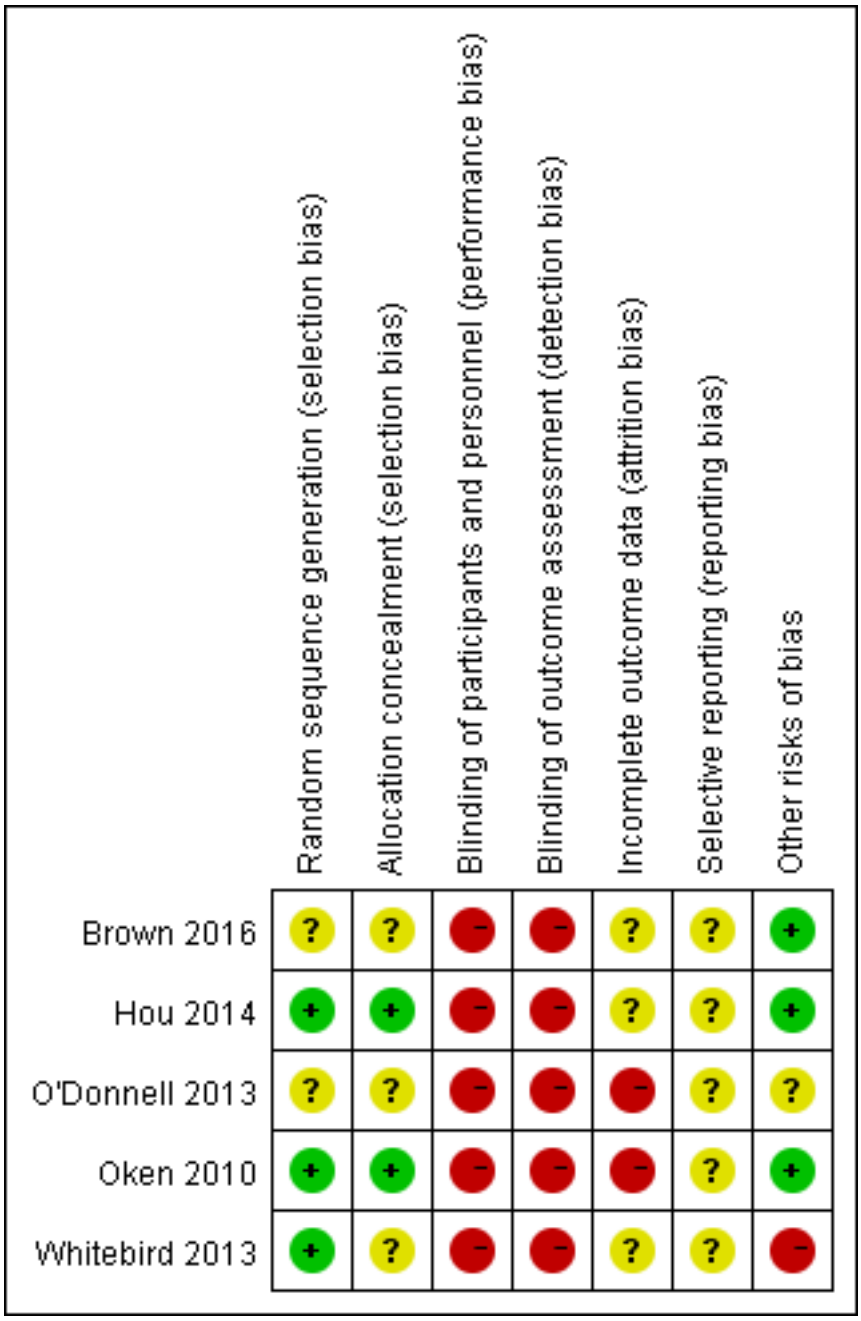


Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



Allocation

Three studies reported adequate sequence generation (low risk of bias), but two were assessed as having an unclear risk of bias in this domain. We rated two studies as at low risk and three as unclear risk of bias for allocation concealment.

Blinding

As it is not possible to blind personnel or participants (or both) to psychosocial interventions of this nature, we rated the risk of performance bias in all included studies as high. This was also true of detection bias due to the lack of blinding and the self report tools used to measure outcomes in the included studies.

Incomplete outcome data

We assessed the risk of attrition bias based on the percentage of missing data, the reasons given for loss of participants in each group, and the method that studies used to deal with incomplete outcome data. We rated two studies as high risk and the remaining studies as unclear risk, mainly due to incomplete information (e.g. concerning the reasons for attrition or the imputation method used for missing data).

Selective reporting

To assess selective outcome reporting, we checked whether publications reported all outcomes described in a protocol. We rated all included trials as being at unclear risk of reporting bias.

Other potential sources of bias

Regarding comparability of baseline characteristics between groups, we rated one study as high risk, one as unclear risk, and the remaining studies as low risk of bias.

Effects of interventions

See: **Summary of findings for the main comparison** MBSR compared to active control for family carers of people with dementia; **Summary of findings 2** MBSR compared to inactive control for family carers of people with dementia

See Summary of findings for the main comparison and Summary of findings 2.

1. MBSR versus active controls immediately after the intervention period

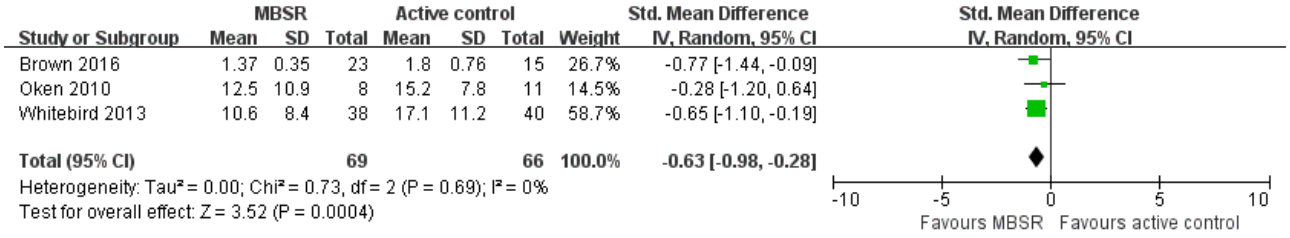
Four trials compared MBSR with active-control interventions (i.e. education, social support, or progressive muscle relaxation).

Primary outcomes

Depressive symptoms

Three trials reported depressive symptoms of carers as continuous outcomes that could be meta-analysed. Pooling the effects in a random-effects meta-analysis demonstrated that MBSR might decrease depressive symptoms of carers compared with the active-control interventions: standardised mean difference (SMD) -0.63 (95% confidence interval (CI) -0.98 to -0.28; P<0.001; 3 trials; 135 participants; low-quality evidence, downgraded one level for serious concern about high risk of bias, and one level for serious concern about imprecision) (Analysis 1.1; Figure 4). One trial also reported carer depression as a categorical outcome. Due to the very low quality of the evidence, we were uncertain whether or not MBSR had any effect on the risk of clinically significant depressive symptoms when compared with progressive muscle relaxation: risk ratio (RR) 0.33 (95% CI 0.04 to 2.77; P = 0.31; 1 trial; 24 participants; very low-quality evidence, downgraded two levels for very serious concern about imprecision and one level for serious concern about high risk of bias) (Analysis 1.2).

Figure 4. Forest plot of comparison: 1 MBSR versus active control at immediately postintervention, outcome: 1.1 Depressive symptoms.



Secondary outcomes

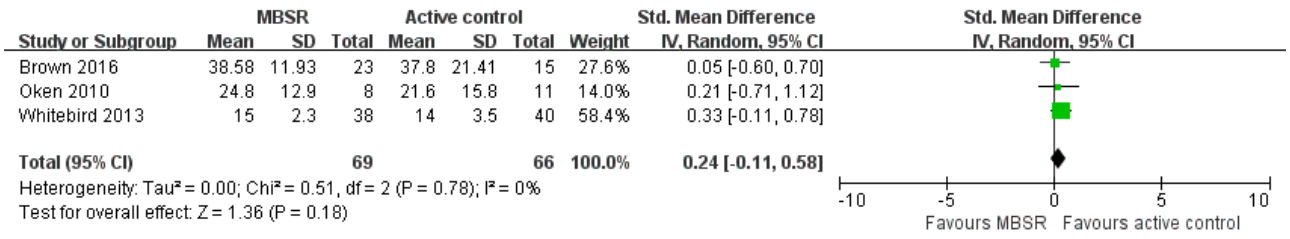
Anxiety

Mindfulness-based stress reduction may reduce carers' anxiety compared with the active-control group (i.e. education and social support) immediately after the intervention period: mean difference (MD) -7.50 (95% CI -13.11 to -1.89; P = 0.009; 1 trial; 78 participants; low-quality evidence, downgraded one level for serious concern about imprecision and one level for serious concern about high risk of bias) (Analysis 1.3).

Carer burden

Three trials reported data on carer burden that could be meta-analysed. Pooling the effects in a random-effects meta-analysis showed that MBSR may slightly increase levels of carer burden compared with active controls immediately after the intervention period, but the result was too imprecise for us to be sure of the size or direction of the effect: SMD 0.24 (95% CI -0.11 to 0.58; P = 0.18; 3 trials; 135 participants; low-quality evidence, downgraded one level for serious concern about imprecision and one level for serious concern about high risk of bias) (Analysis 1.4; Figure 5).

Figure 5. Forest plot of comparison: 1 MBSR versus active control at immediately postintervention, outcome: 1.4 Carer burden.



Coping style

Due to the very low quality of the evidence, we were uncertain whether or not MBSR might improve the use of positive coping strategies compared with the active-control group (i.e. education) immediately after the intervention period: MD 6.00 (95% CI -4.59 to 16.59; P = 0.27; 1 trial; 19 participants; very low-quality evidence, downgraded two levels for very serious concern about imprecision and one level for high risk of bias) (Analysis 1.5).

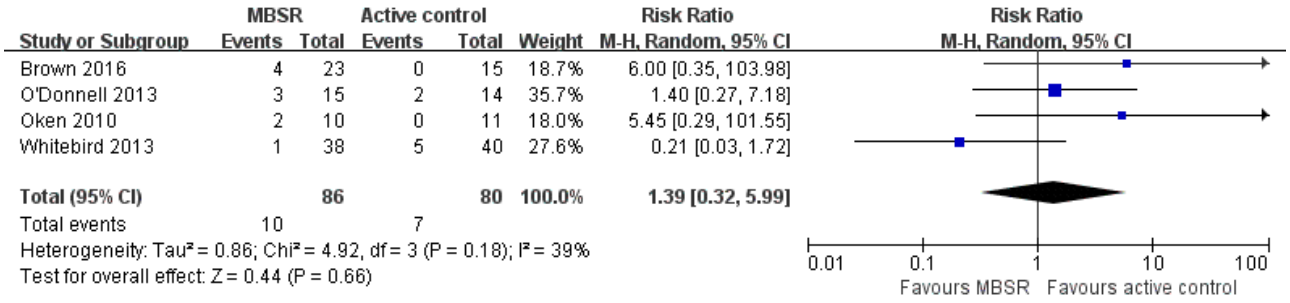
Carers' quality of life

None of the included trials reported this outcome.

Dropout rates

Four trials reported data on rates of dropout from treatment that could be meta-analysed. Pooling the effects in a random-effects meta-analysis, we were uncertain, due to the very low quality of the evidence, whether or not there was a higher risk of dropout in the MBSR group than in the active-control group: RR 1.39 (95% CI 0.32 to 5.99; P = 0.66; 4 trials; 166 participants; very low-quality evidence, downgraded two levels for very serious concern about imprecision and one level for high risk of bias) (Analysis 1.6; Figure 6).

Figure 6. Forest plot of comparison: 1 MBSR versus active control at immediately postintervention, outcome: 1.7 Dropout rates.



Quality of life of people with dementia

None of the included trials reported this outcome.

Institutionalisation

None of the included trials reported this outcome.

2. MBSR versus inactive controls immediately after the intervention period

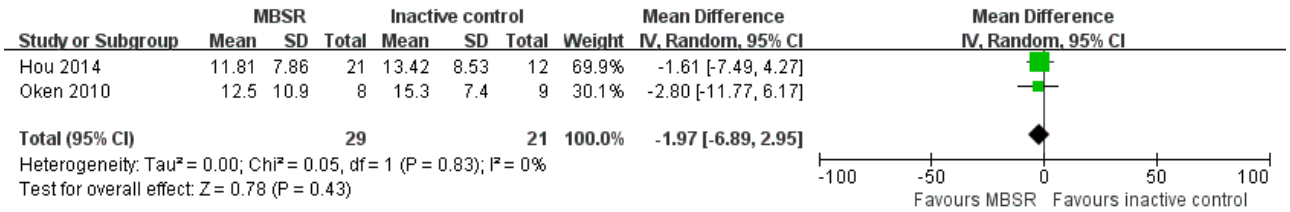
Two trials compared MBSR with inactive controls (i.e. self help education or respite-only control). We considered outcomes immediately after the end of the intervention period for each trial.

Primary outcomes

Depressive symptoms

Two trials reported data on depressive symptoms of carers that could be meta-analysed. Pooling the effects in a random-effects meta-analysis, there was no clear effect on depressive symptoms of carers in the MBSR group compared with the inactive controls immediately after the intervention period; the result was imprecise and compatible with an effect in either direction: MD -1.97 (95% CI -6.89 to 2.95; P = 0.43; 2 trials; 50 participants; low-quality evidence, downgraded one level for serious concern about imprecision and one level for high risk of bias) (Analysis 2.1; Figure 7). One trial reported carer depression as a categorical outcome. Due to the very low quality of the evidence, we were uncertain whether or not MBSR may reduce the risk of clinically significant depressive symptoms compared with the inactive control (i.e. self help education) immediately after the intervention: RR 0.69 (95% CI 0.26 to 1.78; P = 0.44; 1 trial; 33 participants; very low-quality evidence, downgraded two levels for very serious concern about imprecision and one level for high risk of bias) (Analysis 2.2).

Figure 7. Forest plot of comparison: 2 MBSR versus inactive control at immediately postintervention, outcome: 2.1 Depressive symptoms.



Secondary outcomes

Anxiety

The results showed that MBSR may reduce carers' levels of anxiety compared with the inactive control (i.e. self help education) immediately after the intervention period, although due to imprecision, we could not exclude little or no effect: MD -7.27 (95% CI -14.92 to 0.38; P = 0.06; 1 trial; 33 participants; low-quality evidence, downgraded one level for serious concern about imprecision and one level for high risk of bias) (Analysis 2.3).

Carer burden

Compared with the inactive control (i.e. respite-only control), we were uncertain whether or not MBSR could reduce carer burden after the intervention period due to the very low quality of the evidence: MD -1.60 (95% CI -19.48 to 16.28; P = 0.86; 1 trial; 17 participants; very low-quality evidence, downgraded two levels for very serious concern about imprecision and one level for high risk of bias) (Analysis 2.4).

Coping style

Again due to the very low quality of the evidence, we were uncertain whether or not MBSR had any effect on the use of positive coping strategies compared with the respite-only control immediately after the intervention period: MD 7.90 (95% CI -5.41 to 21.21; P = 0.24; 1 trial; 17 participants; very low-quality evidence, downgraded two levels for very serious concern about imprecision and one level for high risk of bias) (Analysis 2.5).

Carers' quality of life

None of the included trials reported this outcome.

Dropout rates

We were uncertain whether or not there was a significant difference in dropout rates in the MBSR group compared with the respite-only control: RR 2.00 (95% CI 0.21 to 18.69; P = 0.54; 1 trial; 20 participants; very low-quality evidence, downgraded two levels for very serious concern about imprecision and one level for high risk of bias) (Analysis 2.6).

Quality of life of people with dementia

None of the included trials reported this outcome.

Institutionalisation

None of the included trials reported this outcome.

3. MBSR versus controls at postintervention follow-up

Two trials reported data at follow-up within three months. Their results were not suitable for meta-analysis because they compared MBSR with different kinds of control groups (i.e. active or inactive control).

- Compared with the active-control intervention, the results for depressive symptoms suggested that there may be little or no effect of MBSR: MD -0.16 (95% CI -0.71 to 0.39; P = 0.57; 1 trial; 38 participants; low-quality evidence, downgraded one level for serious concern about imprecision and one level for high risk of bias) (Analysis 3.1). The results for carer burden favoured the active-control intervention, but was too imprecise for us to be sure of the size or direction of the effect: MD 6.62 (95% CI -4.92 to 18.16; P = 0.26; 1 trial; 38 participants; low-quality evidence, downgraded one level for serious concern about imprecision and one level for high risk of bias) (Analysis 3.2).
- Compared with the inactive control, the results for carers' depressive symptoms slightly favoured MBSR but were too imprecise for us to be sure of the size or direction of the effect: MD -3.00 (95% CI -8.52 to 2.52; P = 0.29; 1 trial; 31 participants; low-quality evidence, downgraded one level for serious concern about imprecision and one level for high risk of bias) (Analysis 4.1). Due to the very low quality of the evidence, we were uncertain whether or not MBSR had any effect on the risk of clinically significant depressive symptoms at follow-up within three months: RR 0.55 (95% CI 0.20 to 1.49; P = 0.24; 1 trial; 31 participants; very low-quality evidence, downgraded two levels for very serious concern about imprecision and one level for high risk of bias) (Analysis 4.2). There may also be a reduction in anxiety in the MBSR group at follow-up within three months, although due to imprecision we could not rule out little or no effect: MD -6.92 (95% CI -14.60 to 0.76; P = 0.08; 1 trial; 31 participants; low-quality evidence, downgraded one level for serious concern about imprecision and one level for high risk of bias) (Analysis 4.3).

Two trials reported data at follow-up between three and six months. Both trials compared MBSR to an active-control intervention.

- Compared with the active-control intervention, the results for carers' depressive symptoms slightly favoured MBSR, although due to imprecision we could not rule out little or no effect: MD -3.20 (95% CI -6.80 to 0.40; P = 0.08; 1 trial; 78 participants; low-quality evidence, downgraded one level for serious concern about imprecision and one level for high risk of bias) (Analysis 5.1). Again due to the very low quality of the evidence, we were uncertain whether or not MBSR had any effect on the risk of clinically significant depressive symptoms: RR 1.00 (95% CI 0.25 to 4.00; P = 1.00; 1 trial; 24 participants; very low-quality evidence, downgraded two levels for very serious concern about imprecision and one level for high risk of bias) (Analysis 5.2). Compared to an active-control intervention, MBSR may reduce levels of anxiety: MD -6.50 (95% CI -12.00 to -1.00; P = 0.02; 1 trial; 78 participants; low-quality evidence, downgraded one level for serious concern about imprecision and one level for high risk of bias) (Analysis 5.3). The results for carer burden also slightly favoured the active-control intervention, but again due to imprecision we could not rule out little or no effect: MD 0.90 (95% CI -0.55 to 2.35; P = 0.22; 1 trial; 78 participants; low-quality evidence, downgraded one level for serious concern about imprecision and one level for high risk of bias) (Analysis 5.4).

4. Subgroup and sensitivity analyses

We did not conduct subgroup analyses due to low levels of heterogeneity in most of the meta-analyses (I^2 = 0%) and an insufficient number of included studies in the comparisons (n < 5).

One included study measured carer burden using two different scales (Oken 2010). The effect of MBSR versus control on carer burden immediately after the intervention period did not change significantly after including outcomes from the alternative scale in the meta-analyses (MBSR versus active control: 3 trials, 135 participants, SMD 0.20, 95% CI -0.14 to 0.55, P = 0.24; MBSR versus

inactive control: 1 trial, 17 participants, MD -1.50, 95% CI -20.12 to 17.15, P = 0.87). Since all of the included trials had a high risk of detection bias, we did not conduct sensitivity analyses by excluding individual studies at high risk of bias.

DISCUSSION

Summary of main results

This review of five randomised controlled trials with a total of 201 family carers of people with dementia evaluated the effects of MBSR on stress-related outcomes. We conducted two comparisons according to the type of control intervention: MBSR versus active control and MBSR versus inactive control.

MBSR versus active control

For our primary review outcome, we found from a meta-analysis of 3 studies (135 participants) that there may be a reduction in depressive symptoms for carers receiving MBSR compared with an active-control intervention immediately after the intervention period (low-quality evidence). One small study (24 participants) reported clinically significant depressive symptoms in participants, but we could not be certain of any effect on this outcome (very low-quality evidence).

Regarding our secondary outcomes, MBSR may reduce carers' anxiety and slightly increase carer burden compared with active control immediately after the intervention period (low-quality evidence), although both results were imprecise, and there could also have been little or no effect. Due to the very low quality of the evidence, we could not be sure of any effect on carers' coping style, nor could we determine whether carers were more or less likely to drop out of treatment. There were no data on quality of life of carers or people with dementia, or on institutionalisation.

Some included trials followed participants up to six months after the end of the intervention, but all results at postintervention follow-up were very imprecise due to small sample sizes.

MBSR versus inactive control

For our primary review outcome of depressive symptoms, the results of a meta-analysis of 2 studies (50 participants) were imprecise and showed no clear evidence of any effect (low-quality evidence). We could not be certain of any effect on clinically significant depressive symptoms (1 trial, 33 participants, very low-quality evidence).

Regarding our secondary outcomes, MBSR may be associated with a reduction of levels of anxiety immediately after the intervention period when compared with an inactive control, although we could not exclude little or no effect (low-quality evidence). Due to the very low quality of the evidence, we could not be certain of any effects of MBSR on carer burden, the use of positive coping strategies, or dropout rates. There were no data on quality of life of carers or people with dementia, or on institutionalisation.

There were very few data from one small trial at follow-up within three months, but the results were all very imprecise.

Adverse events

More information is needed. Only one included study reported on adverse events, noting one adverse event in a man aged 80 who reported neck strain from home practice, suggesting that MBSR practices performed at home, especially those including yoga practices, should be appropriately adapted to the physical limitations of older carers.

Overall completeness and applicability of evidence

We used an extensive search strategy including a comprehensive range of databases and other sources relevant to the focus of the review. It is therefore unlikely that we missed references that meet our eligibility criteria. Another strength of this review is that we included both active and inactive types of control groups. However, the applicability of the evidence was limited by several study characteristics. First, much emphasis of the included trials was placed on measures of depressive symptoms and carer burden, rather than other outcomes such as levels of anxiety, coping style, institutionalisation, or quality of life for carers or people with dementia. Stress theory suggests that stressors such as dementia caregiving may manifest their effects in multiple ways (Almeida 2005; Pearlin 1990). As a consequence, a focus on depression or burden as outcomes may not fully capture what carers of people with dementia might get out of MBSR. Second, the small number of included studies as well as insufficient numbers of participants might be underpowered to detect evidence of small effects favouring MBSR over control, or vice versa, indicating that further large-scale and rigorously designed research is needed in this field. Moreover, as no studies have assessed effects longer than six-month follow-up, the evidence can be applied only to short-term effects.

Quality of the evidence

We assessed the quality of the evidence as low to very low mainly due to high risk of detection and performance bias and imprecision of study results (Summary of findings for the main comparison; Summary of findings 2).

Potential biases in the review process

As described in Assessment of reporting biases, due to the limited data available, we were unable to generate funnel plots. We cannot exclude the possibility of publication bias.

Agreements and disagreements with other studies or reviews

We identified one recent review that concerns mindfulness-based interventions for family carers of people with dementia (Kor 2017). This review included both randomised controlled trials and quasi-experimental studies, unlike our review, which focused exclusively on randomised controlled trials, which is the best available evidence. The reviews also differed in terms of inclusion criteria of interventions or outcomes. We also considered the impact of different types of control groups (i.e. active or inactive control) on the effect of MBSR. In other words, this Cochrane Review differentiates the specific and non-specific effect of MBSR versus controls for family carers of people with dementia.

Despite differences in types of interventions, assessed outcomes, data comparison and analyses between this review and ours, both reviews found that evidence of MBSR for carers is still preliminary, and that based on the available evidence, no clear conclusion could be reached.

AUTHORS' CONCLUSIONS

Implications for practice

The results suggest that mindfulness-based stress reduction (MBSR) has the potential to reduce carers' depressive symptoms and anxiety immediately after the intervention. The evidence considered non-specific effects of MBSR compared with control, although the evidence is currently of low quality. Considered alongside other reviews, we tentatively suggest that clinicians may consider MBSR as a brief alternative or adjunctive treatment to conventional interventions for carers of people with dementia.

Implications for research

The evidence available for this review was limited in quality and quantity. Large-scale and high-quality studies are needed on the effectiveness of MBSR to help carers of individuals with dementia cope with stress. While depression has been emphasised in the research, it is only one of the multiple outcomes of the stress process. Further high-quality trials need also to address this issue and assess the effect of MBSR on measures of stress-related outcomes other than depression, such as aspects of health and quality of life (Zarit 2017).

ACKNOWLEDGEMENTS

We would like to thank the following people from the Department of Psychiatry, the Chinese University of Hong Kong: Prof Linda Chiu-Wa Lam, Prof Sing Lee, and Prof Arthur Dun-Ping Mak for their patient guidance and continuous support throughout the period of study design.

REFERENCES

References to studies included in this review

Brown 2016 *{published data only}*

Brown KW, Coogle CL, Wegelin J. A pilot randomized controlled trial of mindfulness-based stress reduction for caregivers of family members with dementia. *Aging & Mental Health* 2016;**20**(11):1157-66.

Hou 2014 *{published data only}*

Hou RJ, Wong SY, Yip BH, Hung AT, Lo HH, Chan PH, et al. The effects of mindfulness-based stress reduction program on the mental health of family caregivers: a randomized controlled trial. *Psychotherapy and Psychosomatics* 2014;**83**:45-53.

O'Donnell 2013 *{published data only}*

O'Donnell RM. Mindfulness-Based Stress Reduction as an Intervention Among Family Caregivers of Persons With Neurocognitive Disorders [Masters thesis]. The University of Arizona, 2013.

Oken 2010 *{published data only (unpublished sought but not used)}*

Oken BS, Fonareva I, Haas M, Wahbeh H, Lane JB, Zajdel D, et al. Pilot controlled trial of mindfulness meditation and education for dementia caregivers. *Journal of Alternative and Complementary Medicine* 2010;**16**(10):1031-8.

Whitebird 2013 *{published data only (unpublished sought but not used)}*

Whitebird RR, Kreitzer MJ, Crain AL, Lewis BA, Hanson LR, Enstad CJ. Mindfulness-based stress reduction for family caregivers: a randomized controlled trial. *Gerontologist* 2013;**53**(4):676-86.

References to studies excluded from this review

Black 2013 *{published data only}*

Black DS, Cole SW, Irwin MR, Breen E, St Cyr NM, Nazarian N, et al. Yogic meditation reverses NF-kappaB and IRF-related transcriptome dynamics in leukocytes of family dementia caregivers in a randomized controlled trial. *Psychoneuroendocrinology* 2013;**38**(3):348-55.

Danucalov 2013 *{published and unpublished data}*

Danucalov MA, Kozasa EH, Ribas KT, Galduróz JC, Garcia MC, Verreschi IT, et al. A yoga and compassion meditation program reduces stress in familial caregivers of Alzheimer's disease patients. *Evidence-Based Complementary and Alternative Medicine* 2013;**2013**:513149.

NCT02563483. A yoga and compassion meditation program improve quality of life and self-compassion in family caregivers of Alzheimer's disease patients: a randomized controlled trial. clinicaltrials.gov/show/NCT02563483 2007.

Danucalov 2017 *{published data only}*

Danucalov MA, Kozasa EH, Afonso RF, Galduroz JC, Leite JR. Yoga and compassion meditation program improve quality of life and self-compassion in family caregivers of Alzheimer's disease patients: a randomized controlled trial. *Geriatrics & Gerontology International* 2017;**17**(1):85-91.

Dharmawardene 2016 *{published data only}*

Dharmawardene M, Givens J, Wachholtz A, Makowski S, Tjia J. A systematic review and meta-analysis of meditative interventions for informal caregivers and health professionals. *BMJ Supportive & Palliative Care* 2016;**6**(2):160-9.

Hurley 2014 *{published data only}*

Hurley RVC, Patterson TG, Cooley SJ. Meditation-based interventions for family caregivers of people with dementia: a review of the empirical literature. *Aging & Mental Health* 2014;**18**(3):281-8.

ISRCTN53169488 *{published data only}*

ISRCTN53169488. The psychological health benefits of mindfulness-based stress reduction in family caregivers of patients with dementia. isrctn.com/ISRCTN53169488 (first received 11 November 2015).

Jaffray 2016 *{published data only}*

Jaffray L, Bridgman H, Stephens M, Skinner T. Evaluating the effects of mindfulness-based interventions for informal palliative caregivers: a systematic literature review. *Palliative Medicine* 2016;**30**(2):117-31.

Jain 2016 *{published data only}*

Jain FA, Lacoboni M, Moore LC, Abrams M, Benyelles R, Lavretsky H, et al. 4-week mindfulness and guided imagery group for depressed dementia caregivers: feasibility and candidate neural mechanisms. *Biological Psychiatry* 2016;**79**(9 Suppl):S400.

Kor 2017 *{published data only}*

Kor PP, Chien WT, Liu JY, Lai CK. Mindfulness-based intervention for stress reduction of family caregivers of people with dementia: a systematic review and meta-analysis. *Mindfulness* 2017;**9**(1):7-22.

Leach 2014 *{published data only}*

Leach MJ, Francis A, Ziaian T. Improving the health and well-being of community-dwelling caregivers of dementia sufferers: study protocol of a randomized controlled trial of structured meditation training. *Journal of Alternative and Complementary Medicine* 2014;**20**(2):136-41.

Leach 2015 *{published data only}*

Leach MJ, Francis A, Ziaian T. Transcendental meditation for the improvement of health and wellbeing in community-dwelling dementia caregivers [TRANSCENDENT]: a randomised wait-list controlled trial. *BMC Complementary and Alternative Medicine* 2015;**15**(1):145.

Li 2016 *{published data only}*

Li G, Yuan H, Zhang W. The effects of mindfulness-based stress reduction for family caregivers: systematic review. *Archives of Psychiatric Nursing* 2016;**30**(2):292-9.

NCT00558402 *{unpublished data only}*

NCT0058402. Meditation for Alzheimer caregivers: stress & physiology. clinicaltrials.gov/ct2/show/NCT00558402 (first received 15 September 2007).

NCT00615082 *{unpublished data only}*

NCT00615082. Stress reduction for caregivers: a randomized controlled pilot study. clinicaltrials.gov/show/NCT00615082 (first received 14 February 2008).

NCT01537679 2010 *{unpublished data only}*

NCT01537679. Meditation or relaxation used to reduce stress response and improve cognitive functioning in older family dementia caregivers. clinicaltrials.gov/show/NCT01537679 (first received 23 February 2012).

NCT01605448 2010 *{unpublished data only}*

NCT01605448. Mindfulness-based stress reduction for adults with mild cognitive impairment. clinicaltrials.gov/show/NCT01605448 (first received 27 August 2012).

NCT01774448 2013 *{unpublished data only}*

NCT01774448. The efficacy of mindfulness-based cognitive therapy (MBCT) to improve depression symptoms and quality of life in individuals with dementia and their caregivers: a pilot study. clinicaltrials.gov/show/NCT01774448 (first received 24 January 2013).

NCT02122068 2014 *{unpublished data only}*

NCT02122068. Central meditation and imagery therapy for major depressive disorder in family dementia caregivers. clinicaltrials.gov/show/NCT02122068 (first received 24 April 2014).

NCT02286791 2014 *{unpublished data only}*

NCT02286791. Mindful awareness program for the prevention of dementia: a randomized controlled trial. clinicaltrials.gov/show/NCT02286791 (first received 10 November 2014).

NCT02314390 2013 *{unpublished data only}*

NCT02314390. Group- versus individual-mindfulness-based cognitive therapy for patients with a chronic somatic disease and comorbid depressive symptoms: a randomized trial. clinicaltrials.gov/show/NCT02314390 (first received 11 December 2014).

NCT02457936 2015 *{published data only}*

NCT02457936. Examining cognitive mechanisms of clinical improvement following mindfulness based cognitive therapy for depressed individuals. clinicaltrials.gov/show/NCT02457936 (first received 29 May 2015).

NCT02777905 2016 *{unpublished data only}*

NCT02777905. Group mindfulness-based cognitive therapy for the treatment of late-life depression and anxiety symptoms in primary care: a randomized controlled trial. clinicaltrials.gov/show/NCT02777905 (first received 19 May 2016).

NCT02902692 2016 *{unpublished data only}*

NCT02902692. Examining the effects of a brief mindfulness based intervention (BMBI) on mood and cognitive functioning in an older adult population. clinicaltrials.gov/show/NCT02902692 (first received 16 September 2016).

NCT03056105 2013 *{unpublished data only}*

NCT03056105. The psychobiological effects of a one-month insight meditation retreat, a sub-study of The Shamatha Project: a longitudinal, randomized waitlist control study of cognitive, emotional, and neural effects of intensive meditation training. clinicaltrials.gov/show/NCT03056105 (first received 17 February 2017).

NCT03092050 2017 *{unpublished data only}*

NCT03092050. Group therapy for depressed caregivers of Alzheimer's disorder and related dementias. clinicaltrials.gov/show/NCT03092050 (first received 27 March 2017).

Pomykala 2012 *{published data only}*

Pomykala KL, Silverman DH, Geist CL, Voege P, Siddarth P, Nazarian N, et al. A pilot study of the effects of meditation on regional brain metabolism in distressed dementia caregivers. *Aging Health* 2012;**8**(5):509-16.

Waelde 2017 *{published data only}*

Waelde LC, Meyer H, Thompson JM, Thompson L, Gallagher-Thompson D. Randomized controlled trial of inner resources meditation for family dementia caregivers. *Journal of Clinical Psychology* 2017;**73**(12):1629-41.

References to studies awaiting assessment

NCT02667782 2016 *{unpublished data only}*

NCT02667782. Use of a mindfulness-based intervention for family carers of people with dementia in the community: a feasibility study. clinicaltrials.gov/show/NCT02667782 (first received 29 January 2016).

References to ongoing studies

ACTRN12617000347369 2017 *{unpublished data only}*

ACTRN12617000347369. HOMeCare: Caring for the dementia caregiver and their loved one via the HOMeCare exercise and mindfulness for health program. www.anzctr.org.au/ACTRN12617000347369.aspx (first received 7 March 2017).

Additional references

Acton 2001

Acton GJ, Kang J. Interventions to reduce the burden of caregiving for an adult with dementia: a meta-analysis. *Research in Nursing & Health* 2001;**24**(5):349-60.

Almeida 2005

Almeida DM. Resilience and vulnerability to daily stressors assessed via diary methods. *Current Directions of Psychological Science* 2005;**14**:64-8.

Baer 2003

Baer RA. Mindfulness training as a clinical intervention: a conceptual and empirical review. *Clinical Psychology: Science and Practice* 2003;**10**(2):125-43.

Borders 2010

Borders A, Earleywine M, Jajodia A. Could mindfulness decrease anger, hostility, and aggression by decreasing rumination?. *Aggressive Behavior* 2010;**36**(1):28-44.

Cohen 1988

Cohen J. Statistical Power Analysis for the Behavioral Sciences. 2nd Edition. Hillsdale (NJ): Lawrence Erlbaum Associates Inc., 1988.

Cooper 2007

Cooper C, Balamurali TBS, Livingston G. A systematic review of the prevalence and covariates of anxiety in caregivers of people with dementia. *International Psychogeriatrics/IPA* 2007;**19**(2):175-95.

Cuijpers 2005

Cuijpers P. Depressive disorders in caregivers of dementia patients: a systematic review. *Aging & Mental Health* 2005;**9**(4):325-30.

Cullen 2011

Cullen M. Mindfulness-based interventions: an emerging phenomenon. *Mindfulness* 2011;**2**(3):186-93.

Egger 1997

Egger M, Davey-Smith G, Schneider M, Minder C. Bias in meta-analysis detected by a simple, graphical test. *BMJ* 1997;**315**(7109):629-34.

Grossman 2004

Grossman P, Niemann L, Schmidt S, Walach H. Mindfulness-based stress reduction and health benefits. A meta-analysis. *Journal of Psychosomatic Research* 2004;**57**(1):35-43.

Guyatt 2011

Guyatt G, Oxman AD, Akl EA, Kunz R, Vist G, Brozek J, et al. GRADE guidelines: 1. Introduction - GRADE evidence profiles and summary of findings tables. *Journal of Clinical Epidemiology* 2011;**64**(4):383-94.

Haley 1997

Haley WE. The family caregiver's role in Alzheimer's disease. *Neurology* 1997;**48**(5 Suppl 6):S25-9.

Higgins 2003

Higgins JP, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in meta-analyses. *BMJ* 2003;**327**(7414):557-60.

Higgins 2011a

Higgins JPT, Deeks JJ. Chapter 7: Selecting studies and collecting data. In Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from handbook.cochrane.org.

Higgins 2011b

Higgins JP, Altman DG, Gotzsche PC, Juni P, Moher D, Oxman AD, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *BMJ* 2011;**343**:d5928.

Jaffray 2015

Jaffray L, Bridgman H, Stephens M, Skinner T. Evaluating the effects of mindfulness-based interventions for informal palliative caregivers: a systematic literature review. *Palliative Medicine* 2015;**30**:117-31.

Jain 2007

Jain S, Shapiro SL, Swanick S, Roesch SC, Mills PJ, Bell I, et al. A randomized controlled trial of mindfulness meditation versus relaxation training: effects on distress, positive states of mind, rumination, and distraction. *Annals of Behavioral Medicine* 2007;**33**(1):11-21.

Kabat-Zinn 2013

Kabat-Zinn J. Full Catastrophe Living: Using the Wisdom of Your Body and Mind to Face Stress, Pain and Illness. New York: Delacorte, 2013.

Keng 2011

Keng SL, Smoski MJ, Robins CJ. Effects of mindfulness on psychological health: a review of empirical studies. *Clinical Psychology Review* 2011;**31**(6):1041-56.

Lawton 1989

Lawton MP, Kleban MH, Moss M, Rovine M, Glicksman A. Measuring care-giving appraisal. *Journal of Gerontology* 1989;**44**(3):61-71.

Mausbach 2007

Mausbach BT, Patterson TL, Rabinowitz YG, Grant I, Schulz R. Depression and distress predict time to cardiovascular disease in dementia caregivers. *Health Psychology* 2007;**26**:539.

McNair 1971

McNair DM, Lorr M, Droppleman LF. Profile of Mood States. San Diego (CA): Educational and Industrial Testing Service, 1971.

Montgomery 2002

Montgomery RJV. Using and interpreting the Montgomery Borgatta Caregiver Burden Scale. www4.uwm.edu/hbssw/PDF/Burden%20Scale.pdf (accessed 5 January 2018).

Moos 1988

Moos RH. Coping Response Inventory Manual. Palo Alto: Stanford University Medical Center and Department of Veterans Administration Medical Center, 1988.

Peacock 2003

Peacock S, Forbes DA. Interventions for caregivers of persons with dementia: a systematic review. Canadian Journal of Nursing Research 2003; Vol. 35, issue 4:88-107.

Pearlin 1990

Pearlin LI, Mullan JT, Semple SJ, Skaff MM. Caregiving and the stress process: an overview of concepts and their measures. *Gerontologist* 1990;**30**:583-94.

Pinquart 2006

Pinquart M, Sörensen S. Helping caregivers of persons with dementia: which interventions work and how large are their effects?. *International Psychogeriatrics/IPA* 2006;**18**(4):577-95.

Prince 2015

Prince M, Wimo A, Guerchet M, Ali GC, Wu Y, Prina AM. World Alzheimer Report 2015: the global impact of dementia. An analysis of prevalence, incidence, costs and trends, 2015. www.alz.co.uk/research/statistics.htnril (accessed 13 December 2016).

Radloff 1977

Radloff LS. The CES-D scale: a self-report depression scale for research in the general population. *Applied Psychological Measurement* 1977;**1**(3):385-401.

RevMan 2014 [Computer program]

Nordic Cochrane Centre, The Cochrane Collaboration. Review Manager (RevMan). Version 5.3. Copenhagen: Nordic Cochrane Centre, The Cochrane Collaboration, 2014.

Ryan 2016a

Ryan R, Hill S. How to GRADE the quality of the evidence. Version 3.0, December 2016. Cochrane Consumers and Communication Group, available at cccrg.cochrane.org/author-resources.

Ryan 2016b

Ryan R, Synnot A, Hill S. Describing results. Version 2.0, December 2016. Cochrane Consumers and Communication Group, available at cccrg.cochrane.org/author-resources.

Schulz 1999

Schulz R, Beach SR. Caregiving as a risk factor for mortality: the Caregiver Health Effects Study. *JAMA* 1999;**282**:2215-9.

Selwood 2007

Selwood A, Johnston K, Katona C, Lyketsos C, Livingston G. Systematic review of the effect of psychological interventions on family caregivers of people with dementia. *Journal of Affective Disorders* 2007;**101**(1-3):75-89.

Spielberger 1983

Spielberger CD, Gorusch RL, Lushehe R, Vagg PR, Jacobs GA. Manual for the State-Trait Anxiety Inventory. Mountain View (CA): Consulting Psychologist Press, 1983.

Spijker 2008

Spijker A, Vernooij-Dassen M, Vasse E, Adang E, Wollersheim H, Grol R, et al. Effectiveness of nonpharmacological interventions in delaying the institutionalization of patients with dementia: a meta-analysis. *Journal of the American Geriatrics Society* 2008;**56**(6):1116-28.

Sterne 2011

Sterne JAC, Egger M, Moher D. Chapter 10: Addressing reporting biases. In: Higgins JP, Green S, editor(s). Cochrane Handbook for Systematic Reviews of Intervention Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from handbook.cochrane.org. Chichester (UK): John Wiley & Sons.

Sörensen 2002

Sörensen S, Pinquart M, Duberstein P. How effective are interventions with caregivers? An updated meta-analysis. *Gerontologist* 2002;**42**(3):356-72.

Teri 1992

Teri L, Truax P, Logsdon R, Uomoto J, Zarit S, Vitaliano PP. Assessment of behavioral problems in dementia: The Revised Memory and Behavior Problems Checklist. *Psychology and Aging* 1992;**7**(4):622-31.

Thomas 2006

Thomas P, Lalloué F, Preux PM, Hazif-Thomas C, Pariel S, Inscale R, et al. Dementia patients caregivers quality of life: the PIXEL study. *International Journal of Geriatric Psychiatry* 2006;**21**(1):50-6.

Yesavage 1983

Yesavage JA, Brink TL, Rose TL, Lum O, Huang V, Adey M, et al. Development and validation of a geriatric depression screening scale: a preliminary report. *Journal of Psychiatric Research* 1983;**17**(1):37-49.

Zarit 1980

Zarit SH, Reever KE, Bach-Peterson J. Relatives of the impaired elderly: correlates of feelings of burden. *Gerontologist* 1980;**20**(6):649-55.

Zarit 2017

Zarit SH. Past is prologue: how to advance caregiver interventions. *Aging & Mental Health* 2017;**21**:1-6.

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Brown 2016

Methods	**Study design:** randomised controlled trial **Study grouping:** parallel group
Participants	**Inclusion criteria:** family carers of individuals with early-stage dementia

Brown 2016 *(Continued)*

	Exclusion criteria: individuals with psychiatric disorders; major, uncorrected sensory impairments; or cognitive deficits **Baseline characteristics of carers** • N = 38 • Mean age: 61.1 (SD 10.4) • Percentage of females: 84.2% • Relationship to individuals with dementia: 42.1% spouse, 50% child, 7.9% others • Average levels of carers' depressive symptoms at baseline (measured by depressive symptoms subscale of POMS): 1.97 (SD 0.58) for participants in intervention, 2.18 (1.24) for participants in control • Average levels of carer burden at baseline (measured by ZBI): 48.17 (SD 12.34) for participants in intervention, 40.60 (SD 16.71) for participants in control

Interventions	**MBSR**
	
	• Duration: 8 weeks
	• No. of sessions: 8 sessions, 90 to 120 minutes per session
	• Frequency: weekly
	• Delivery: face-to-face, group
	• Content of intervention:
	  * class activities of MBSR
	  * a day-long intensive mindfulness practice
	
	Social support
	
	• Duration: 8 weeks
	• No. of sessions: 8 sessions, 90 to 120 minutes per session
	• Frequency: weekly
	• Delivery: face-to-face, group
	• Content of intervention: group discussion of topics related to dementia caregiving

Outcomes	**Carers' depressive symptoms** • Outcome type: continuous outcome • Reporting: fully reported • Scale: POMS (depressive symptoms subscale) • Direction: lower is better • Data value: endpoint **Carer burden** • Outcome type: continuous outcome • Reporting: fully reported • Scale: ZBI • Direction: lower is better • Data value: endpoint
Identification	**Sponsorship source:** National Institutes of Health (U19 AT002656, P30 AG008017, K24 AT005121, and UL1 RR024140) and the Oregon Partnership for Alzheimer's Research Oregon Tax Check-Off Grant **Country:** USA
Notes	Adherence to intervention was not reported in the study. The study made adaptations for carers (e.g. focus of class discussion of caregiving; adjustments to accommodate physical limitations).

Brown 2016 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	A full description of sequence generation was not reported.
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	It is not possible to blind personnel or participants (or both) to psychosocial interventions of this nature.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Results from self reported scales may lead to a risk of detection bias.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	• The attrition rates between the 2 groups were not balanced (17.4% in intervention vs 0% in control). • Reasons for attrition were not fully described. • The study used intention-to-treat analyses, however the imputation method for missing data was not described.
Selective reporting (reporting bias)	Unclear risk	We could not find a published protocol.
Other risks of bias	Low risk	Not identified

Hou 2014

Methods	**Study design:** randomised controlled trial **Study grouping:** parallel group
Participants	**Inclusion criteria:** • Adults aged 18 or above • Cantonese speaker • Long-term caregiving responsibility for first-degree relatives with chronic illness conditions • Score of 7 or above in the Caregiver Strain Index • No self reported doctor's diagnosis of psychiatric illnesses and impaired cognitive status **Exclusion criteria:** • Serious diseases or disorders that could potentially affect participation • Care recipients had passed away before the study • Previous participation in a mindfulness-based, meditation, or similar programme within the preceding year **Characteristics of carers of people with dementia** • N = 41 • Mean age: 59.8 (SD 9.29) years • Percentage of females: 78%

Hou 2014 *(Continued)*

- Relationship to individuals with dementia: 51.2% spouses, 31.7% children, 12.2% parents, 4.9% relatives
- Average levels of carers' depressive symptoms at baseline (measured by CESD): 16.91 (SD 8.91) for participants in intervention group, 17.55 (SD 8.92) for participants in control group
- Average levels of carer burden (measured by Caregiver Strain Index) at baseline: 9.32 (SD 1.70)
- Notes: We included only carers of individuals with dementia in this review

Interventions	**MBSR**
	• Duration: 8 weeks
	• No. of sessions: 8 sessions, 2 hours per session
	• Frequency: weekly
	• Delivery: face-to-face, group
	• Content of intervention:
	  * class activities of MBSR
	  * 1-day retreat
	  * home practice: "participants were instructed to do CD-guided home practice for 30-45 minutes per day"
	Self help control
	• Content of intervention: "The control group received self-help health education booklets."

Outcomes	**Carers' depressive symptoms** • Outcome type: continuous outcome • Reporting: fully reported • Scale: CESD • Direction: lower is better • Data value: endpoint • Notes: "Mean refers to estimated marginal mean adjusted by the baseline measure." **Carers' anxiety** • Outcome type: continuous outcome • Scale: STAI-state anxiety • Direction: lower is better • Data value: endpoint • Notes: "Mean refers to estimated marginal mean adjusted by the baseline measure."
Identification	**Sponsorship source:** research grant from the Food and Health Bureau **Country:** Hong Kong, China
Notes	Adherence to intervention: "83% participants attended at least 6 sessions in MBSR and 43% attended all 8 sessions" Adverse events: "Only 1 male aged 80 strained his neck when practicing yoga at home, which did not inhibit him from participating in the weekly MBSR course."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	**Quote**: "Randomization was conducted independently by a research assistant using the random numbers generated in Microsoft Excel 2003 and was not disclosed

Hou 2014 *(Continued)*

		until the eligible participants completed baseline assessment and signed the informed consent form." **Comment**: Adequate sequence generation
Allocation concealment (selection bias)	Low risk	**Quote**: "the random numbers generated in Microsoft Excel 2002 and was not disclosed until the eligible participants completed baseline assessment and signed the informed consent form **Comment**: Adequate allocation concealment
Blinding of participants and personnel (performance bias) All outcomes	High risk	**Quote**: "The intervention group received MBSR, while the control group received self-help health education booklets"; "The first and most important limitation is that we did not employ an active control group. The effects of MBSR can be overestimated because of the potential beneficial effects of social interaction and extra attention given to them by the intervention." **Comment**: Inactive control used in this study, plus the challenge of blinding participants or personnel or both for psychosocial interventions of this nature
Blinding of outcome assessment (detection bias) All outcomes	High risk	**Quote**: "participants were asked to self-administer the questionnaires." **Comment**: Results from self reported scales may lead to a risk of detection bias.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	**Quote:** "The total attrition rate of this study was 19.9%; the MBSR group had a significantly lower attrition rate than the control group (12.9% vs. 26.8%; P < 0.05)." "The attritions were significantly younger (P < 0.05) and had a lower level of physical activity (P < 0.05)." **Comment:** The study used intention-to-treat analyses, however the imputation method for missing data was not described.
Selective reporting (reporting bias)	Unclear risk	**Comment**: We did not find a published protocol.
Other risks of bias	Low risk	Not identified

O'Donnell 2013

Methods	**Study design:** randomised controlled trial

O'Donnell 2013 *(Continued)*

Study grouping: parallel group

Participants	**Inclusion criteria:** • Age 55 years or older • Living independently in the community • A primary carer for a person with dementia and other neurocognitive disorders • Other requirements satisfied for intervention attendance **Exclusion criteria:** not reported **Baseline characteristics of carers** • N = 24 • Mean age: 71.3 • Percentage of females: 92% • Relationship to individuals with dementia: 85.7% spouses, 14.3% adult children • Average levels of carers' depressive symptoms at baseline (measured by GDS): 16.7% met criteria for identifying clinically significant depression • Average levels of carer burden at baseline: not reported

Interventions	**MBSR**
	• Duration: 8 weeks
	• No. of sessions: 8 sessions, 2.5 hours per session
	• Frequency: weekly
	• Delivery: face-to-face, group
	• Content of intervention:
	  * class activities of MBSR ("the body scan, sitting meditation, mindful hatha yoga, and walking meditation")
	  * 1-day silent retreat (7.5 hours)
	  * home practice (45 to 60 minutes of practices 6 days a week)
	
	Progressive muscle relaxation (PMR)
	• Duration: 8 weeks
	• No. of sessions: 8 sessions
	• Frequency: weekly
	• Delivery: face-to-face, group
	• Content of intervention:
	  * class activities of PMR (autogenic training, progressive relaxation training, and gentle hatha yoga)
	  * a day of relaxation
	  * home practice

Outcomes	**Carers' depressive symptoms** • Outcome type: dichotomous outcome • Reporting: fully reported • Scale: Geriatric Depression Scale • Data value: endpoint • Notes: a cut-score for identifying clinically significant depression symptoms of 4/5
Identification	**Sponsorship source:** "Francisco J. Varela award" in the Mind and Life Summer Research Institute **Country:** USA

O'Donnell 2013 *(Continued)*

Notes	Adherence to intervention: Participant attendance rates at classes were similarly high for the 2 groups (MBSR = 93%, PMR = 94%). Concerning home assignments, MBSR and PMR participants reported an average of 57% and 48% of recommended practices. Compared to the standard MBSR, the study made modifications to the yoga postures to accommodate physical limitations of the carers.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	**Quote:** "In order to select an equal number of participants for each condition, participant identification numbers were randomly drawn sequentially and alternately placed in one of two groups." **Comment:** Sequence generation not fully described.
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	**Comment:** It is not possible to blind personnel or participants (or both) to psychosocial interventions of this nature.
Blinding of outcome assessment (detection bias) All outcomes	High risk	**Quote:** "Blinding was not possible as the principal investigator taught both interventions and conducted and supervised the assessments." **Comment**: Results of the study show risk of detection bias.
Incomplete outcome data (attrition bias) All outcomes	High risk	**Comment:** • Attrition percentage: 17.2% (20% in intervention, 14% in control) • Reasons for attrition were given: 1 participant "declined to participate" after randomisation to control, and another participant in the control group dropped out "stating that she had not kept up with the practices, found it too painful to practice yoga and was feeling depressed"; 3 participants in the MBSR group dropped out due to "relocating", "her spouse's hospitalisation", or finding "the program too great a commitment". • The included study only used the completer analyses.
Selective reporting (reporting bias)	Unclear risk	**Comment:** We did not find a published protocol.
Other risks of bias	Unclear risk	**Quote:** "These two groups did not differ significantly on age, gender, level of education achieved, length of illness of the care recipient, or scores on the Mini-Mental State Examination" **Comment:**

O'Donnell 2013 *(Continued)*

	The comparison of the relationship of the carers to the individuals with dementia between two arms, which is known to impact caregiver stress, was not found.

Oken 2010

Methods	**Study design:** randomised controlled trial **Study grouping:** parallel group
Participants	**Inclusion criteria:** • Healthy adults 45 to 85 years old caring for a family member with dementia • Providing at least 12 hours per week of assistance for the person with dementia **Exclusion criteria:** • Unstable medical conditions • Cognitive dysfunction • Medications that were not stable for at least 2 months • Significant visual impairment • Previous experience with similar classes for stress reduction **Characteristics of carers** • N = 28 • Mean age: 62.50 (SD 11.61) for participants in meditation group; 67.09 (SD 8.36) for participants in education group; 63.80 (SD 7.93) for participants in respite-only group • Percentage of females: 80.6% • Relationship to individuals with dementia: 74.2% spouse, 25.8% children • Average levels of carers' depressive symptoms at baseline (measured by CESD): 15.8 (SD 7.7) for participants in meditation; 16.9 (SD 10.0) for participants in education; 14.5 (SD 7.7) for participants in respite-only group • Average levels of carer burden at baseline (measured by Caregiver Appraisal Tool): 89.1 (SD 14.7) for participants in meditation; 91.2 (SD 17.2) for participants in education; 89.7 (SD 11.2) for participants in respite-only group

Interventions	**Mindfulness meditation**
	
	• Duration: 7 weeks
	• No. of sessions: 7 sessions, 90 minutes per session
	• Frequency: weekly
	• Delivery: face-to-face, group
	• Content of intervention:
	  * class activities: first class (education) same as that in education group; the other 6 sessions related to MBSR and MBCT
	  * home assignments: participants were encouraged to practice daily
	
	Education
	
	• Duration: 7 weeks
	• No. of sessions: 7 sessions, 90 minutes per session
	• Frequency: weekly
	• Delivery: face-to-face, group

Oken 2010 *(Continued)*

- Content of intervention:
  * education classes adapted from "Powerful Tools for Caregivers"
  * home assignments: daily reading and action plans

Respite-only

- Duration: 7 weeks
- No. of sessions: 7 sessions, 3 hours per session
- Frequency: weekly
- Content of intervention: respite care

Outcomes	**Carers' depressive symptoms** • Outcome type: continuous outcome • Reporting: fully reported • Scale: CESD • Data value: endpoint **Carer burden** • Outcome type: continuous outcome • Reporting: fully reported • Scale: the reaction subscale of RMBPC; Caregiver Appraisal Tool • Data value: endpoint **Carer coping style** • Outcome type: continuous outcome • Reporting: fully reported • Scale: Coping Responses Inventory • Data value: endpoint
Identification	**Sponsorship source:** "This project was supported in part by NIH, and UL1 and the Oregon Parternership for Alzheimer's Research Oregon Tax Check-Off Grant." **Country:** USA
Notes	Adherence to intervention: participant attendance rates were 85% for education group and 88% for meditation group. The study made adaptations to meet time demands of carers.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	**Quote**: "a dynamic randomization approach was used to balance the distribution of four baseline characteristics" **Comment**: Adequate sequence generation
Allocation concealment (selection bias)	Low risk	**Quote**: "Randomization was performed following the baseline visit 1 using the dynamic randomization program concealing assignment during the outcome assessment from the blinded research assistant assessors."

Oken 2010 *(Continued)*

		Comment: Adequate allocation concealment
Blinding of participants and personnel (performance bias) All outcomes	High risk	**Comment**: It is not possible to blind personnel or participants (or both) to psychosocial interventions of this nature.
Blinding of outcome assessment (detection bias) All outcomes	High risk	**Comment**: Self report scales were used as measures in this study.
Incomplete outcome data (attrition bias) All outcomes	High risk	**Comment**: • Attrition percentages: 20% in the meditation group, 27% in the education group, and 10% in the respite-only group • Reason for attrition: not reported • The included study only used the completer analyses.
Selective reporting (reporting bias)	Unclear risk	**Comment**: We did not find a published protocol.
Other risks of bias	Low risk	Not identified

Whitebird 2013

Methods	**Study design:** randomised controlled trial **Study grouping:** parallel group
Participants	**Inclusion criteria:** • Primary carer of individuals with dementia living in the community • Older than 21 • Satisfying requirements for intervention participation • No participation in a community carer support programme or similar programme (meditation or yoga and others) • Moderate-to-high level of self perceived stress **Exclusion criteria:** • Psychiatric hospitalisations in the previous 2 years • Diagnoses of mental illness in the previous 2 years • Taking antipsychotic or anticonvulsion medication • Thoughts of harming themselves in the previous 6 months **Characteristics of carers:** • N = 78 • Mean age: 56.8 (SD 9.9) • Percentage of females: 88.5% • Relationship to individuals with dementia: adult children (74.4%); spouse, sibling, or friend (25.6%) • Average levels of carers' depressive symptoms at baseline (measured by CESD): 17.9 (SD 8.9) for participants in the intervention group, 19.2 (SD 11.8) for participants in the control group

Whitebird 2013 *(Continued)*

- Average levels of carer burden at baseline (measured by subjective stress burden subscale of MBCBS): 16.7 (SD 2.3) for participants in the intervention group, 16.9 (SD 2.8) for participants in the control group

Interventions	**MBSR**
	• Duration: 8 weeks
	• No. of sessions: 8 sessions, 2.5 hours per session
	• Frequency: weekly
	• Delivery: face-to-face, group
	• Content of intervention:
	  * class activities ("sitting and walking meditation, body scan meditation, and gentle Hatha yoga and stretching exercises")
	  * 5-hour retreat day
	  * home practice: participants were encouraged to practice daily
	A standard community caregiver education and social support (CCES)
	• Duration: 8 weeks
	• No. of sessions: 8 sessions, 2.5 hours per session
	• Frequency: weekly
	• Delivery: face-to-face, group
	• Content of intervention:
	  * class activities (education, group-based discussion, and social support)
	  * 5-hour wellness day
	  * home practice: participants were encouraged to implement what they had learned

Outcomes	**Carers' depressive symptoms** • Outcome type: continuous outcome • Reporting: fully reported • Scale: CESD • Data value: endpoint **Carers' anxiety** • Outcome type: continuous outcome • Reporting: fully reported • Scale: STAI-state • Data value: endpoint **Carer burden** • Outcome type: continuous outcome • Reporting: fully reported • Scale: MBCBS-subjective stress burden subscale • Data value: endpoint
Identification	**Sponsorship source:** National Center for Complementary and Alternative Medicine of the National Institutes of Health under award number R21AT003654 **Country:** USA
Notes	Adherence to intervention: 83% of participants attended at least 7 of the 8 weekly sessions; MBSR participants reported an average of 29 minutes per day of home practice.
Risk of bias	

Whitebird 2013 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	**Quote**: "... were randomly assigned using a computerized algorithm for simple randomization" **Comment:** Adequate allocation concealment
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	**Comment**: It is not possible to blind personnel or participants (or both) to psychosocial interventions of this nature.
Blinding of outcome assessment (detection bias) All outcomes	High risk	**Comment**: Assessment tools were self reported measures.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	**Comment**: • Attrition percentages: 2.6% participants in the intervention group, 12.5% participants in the control group • Reasons for attrition: institutionalisation; time constraints; dissatisfaction with assignment to the control group • The study used intention-to-treat analyses, however the imputation method for missing data was not described.
Selective reporting (reporting bias)	Unclear risk	**Comment**: We did not find a published protocol.
Other risks of bias	High risk	We suspected a high risk of bias for inexplicable baseline imbalances, as anxiety in the control group was significantly higher than in the intervention group ($P < 0.05$).

CESD: Center for Epidemiological Studies Depression Scale
GDS: Geriatric Depression Scale
MBCBS: Montgomery Borgatta Caregiver Burden Scale
MBCT: mindfulness-based cognitive therapy
MBSR: mindfulness-based stress reduction
POMS: Profile of Mood States
RMBPC: Revised Memory and Behavior Problems Checklist
SD: standard deviation
STAI: State-Trait Anxiety Inventory
ZBI: Zarit Burden Interview

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Black 2013	Wrong intervention

Study	Reason for exclusion
Danucalov 2013	Wrong intervention
Danucalov 2017	Wrong intervention
Dharmawardene 2016	A systematic review
Hurley 2014	A systematic review
ISRCTN53169488	Wrong study design
Jaffray 2016	A systematic review
Jain 2016	Wrong intervention
Kor 2017	A systematic review
Leach 2014	Wrong intervention
Leach 2015	Wrong intervention
Li 2016	A systematic review
NCT00558402	Repeated study
NCT00615082	Repeated study
NCT01537679 2010	Wrong intervention
NCT01605448 2010	Wrong population
NCT01774448 2013	Wrong intervention
NCT02122068 2014	Wrong intervention
NCT02286791 2014	Wrong population
NCT02314390 2013	Wrong population
NCT02457936 2015	Wrong population
NCT02777905 2016	Wrong population
NCT02902692 2016	Wrong population
NCT03056105 2013	Wrong population
NCT03092050 2017	Wrong study design
Pomykala 2012	Wrong intervention
Waelde 2017	Wrong intervention

Characteristics of studies awaiting assessment *[ordered by study ID]*

NCT02667782 2016

Methods	**Study design:** randomised controlled trial **Study grouping:** parallel group
Participants	**Inclusion criteria:** primary carer of an adult with a confirmed diagnosis of dementia **Exclusion criteria:** • Having a major active psychiatric illness • Undergoing cancer treatment • Having severe chronic pain
Interventions	**Experimental:** mindfulness-based stress reduction **Experimental:** mindfulness-based cognitive therapy
Outcomes	**Primary outcome:** change of Perceived Stress Scale, measured at baseline, 2 months, 4 months, and 7 months **Secondary outcomes:** change of anxiety, depressive symptoms, and carer burden
Notes	Author reply (on 13 December 2017): "Our study has just been completed and we are going to write for publication very soon."

Characteristics of ongoing studies *[ordered by study ID]*

ACTRN12617000347369 2017

Trial name or title	HOMeCare: caring for the dementia caregiver and their loved one via the HOMeCare exercise and mindfulness for health program
Methods	Randomised controlled trial
Participants	**Unit:** a dyad composing of 1 carer (family or friend) and 1 individual with mild-to-moderate dementia **Inclusion criteria for carers:** • 18 years or older • Able to use iPad programs **Inclusion criteria for the participant with dementia:** • Living in the community • Mini-Mental State Exam score 12 to 24/30 • Mild deficits in functional mobility (Short Physical Performance Battery score < 10/12) • Ambulatory over short distances without the assistance of others **Exclusion criteria:** • Disease or illness resulting in carers or individuals with dementia not being able to perform interventions • Having a severe dementia (Mini-Mental Exam score < 12) for the participant with dementia • Having moderate-to-severe deficits in functional mobility (Short Physical Performance Battery score of > 10/12) for the participant with dementia

ACTRN12617000347369 2017 *(Continued)*

Interventions	**Intervention:** an online 8-week mindfulness-based stress reduction training for the carer followed by a 16-week home-based exercise programme for the individual with dementia **Control:** usual care
Outcomes	**Primary outcomes:** funtional mobility for the adult with dementia and state mindfulness for the carer at baseline, 8 weeks, and 6 months **Secondary outcomes:** quality of life of the individual with dementia, carer depression, quality of life of carers, cognition of the person with dementia, physical capacity of the adult with dementia, etc.
Starting date	Date of first participant enrolment: 12 June 2017
Contact information	Mr Kenneth Daniel, University of Sydney, kenneth.daniel@sydney.edu.au
Notes	Contact person reply (13 December 2017): "The HOMeCARE study is currently ongoing as we are still recruiting more potential participants for the study. Publication of the paper would most likely occur sometime in the next year (2018)."

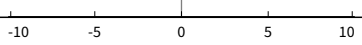
DATA AND ANALYSES

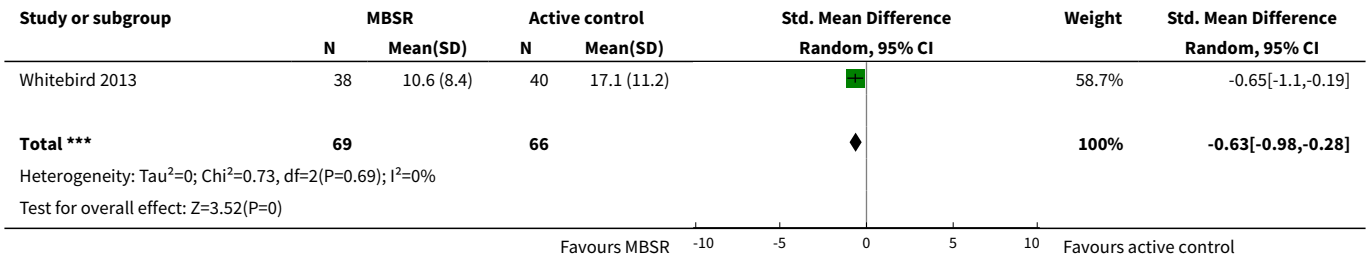
Comparison 1. MBSR versus active control immediately postintervention

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Depressive symptoms	3	135	Std. Mean Difference (IV, Random, 95% CI)	-0.63 [-0.98, -0.28]
2 Clinically significant depressive symptoms	1	24	Risk Ratio (M-H, Random, 95% CI)	0.33 [0.04, 2.77]
3 Anxiety	1	78	Mean Difference (IV, Random, 95% CI)	-7.5 [-13.11, -1.89]
4 Carer burden	3	135	Std. Mean Difference (IV, Random, 95% CI)	0.24 [-0.11, 0.58]
5 Coping style	1	19	Mean Difference (IV, Random, 95% CI)	6.0 [-4.59, 16.59]
6 Dropout rates	4	166	Risk Ratio (M-H, Random, 95% CI)	1.39 [0.32, 5.99]

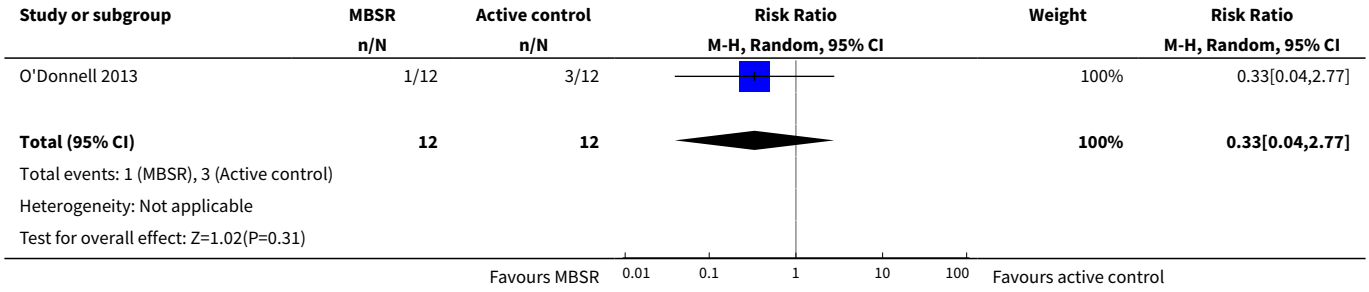
Analysis 1.1. Comparison 1 MBSR versus active control immediately postintervention, Outcome 1 Depressive symptoms.

Study or subgroup	MBSR		Active control		Std. Mean Difference	Weight	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI		Random, 95% CI
Brown 2016	23	1.4 (0.4)	15	1.8 (0.8)		26.75%	-0.77[-1.44,-0.09]
Oken 2010	8	12.5 (10.9)	11	15.2 (7.8)		14.55%	-0.28[-1.2,0.64]

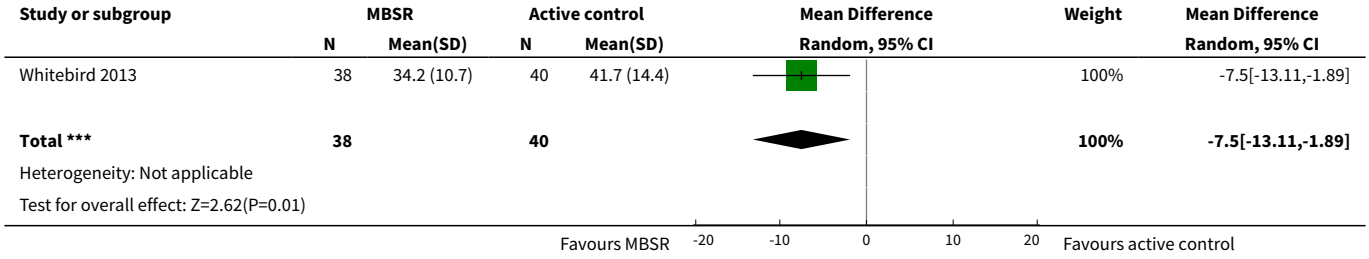




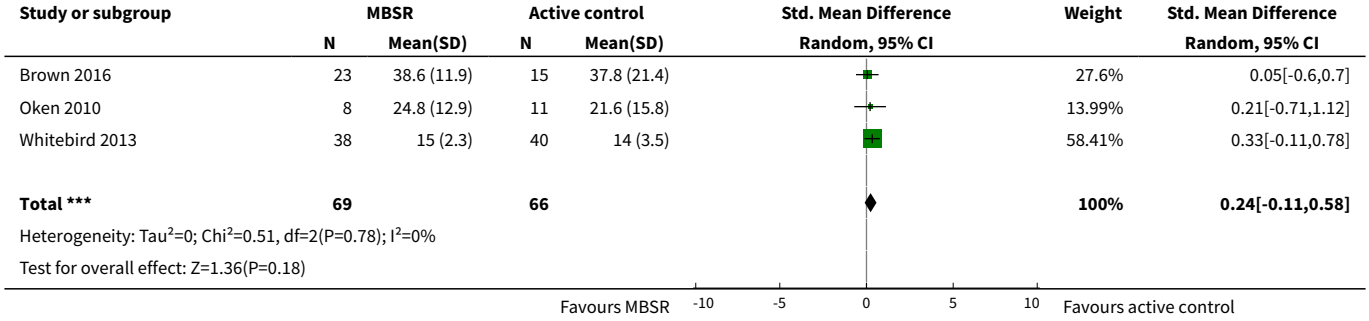
Analysis 1.2. Comparison 1 MBSR versus active control immediately postintervention, Outcome 2 Clinically significant depressive symptoms.



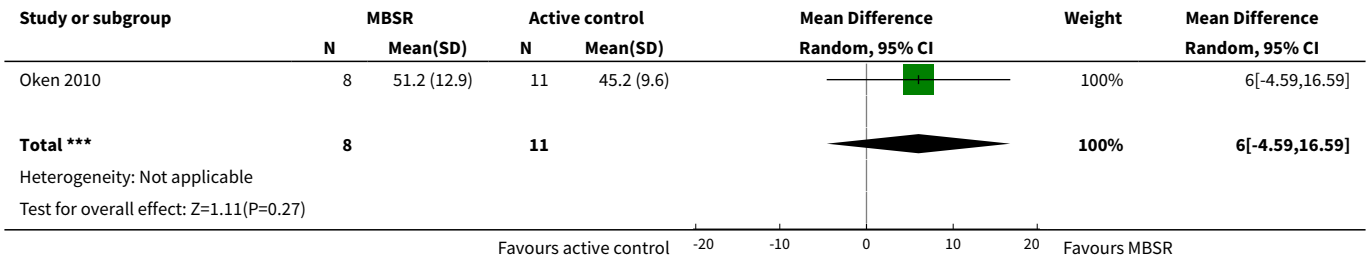
Analysis 1.3. Comparison 1 MBSR versus active control immediately postintervention, Outcome 3 Anxiety.



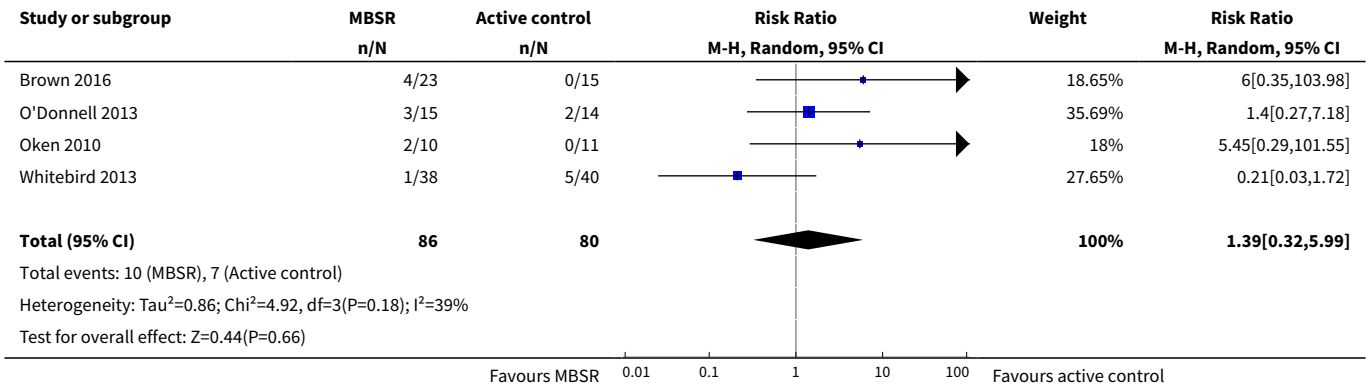
Analysis 1.4. Comparison 1 MBSR versus active control immediately postintervention, Outcome 4 Carer burden.



Analysis 1.5. Comparison 1 MBSR versus active control immediately postintervention, Outcome 5 Coping style.



Analysis 1.6. Comparison 1 MBSR versus active control immediately postintervention, Outcome 6 Dropout rates.

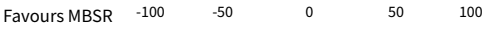


Comparison 2. MBSR versus inactive control immediately postintervention

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Depressive symptoms	2	50	Mean Difference (IV, Random, 95% CI)	-1.97 [-6.89, 2.95]
2 Clinically significant depressive symptoms	1	33	Risk Ratio (M-H, Random, 95% CI)	0.69 [0.26, 1.78]
3 Anxiety	1	33	Mean Difference (IV, Random, 95% CI)	-7.27 [-14.92, 0.38]
4 Carer burden	1	17	Mean Difference (IV, Random, 95% CI)	-1.60 [-19.48, 16.28]
5 Coping style	1	17	Mean Difference (IV, Random, 95% CI)	7.90 [-5.41, 21.21]
6 Dropout rates	1	20	Risk Ratio (M-H, Random, 95% CI)	2.0 [0.21, 18.69]

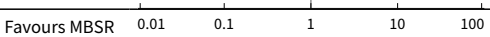
Analysis 2.1. Comparison 2 MBSR versus inactive control immediately postintervention, Outcome 1 Depressive symptoms.

Study or subgroup	MBSR N	MBSR Mean(SD)	Inactive control N	Inactive control Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Hou 2014	21	11.8 (7.9)	12	13.4 (8.5)		69.92%	-1.61[-7.49,4.27]
Oken 2010	8	12.5 (10.9)	9	15.3 (7.4)		30.08%	-2.8[-11.77,6.17]
Total ***	**29**		**21**			**100%**	**-1.97[-6.89,2.95]**
Heterogeneity: Tau²=0; Chi²=0.05, df=1(P=0.83); I²=0%							
Test for overall effect: Z=0.78(P=0.43)							



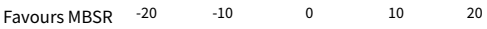
Analysis 2.2. Comparison 2 MBSR versus inactive control immediately postintervention, Outcome 2 Clinically significant depressive symptoms.

Study or subgroup	MBSR n/N	Inactive control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Hou 2014	6/21	5/12		100%	0.69[0.26,1.78]
Total (95% CI)	**21**	**12**		**100%**	**0.69[0.26,1.78]**
Total events: 6 (MBSR), 5 (Inactive control)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.78(P=0.44)					



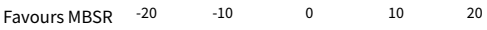
Analysis 2.3. Comparison 2 MBSR versus inactive control immediately postintervention, Outcome 3 Anxiety.

Study or subgroup	MBSR N	MBSR Mean(SD)	Inactive control N	Inactive control Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Hou 2014	21	40.5 (8.4)	12	47.8 (12)		100%	-7.27[-14.92,0.38]
Total ***	**21**		**12**			**100%**	**-7.27[-14.92,0.38]**
Heterogeneity: Not applicable							
Test for overall effect: Z=1.86(P=0.06)							

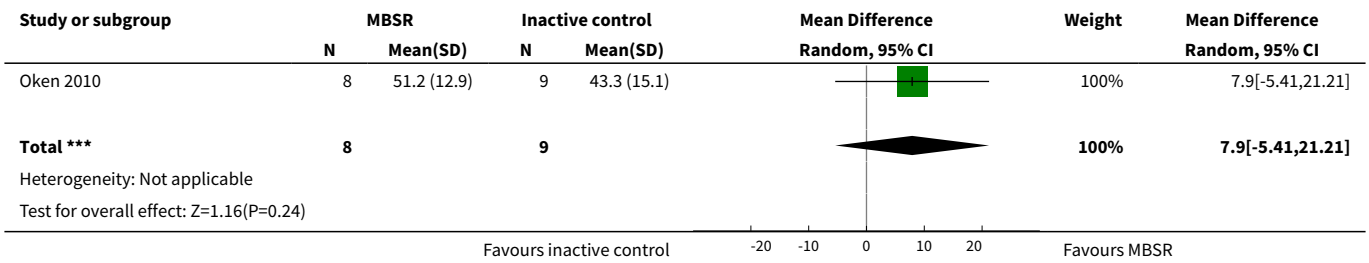


Analysis 2.4. Comparison 2 MBSR versus inactive control immediately postintervention, Outcome 4 Carer burden.

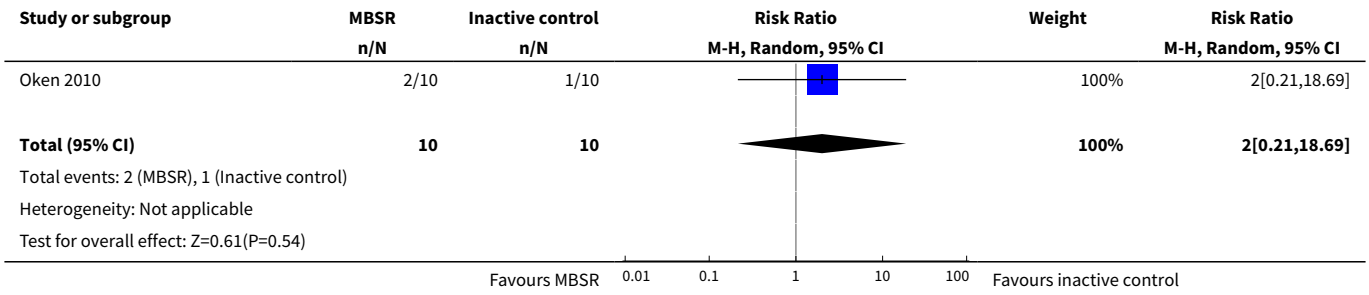
Study or subgroup	MBSR N	MBSR Mean(SD)	Inactive control N	Inactive control Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Oken 2010	8	24.8 (12.9)	9	26.4 (23.7)		100%	-1.6[-19.48,16.28]
Total ***	**8**		**9**			**100%**	**-1.6[-19.48,16.28]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.18(P=0.86)							



Analysis 2.5. Comparison 2 MBSR versus inactive control immediately postintervention, Outcome 5 Coping style.



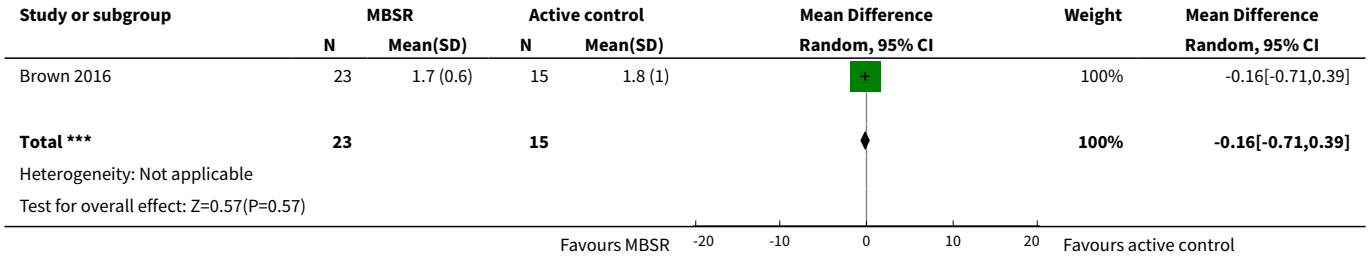
Analysis 2.6. Comparison 2 MBSR versus inactive control immediately postintervention, Outcome 6 Dropout rates.



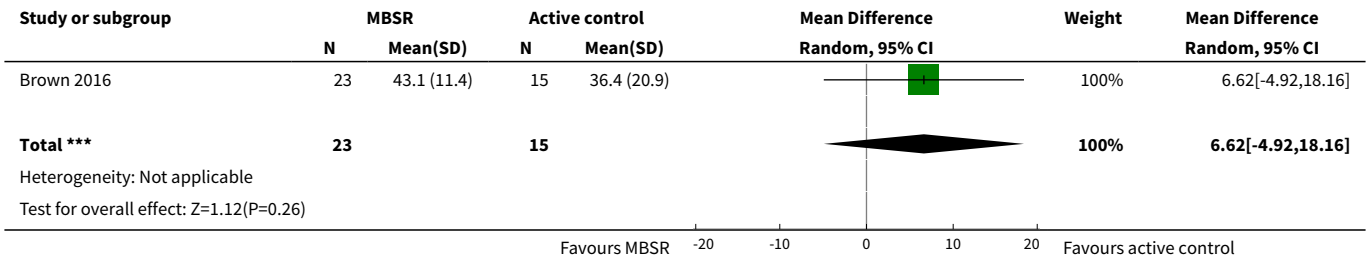
Comparison 3. MBSR versus active control within 3-month follow-up

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Depressive symptoms	1	38	Mean Difference (IV, Random, 95% CI)	-0.16 [-0.71, 0.39]
2 Carer burden	1	38	Mean Difference (IV, Random, 95% CI)	6.62 [-4.92, 18.16]

Analysis 3.1. Comparison 3 MBSR versus active control within 3-month follow-up, Outcome 1 Depressive symptoms.



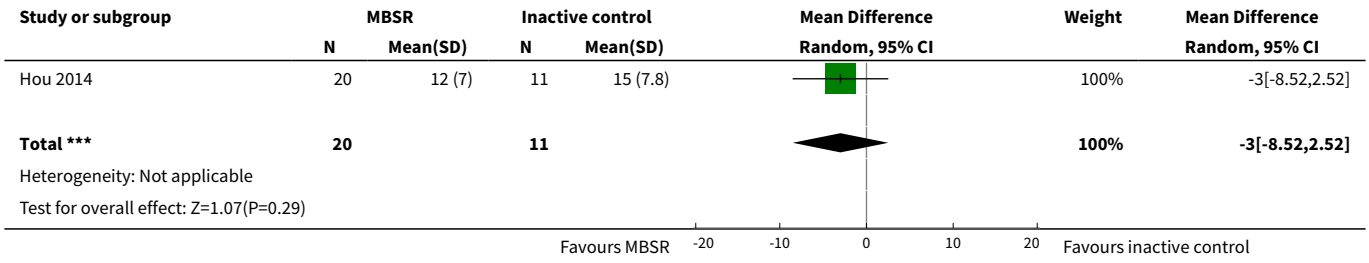
Analysis 3.2. Comparison 3 MBSR versus active control within 3-month follow-up, Outcome 2 Carer burden.



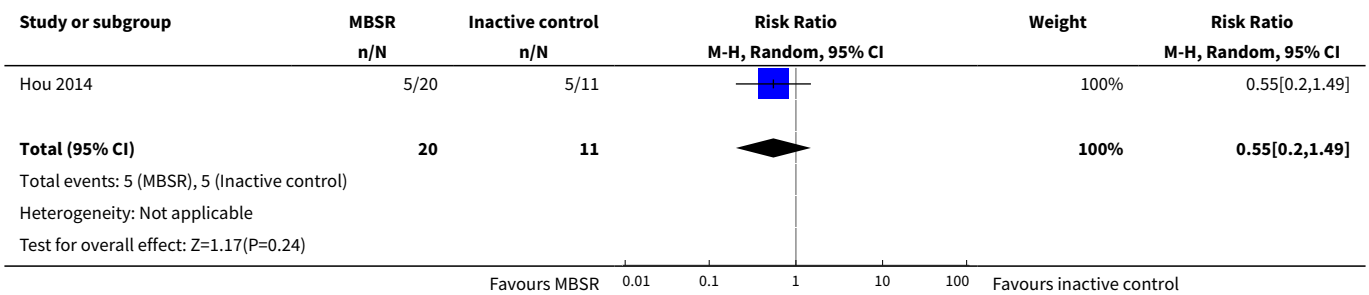
Comparison 4. MBSR versus inactive control within 3-month follow-up

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Depressive symptoms	1	31	Mean Difference (IV, Random, 95% CI)	-3.0 [-8.52, 2.52]
2 Clinically significant depressive symptoms	1	31	Risk Ratio (M-H, Random, 95% CI)	0.55 [0.20, 1.49]
3 Anxiety	1	31	Mean Difference (IV, Random, 95% CI)	-6.92 [-14.60, 0.76]

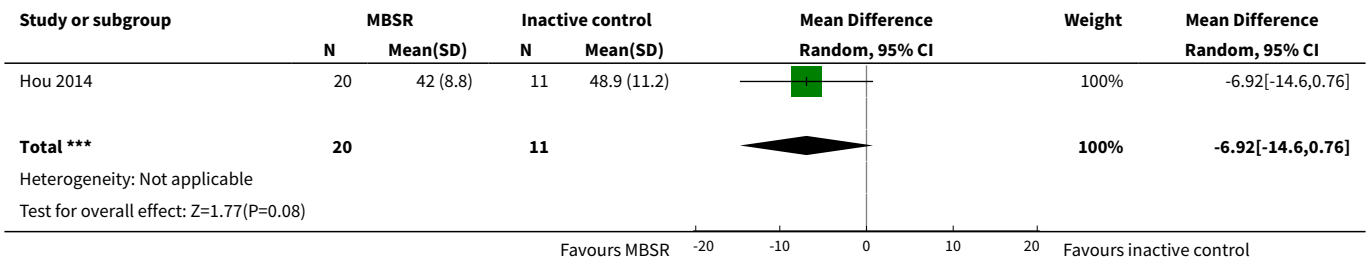
Analysis 4.1. Comparison 4 MBSR versus inactive control within 3-month follow-up, Outcome 1 Depressive symptoms.



Analysis 4.2. Comparison 4 MBSR versus inactive control within 3-month follow-up, Outcome 2 Clinically significant depressive symptoms.



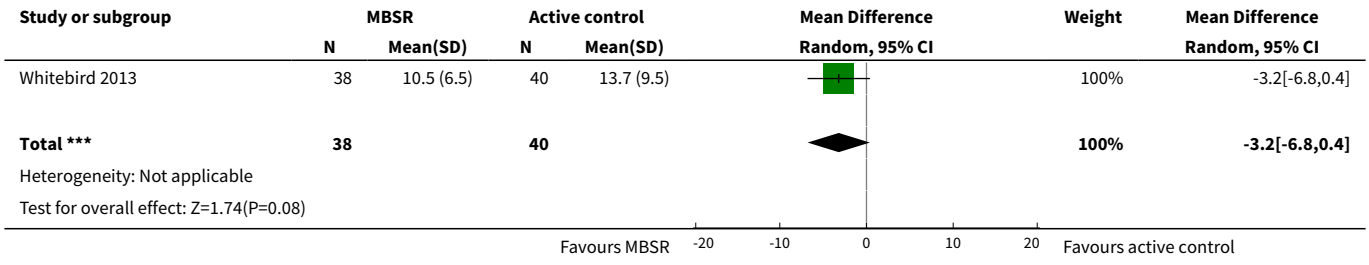
Analysis 4.3. Comparison 4 MBSR versus inactive control within 3-month follow-up, Outcome 3 Anxiety.



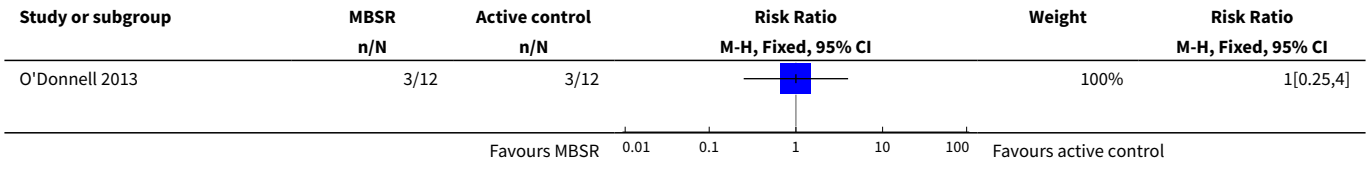
Comparison 5. MBSR versus active control within 3- to 6-month follow-up

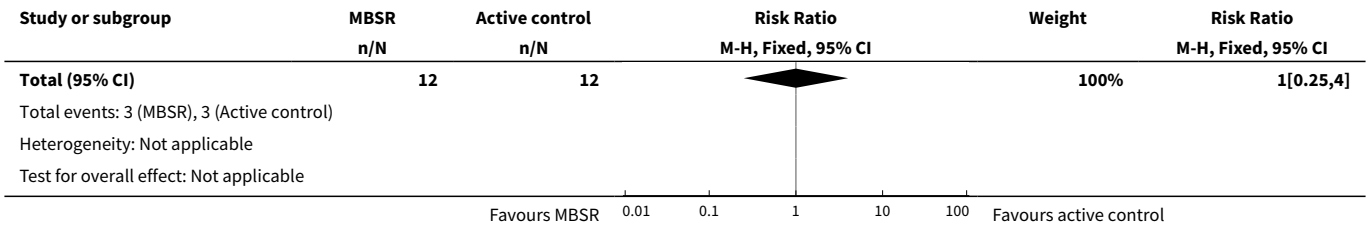
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Depressive symptoms	1	78	Mean Difference (IV, Random, 95% CI)	-3.20 [-6.80, 0.40]
2 Clinically significant depressive symptoms	1	24	Risk Ratio (M-H, Fixed, 95% CI)	1.0 [0.25, 4.00]
3 Anxiety	1	78	Mean Difference (IV, Fixed, 95% CI)	-6.5 [-12.00, 1.00]
4 Carer burden	1	78	Mean Difference (IV, Fixed, 95% CI)	0.90 [-0.55, 2.35]

Analysis 5.1. Comparison 5 MBSR versus active control within 3- to 6-month follow-up, Outcome 1 Depressive symptoms.

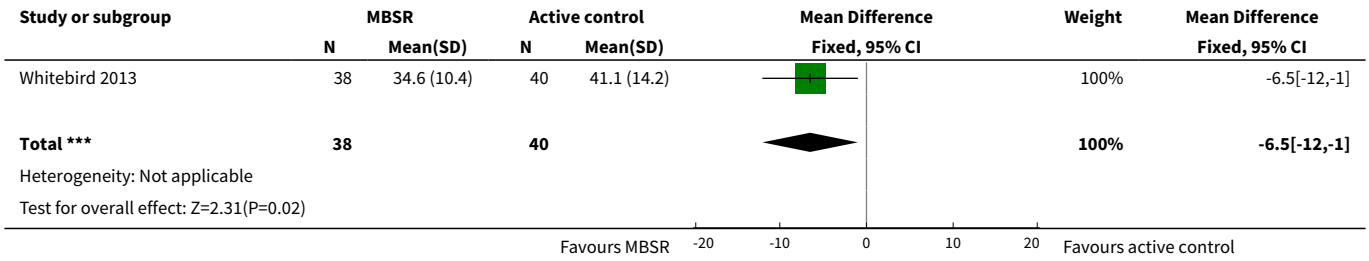


Analysis 5.2. Comparison 5 MBSR versus active control within 3- to 6-month follow-up, Outcome 2 Clinically significant depressive symptoms.

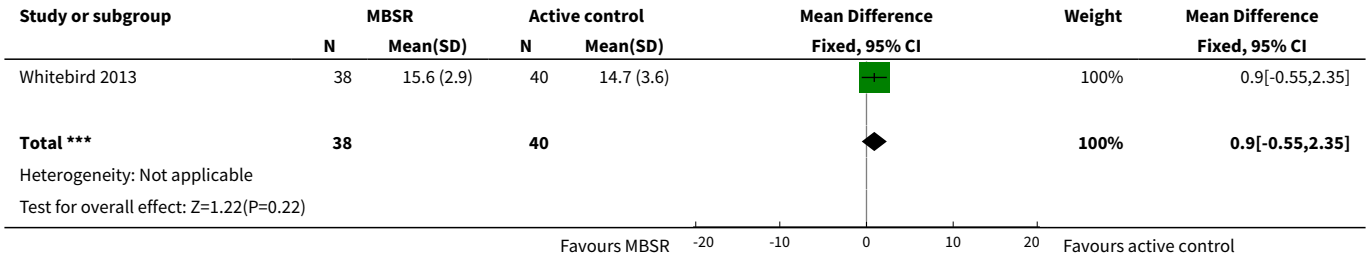




Analysis 5.3. Comparison 5 MBSR versus active control within 3- to 6-month follow-up, Outcome 3 Anxiety.



Analysis 5.4. Comparison 5 MBSR versus active control within 3- to 6-month follow-up, Outcome 4 Carer burden.



APPENDICES

Appendix 1. Sources searched and search strategies

Source	Search strategy	Hits retrieved
ALOIS (www.medicine.ox.ac.uk/alois) Search range: all years to 6 September 2017	mindfulness OR meditation	24
CENTRAL (the Cochrane Library) crso.cochrane.org	#1 MESH DESCRIPTOR Dementia EXPLODE ALL TREES #2 MESH DESCRIPTOR Delirium EXPLODE ALL TREES #3 MESH DESCRIPTOR Wernicke Encephalopathy EXPLODE ALL TREES	33

(Continued)

Search range: all years to Issue 9 of 12, 2017 (6 September 2017)	#4 MESH DESCRIPTOR Neurocognitive Disorders EXPLODE ALL TREES #5 dement*:TI,AB,KY #6 alzheimer*:TI,AB,KY #7 ((lewy* adj2 bod*)):TI,AB,KY #8 ((chronic adj2 cerebrovascular)):TI,AB,KY #9 (("organic brain disease" or "organic brain syndrome")):TI,AB,KY #10 ("benign senescent forgetfulness"):TI,AB,KY #11 ((cerebr* adj2 deteriorat*)):TI,AB,KY #12 ((cerebral* adj2 insufficient*)):TI,AB,KY #13 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 #14 MESH DESCRIPTOR Caregivers EXPLODE ALL TREES #15 (caregiver* or care-giver* or "care giver*" or carer* or daughter* or dependents or families* or family* or folk* or kinship or parent* or relatives or spouse* or wife* or wives* or husband*):TI,AB,KY #16 #14 OR #15 #17 MESH DESCRIPTOR Mindfulness EXPLODE ALL TREES #18 MBSR:TI,AB,KY #19 MBCT:TI,AB,KY #20 mindful*:TI,AB,KY #21 ("mind ful*"):TI,AB,KY #22 MESH DESCRIPTOR meditation EXPLODE ALL TREES #23 meditat*:TI,AB,KY #24 ("Acceptance and commitment therapy"):TI,AB,KY #25 ("Dialectic behavior therapy"):TI,AB,KY #26 DBT:TI,AB,KY #27 #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 #28 #13 AND #16 AND #27	
MEDLINE In-process and other non-indexed citations and MEDLINE 1950-present (Ovid SP) Search range: 1950 to 6 September 2017	1 exp Dementia/ 2 Delirium/ 3 Wernicke Encephalopathy/ 4 Delirium, Dementia, Amnestic, Cognitive Disorders/ 5 dement*.mp. 6 alzheimer*.mp. 7 (lewy* adj2 bod*).mp.	27

(Continued)

	8 (chronic adj2 cerebrovascular).mp.	
	9 ("organic brain disease" or "organic brain syndrome").mp.	
	10 "benign senescent forgetfulness".mp.	
	11 (cerebr* adj2 deteriorat*).mp.	
	12 (cerebral* adj2 insufficient*).mp.	
	13 or/1-11	
	14 Caregivers/	
	15 (caregiver* or care-giver* or "care giver*" or carer* or daughter* or dependents or families* or family* or folk* or kinship or parent* or relatives or spouse* or wife* or wives* or husband*).ti,ab.	
	16 or/14-15	
	17 exp Mindfulness/	
	18 MBSR.ti,ab.	
	19 MBCT.ti,ab.	
	20 mindful*.ti,ab.	
	21 "mind ful*".ti,ab.	
	22 meditation/	
	23 meditat*.ti,ab.	
	24 "Acceptance and commitment therapy".ti,ab.	
	25 "Dialectic behavior therapy".ti,ab.	
	26 DBT.ti,ab.	
	27 or/17-26	
	28 randomized controlled trial.pt.	
	29 controlled clinical trial.pt.	
	30 randomized.ab.	
	31 placebo.ab.	
	32 drug therapy.fs.	
	33 randomly.ab.	
	34 trial.ab.	
	35 groups.ab.	
	36 or/28-35	
	37 13 and 16 and 27 and 36	
	38 from 37 keep 1-27	
Embase (Ovid SP)	1 Dementia/	43
	2 Delirium/	

(Continued)

Search range: 1974 to 6 September 2017	3 Wernicke Encephalopathy/ 4 ("benign senescent forgetfulness" or ("normal pressure hydrocephalus" and "shunt*") or ("organic brain disease" or "organic brain syndrome") or ((cerebral* or cerebrovascular or cerebro-vascular) adj2 insufficien*) or (cerebr* adj2 deteriorat*) or (chronic adj2 (cerebrovascular or cerebro-vascular)) or (creutzfeldt or jcd or cjd) or (lewy* adj2 bod*) or (pick* adj2 disease) or alzheimer* or binswanger* or deliri* or dement* or huntington* or korsako*).tw. 5 or/1-4 6 Caregivers/ 7 (caregiver* or care-giver* or "care giver*" or carer* or daughter* or dependents or families* or family* or folk* or kinship or parent* or relatives or spouse* or wife* or wives* or husband*).ti,ab. 8 or/6-7 9 exp Mindfulness/ 10 MBSR.ti,ab. 11 MBCT.ti,ab. 12 mindful*.ti,ab. 13 "mind ful*".ti,ab. 14 meditation/ 15 meditat*.ti,ab. 16 "Acceptance and commitment therapy".ti,ab. 17 "Dialectic behavior therapy".ti,ab. 18 DBT.ti,ab. 19 or/9-18 20 randomized controlled trial/ 21 controlled clinical trial/ 22 random$.ti,ab. 23 randomization/ 24 intermethod comparison/ 25 placebo.ti,ab. 26 (compare or compared or comparison).ti. 27 ((evaluated or evaluate or evaluating or assessed or assess) and (compare or compared or comparing or comparison)).ab. 28 (open adj label).ti,ab. 29 ((double or single or doubly or singly) adj (blind or blinded or blindly)).ti,ab. 30 double blind procedure/ 31 parallel group$1.ti,ab.

(Continued)

	32 (crossover or cross over).ti,ab. 33 ((assign$ or match or matched or allocation) adj5 (alternate or group$1 or intervention$1 or patient$1 or subject$1 or participant$1)).ti,ab. 34 (controlled adj7 (study or design or trial)).ti,ab. 35 (volunteer or volunteers).ti,ab. 36 trial.ti. 37 or/20-36 38 5 and 8 and 19 and 37 39 from 38 keep 1-43	
PsycINFO (Ovid SP) Search range: 1806 to 6 September 2017	1 exp Dementia/ 2 exp Delirium/ 3 exp Huntingtons Disease/ 4 exp Kluver Bucy Syndrome/ 5 exp Wernickes Syndrome/ 6 exp Cognitive Impairment/ 7 dement*.mp. 8 alzheimer*.mp. 9 (lewy* adj2 bod*).mp. 10 deliri*.mp. 11 (chronic adj2 cerebrovascular).mp. 12 ("organic brain disease" or "organic brain syndrome").mp. 13 "supranuclear palsy".mp. 14 ("normal pressure hydrocephalus" and "shunt*").mp. 15 "benign senescent forgetfulness".mp. 16 (cerebr* adj2 deteriorat*).mp. 17 (cerebral* adj2 insufficient*).mp. 18 (pick* adj2 disease).mp. 19 (creutzfeldt or jcd or cjd).mp. 20 huntington*.mp. 21 binswanger*.mp. 22 korsako*.mp. 23 ("parkinson* disease dementia" or PDD or "parkinson* dementia").mp. 24 or/1-23 25 Caregivers/	18

(Continued)

	26 (caregiver* or care-giver* or "care giver*" or carer* or daughter* or dependents or families* or family* or folk* or kinship or parent* or relatives or spouse* or wife* or wives* or husband*).ti,ab.	
	27 or/25-26	
	28 exp Mindfulness/	
	29 MBSR.ti,ab.	
	30 MBCT.ti,ab.	
	31 mindful*.ti,ab.	
	32 "mind ful*".ti,ab.	
	33 meditation/	
	34 meditat*.ti,ab.	
	35 "Acceptance and commitment therapy".ti,ab.	
	36 "Dialectic behavior therapy".ti,ab.	
	37 DBT.ti,ab.	
	38 or/28-37	
	39 exp Clinical Trials/	
	40 randomly.ab.	
	41 randomi?ed.ti,ab.	
	42 placebo.ti,ab.	
	43 groups.ab.	
	44 "double-blind*".ti,ab.	
	45 "single-blind*".ti,ab.	
	46 RCT.ti,ab.	
	47 or/39-46	
	48 24 and 27 and 38 and 47	
CINAHL (EBSCOhost) Search range: all dates to 6 September 2017	1 (MH "Dementia+")	11
	2 MH "Delirium") or (MH "Delirium, Dementia, Amnestic, Cognitive Disorders")	
	3 (MH "Wernicke's Encephalopathy")	
	4 TX dement*	
	5 TX alzheimer*	
	6 TX lewy* N2 bod*	
	7 TX deliri*	
	8 TX chronic N2 cerebrovascular	
	9 TX "organic brain disease" or "organic brain syndrome"	
	10 TX "normal pressure hydrocephalus" and "shunt*"	

(Continued)

	11 TX "benign senescent forgetfulness"	
	12 TX cerebr* N2 deteriorat*	
	13 TX cerebral* N2 insufficient*	
	14 TX pick* N2 disease	
	15 TX creutzfeldt or jcd or cjd	
	16 TX huntington*	
	17 TX binswanger*	
	18 TX korsako*	
	19 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18	
	20 (MH "Caregivers")	
	21 TX caregiver* or care-giver* or "care giver*" or carer* or daughter* or dependents or families* or family* or folk* or kinship or parent* or relatives or spouse* or wife* or wives* or husband*	
	22 (S20 OR S21)	
	23 (MH "Mindfulness")	
	24 TX MBSR	
	25 TX "mind ful*"	
	26 (MH "Meditation")	
	27 TX meditat*	
	28 TX "Acceptance and commitment therapy"	
	29 TX DBT	
	30 S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29	
	31 MH "Clinical Trials"	
	32 TX trial	
	33 TX "single-blind*"	
	34 TX "double-blind*"	
	35 TX "treatment as usual"	
	36 TX randomly	
	37 S31 OR S32 OR S33 OR S34 OR S35 OR S36	
	38 S19 AND S22 AND S30 AND S37	
ISI Web of Science – all databases [includes: Web of Science (1945-present); BIOSIS Previews (1926-present); MEDLINE (1950-	TOPIC:((dement* OR alzheimer* OR "vascular cognitive impairment" OR "lew* bod*" OR CADASIL OR "cognit* impair*" OR FTD OF FTLD OR "cerebrovascular insufficienc*" OR AD OR VCI)) AND TOPIC: (caregiver* or care-giver* or "care giver*" or carer* or daughter* or dependents or families* or family* or folk* or kinship or parent* or relatives or spouse* or wife* or wives* or husband*) AND TOPIC:(Mindful* OR MBSR OR MBCT. OR meditat*) AND TOPIC: (randomly OR	48

(Continued)

present); Journal Citation Reports] Search range: 1945 to 6 September 2017	randomised OR randomized OR "random allocat*" OR RCT OR CCT OR "double blind*" OR "single blind*" OR "double blind*" OR "single blind*" OR trial) Timespan: All years. Search language=Auto	
LILACS (BIREME) Search range: all dates to 6 September 2017	mindful$ OR meditat$ [Words] and alzheimer OR alzheimers OR alzheimer's OR dementia OR demenc$ [Words]	1
ClinicalTrials.gov (www.clinicaltrials.gov) Most recent search: 6 September 2017	dementia OR alzheimers OR cognition OR cognitive | mindfulness OR mindful OR meditate OR meditation	198
ICTRP (apps.who.int/trialsearch) Most recent search: 6 September 2017	dementia OR alzheimers OR cognition OR cognitive | mindfulness OR mindful OR meditate OR meditation TI	78
TOTAL before de-duplication		403
TOTAL after de-duplication		301
TOTAL after first assessment based on title and abstract performed by CDCIG Information Specialists		64

CONTRIBUTIONS OF AUTHORS

ZL: designed the study and drafted the full review.

YYS and BLZ: took part in the study design, data collection, and analysis.

DECLARATIONS OF INTEREST

Zheng Liu: none known
Yu-Ying Sun: none known
Bao-liang Zhong: none known

SOURCES OF SUPPORT

Internal sources

- Department of Psychiatry, the Chinese University of Hong Kong, China.
- School of Public Health, Peking University, China.

External sources

- NIHR, UK.

This review was supported by the National Institute for Health Research (NIHR), via Cochrane Infrastructure funding to the Cochrane Dementia and Cognitive Improvement group. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, National Health Service or the Department of Health

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

- Due to the paucity of information on adverse events, we described our study objectives as "to assess the effectiveness of MBSR in reducing the stress of family carers of people with dementia."
- Due to the variability of control groups, we regrouped outcomes into two comparisons: MBSR versus active controls, and MBSR versus inactive controls.
- As no included studies evaluated the effects of MBSR on institutionalisation, we did not report this outcome in the 'Summary of findings' tables.
- We reported adverse events as one of main results in the review.

INDEX TERMS

Medical Subject Headings (MeSH)

Anxiety [prevention & control]; Caregivers [*psychology]; Dementia [*nursing]; Depression [prevention & control]; Family [*psychology]; Mindfulness [*methods]; Patient Dropouts [statistics & numerical data]; Randomized Controlled Trials as Topic; Stress, Psychological [*prevention & control]

MeSH check words

Adult; Humans