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Conceptual Congruence in Mindfulness-Based Weight Loss Intervention Studies

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Abstract

Whether one kind of mindfulness applies to all situations or only some (i.e., scope) is controversial. Eating may not be an everyday behavior subsumed under everyday mindfulness. To rigorously test the efficacy of mindfulness-based weight loss interventions, researchers must use scales that measure the type of mindfulness manipulated by the intervention. The mixed findings of mindfulness-based weight loss intervention studies may be related to the lack of conceptual congruence (i.e., the pairing of interventions and measures of the same scope). The aims of this systematic review were to: (a) describe the scopes of the mindfulness interventions and measures used in mindfulness-based weight loss intervention studies; and (b) compare conceptual congruence to the statistical significance of mindfulness and weight outcomes of each study. All articles published prior to December 31, 2016 were retrieved from PubMed, CINAHL, PsycINFO, and Embase. After screening and full-text review, eight articles were included in the review. Five studies paired mindfulness-based eating interventions with general mindfulness measures; two studies paired mindfulness-based eating interventions with eating-specific mindfulness measures; and one study paired a general mindfulness intervention with a general mindfulness measure. There was no apparent relationship between conceptual congruence and the statistical significance of the mindfulness and weight outcomes. However, given other findings and the limitations of this review, further investigation is needed. In particular, future studies should include mediation analyses using both general and eating-specific mindfulness measures.

Keywords

mindfulness; measurement; intervention; eating; obesity; weight

Introduction

The definition of mindfulness is not homogeneous across mindfulness-based health research. Some of this heterogeneity may be related to the existence of many types of mindfulness in Buddhism (An layo 2016; Marx 2015); however, it may also be related to the secularization of the concept by individuals with varied familiarity with or concern for its meaning within

Buddhism (Van Gordon et al. 2015b). Heterogeneity in the definition of mindfulness presents a challenge to mindfulness-based health research—especially intervention studies.

Intervention studies should test whether the active ingredient of the intervention influences a health outcome. Consequently, mindfulness-based health interventions should test whether mindfulness practice influences health outcomes. The validity of this test depends on the definition of mindfulness. Using a mindfulness scale that has not been validated to measure mindfulness as defined in the intervention undermines the ability to determine whether the intervention manipulates the relevant type of mindfulness, which undermines conclusions about the efficacy or effectiveness of the intervention.

Several recent review articles showed that the efficacy and effectiveness of mindfulness-based weight loss interventions were mixed but not without promise (Katterman et al. 2014; Olson and Emery 2015; O'Reilly et al. 2014; Rogers et al. 2017; Ruffault et al. 2016). The pairing of interventions and scales with different definitions of mindfulness, referred to as *conceptual incongruence*, may have contributed to the mixed findings by undermining the ability to determine whether the intervention manipulated the targeted type of mindfulness.

In first-generation mindfulness-based interventions, mindfulness is broadly characterized as the present-minded, non-judgmental, non-reactive attention to one's thoughts, emotions, and body sensations (Baer 2011; Van Gordon et al. 2015a). Critics of mindfulness-based health research have typically focused on the fidelity of the secular conceptualization of mindfulness to the original Buddhist conceptualization (Grossman 2008; Van Gordon et al. 2015b). This criticism, however, is somewhat beside the point given that mindfulness is not categorically Buddhist. Although it derives from the Buddhist psychological taxonomy, it does not entail Buddhist ethical or ontological commitments (Marx 2015). Mindfulness in first-generation mindfulness-based health interventions (e.g., Mindfulness-Based Stress Reduction and Mindfulness-Based Cognitive Therapy) is intentionally divorced from the ethical and ontological commitments of Buddhism; these interventions are not Buddhist practices (Crane et al. 2016). This separation is important because the terminal outcome of mindfulness-based health interventions is not the cessation of suffering in the Buddhist sense; rather, it is the manipulation of a health outcome, such as adiposity. Because the terminal outcome of secular mindfulness practice in health interventions is narrower than that of Buddhist practice, its scope must be considered.

Scope can be expressed in two related questions: *Is mindfulness a state or a trait? Is it general or domain-specific?* Although trait mindfulness indicates the frequency of state mindfulness across everyday situations, the assumption that the likelihood of entering a mindful state is equal across everyday situations is dubious (Thompson and Waltz 2007; Kiken et al. 2015). Eating may be a powerful exception to a general tendency toward mindfulness. Eating is often an automatic—or *mindless*—behavior (Cohen and Farley 2008). Calorie intake can be unconsciously influenced by several factors, such as food proximity, social context, and distractions (Cohen and Farley 2008; Cruwys et al. 2015; Robinson et al. 2013; Wansink et al. 2006). The detriment of mindless eating can be compounded by the consumption of highly palatable foods, which are generally high in fat, salt, and refined sugar (Meule 2011; Volkow et al. 2011). Chronic consumption of these

foods may induce changes in brain activity like those seen in drug addiction, which may perpetuate obesogenic eating behaviors, such as mindless eating (Ahmed et al. 2013; Lustig 2013; Volkow et al. 2008).

The development of Mindfulness-Based Eating Awareness Training (MB-EAT) and the Mindful Eating Questionnaire (MEQ) suggest that eating is a special type of behavior that may not be reliably subsumed under everyday mindfulness and is domain-specific. MB-EAT was originally developed to address binge eating disorder, a psychiatric disorder characterized by distressing, excessive, uncontrolled food intake (American Psychiatric Association 2013; Kristeller and Hallett 1999; Kristeller and Wolever 2011). The intervention's primary purpose is to improve eating behavior by improving awareness of the factors that influence eating behaviors, while also incorporating elements of non-judgment and self-compassion. In addition to meditation, MB-EAT participants engage in mindful eating exercises, during which participants learn to recognize hunger and satiety cues and to nonjudgmentally attend to thoughts and sensations experienced while eating.

Recognizing the need for a new measure to assess the effect of mindfulness practice on eating behavior, Framson et al. (2009) developed the MEQ. Drawing upon the principal constructs of common mindfulness and eating behavior questionnaires, the MEQ assesses mindful eating across five factors (viz., disinhibition, awareness, external cues, emotional response, and distraction; Framson et al. 2009, p. 1441). Supporting domain specificity, Apolzan et al. (2016) found that the awareness subscale of the MEQ was not correlated with the Mindful Attention Awareness Scale in a sample of pregnant women. Because the awareness subscale and MAAS both assess the present-moment orientation of awareness and attention, the absence of correlation suggests that an individual's awareness or attention while eating may not be present-oriented in spite of a general tendency toward present-orientation in everyday situations (Brown and Ryan 2003; Framson et al. 2009).

The aims of this systematic review were: (a) to describe the scopes of the interventions and measures used in mindfulness-based weight loss intervention studies; and (b) to compare conceptual congruence to the statistical significance of mindfulness and weight outcomes of each study. The purpose of this review was not to provide definitive evidence of the relationship of conceptual congruence to the significance of mindfulness and weight outcomes; rather, its purpose was to explore the idea of conceptual congruence and its implications for study outcomes. Although this review focused on conceptual congruence in mindfulness-based weight loss intervention studies, conceptual congruence is relevant to all mindfulness-based health research.

Method

All articles published prior to December 31, 2016 were retrieved from PubMed, CINAHL, PsycINFO, and Embase with the following keywords: *mindful eating*, *mindfulness*, *mindful*, *obesity*, *weight*, *overweight*, and *body mass index*. Only English language mindfulness-based intervention studies for weight loss that measured mindfulness and weight before and after the intervention were included. Although acceptance-based weight loss interventions include an element of mindfulness, they were excluded from this review because acceptance

(in the context of Acceptance and Commitment Therapy) and mindfulness are conceptually distinct (Hayes et al. 2006; Katterman et al. 2014). Additionally, studies explicitly focused on individuals with binge eating disorder were excluded to maximize the generalizability of the review findings to the general population. Single case studies, preliminary findings for ongoing studies, dissertations, and substudies of eligible studies for this review were excluded. To accomplish the purpose of this review, I extracted the following data: study design; sample characteristics; intervention characteristics, including type and duration; mindfulness measure characteristics, including reliability and validity; and mindfulness and weight outcomes.

To adequately assess outcomes for risk of bias, I also extracted data regarding study retention, treatment adherence, data source (e.g., self-report or research staff), and intervention fidelity procedures (Cooper 2010). I consulted the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines to promote rigor in this review (Liberati et al. 2009).

Results

As shown in Figure 1, the database searches yielded 764 citations after removing duplicates. No citations were identified in the reference lists of other articles. Twenty-one articles received full-text review after title and abstract screening. Of those 21 articles, 13 were excluded: eight did not test did not report pre- and post-intervention or mindfulness measurements; two did not report pre- and post-intervention weight measurements; one lacked a mindfulness-based intervention; one reported a substudy of another study eligible for full-text review; and one did not test a weight loss intervention. The Ingraham et al. (2016) article was excluded on the basis that it did not test a weight loss intervention because the authors noted that their intervention was designed to accommodate their target population, who were politically opposed to weight loss interventions. Eight studies were included in the review.

General Study Characteristics

The eight included studies were summarized in Table 1. Approximately 63% (5/8) of the studies were randomized controlled trials (RCT) and 37% (3/8) were uncontrolled trials (i.e., single-group intervention studies). Recruited sample sizes ranged from 10 to 170 participants; however, sample sizes for analyses were smaller. In three studies, participants were primarily white, middle-aged women (Dalen et al. 2010; Daubenmier et al. 2011; Miller et al. 2014). Participants in the Chung et al. (2016) and Kidd et al. (2013) studies were primarily or exclusively African American. Participants in the Mantzios and Giannou (2014) and Mantzios and Wilson (2014) studies were exclusively Greek university students. Participants in Daly et al. (2016) study were exclusively Latina high school students.

The interventions largely consisted of group training. Group training sessions met either every week or every other week and lasted between 60 and 150 minutes. Two studies tested interventions based exclusively on independent practice; however, three group-based interventions also recommended or required independent meditation practice. Intervention durations ranged from five to 12 weeks.

The Scope of Mindfulness Practice

One of the eight included studies tested a general mindfulness intervention. The Mantzios and Giannou (2014) intervention consisted of mindfulness meditation based on Mahayana and Theravada Buddhism. By design, none of the mindfulness practice in this study focused on eating.

Seven of the eight included studies tested mindfulness-based eating (MBE) interventions. These interventions were largely domain-specific; they focused on the thoughts, emotions, and sensations associated with food and eating. The extent to which mindfulness practice was limited to eating, however, varied among the studies. As shown in Table 2, the interventions were classified as one of two subtypes: focused or comprehensive.

Four studies used focused interventions. Mindfulness training and practice in these interventions were largely limited to MBE. The Chung et al. (2016), Daly et al. (2016), and Kidd et al. (2013) studies integrated brief general mindfulness practices in their group sessions; however, daily (or near daily) practice was not a formal intervention component. The Mantzios and Wilson (2014) intervention was based on mindful concrete construal, wherein participants described how to eat in a diary prior and during meals. These descriptions focused on process of eating, including the thoughts, emotions, and sensations therein experienced.

Three studies used comprehensive interventions. In addition to MBE training, these interventions integrated general mindfulness training and practice, including daily (or near daily) mindfulness meditation.

The Scope of Mindfulness Measures

The instruments used to measure mindfulness were summarized in Table 2. Among the eight included studies, four questionnaires were used to measure trait mindfulness: the Mindful Eating Questionnaire (MEQ; Framson et al. 2009); the Kentucky Inventory of Mindfulness Skills (KIMS; Baer et al. 2004); the Five-Facet Mindfulness Questionnaire (FFMQ; Baer et al. 2006); and the Mindful Attention Awareness Scale (MAAS; Brown and Ryan 2003). The MEQ was the only eating-specific mindfulness measure used; the KIMS, FFMQ, and MAAS measured facets of everyday mindfulness.

Outcomes and Conceptual Congruence

As shown in Tables 1 and 2, six of the eight included studies reported statistically significant within- or between-group increases in mindfulness. Of these six studies, two were conceptually congruent. Chung et al. (2016) matched their domain-specific mindfulness intervention (viz., MBE) with a domain-specific mindfulness measure (viz., MEQ), while Mantzios and Giannou (2014) matched their general mindfulness intervention with a general mindfulness measure (viz., MAAS). The remaining four studies were not conceptually congruent, pairing MBE interventions with general mindfulness measures.

Two studies did not report significant differences in mindfulness. The Kidd et al. (2013) study was conceptually congruent, pairing their MBE intervention with an eating-specific

measure. The Daly et al. (2016) study was not conceptual congruent, pairing their MBE intervention with a general mindfulness measure.

As shown in Tables 1 and 2, six of the studies reported statistically significant within- or between-group weight or BMI reductions. Of those six studies, only the Chung et al. (2016) and Mantzios and Giannou (2014) studies were conceptually congruent. The remaining studies paired MBE interventions with general mindfulness measures.

Two studies did not report statistically significant weight loss. As noted above, the Kidd et al. (2013) study was conceptually congruent. The Daubenmier et al. (2011) study was not conceptually congruent, pairing an MBE intervention with a general mindfulness measure.

Risk of Bias

Several factors other than conceptual incongruence may have biased the findings of the included studies. Only one study reported a statistical power analysis (Miller et al. 2014). The Daubenmier et al. (2011) and Mantzios and Giannou (2014) study groups differed on at least one characteristic at baseline. Attrition ranged from 0% to 47% (Dalen et al. 2010; Mantzios and Wilson 2014). Three of the seven studies with attrition tested whether individuals who did not complete the study differed from those who did (Miller et al. 2014; Mantzios and Giannou 2014, Mantzios and Wilson 2014). Mantzios and Giannou (2014) and Mantzios and Wilson (2014) both reported that fewer females completed their studies than males. Four of the included eight studies reported intervention fidelity activities. Daubenmier et al. (2011), Mantzios and Giannou (2014), and Mantzios and Wilson (2014) reported using adherence or participation logs. The principal investigator attended 20% of the intervention sessions to ensure fidelity in Miller et al. (2014) study. A minimum intervention dose was reported by three studies (Daly et al. 2016; Daubenmier et al. 2011; Mantzios and Wilson 2014). Additional assessment of risk of bias can be found in several recent systematic reviews (see Katterman et al. 2014; Olson and Emery 2015; O'Reilly et al. 2014; Rogers et al. 2017; Ruffault et al. 2016).

Discussion

Three of the eight included studies were conceptually congruent. Approximately two-thirds of the included studies reported increased mindfulness and decreased weight or BMI—regardless of conceptual congruence. Although two of the three studies that reported null findings were not conceptually congruent, other factors discussed below may have better accounted for these findings. There was no apparent relationship of conceptual congruence to the statistical significance of mindfulness and weight outcomes in mindfulness-based weight loss intervention studies.

Despite the lack of an apparent relationship of conceptual congruence to mindfulness and weight outcomes, the findings of this review support the need to better understand the mechanism by which mindfulness-based interventions affect weight loss. The included studies neither measured mindfulness with both general and eating-specific scales nor reported mediation analyses. Consequently, whether general and eating-specific mindfulness differentially influenced weight is unknown. This unknown is concerning because other

factors seem to have influenced weight loss. For example, Mantzios and Giannou (2014) compared the effects of group and independent mindfulness meditation on BMI. Although BMI significantly decreased in both study groups, the group meditation study group experienced a greater decrease. However, mindfulness significantly increased only in the independent meditation study group. Likewise, the Daly et al. (2016) study compared a group mindfulness-based eating intervention to an independent nutrition and exercise education intervention. Although there was no change in mindfulness, the mindfulness-based eating group experienced a greater reduction in BMI than the comparison group. In both studies, social support associated with face-to-face group meetings plausibly influenced BMI more than mindfulness (Lemstra et al. 2016; Wing and Jeffery 1999). These findings emphasize the need for mediation analyses in studies that report significant changes in both mindfulness and weight. Mindfulness should not be assumed to be the mechanism by which mindfulness-based interventions influence weight. And when mindfulness is the mechanism of change, the scope of mindfulness should not be assumed to be general or eating-specific.

Conceptual congruence is not a purely theoretical consideration. Although, as demonstrated in this review, conceptually incongruent studies can produce desirable outcomes, conceptually congruent studies should be more efficient in doing so. If one type of mindfulness (e.g., general or eating-specific) mediates the relationship between a mindfulness-based intervention and weight loss, then the intervention should be refined to maximize its effect on that type of mindfulness. Conceptual congruence based on mediation analyses is not a matter of right or wrong conceptualizations of mindfulness; it is a practical matter of determining which available conceptualization works best to produce the desired outcome (e.g., weight loss).

Limitations and Future Research Directions

This review had several limitations. Its sample of eight studies was small. Additionally, risk of bias and heterogeneity among the included studies challenged any conclusions about the relationship of conceptual congruence to the statistical significance of mindfulness or weight outcomes. Small sample sizes and the lack of power analyses posed the greatest threat. None of the three studies that reported null findings reported power analyses (Daly et al. 2016; Daubenmier et al. 2011; Kidd et al. 2013). Moreover, the sample sizes for the Daly et al. (2016) and Kidd et al. (2013) studies, respectively, were 23 and 7 to 12 (the actual number included in analysis was unclear). These samples were unlikely to be large enough to provide adequate statistical power. And because interventions were heterogeneous in composition (e.g., mindfulness practices varied; some interventions included nutrition and exercise training or advice), differences in mindfulness and weight outcomes may have been related to practical differences as opposed to conceptual congruence. Finally, vote counting (i.e., considering one study at a time) was the grossest available method to explore the relationship of conceptual congruence to the statistical significance of mindfulness and weight outcomes. Ideally, meta-analytic methods would have been used to combine the findings of conceptual congruent and incongruent studies, respectively, to explore the relationship in question.

Despite its limitations, this review presented challenges and opportunities for future research. Although the review focused on first-generation mindfulness-based weight loss intervention studies, conceptual congruence is also relevant to second-generation mindfulness-based health interventions and other clinical populations or problems. Second-generation mindfulness-based interventions are explicitly spiritual and supplemented with ethics and ontology teachings. These interventions potentially blur the distinction between secular and Buddhist practices (Baer 2015; Shonin et al. 2014; Shonin et al. 2015; Van Gordon et al. 2015). Although second-generation mindfulness-based interventions are designed to help participants produce a limited outcome and not relieve suffering in the Buddhist sense, the ethics and ontology training components are likely applicable across everyday situations. For example, Shonin et al. (2014) used Meditation Awareness Training (MAT) to improve work-related wellbeing among middle managers. In addition to meditation practice, the intervention incorporated teachings about compassion, generosity, impermanence, and emptiness, among other things. Based on semi-structured interviews with a subsample of the middle managers, MAT seemed to confer benefits related to general—not work-specific—present-orientation, decenteredness, and spiritual growth (Shonin and Van Gordon 2015). Because Shonin et al. (2014) did not measure general mindfulness and—to my knowledge—there are no work-specific mindfulness questionnaires, mediation analyses could not be used to disambiguate general and domain-specific effects of MAT.

Shonin et al. (2014) and Shonin and Van Gordon (2015) exemplify the challenge to future mindfulness-based health research. Most currently available scales measure general mindfulness; few domain-specific scales exist. Scale development is a resource-intensive process that requires a solid conceptual foundation. Given the remarkable effects of MAT and the seemingly general mechanism of change, the development of a work-specific mindfulness scale may not be useful. In contrast, given the case for eating being a special behavior not subsumed under everyday mindfulness and the availability of the MEQ, the examination of general and domain-specific effects using mediation analyses in mindfulness-based weight loss research is likely to be useful. Furthermore, mindfulness-based weight loss research may act as an exemplar to help determine whether domain-specific scale development and mediation analyses for general and domain-specific effects are worthwhile in other areas of mindfulness-based health research.

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Fig 1.
Citation selection flowchart

Table 1

Summary of study designs, interventions, and findings

Study Citation	Study Design	Population (Sample Size for Analyses)	Intervention Type (Intervention Foundation)	Intervention Duration and Activities	Findings
Daubenmier et al. 2011	RCT	Overweight and obese women (n=40/ <i>ITT</i>)	Group mindfulness training, nutrition/exercise training, and independent meditation (MBSR, MBCT, MB-EAT)	9 weekly 2.5-hr mindfulness training sessions; 1 7-hr group silent meditation session; 1 2-hr nutrition/exercise class; independent 30-min meditation recommended 6 days/week	↑ mindfulness ^{* b} <i>ITT</i> weight <i>ns</i> ^b <i>ITT</i>
Daly et al. 2016	RCT	Latina high school students with BMI >90 th percentile (n=23)	Group mindfulness training and eating exercises (MEAL)	6 weekly 90-min mindful eating training sessions	mindfulness <i>ns</i> ↓ BMI ^{*w} , ^{*** b}
Mantzios and Giannou 2014	RCT	Greek university students (n=152)	Group or independent meditation practice (Mahayana and Theravada Buddhism)	1-day meditation training session; ~20-min independent or group daily meditation for 6 weeks	↑ mindfulness ^{*** w} ↓ BMI ^{*** b} <i>w</i>
Mantzios and Wilson 2014	RCT	Greek university students (n=72)	Independent mindfulness practice (mindful concrete construal)	Daily concrete construal before and during meals for 5 weeks	↑ mindfulness ^{*** b} <i>w</i> ↓ weight ^{*** b}
Miller et al. 2014	RCT	Overweight or obese middle-aged adults with Type II diabetes (n=52)	Group and independent mindfulness training and meditation practice (MB-EAT-D)	10 2.5-hr group mindful eating training sessions over 3 months; independent meditation recommended 6 days/week	↑ mindfulness ^{* b} <i>w</i> ↓ weight ^{* w}
Chung et al. 2016	UT	African American women with BMI >25 who have completed breast cancer treatment (n=22)	Group mindfulness training and individualized nutrition counselling (not reported)	5 2-hr group mindful eating training sessions over 12 weeks	↑ mindfulness ^{***w} ↓ weight & BMI ^{*w}
Dalen et al. 2010	UT	Obese adults (n=10)	Group mindfulness training, eating exercises, and independent meditation practice (MEAL)	6 weekly 2-hr group mindful eating training sessions; daily 10-min independent meditation	↑ mindfulness ^{* w} ↓ weight & BMI ^{*** w}
Kidd et al. 2013	UT	Obese, low-income women (n=7–12) [?]	Group mindfulness training (see Albers 2008)	8 weekly 60–90-min group mindful eating training sessions	mindfulness <i>ns</i> ^w weight & BMI <i>ns</i> ^w

Note.

ITT =intention-to-treat analysis;[?] =sample size for analyses unclear;*ns*=not statistically significant;^{*} *p*<0.05;^{**} *p*<0.01;^{***} *p*<0.001;^{****} *p*<0.0001.

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q between-group comparison;
 w within-group comparison.

BMI=body mass index; RCT=randomized controlled trial; UT=uncontrolled trial (single-group intervention study); MBSR=Mindfulness-Based Stress Reduction; MBCT= Mindfulness-Based Cognitive Therapy; MB-EAT= Mindfulness-Based Eating Awareness Training; MB-EAT-D=Mindfulness-Based Eating Awareness Training for Diabetes; MEAL=Mindful Eating and Living

Table 2

Summary of intervention types, mindfulness types, and findings

Study Citation	Intervention Type [Subtype]	Measure Type	Measure Name	Findings
Chung et al. 2016	Mindfulness-based eating (MBE) [focused]	Eating-specific	Mindful Eating Questionnaire (MEQ)	↑ mindfulness ^{***} <i>w</i> ↓ weight & BMI [*] <i>w</i>
Dalen et al. 2010	MBE [comprehensive]	General	Kentucky Inventory of Mindfulness Skills (KIMS)	↑ mindfulness [*] <i>w</i> ↓ weight & BMI ^{**} <i>w</i>
Daly et al. 2016	MBE [focused]	General	Mindful Attention Awareness Scale (MAAS)	mindfulness <i>ns</i> ↓ BMI [*] <i>w</i> , ^{***} <i>b</i>
Daubenmier et al. 2011	MBE [comprehensive]	General	KIMS	↑ mindfulness [*] <i>b</i> <i>ITT</i> weight <i>ns</i> ^b <i>ITT</i>
Kidd et al. 2013	MBE [focused]	Eating-specific	MEQ	mindfulness <i>ns</i> ^w BMI <i>ns</i> ^w
Mantzios and Giannou 2014	General mindfulness	General	MAAS	↑ mindfulness ^{***} <i>w</i> ↓ BMI ^{***} <i>b</i> <i>w</i>
Mantzios and Wilson 2014	MBE [focused]	General	MAAS	↑ mindfulness ^{***} <i>b</i> <i>w</i> ↓ weight ^{***} <i>b</i>
Miller et al. 2014	MBE [comprehensive]	General	Five-Facet Mindfulness Questionnaire (FFMQ)	↑ mindfulness [*] <i>b</i> <i>w</i> ↓ weight [*] <i>w</i>

Note.

ITT =intention-to-treat analysis;*ns*=not statistically significant;^{*} *p*<0.05;^{**}*p*<0.01;^{***}*p*<0.001;^{****}*p*<0.0001.*b*₁ between-group comparison;*w* within-group comparison; BMI=body mass index