

Stress regulation via self-administered mindfulness and biofeedback interventions in adults: A pre-registered meta-analysis

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Abstract

We conducted a pre-registered meta-analysis to appraise available evidence on two stress regulation strategies: Self-administered mindfulness meditation and heart rate variability biofeedback. We used a combination of keywords to find as many experimental and observational studies as possible, all of which highlighted a link between the two strategies and different components of stress (physiological, affective, and cognitive) and affective consequences of stress. We found 35 effects for self-administered mindfulness reported in 14 papers (total $N=1141$, $Mdn_N=67$) and 31 effects for biofeedback reported in 13 papers (total $N=468$, $Mdn_N=27$). We found no evidence for the efficacy of self-administered mindfulness (Hedges's $g = .25$, $p = .21$) and biofeedback (Hedges's $g = .40$, $p = .15$). The lack of an effect was mostly due to the high heterogeneity, high risk of bias, and the lack of Registered Reports of the included literature.

Keywords: Stress regulation, self-administered mindfulness, biofeedback, meta-analysis, publication bias

Stress regulation via self-administered mindfulness and biofeedback intervention for adults: A pre-registered meta-analysis

Stress can influence how we experience emotions, how our body functions, and how we think (Aldwin 2007; Lazarus & Folkman, 1984). When stress gets excessive, it can even compromise people's everyday functioning (Jiaxuan et al., 2018). In cases when excessive stress lasts for extended periods of time, it can become an important driver in developing depression and/or anxiety disorders (Yang et al., 2015). Thus, knowing how to regulate stress effectively is vital. But it is not always desirable to utilize pharmacological interventions, as these may come with side effects. Further, pharmacological interventions may simply not be the most cost-effective way to deal with stress. It is thus essential to develop cost-effective (and non-pharmacological) interventions in order to cope with stress (q.v., de Witte et al., 2019).

Two very popular and non-pharmacological ways to regulate stress are self-administered mindfulness (a type of meditation that does not require an instructor) and “biofeedback” (a self-regulation training based on feedback on physiological mechanisms). Here, we plan to synthesize the evidence on these two strategies via a meta-analysis. Our primary reason to choose these interventions are because they are non-invasive and do not require the presence of other people. However, the choice is also partly arbitrary as the synthesis of these strategies will be a first step towards building a more comprehensive database to understand various stress-regulation strategies and their efficacy¹.

Overall, our motivation to conduct this meta-analysis is to assess the state-of-the-art in stress-regulation research and to provide directions on how to improve stress-regulation research moving forward. To accomplish this goal, we reviewed the existing literature and

¹ In a follow-up meta-analysis, we continued our approach to better understanding stress regulation, as we there appraised the available evidence of two external stress regulation strategies, namely being in nature and emotional social support (see Sparacio et al., 2023)

addressed some important questions: For which components (physiological, emotional, cognitive) underpinning biofeedback and self-administered mindfulness is there adequate empirical support? In addition, are individual differences taken into account when it comes to the efficacy of different stress regulation intervention? Is it possible to identify for whom certain strategies work and for whom they don't? We intend to shed light on the mechanisms underpinning stress regulation by employing a workflow incorporating various publication bias-detection techniques. To be as inclusive as possible, we also included in our meta-analysis affective states that are consequences of stress.

Stress regulation

Stress is generally understood as a non-specific response of the body, which occurs when external demands exceed internal resources (Lazarus & Folkman, 1984; Selye, 1956). The response to stress can be thought of as separated in three different components: Affective (Watson & Clark, 1988), physiological (Schneiderman et al., 2005) and cognitive (Du, Huang et al., 2018). We use these components as tools for our meta-analysis; we nevertheless agree with the theoretical position that these different types of response do not really present conceptual distinctions (Pessoa, 2008; Phelps, 2006) and that the systems underlying these three components influence each other during stress (De Witte et al., 2019; McEwen & Gianaros, 2010). But yet, splitting them into three different categories allows us to better understand the potential applied value of certain stress-regulation strategies.

The first of the three components, the affective one, is characterized by feelings of nervousness, strain, and tensions that arise when individuals are overrun by external demands (Ratanasiripong et al., 2012). The second, the physiological component, is characterized by an activation of the hypothalamic–pituitary–adrenal axis (HPA axis; Stephens & Wand, 2012). Physiological responses include, but are not limited to, the activation of the autonomic nervous system, which can be assessed through changes in heart rate, heart rate variability,

systolic and diastolic blood pressure, skin conductance, and cortisol (Bally et al., 2003). At the level of the cognitive response, stress has been found to be associated with changes in cognitive functions (which include processes like reflection and rumination; McFarland et al., 2007). For the present meta-analysis, we decided to focus on measurements of perseverative thinking and rumination.

The lack of a true separation between these components also means that stress does not stand on its own; when stress exceeds what one can handle, longer-term affective consequences may emerge, like depression or chronic anxiety (Cohen et al., 1983). Regulation strategies for stress oftentimes include ways to shield oneself from such longer-term consequences of stress. In his model, Russel (1980) classifies affect (and longer-term affective consequences) into valence (positive vs. negative) and arousal (high vs. low). The former is related to the degree of pleasantness of the affective experience while the latter is related to the level of arousal of the affective experience (Feldman, 1995; Russel, 1980). Crossing these two foci lets us categorize the majority of the affective experiences.

To downregulate stress people may rely on strategies, like self-administered mindfulness meditation and heart rate variability biofeedback. Self-administered mindfulness shares features, such as a non-judgmental attitude and an acceptance of inner experience, with other mindfulness protocols. In contrast with other protocols, however, self-administered mindfulness does not require the presence of an instructor, is available 24/7 to people, and tends to be one of the least costly ones (Spijkerman et al., 2016). Self-administered mindfulness can be administered via smartphone applications, audio files, and books which can guide the user through self-administered mindfulness exercises.

In the empirical literature, a two-week self-administered mindfulness meditation intervention (compared to a passive control group), has been found to influence the affective component by reducing self-reported stress (Cavanagh et al., 2013; Cavanagh et al., 2018).

We have found no studies on self-administered mindfulness that address the physiological component (probably due to the fact that self-administered protocols are mostly administered online). For traditional mindfulness interventions, Sanada et al. (2016) found slightly lower cortisol levels after intervention. For what concerns the cognitive component, a brief protocol of self-administered mindfulness compared to a waitlist control, reduced maladaptive cognitions like perseverative thinking (Cavanagh et al., 2018). Finally, a daily guided self-administered mindfulness intervention via an audio CD (compared to a passive control group) has been found to lead to a significant reduction in depression (May Barry et al., 2018).

The other strategy, biofeedback, is a technique that allows people to have immediate feedback on a specific physiological function (such as heart rate) that is under the control of the autonomic nervous system. Biofeedback interventions are thought to recruit the parasympathetic branch of the nervous system, thereby inhibiting sympathetic activity. (Frank et al., 2010). Based on the biofeedback received, people can learn how to change a behavior (e.g., their breathing rate) in order to improve the particular function they are monitoring. Biofeedback is typically delivered via computers or smartphones and is thought to improve self-regulatory capacities (Gross, 1998). For the present meta-analysis, we have decided to focus on one type of biofeedback called heart rate variability biofeedback. Heart rate variability biofeedback is, after all, the most used and thought to be the most efficacious in reducing stress (Lehrer & Gevirtz, 2014).

In one study, female nursing students participated in a 5-week intervention relying on three biofeedback sessions per day. The experimental (as compared to a passive control) group showed a significant reduction in self-reported levels of stress (Ratanasiripong, et al., 2012). In another study, evidence was more mixed: Participants in a biofeedback (compared to an active control group) condition showed improvements in respiratory rate, but no changes in blood pressure were found (Prinsloo et al., 2011). For what concerns the cognitive

component, several authors found a negative association between heart rate variability and perseverative thinking (Eddie et al., 2014; Thayer & Friedman, 2002). Finally, in one study, six sessions of heart rate variability biofeedback (compared with an active control group) interventions improved symptoms of depression at post testing and at 1 month follow-up (Lin et al., 2019).

Bias in estimating the efficacy of stress regulation

Nearly all of science, including psychology, is affected by publication bias (the likelihood that positive results have a higher probability of getting published; Rosenthal, 1979) and data contingent analyses (Gelman & Loken, 2013). Fanelli (2010), for example, estimated that psychology's and psychiatry's published findings contain over 90% significant results. Such a high positive ratio of findings is statistically highly unlikely, as the concerned literature is underpowered (Maxwell, 2004). The psychological literature thus likely contains a large number of false-positive and overestimated effects, as also hinted at by the growing body of replication studies in psychological science. When researchers repeat earlier found results with the same procedures, they often fail to find the same results (Klein et al. 2018; Maxwell et al., 2015; Open Science Collaboration, 2015).

It is reasonable to assume that some proportion of the literature on stress – like any other literature in psychology – suffers from replicability issues. To be able to provide people with advice on appropriate stress-regulation strategies, a meta-analytic assessment is thus needed to assess the extent of how empirically robust the published findings are (cf., IJzerman et al., 2021). Past meta-analyses on self-administered mindfulness interventions (Cavanagh, et al., 2014; Taylor et al., 2021) and biofeedback (Goessl et al., 2017) have tried to estimate the severity of publication bias in the literature. All three meta-analyses have found that biofeedback and self-administered mindfulness are moderately effective in reducing stress, depression, and anxiety.

However, neither meta-analysis has dealt with publication bias adequately. Taylor et al. (2021) and Cavanagh et al. (2014), for example, assessed publication bias with funnel plots and fail-safe N , without carrying out formal adjustment. The former technique is a mere descriptive visualization requiring subjective judgment. The latter is also not a formal detection or adjustment method, resting on problematic assumptions, and is now widely considered to be outdated (see Ferguson & Heene, 2012). Goessl et al. (2017) instead addressed publication bias using the trim-and-fill, which itself too is known to be problematic. Trim-and-fill is known to have an excessive false-positive rate under even the most realistic conditions (Carter et al., 2019; Hong et al., 2020).

To deal with publication bias, we employed several state-of-the-art publication bias correction methods, assuming a more realistic data-generating process behind the published effects of stress-regulation strategies. In doing so, we followed the workflow of IJzerman et al. (2021), assessing the evidential value of the literature using a permutation-based p -curve analysis and by estimating a naive meta-analytic effect size (and its heterogeneity) using a RVE-based multilevel model, assuming correlated and hierarchical effects (CHE working model; Pustejovsky & Tipton, 2020).

Then, we employed a tandem procedure involving the 4-parameter selection model (McShane, et al., 2016) and the regression-based PET-PEESE method (Stanley & Doucouliagos, 2014) to try to correct for publication bias. We considered an effect to be present only if all of the meta-analytic techniques detected one. This approach was highly conservative, but intentionally so to mitigate the risk that publication bias is a sole explanation of the target effect.

Research overview

To appraise the available evidence on the effects of self-administered mindfulness and biofeedback on stress in a more detailed manner, we have conducted a meta-analysis with the

following objectives: 1) To assess the evidential value of identified studies in both literatures, 2) for either regulation strategy, to estimate mean effect sizes for the three components of stress (affective, physiological, cognitive), 3) for either regulation strategy, to estimate the mean effect sizes for the affective consequences of stress, 4) to adjust the target estimates for publication bias using various techniques, and 5) to determine whether personality traits were taken into account in these literatures.

Method

Transparency and openness

The present meta-analysis aimed to be reproducible and fully transparent. In order to accomplish this goal, we made analysis scripts and the data for this study publicly available on our project page on the OSF (<http://bit.ly/39MifmH>). We intended to map the methodological quality and possible biases in this field, carrying out several sensitivity analyses with respect to our main results, and controlling for prognostic methodological factors related to the magnitude and precision of the reported effects in subgroup analyses.

Our meta-analysis was pre-registered on PROSPERO with protocol number [CRD42020179810] and on the OSF (<http://bit.ly/39MifmH>). Any changes to the pre-registration are fully disclosed on our OSF page (using the template provided by Moreau and Gamble 2020; Appendix A. All appendices can be found in the material section on the OSF page <http://bit.ly/39MifmH>). We intend to build a cumulative scientific knowledge base by depositing the data of our meta-analysis to PsychOpen CAMA, a platform whose aim is to construct a community-augmented meta-analysis (Burgard et al., 2021; Tsuji et al., 2014).

Inclusion criteria, and search strategy

To frame our research question in a structured way, we followed the Participants, Intervention, Comparator, and Outcome (PICO) Framework (Schardt et al., 2007). We chose to only include studies on participants that are adults (people aged 18 years or older). We

only included two interventions (self-administered mindfulness and biofeedback based on heart rate variability). For designs comparing groups, we included effects based on a comparison to an active control condition, meaning that participants engage in some tasks during the intervention period or to a passive control condition (participants are in an untreated comparison group; e.g., waitlist control). If there was more than one comparator in the same study (i.e., presence of both an active and a passive control group), we chose the contrast with the active control group. The main outcome of this meta-analysis was the level of stress after intervention, divided into three components (affect, cognition, and physiology). We relied on self-report measures (for the affective and the cognitive component and for the longer-term affective consequences of stress) taken at post-test (immediate and/or delayed) of the two groups (experimental and control). For the physiological component, we relied on changes in the activation of the hypothalamic-pituitary adrenal axis (e.g., via cortisol levels or heart rate) taken at post-test (immediate and/or delayed) of the two groups (experimental and control).

After framing our search strategy, we conducted a preliminary search to pilot the planned strategy and coding scheme (on a dozen eligible articles randomly chosen from each strategy category). To guarantee the reproducibility of the literature search, we followed the recommendations by Maggio et al. (2011), who provided guidelines to specify 1) which databases we used 2) which search terms we used, 3) which Medical Subject Headings (MeSH) or thesaurus terms we used, 4) on which dates we searched, and 5) what our search limits were. We searched the literature using the following sources: ProQuest, (an online platform which included research coming from APA PsycArticles, APA Psycinfo, ProQuest Dissertations & Theses Global), PubMed, and Scopus.

The first author (AS) conducted the literature search and excluded articles which were not relevant to the aim of the present meta-analysis. Screening by title and abstract was

carried out using Rayyan QCRI (Ouzzani et al., 2016). He then manually searched reference lists for more studies and unpublished reports. Finally, we asked for unpublished results via social networks (Facebook Groups and Twitter), via relevant mailing lists (SPSP, EASP, ESCAN), and via listservs of an association of clinical and health psychology (EACLIPT). Furthermore, to have a wider coverage of the literature, we contacted authors that have published studies on the topic to see if they have any unpublished research, in-progress manuscripts, or in-press manuscripts (see our templates in Appendices B and C). We also included articles from previous meta-analyses that we may have missed with other search methods (the articles that we obtained from these meta-analyses are included in Appendix D).

The inclusion criteria for our meta-analysis were as follows: 1) We included published primary studies, preprint articles, working papers, dissertations, and books (we included only studies published in English), 2) we included both randomized control trials and observational studies that estimated the effect of (or exposure to) one of the two stress regulation strategies, 3) we included studies that measured at least one of the three components of the stress response, which we included in the meta-analysis (physiological, affective, and cognitive), or at least that measured the affective consequences of stress, and 4) the participants of the study had to be humans. Studies were excluded if 1) the paper was a review or a meta-analysis, 2) participants were adolescents (under 18 years of age), 3) a common-metric effect size reflecting a bivariate effect or relationship could not be computed, or 4) the two types of intervention included in our meta-analysis (self-administered mindfulness & biofeedback based on heart rate variability) were combined with other active treatment (e.g., cognitive behavioral therapy or physical exercise).

We then added sub-exclusion criteria related to the two stress-regulation strategies. For self-administered mindfulness, we excluded studies 1) which involved the presence of an instructor, 2) which cannot be self-administered, and 3) which require meditation practices in

groups with other people. For each study on self-administered mindfulness, we coded the source from which participants got the instructions for doing the mindfulness exercises (e.g., an audio source or via a website). For biofeedback, we excluded from the meta-analysis any kind of biofeedback that was not based on heart rate variability. A PRISMA flow chart of the overall literature search and inclusion procedure is shown in Appendices E and F.

Coding and data preparation

The coding was carried out by two independent coders, with the first author coding all the included literature and the second coder coding at least 20% of the data for cross-checking. The coding process was cross-checked after the first 10% and after the second 10%. To evaluate the inter-rater reliability, Cohen's Kappa and inter-rater agreement were calculated. We double-coded a subset of the data, including the part of the statistics and characteristics of the individual studies. Following the guidelines of Landis and Koch (1977), we considered an agreement of $\kappa > 0.60$ for metric or multinomial variables acceptable. Consensus between two coders was reached through discussion in case of coding disagreements.

We extracted data for the following variables: Publication year, the number of citations of the paper, country, journal name, reported overall N , gender ratio, publication status, reported effect sizes, total N , cell means, standard deviations and N s, test statistic, degrees of freedom, the type of effect (e.g., main omnibus, main bivariate, or interaction), the reported p -value, the design, the type of population, the nationality of participants, whether individual differences were taken into account or not, the name of stress test used in experiments, the duration of the intervention, the type of intervention, the category of stress-regulation strategy (self-administered mindfulness or biofeedback), the type of control group (active or passive), whether it was one of the components of stress (affective, cognitive, or physiological) or an affective consequences of stress, the number of measurements, the

instrument employed to assess stress levels, the number, and the duration and the frequency of interventions. We also coded whether the effect was “focal” from the perspective of the author (if mentioned in the abstract, we coded it as focal).

We converted all the relevant bivariate effect sizes to a common metric (Hedges’ g), which is a standardized mean difference corrected for small sample bias (Hedges & Olkin, 1985). We also extracted the reported degrees of freedom as a more accurate estimate of the sample size because dropping of participants may have not been properly disclosed. For designs with two or more experimental groups, we checked the accuracy of the sample size in two ways: First, we looked at the reported N s of each group and computed the total N . If the sum matched the overall sample size ± 2 , the reported group cell sizes were used. If that was not the case, the cell N s were computed from the degrees of freedom, assuming a balanced design. In the case that the authors provided information only for the total sample size, we also assumed equal cell sizes. For within-participants designs, a conservative correlation between the measurements of $r = .50$ was assumed. Lastly, we conducted a sensitivity analysis varying the assumed correlation from .10 to .90, in steps of .20 in order to determine the impact on the overall effect size estimate.

Analyses

Analysis strategy

Following the workflow of IJzerman et al. (2023) and of Sparacio et al., (2023) we utilized a multilevel random-effects meta-analysis model using the restricted maximum-likelihood estimation with the R package *metafor*, version 2.0 (Viechtbauer, 2010). We included all the important dependent variables in our models even if some of them came from a single study. To deal with dependencies in the data, we employed a robust sandwich-type variance estimation (RVE) with the CHE working model (Correlated and Hierarchical Effects; Pustejovsky & Tipton, 2020). The aim was to simultaneously account for both types

of dependencies in the data, nesting of effects within studies and clustering due to the fact that some effects were estimated on the same participants. Here, we assumed a constant sampling correlation of .5, since sampling correlations among the effects are usually not reported. As a sensitivity analysis, we relaxed this assumption by varying the sampling correlation from 0 to .6 in steps of .2. We estimated the heterogeneity using τ (SD of the distribution of true effects) and I^2 (proportion of total variation in study estimates due to heterogeneity). We did not interpret any estimates when the number of included effects (k) were less than 10, because of the large expected sampling variability of such estimates, leading to estimates that are not precise enough to be useful.

In the analysis, we first excluded studies with high risk of bias and effects based on mathematically inconsistent means or standard deviations. We then carried out an in-depth diagnosis of the random-effects meta-analytic model, analyzing especially the presence of influential outliers. In case that there were excessively influential outliers (based on Beaujat plot and influence diagnostic indices), we examined their effect on the overall result in a sensitivity analysis. With this subset of studies, we first tested the overall effect sizes of the two different strategies (self-administered mindfulness and biofeedback) on the components of stress and the affective consequences of stress. Subsequently, we adjusted for publication bias to assess the level of empirical support for the specific intervention. We then proceeded with subgroup analyses to determine whether the intervention efficacy varied as a function of study or intervention characteristics.

For what concerns both strategies, five moderator variables were taken into account: Number of sessions (of self-administered mindfulness or biofeedback), intervention duration, number of females versus males, type of comparison group (active or passive control), and timing of the effect (after the intervention, after last follow-up). Lastly, we included a subgroup analysis related to the type of population (student non-clinical, non-student non-

clinical, clinical): If we were to find considerable heterogeneity, we conducted subgroup analyses on these groups to check if it was the source of heterogeneity. Again, for all subgroup analyses, effect sets with less than 10 effects were not analyzed. To test for equality of effect sizes across levels of the moderators, we used the robust HTZ-type Wald test.

Lastly, we omitted observational studies in a sensitivity analysis. A figure of the analysis workflow can be found in Appendix G. If we decided that additional subgroup analyses would be necessary exploratorily, we disclosed them on our OSF page (again, see Appendix A).

Correction for publication bias

Under publication bias, meta-analytic effect size estimates tend to have a high false-positive rate (if H_0 is true) or they end up being overestimated (if H_0 is false; Carter, et al., 2019; Ioannidis, 2008). A secondary consequence of publication bias is the fact that researchers might conduct data-contingent analyses (Simmons et al., 2011) to obtain p -values less than .05.

To try to mitigate these problems and estimate an unbiased effect size of stress regulation strategies, we tried to account for publication bias using a variety of approaches. Using a similar procedure as IJzerman et al. (2021), we first estimated the evidential value with the p -curve method, applied on a set of significant results (Simonsohn et al., 2014). Second, we tried to estimate an unbiased average effect using techniques that have only recently become available: The 4-parameter selection model (McShane et al., 2016) and a mixed-effects implementation of PET-PEESE (Stanley & Doucouliagos, 2014).

P-curve

P -curve is a technique used to assess the evidential value in a set of significant findings (Simonsohn et al., 2014). According to Simonsohn, Nelson, and Simmons (2014), we can infer the presence of bias by observing the shape of the p -curve. Under a null effect (d

= 0) the distribution of p -values is uniform. When an effect is present ($d \neq 0$) the results of that experiment are more likely to be associated with small rather than high p -values. The greater the statistical power, the steeper the p -curve (leading to a higher degree of right-skew in p -values). A p -curve with a left-skewed distribution of significant p -values may instead suggest the presence of questionable research practices. To handle the dependencies among the effects, we subsetting only the focal effects, randomly selected only a single effect size for each dependent set of effects, permuted this procedure in 5000 iterations, and selected the model with the median z -score for the right-skew of full p -distribution.

4-parameter selection model (4PSM)

The 4PSM is an implementation of selection methods, which are techniques that estimate and correct for publication biases regarding the size, direction, and statistical significance of study results (McShane et al., 2016). The 4PSM is a statistical model that has two components: 1) a data model describing how the data are generated when there is no publication bias and 2) a selection model that emulates the publication process. Each of them consists of two parameters. The two data model parameters are: a) Effect size parameter, which models the population average effect size and b) heterogeneity parameter. The selection model is represented by c) a weight parameter, which models the likelihood that a study with non-significant results is published compared to a study with a p -value below .05 and d) the likelihood of a result being in the opposite direction. These parameters allow for an estimate of the effect size and degree of heterogeneity in a way that accounts for publication bias (McShane et al., 2016). If a given set of results yielded less than four p -values per interval, the model dropped the fourth parameter to provide for a more stable estimation. Just like the p -curve, the 4PSM also assumes the included effect sizes to be independent. Therefore, we implemented the same permutation-based procedure, iteratively selecting only independent effect sizes, estimating the models, and averaging over the estimates.

As a sensitivity analysis, we have also applied the Vevea and Woods approach (2005) with a priori defined selection weights. Using a series of fine-grained step function models, this allowed us to examine the results when varying the assumed severity of bias (modeling moderate, severe, and extreme selection). The dependencies among the effects were handled using a permutation approach. The exact specification of these step function models can be seen or easily customized by the user in the accompanying script.

PET-PEESE

PET-PEESE is a conditional regression-based meta-analytic model that aims to correct for publication bias. The difference between PET and PEESE is that in the former, the effect size is regressed on the standard error while in the latter, the effect size is regressed on the squared standard error (variance) instead. A slope of the regression line indicates a relationship between the standard error and the effect size. This pattern hints at the presence of publication bias or other small-study effects. Because the PET model has a greater accuracy when the effect is absent and the PEESE model is more accurate when the effect is present, Stanley and Doucouliagos (2014) suggested using the PET model first. If the estimate of the PET is significantly different from zero, PEESE is used, and its result is taken as the bias-corrected effect size of interest. If PET does not detect any effect, the estimate of the PET is retained instead.

However, in many realistic situations, PET tends to have an unfavorable combination of false-positive rate and statistical power. Here, we used the 4PSM as a conditional estimator for PET-PEESE, as it was shown to have a relatively adequate false-positive rate under most conditions (Carter et al., 2019, Hong et al., 2020). Dependencies among the effects were modeled by employing a RVE-based multi-level model, assuming correlated and hierarchical effects (CHE working model; Pustejovsky & Tipton, 2020). A chart of the techniques employed to account for publication bias can be found in Appendix H.

Quality assessment

As a first step to assess study quality, we identified whether some study values were mathematically impossible. If in our studies the outcome was a discrete variable (as is the case for Likert scale items), means and standard deviations follow fixed granular pattern for each combination of N and number of items (Anaya, 2016; Brown & Heathers, 2016), rendering some values mathematically impossible.

Additionally, we used the Risk of Bias 2 (RoB 2) Tool by the Cochrane Foundation (2020). Using the RoB 2, we assessed the risk of bias corresponding to five predetermined domains: 1) risk of bias arising from the randomization process, 2) risk of bias due to deviations from the intended intervention (effect of assignment to intervention), 3) risk of bias due to missing outcome data, 4) risk of bias in the measurement of the outcome, and 5) risk of bias in the selection of the reported result. Within each domain, a series of signaling questions were answered to determine the relative risk of bias for each domain. Based on the answer to these questions, we used the algorithmic approach to assess the risk of bias corresponding to each domain as “low”, “some concerns”, and “high”. Then, based on the judgment for each individual domain, an overall rating on the risk of bias was determined. A study was categorized as having a Level 3 overall score (“high risk of bias”), if one of two conditions were met: A) the study scores having high risk of bias in at least one of the five domains or B) the study led to some concerns for at least three of the five domains.

Inter-rater agreement

We calculated the inter-rater agreement for the first 10% of the coded articles. For the variables for which Cohen’s Kappa was lower than our acceptance threshold ($< .60$), the coding strategy was respecified. For the first 10% of articles there were 4 variables that had values lower than the acceptance threshold, indicating an underdeveloped coding scheme for

these variables. The procedure was repeated after coding the second 10% of the data. The discrepancies in the rest of the data were resolved by discussion.

Results

The first search was conducted the 3/6/2020, and the second search was conducted the 28/6/2021. We found a total of 1318 articles, but this number dropped to 749 articles after we removed duplicates. Finally, after excluding articles that did not meet our inclusion criteria, we ended up with a total of 46 articles (26 for self-administered mindfulness and 20 for biofeedback). The final meta-analytic data set consisted of 76 effects for self-administered mindfulness and of 43 effects for biofeedback.

In line with the pre-registration, we applied strict selection criteria for the effects and we excluded studies that scored high in risk of bias² assessment and single effects with mathematically inconsistent means or standard deviations. We also screened the data set for outliers using the Baujat and Gosh plot and carried out influence diagnostics. None of the coded effects was found to exert an undue influence on the meta-analytic models. After the exclusions, 35 effects for self-administered mindfulness and 31 for biofeedback met the inclusion criteria for a meta-analytic synthesis. In what follows, we will address the core questions of our meta-analysis and we will present the set of subgroup analyses that we performed.

Answering the four core questions of the meta-analysis

In Table 1, we provide a summary of the questions we asked in our pre-registration. Overall, we did not find sufficient evidence for the overall efficacy of self-administered mindfulness and biofeedback. We also did not find evidence for the reduction of stress regulation for the different components of the stress response nor as they pertain to reducing

² We pre-registered that we would have included observational studies at first, and that then, we would have excluded them via a sensitivity analysis. However, we excluded them before running any analyses.

the affective consequences of stress. For the different subgroup analyses we conducted, publication bias adjustments were not applied due to the low number of effects; these results should therefore be interpreted with caution.

Table 1.
Core questions of the meta-analysis.

Question	Conclusion
Is there support for the reduction of stress through self-administered mindfulness and biofeedback?	No support.
For which components (physiological, emotional, cognitive) underpinning biofeedback and self-administered mindfulness is there adequate empirical support?	The status of any of these components is unclear. We found some empirical support for the affective component for self-administered mindfulness and for the physiological component for biofeedback, but publication bias adjustment could not be applied.
Are individual differences taken into account in primary studies when it comes to the efficacy of different stress regulation interventions?	Individual differences were not taken into account in the focal analyses as they were only used as exclusion criteria in the included studies.
Can we infer for whom certain strategies work and for whom they do not?	Women seem to benefit more from a biofeedback intervention as compared to men.

Do self-administered mindfulness or biofeedback reduce stress?

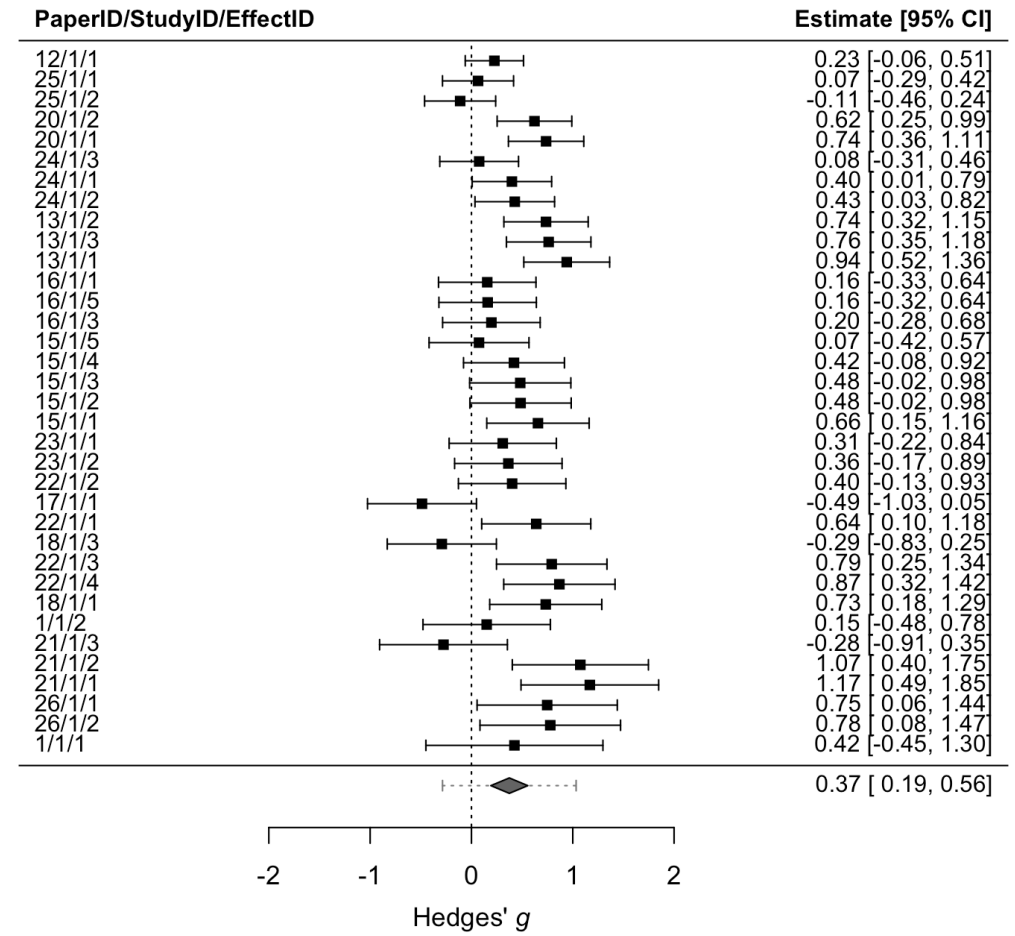
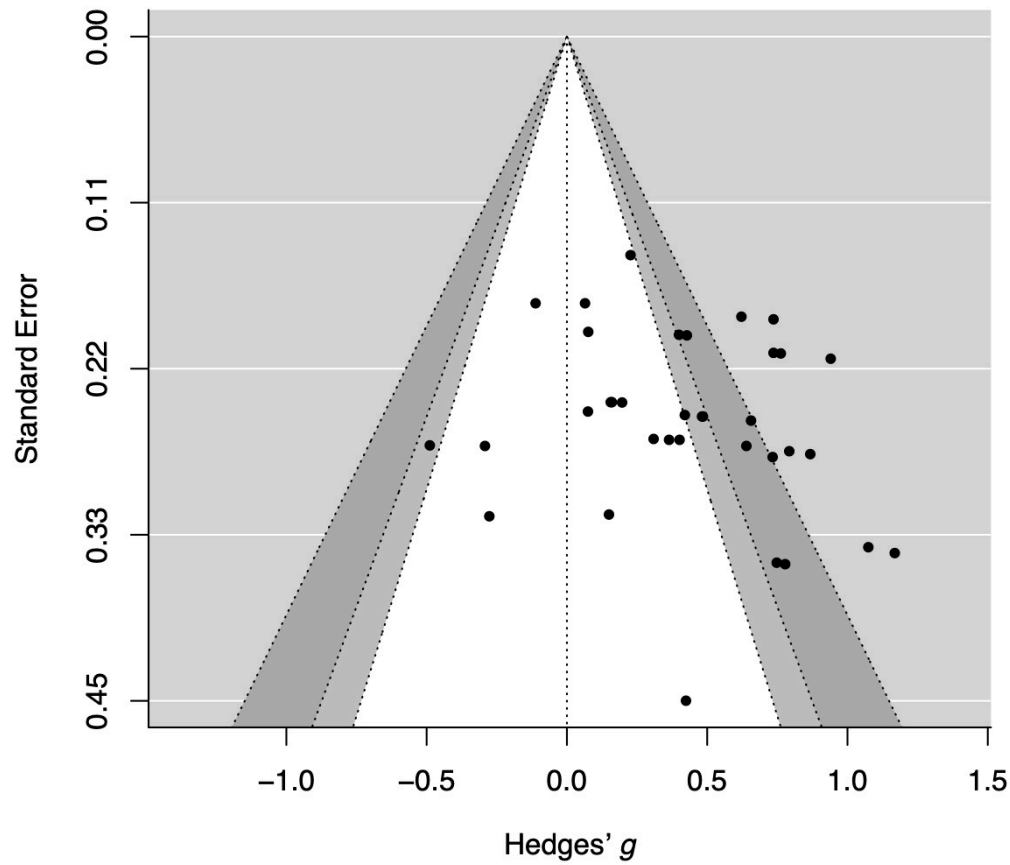
We did not find evidence for the effect of self-administered mindfulness on the three components of stress (affective, physiological, cognitive), nor on the affective consequences of stress. Using a random-effects meta-analysis, we found that out of all eligible coded effects ($k = 35$), 46% were statistically significant. The overall meta-analytic estimate was at $g = .37$, 95% CI [.19, .56], $p < .001$, suggesting the presence of an effect³ of self-administered mindfulness on reducing stress levels. The 95% prediction interval was broad however, with the true effect in a new published study being expected to fall between -0.29 and 1.03. In the examined set of effects, the amount of absolute heterogeneity was significant and substantial, $\tau = .29$. Only $I^2 = 59.8\%$ of the total variance across observed effect estimates was systematic (20.0% due to between- and 39.8% due to within-cluster heterogeneity). Forest plot and the contour-enhanced funnel plot are displayed in Figure 1.

In a second step, the full and half p -curve tests ($z = -3.34$ and $z = -3.66$, respectively) were significant (both $p < .001$). Thus, the p -curve suggested the presence of evidential value in the given set of included significant effects that were considered focal (however, the permuted model with a median z -score was based on only $k = 4$ independent effects). We then applied publication bias-correction techniques. The 4-parameter selection model did not detect a significant effect, with $g = .25$, 95% CI [-.14, .63], $p = .21$. When varying the assumption about the severity of the publication bias using the Vevea and Woods approach (2005), the estimates ranged from $g = .23$, $p = .06$ (for moderate selection) to $g = .02$, $p = .84$ (for extreme selection). PET (and also PEESE) model corroborated the result of the

³ The effects in Figure 1 represent the positive influence of self-administered mindfulness intervention on reducing stress levels (i.e., higher scores correspond to lower stress levels).

Figure 1.

Contour-enhanced funnel and forest plot for self-administered mindfulness.



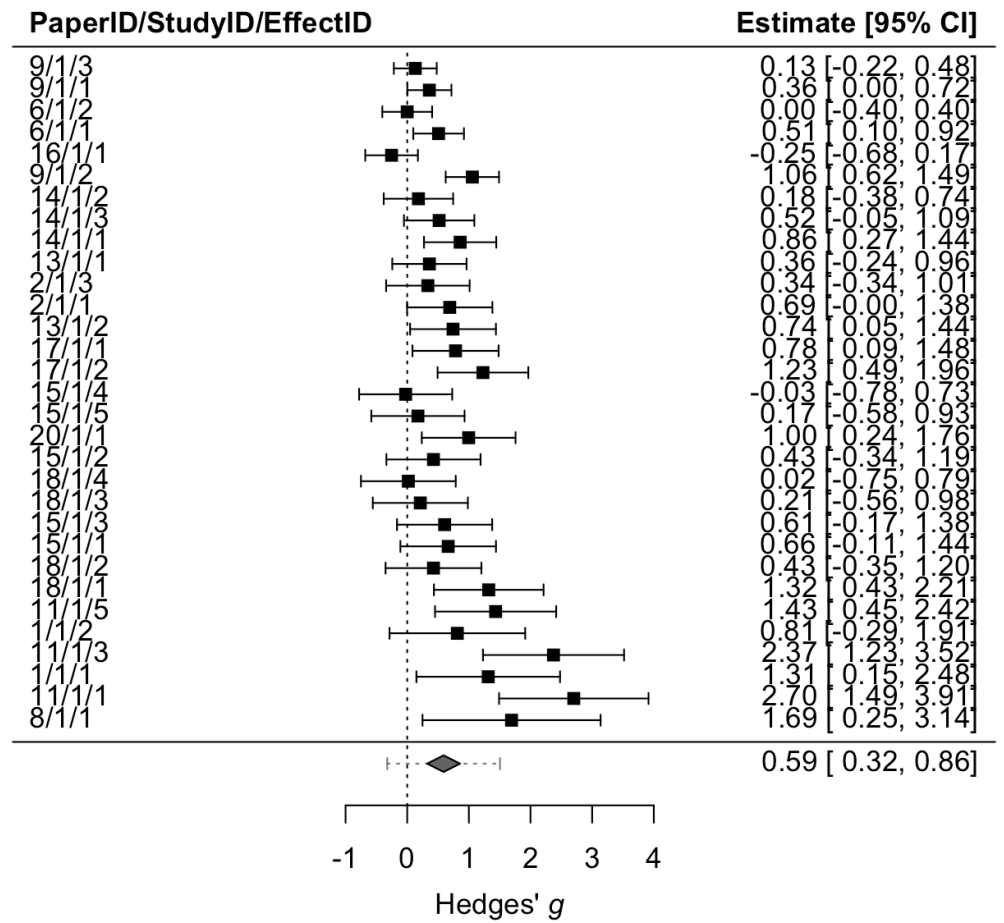
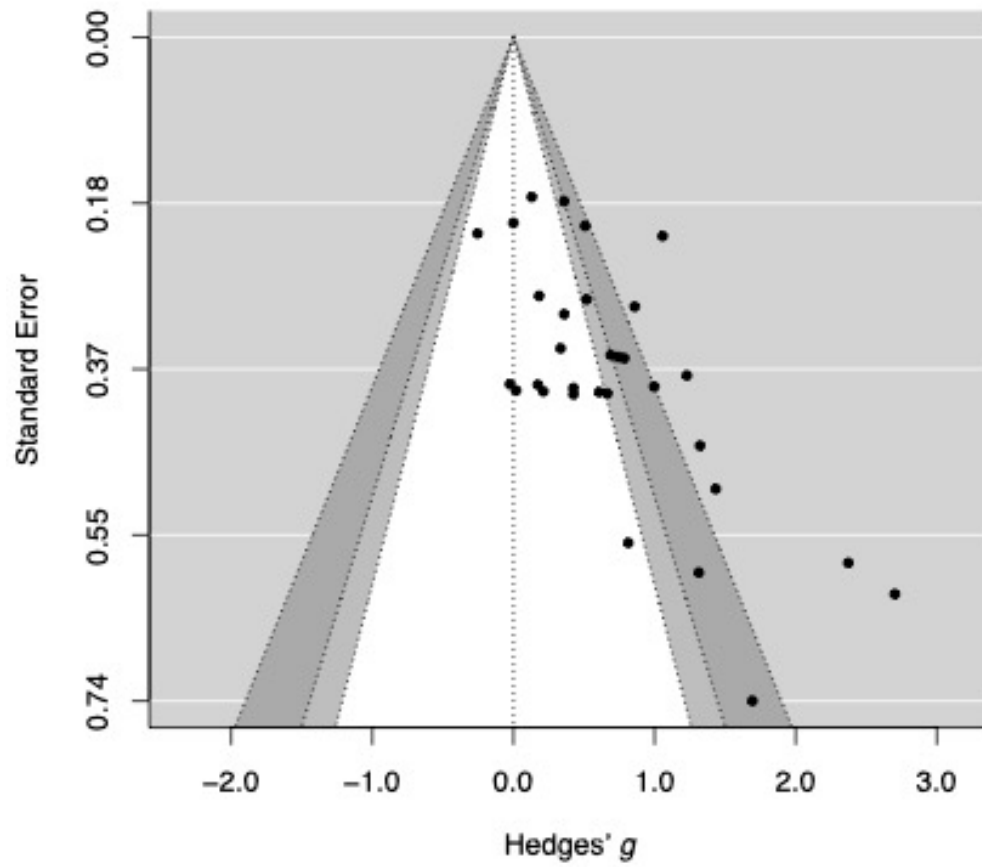
4-parameter selection model, with PET at $g = .16$. This estimate was relatively imprecise, as is obvious from the 95% CI of $[-.65, .97]$, associated with $p = .68$.

Overall, based on our inferential criteria that all of our analysis techniques should show an effect, we were not able to reject the null hypothesis of zero efficacy of self-administered mindfulness. Although the naive meta-analytic estimate and the p -curve suggested the presence of an effect, the 4-parameter selection model and subsequent PET model were not able to detect an effect.

Relatedly, the power of the literature was low. The average power in the set of included studies to detect small effects ($d = .20$) was .21, but was adequate (.82) by conventional criteria to detect effects of $d = .50$ or larger. With regards to the quality and integrity of the underlying evidence, 37% of the coded effect sizes came from designs judged to have low risk of bias, 39% from designs showing some concerns, and 24% originated from designs with high risk of bias. None of the coded effects were based on mathematically inconsistent means or standard deviations.

For biofeedback, we also did not find robust evidence as the techniques employed did not all converge on the presence of an effect. We first calculated the overall meta-analytic effect for biofeedback. Among the biofeedback effects reported in the literature, 35% were statistically significant. The overall meta-analytic estimate was at $g = .59$, 95% CI $[.32, .86]$, $p < .001$. The 95% prediction interval was wide, with the true effect in a new published study being expected in the range from -0.32 to 1.51. We found high heterogeneity, $\tau = .40$, $I^2 = 61.66\%$ (18.9% due to between and 42.8% due to within-cluster heterogeneity). The forest plot and contour-enhanced funnel plot for this set of effects can be seen in Figure 2. P -values for both, the full p -curve ($z = -2.19$, $p = .01$) and the half p -curve tests ($z = -1.40$, $p = .08$)

Figure 2.
Contour-enhanced funnel and forest plot for biofeedback.



were below $\alpha = .10^4$, indicating the presence of evidential value for the p -curve in the given set of included significant focal effects (again, based only on $k = 4$ independent effects for the median model). For what concerns the correction for publication bias, the 4-parameter selection model was not significant $g = .40$, 95% CI $[-.14, .95]$, $p = .15$.

The estimates proved to be sensitive to the degree of assumed severity of publication bias, ranging from a significant $g = .47$, $p = .01$ for moderate selection, to $g = .18$, $p = .26$ for extreme selection. Subsequent PET (and also even PEESE) estimate was in the opposite direction $g = -.72$, 95% CI $[-1.47, 0.04]$, $p = .061$, which can be regarded nil.

The average power across the literature to detect at least small effects ($d = .20$) and medium-sized effects ($d = .50$) was only .11 and .44, respectively. Lastly, with respect to the quality of evidence and reporting inconsistencies, 15% of the coded effects came from studies with low risk of bias, 76% from study designs having some concerns, and 9% of the effects came from studies with high risk of bias. A sizable proportion (26%, $k = 5$) of the coded effects were based on means or standard deviations that were inconsistent with the reported cell sizes.

Thus, similarly to self-administered mindfulness, the present data did not provide evidence for the presence of an empirically robust effect. To formally compare the relative efficacy of the two strategies, we used a meta-regression model controlling for design-related factors that might be prognostic with respect to the unadjusted effect sizes (i.e., might vary between the two strategies). As these covariates, we included the study design, type of population, type of comparison group, published status, and the assessment of the risk of bias. Using a robust Wald's-type test, we did not find a significant difference in the efficacy of the two strategies, $F(1, 7.31) = 1.91$, $p = .21$. Nor did we find an effect in a model without

⁴ If the half p -curve test is right-skewed with $p < .05$ or both the half and full test are right-skewed with $p < .1$, then p -curve analysis indicates the presence of evidential value (Simonsohn, Nelson, & Simmons 2014).

covariates ($p = .24$). Table 2 summarizes the results for the overall effect of self-administered mindfulness and biofeedback.

Table 2.

Meta-analysis for self-administered mindfulness and biofeedback. Values in brackets represent 95% CI.

	k	g [95% CI]	SE	τ	I^2	4PSM estimate	4PSM p -value	PET-PEESE estimate	PET-PEESE p -value
Self-administered mindfulness	35	.37 [.19, .56]	.08	.29	59.8%	.25 [-.14, .63]	.21	.16 [-.65, .97]	.68
Biofeedback	31	.59 [.32, .86]	.12	.40	61.66%	.40 [-.14, .95]	.15	-.72 [-1.47, 0.04]	.061

For which components is there adequate empirical support?

In order to establish the presence of adequate empirical support, each meta-analytic technique should have converged on the presence of an effect. However, it was not possible to answer this question exhaustively due to an insufficient number of studies which made it infeasible to employ publication bias adjustment techniques. Thus, the empirical support that we retrieved should be considered suggestive, not conclusive. For self-administered mindfulness, we categorized most of the effects as falling in the affective component ($k = 26$). We classified many fewer effects as falling into the physiological ($k = 4$, $g = .09$) or cognitive component ($k = 2$, $g = .23$). Finally, we classified $k = 3$ effects as being part of affective consequences of stress. The affective component was associated with a large effect size $g = .39$, 95% CI [.21, .58] (it did not make sense to analyze the others due to a low k). The differences between the components in terms of effect size was not statistically significant, Wald's test $p = .18$.

For biofeedback, we categorized the majority of the effects as falling in the physiological component ($k = 11$), followed by the affective component ($k = 10$) and the

cognitive component ($k = 1$). Finally, we classified $k = 7$ effects as being part of the affective consequences of stress. The average effect size for the physiological component was large, with $g = .51$, 95% CI [.19, .82] and similar in size to the affective component with $g = .61$, 95% CI [.23, .99]. The difference between the components in terms of effect size was not statistically significant, Wald's test $p = .78$.

Are individual differences taken into account?

For self-administered mindfulness, 19 studies out of 26 reported some assessments of individual differences. For biofeedback, there were 17 studies that reported some assessments of individual differences (out of 20). In most of the cases, these assessments underlay exclusion criteria. For example, for self-administered mindfulness, participants were excluded if they had previous meditation experience (e.g., if they meditated 6 months before the experiment) or if they suffered from certain psychological symptoms (e.g., exceeding a certain threshold for trait anxiety).

For biofeedback, in some cases, participants were excluded if they did not meet certain criteria that made them suitable for that clinical trial (e.g., reporting subclinical psychotic symptoms over a certain threshold). However, for either strategy, all measurements of individual differences were used as exclusion criteria or as baseline measurements. In the included studies, individual differences were never taken into account in any of the analyses. Thus, it was not possible to make any kind of inference as to which strategy is most effective in reducing stress levels based on individual characteristics.

For whom do certain strategies work and for whom do they not?

Although we had little information to understand for whom these strategies work and for whom they don't, we can however indirectly examine whether the two strategies had a different efficacy, throughout all stress components, based on characteristics of the

population. In line with the pre-registration, we performed subgroup analyses as we found considerable heterogeneity for both strategies.

For self-administered mindfulness, the mean proportion of female participants across the included studies was 66.5%. We did not find an effect of gender on the efficacy of self-administered mindfulness interventions in reducing stress ($p = .61$). Next, we conducted a subgroup analysis to examine whether students' samples yielded larger effect sizes as compared to other groups; the effect size coming from a population of students ($k = 12$), was not larger when compared to non-student healthy participants ($k = 14$), or to a clinical population ($k = 9$; Wald's test $p = .87$).

For biofeedback, most of the participants were also women (67.6%). However, in this case, stress reduction was more pronounced after a biofeedback intervention in women than in men ($B = .008$; $p = .002$). Next, we again conducted a subgroup analysis to examine whether the efficacy of biofeedback interventions varied as a function of the type of population. For this strategy, the effects were mostly coming from a non-student healthy participants ($k = 13$) and non-student ($k = 15$) clinical population. The difference between groups was not significant (Wald z-test $p = .72$). Based on the characteristics of the population, the only indication we can draw is that women may benefit more than men from biofeedback intervention.

Methodological moderators

In the next set of moderator analyses, we examined which characteristics of interventions and methodological characteristics of included studies were most effective in terms of stress reduction, taking together the full set of studies per domain.

Characteristics of the intervention

First, we tested whether the efficacy of self-administered mindfulness and biofeedback varied as a function of the number, frequency, and the duration of the

interventions. The number of intervention sessions in the included studies ranged from 1 to 64 ($M = 29.3$; $Mdn = 27$). There was no evidence for the effect of the total number of intervention sessions ($b = .01$; $t = 1.93$; $p = .053$). However, the intensity/frequency of intervention (i.e., the number of sessions per week until the end of treatment) was significantly associated with a reduction in levels of stress ($b = .07$; $t = 4.7$; $p < .001$). Similarly, spending a greater number of hours engaging in self-administered mindfulness was significantly related to the reduction of stress ($b = .04$; $t = 4.2$; $p < .001$).

Next, we examined whether there was a moderation by the source of the mindfulness intervention. Interventions can namely be delivered via web-based platforms, smartphone applications, books, audio files, or a mix of these sources. The most frequent sources were: Web-based platforms ($k = 12$, $g = .40$) and books ($k = 9$, $g = .54$). The difference between sources was, however, not significant (Wald z-test $p = .77$).

The number of interventions in the included studies for biofeedback ranged from 1 to 40 interventions ($M = 9.5$, $Mdn = 6$). The effect for the number of intervention sessions was not significant ($b = .03$, $t = 1.02$, $p = .31$), just as the overall duration of the biofeedback interventions ($b = .04$, $t = 1.28$, $p = .2$). Having a greater number of biofeedback interventions per week was however associated with a significant reduction in stress ($b = .15$, $t = 3.00$, $p = .003$). Again, all the aforementioned analyses should be interpreted as only suggestive, given the low number of k .

Study design characteristics

We studied how several design characteristics of the included studies related to the effect sizes of those studies. First, we checked whether effects of the studied interventions were smaller when passive control groups were utilized compared to when active control groups were used. We did not detect such an effect for either of the intervention strategies, Wald's test $p = .35$ and $.50$ for self-administered mindfulness and biofeedback, respectively.

Second, we tested whether the effects of self-administered mindfulness interventions persisted over time after the end of the treatment (by looking at follow-up measurements when reported). There was no difference between measures immediately after the end of the intervention and follow-up measurements, with $p = .52$ and $p = .54$ for self-administered mindfulness ($k = 35$ post-intervention measurements, $k = 28$ follow-up measurements) and biofeedback ($k = 31$ post-intervention measurements, $k = 4$ follow-up measurements), respectively. Note however that only very few studies were eligible for the analysis for biofeedback⁵.

Including studies with high risk of bias and inconsistent means or *SDs*

As the primary analysis, we aimed to investigate whether self-administered mindfulness and biofeedback reduce stress. We conducted our analyses by excluding effects based on designs with a high risk of bias assessment and those based on inconsistent means or *SDs*). We did not pre-register this analysis, however, as the scope of a meta-analysis is a comprehensive assessment of the evidence on a given phenomenon, we also carried out a synthesis involving *all* theoretically relevant effects regardless of methodological quality or issues of reporting integrity. The full set of the coded effects included 119 effects (72 for self-administered mindfulness and 42 for biofeedback).

When analyzing all the coded effects ($k = 72$) related to the efficacy of self-administered mindfulness interventions, the overall meta-analytic estimate was $g = .31$, 95% CI [.10, .51] with the true effect in a new study being expected to fall between -0.66 and 1.27. In this full set of studies, the amount of heterogeneity was even more substantial than in our primary analysis, $\tau = .45$, $I^2 = 79.4\%$ (18.3% due to between- and 61.1% due to within-cluster heterogeneity).

⁵ Detailed results for all the above-described analyses and for those that were not pre-registered can be found in the material section on the OSF.

After adjusting for publication bias, the 4-parameter selection model still yielded a non-significant result, $g = .21$, 95% CI $[-.22, .65]$, $p = .34$. The PET model again did not find an underlying effect for self-administered mindfulness $g = -.03$, 95% CI $[-.72, .65]$, $p = .92$. When we analyzed the full set of effects for biofeedback, the overall meta-analytic estimate was at $g = .65$, 95% CI $[.39, .92]$, The 95% prediction interval was wide, ranging from -0.28 to 1.59. The heterogeneity was, again, high, $\tau = .42$, $I^2 = 65.5\%$ (35.5% due to between- and 30.0% due to within-cluster heterogeneity).

For what concerns the correction for publication bias, the 4-parameter selection model was significant $g = .51$, 95% CI $[.09, .93]$, $p = .02$. However, the PEESE estimate provided a non-significant estimate $g = .17$, 95% CI $[-.25, .58]$, $p = .41$. The fact that the two techniques did not converge on the same conclusion means that the overall effect for biofeedback regarding the regulation of stress should only be considered as suggestive concerning the presence of an effect. Thus, there was a lack of evidence for both strategies even when we included *all* theoretically relevant effects regardless of methodological quality or issues of reporting integrity. Table 3 summarizes the results for the overall effect of self-administered mindfulness and biofeedback.

Table 3.
Meta-analysis for self-administered mindfulness and biofeedback. Values in brackets represent 95% CI.

	k	g [95% CI]	SE	τ	I^2	4PSM estimate	4PSM p -value	PET-PEESE estimate	PET-PEESE p -value
Self-administered mindfulness	76	.31 [.10, .51]	.07	.45	79.4%	.21 [-.22, .65]	.34	-.03 [-.72, .65]	.92
biofeedback	43	.65 [.39, .92]	.12	.42	65.5%	.51 [.09, .93]	.02	.17 [-.25, .58]	.41

Discussion

In this pre-registered meta-analysis, we evaluated whether two popular non-pharmacological strategies - self-administered mindfulness and biofeedback - have demonstrated efficacy in decreasing levels of stress. Random-effects meta-analysis assuming no selection on statistical significance suggested the presence of systematic, but highly heterogeneous true effects for both strategies. However, after correcting for publication bias, we found no evidence for the effects of self-administered mindfulness or biofeedback on stress regulation, regardless of whether we analyzed the results with more strict or less strict exclusion criteria. The lack of observed evidence is largely due to the high degree of heterogeneity, the low power, and publication bias, which all severely limited the interpretability of our results. The lack of evidence was mirrored for the components of the stress response and for the affective consequences of stress for both self-administered mindfulness and biofeedback.

Note that the current meta-analysis only focused on the literature in English. It is unclear how our results extend to literature in other languages. In what follows we refine our conclusions by assessing the quality of the literature and by discussing seemingly contradictory findings.

How interventions may differ across situations and across people

We were not able to draw any conclusions regarding the role of individual differences in moderating the effects of self-administered mindfulness on stress regulation, based on what we found in primary studies. Individual differences were mostly used as exclusion criteria and were not taken into account in any of the conducted analyses. It is theoretically plausible – perhaps even likely - that people differ in how much they benefit from different types of stress regulation strategies.

For traditional mindfulness protocols, some studies have investigated a potential connection between personality traits and effectiveness of mindfulness training (Tang & Braver, 2020). Trait mindfulness (i.e., the dispositional ability of being grounded in the present moment) has often been linked to mindfulness training outcomes and effectiveness (Tang & Braver, 2020), as such training seems more efficient for individuals scoring high in this trait. Moreover, neuroticism is the Big Five dimension with the strongest link with mindfulness ($r = -0.45$) according to a recent meta-analysis (Giluk et al., 2009), while De Vibe et al. (2015) found that participants higher in neuroticism showed greater improvement in psychological distress and well-being compared to those in a control group after a MBSR intervention. For biofeedback the literature appears to be less developed as to which individual differences may play a major role, compared to mindfulness. One possibility to find potentially relevant moderators for biofeedback would be to test the traits that have already been found as moderators in other stress regulation interventions (e.g., neuroticism; Schneider et al., 2012). However, because of the lack of information on the topic, our meta-analysis cannot speak to these ideas.

It is important that primary studies on stress regulation in general, and self-administered mindfulness and biofeedback specifically, start taking into account personality traits that might play a role in the effectiveness of stress regulation strategies. When researchers record these personality traits and other potentially relevant aspects they can deposit them in a database so that meta-analysts can understand across different studies for whom, under which conditions, and with which kind of parameters the interventions function most optimally. We created a protocol in Appendix I, which includes traits that we think should be measured to better understand how stress is regulated by different people.

Quality of the literature

The most pernicious issue concerns the quality of the stress regulation literature. For self-administered mindfulness, we had to exclude 54% of the effects because they were based on inconsistent means or standard deviations or because the study designs they came from were judged to be at a high risk of bias. For biofeedback, the percentage of excluded studies was lower but still substantial, with approximately one third of the effects being excluded. We nevertheless repeated our analyses this time including these low quality studies, but these did not change our conclusions⁶.

Another problematic issue is that, for the majority of the studies (30/32 for self-administered mindfulness and 23/31 for biofeedback) included in our meta-analysis, the experimental group was matched with a passive instead of an active control condition. Future studies need to employ a well-matched active control that is structurally equivalent to the experimental condition for a more accurate estimate of the effect of interest (MacCoon et al., 2013). Even when we exclude these low-quality studies, we conclude that both literatures suffer from publication bias and from substantial heterogeneity, severely limiting what we can infer from the literature in terms of evidential value.

Why do the results from different techniques differ?

When analyzing the data, the naive meta-analytic estimate and the p -curve seemed to provide evidence in favor of the efficacy of self-administered mindfulness and biofeedback strategies, while PET-PEESE and 4PSM did not provide evidence in favor of the efficacy of either strategy. P -curve, however, is known to overestimate the effect under conditions of substantial heterogeneity (Simonsohn, Nelson, & Simmons, 2014), while PET-PEESE has been found to perform poorly in scenarios when used on a small number of studies that are

⁶ For biofeedback, when we excluded effects from designs having high risk of studies ($k = 28$), both bias-correction techniques failed to find an effect. However, when we analyzed the full set of effects ($k = 41$) the 4-parameter selection model suggested the presence of an effect, while the PEESE was not able to detect any signal.

underpowered and are highly heterogeneous (Carter et al., 2019). This means that because of the relative imprecision of these publication bias techniques, we have an effect that has been corrected, but we cannot know how accurate it is.

When considering different interventions to downregulate stress based on the available evidence, it is vital to be accurate and clear about which evidence exists. Choosing the wrong strategy could have no effect on stress regulation or, worse, cause adverse effects (IJzerman et al., 2020). For instance, mindfulness interventions have at times (and anecdotally) resulted in psychotic episodes, panic attacks, and depersonalization (Van Gordon et al., 2017). Moreover, some studies have even found that mindfulness interventions do not reduce people's self-focus and desire to be better than others, but instead bolstered self-enhancement (Gebauer et al., 2018; Vaughan-Johnston et al., 2021).

We thus believe that our conservative approach was the most suitable: Only if all bias correction techniques point in the same direction did we accept that the stress regulation strategy was efficacious. At present, our best answer is that we simply do not know whether biofeedback or self-administered mindfulness work in downregulating stress. The only way to answer this question is by improving the quality of primary studies in these literatures.

Prevalence and use of self-administered mindfulness and biofeedback

Self-administered mindfulness has seen a rise of accessibility and popularity in recent years (Cavanagh et al., 2018). This increase was due to a combination of factors, such as the secularization of the Buddhist concept of mindfulness, introduced in North America by Jon Kabat-Zinn in 1970, and the emergence of technologies (e.g., smartphone applications) that enabled people's access to forms of self-administered mindfulness. In particular, in the last few years there has been a surge in downloads of mindfulness applications, especially after the COVID-19 outbreak. For example, 'Calm', the top English-language meditation app, saw

almost 4 million downloads in April 2020, the month in which more people around the globe experienced the first lockdown (Perez, 2020).

A large and very heterogeneous group of people very likely tried to apply self-administered mindfulness through these apps. But to date, there is no evidence that self-administered mindfulness is efficacious in reducing stress, depression, or anxiety. Moreover, *if* self-administered mindfulness does work, we have no knowledge how it functions across different individuals. A number of studies have been conducted using Headspace (Headspace, 2021), a widely used mindfulness application, to investigate the beneficial effects of self-administered mindfulness. Two studies using Headspace for its intervention met our inclusion criteria for our meta-analysis and they had similar problems as what we observed throughout the literature: They were underpowered (Economides et al., 2018; Rich et al., 2021) and/or only employed a passive, not an active, control condition (Rich et al., 2021). Given the lack of evidence behind self-administered mindfulness that we observe in our meta-analysis, we warn the reader to put too much stock into the evidence cited by such commercial initiatives until high-quality pre-registered studies are conducted about their efficacy.

Heart rate variability biofeedback saw a smaller increase in prevalence than self-administered mindfulness, perhaps due to a general higher cost of the practice.

These higher costs may be the reason that biofeedback is often more employed in clinical settings, such as in the treatment of some disorders (asthma, COPD, fibromyalgia; Gevirtz, 2013) than in non-clinical settings. Consistent with this possibility, eight studies out of twenty included in our meta-analysis involved a clinical population. Although various manuals and protocols exist - in contrast to self-administered mindfulness - the need for high-quality, pre-registered studies here is similar as for self-administered mindfulness before clinicians apply them in their practice. We simply do not observe evidence behind the idea that biofeedback downregulates stress, depression, or anxiety. In what follows we tried to

understand why we were unable to find evidence, followed by methodological recommendations for future studies.

The signal might be present, but we were unable to detect it

The fact that we did not detect a signal does not necessarily mean that self-administered mindfulness or biofeedback are not effective in reducing stress levels. Indeed, the primary studies we analyzed were either of insufficient quality or they were largely underpowered to detect a small-to-modest effect size. The median power for detecting a small effect size ($d = .20$) was at .21 for self-administered mindfulness and .11 for biofeedback. Studies on these two strategies require much larger sample sizes to detect a signal, if it is present.

Our conclusions seemingly contradict prior meta-analyses on self-administered mindfulness and biofeedback, who did detect a moderate size effect (Cavanagh et al., 2014; Goessl et al., 2017; Taylor et al., 2021). However, we think that the conclusions of our and their meta-analyses are largely consistent with each other and that the differences can be explained by two factors. First, our selection criteria were much stricter in checking the quality of the literature: a) In comparison to Taylor et al. (2021), we excluded studies on the basis of mathematically inconsistent data (they did not). Further b) their active comparator conditions consisted of many heterogeneous treatments (e.g., progressive muscle relaxation, psychoeducation for pain and stress managements). With such a heterogeneous active control group their estimation of the effect sizes tends to be biased, because the mindfulness groups are compared with treatments with a different effectiveness in terms of stress reduction. For that reason, we instead opted for active control conditions in which participants engaged in some task *not* intended to diminish levels of stress. All in all, this means that we ended up with much fewer studies (26 versus 47 for the relevant variables, not taking into account the

different additional foci by Taylor et al. on wellbeing and quality of life that we did not focus on, which consisted of a further 36 number of studies).

Second, our meta-analysis relies on the state-of-the-art in publication bias correction techniques and provides a much more accurate estimate of the effect size that can be expected when using similar sample sizes and study designs in comparison to all three prior meta-analyses on the topic (Cavanagh et al., 2015; Goessl et al., 2017; Taylor et al., 2021). All together, we believe that our stringent workflow provides a much more precise estimate of the target effect, as compared to the three prior meta-analyses. Before correction of the effect, we also find moderately sized effects, but these effects disappear when we provide our stricter - and more accurate - corrections.

The efficacy of these two strategies may depend on the type of protocol used

For both strategies we observed a substantial variance for what concerns the type of the treatment. For self-administered mindfulness, the number of intervention sessions in the included studies ranged from 1 to 64 ($M = 29.3$; $Mdn = 27$). The same was true for biofeedback, where the number of interventions ranged from 1 to 40 ($M = 9.5$; $Mdn = 6$). The total time spent by participants doing meditation or alternatively having a biofeedback intervention also varied substantially: Self-administered mindfulness included really brief (lasting 5 minutes) and longer interventions (lasting overall 16 hours), the same being true for biofeedback (5 minutes for the shortest to 22 hours for the longest). Furthermore, the total duration of the intervention could last a single day or up to two months for self-administered mindfulness and could range from a single day up to six weeks for biofeedback.

The heterogeneity in the self-administered mindfulness literature should not come as a surprise. Self-administered mindfulness does not currently and necessarily follow a well-established protocol like other traditional mindfulness programs such as mindfulness-based stress reduction (MBSR; Kabat-Zinn, 2008) or mindfulness-based cognitive therapy (MBCT;

Segal et al., 2002). Similarly, attempts have been made to develop a manualized heart rate variability protocol for biofeedback. Lehrer et al. (2000) developed a ten-sessions HRV-biofeedback protocol with two kinds of instruments, for office and home use respectively. This protocol was further improved (Lehrer et al., 2013) and the number of sessions was halved. The reason for shortening this protocol is that HRV biofeedback could be learned in fewer visits (Vaschillo et al., 2006).

However, as we have seen in our meta-analysis, each study seemed to rely on a different pattern regarding the length, the frequency, and duration of sessions. This suggests that there is no consensus on a standardized protocol for experimental and clinical practice. According to the results of our meta-analysis, the frequency of the intervention could potentially play a role in the efficacy in reducing stress (i.e., the more weekly interventions, the lower the experienced stress). The inferences from these analyses should, nevertheless, be regarded with considerable caution, as we could not apply publication bias correction techniques to these subgroup analyses.

Limitations of our assessment: Constraints on generality (Simons et al., 2017)

Based on the results of this meta-analysis and after applying publication bias techniques, there is no evidence that self-administered mindfulness and biofeedback are effective interventions to reduce stress. However, this applies only for the studies that satisfied the inclusion criteria of our meta-analytic approach. For instance, we do not know whether our findings are the same for people under 18 and we are not aware if studies of other languages would have led to different results. Nevertheless, given the state of the literature, we expect similar problems with publication bias to hold.

Keys area for improvement

Given the current state of the literature on stress, rigorous experimental studies must be conducted to evaluate whether such regulation strategies are able to effectively help

decrease the level of stress. Potential sources of bias (e.g., selective reporting) can be mitigated by the implementation of open sciences practices such as pre-registration and Registered Report (a peer-reviewed pre-registration; Chambers, 2013). To further improve the literature, we recommend publishing data of studies on stress regulation strategies (including, but not limited to, self-administered mindfulness and biofeedback) into an open repository (e.g., PsychOpen CAMA; Burgard et al., 2021). This would foster transparency and would allow other researchers to contribute with their data to accumulate evidence of different stress regulation strategies. In sharing data to an open repository, we recommend using our protocol in Appendix I so that meta-analysts can understand the differences across context and people across studies.

Conclusions

We conducted a meta-analysis of strategies contributing to stress regulation, including 26 articles and 35 effects for self-administered mindfulness and 20 articles and 31 effects for biofeedback. The results do not allow us to conclude that neither strategy has a demonstrated efficacy in reducing stress. We therefore suggest Registered Reports as an intervention to better understand the (lack of) efficacy of either strategy, taking into account the limitations of the existing literature that we highlighted in the present meta-analytic synthesis.

Declaration of Competing Interest

Declarations of interest: None.

References

- Aldwin, C. M. (2007). *Stress, coping, and development: An integrative perspective* (2nd ed.). Guilford Press.
- Anaya, J. (2016). The GRIMMER test: A method for testing the validity of reported measures of variability. *PeerJ Preprints*, <https://doi.org/10.7287/peerj.preprints.2400v1>.
- Bally, K., Campbell, D., Chesnick, K., & Tranmer, J. E. (2003). Effects of patient-controlled music therapy during coronary angiography on procedural pain and anxiety distress syndrome. *Critical Care Nurse*, 23(2), 50–58.
- Brown, N. J. L., & Heathers, J. A. J. (2016). The GRIM test. *Social Psychological and Personality Science*, 8(4), 363–369.
- Burgard, T., Bosnjak, M., & Studtrucker, R. (2021). Towards cumulative evidence and reproducible meta-analyses. Introduction and demonstration of PsychOpen CAMA. ZPID (Leibniz Institute for Psychology). <https://doi.org/10.23668/PSYCHARCHIVES.4809>
- Carter, E. C., Schönbrodt, F. D., Gervais, W. M., & Hilgard, J. (2019). Correcting for bias in psychology: A comparison of meta-analytic methods. *Advances in Methods and Practices in Psychological Science*, 2(2), 115–144.
- Cavanagh, K., Strauss, C., Cicconi, F., Griffiths, N., Wyper, A., & Jones, F. (2013). A randomized controlled trial of a brief online mindfulness-based intervention. *Behaviour Research and Therapy*, 51(9), 573–578.
- Cavanagh, K., Strauss, C., Forder, L., & Jones, F. (2014). Can mindfulness and acceptance be learnt by self-help?: A systematic review and meta-analysis of mindfulness and acceptance-based self-help interventions. *Clinical Psychology Review*, 34(2), 118–129.

- Cavanagh, K., Churchard, A., O'Hanlon, P., Mundy, E., Votolato, P., Jones, F., Gu, J. & Strauss, C. (2018). A randomised controlled trial of a brief online mindfulness-based intervention in a non-clinical population: Replication and extension. *Mindfulness*, 9(4), 1191–1205.
- Chambers, C. D. (2013). Registered reports: A new publishing initiative at Cortex. *Cortex*, 49, 609-610.
- Christley, R., M., (2010). Power and error: Increased risk of false positive results in underpowered studies. *The Open Epidemiology Journal*, 3, 16-19.
- Cohen, S., Kamarck, T., & Mermelstein, R. (1983). A global measure of perceived stress. *Journal of Health and Social Behavior*, 24(4), 385–396.
- Cooper, C. L., & Payne, R. (1991). *Personality and stress: individual differences in the stress process*. John Wiley & Sons.
- De Bruin, E. I., Topper, M., Muskens, J. G. A. M., Bögels, S. M., & Kamphuis, J. H. (2012). Psychometric properties of the five facets mindfulness questionnaire (FFMQ) in a meditating and a non-meditating sample. *Assessment*, 19(2), 187–197.
- De Vibe, M., Solhaug, I., Tyssen, R., Friberg, O., Rosenvinge, J. H., Sørli, T., ... Bjørndal, A. (2015). Does personality moderate the effects of mindfulness training for medical and psychology students? *Mindfulness*, 6(2), 281–289.
- De Witte, M., Spruit, A., van Hooren, S., Moonen, X., & Stams, G.-J. (2019). Effects of music interventions on stress-related outcomes: A systematic review and two meta-analyses. *Health Psychology Review*, 14(2), 294-324.
- Desteno, D., Lim, D., Duong, F., & Condon, P. (2018). Meditation inhibits aggressive responses to provocations. *Mindfulness*, 9(4), 1117-1122.
- Du, J., Huang, J., An, Y., & Xu, W. (2018). The relationship between stress and negative emotion: The mediating role of rumination. *Clinical Research and Trials*, 4(1), 1–5.

- Economides, M., Martman, J., Bell, M.J., & Sanderson, B. (2018). Improvements in stress, affect, and irritability following brief use of a mindfulness-based smartphone app: a randomized controlled trial. *Mindfulness*, 9(5), 1584-1593.
- Eddie, D., Kim, C., Lehrer, P., Deneke, E., & Bates, M. E. (2014). A pilot study of brief heart rate variability biofeedback to reduce craving in young adult men receiving inpatient treatment for substance use disorders. *Applied Psychophysiology and Biofeedback*, 39(3-4), 181–192.
- Feldman, L. A. (1995). Valence focus and arousal focus: Individual differences in the structure of affective experience. *Journal of Personality and Social Psychology*, 69(1), 153–166.
- Ferguson, C., & Heene, M. (2012). A vast graveyard of undead theories. *Perspectives on Psychological Science*, 7, 555 - 561.
- Frank, D. L., Khorshid, L., Kiffer, J. F., Moravec, C. S., & McKee, M. G. (2010). Biofeedback in medicine: who, when, why and how? *Mental Health in Family Medicine*, 7(2), 85–91.
- Gebauer, J. E., Nehrlich, A. D., Stahlberg, D., Sedikides, C., Hackenschmidt, A., Schick, D., Stegmaier, C. A., Windfelder, C. C., Bruk, A., & Mander, J. (2018). Mind-Body practices and the self: Yoga and meditation do not quiet the ego but instead boost self-enhancement. *Psychological Science*, 29(8), 1299–1308.
- Gevirtz, R. (2013). The promise of heart rate variability biofeedback: Evidence-based application. *Biofeedback*, 41(3), 110–120.
- Giluk, T. L. (2009). Mindfulness, big five personality, and affect: A meta-analysis. *Personality and Individual Differences*, 47(8), 805–811.
- Goessl, V. C., Curtiss, J. E., & Hofmann, S. G. (2017). The effect of heart rate variability

- biofeedback training on stress and anxiety: A meta-analysis. *Psychological Medicine*, 47(15), 2578–2586.
- Gross, J. J. (1998). The emerging field of emotion regulation: An integrative review. *Review of General Psychology*, 2(3), 271–299.
- Headspace (2021). *Researching meditation and mindfulness*. Retrieved from <https://www.headspace.com/science/meditation-research>.
- Hedges, L.V. & Olkin, I. (1985). *Statistical methods for meta-analysis*. Academic Press.
- Hong, S., & Reed, W. R. (2020). Using Monte Carlo experiments to select meta-analytic estimators. *Research Synthesis Methods* 12(2), 192–215.
- IJzerman, H., Lewis, N. A., Przybylski, A. K., Weinstein, N., DeBruine, L., Ritchie, S. J., ... & Anvari, F. (2020). Use caution when applying behavioural science to policy. *Nature Human Behaviour*, 4(11), 1092-1094.
- IJzerman, H., Hadi, R., Coles, N. A., Paris, B., Sarda, E., Fritz, W., Klein, R., Ropovik, I. (2023). Social Thermoregulation: A Meta-Analysis. *Available via PsyArxiv*, <https://doi.org/10.31234/osf.io/fc6yq>.
- Ioannidis, J. P. A. (2008). Why most discovered true associations are inflated. *Epidemiology*, 19(5), 640–648.
- Iyengar, S., & Greenhouse, J., B. (1988). Selection models and the file drawer problem. *Statistical Science*, 3(1), 109–117.
- Kabat-Zinn, J. (2008). *Full catastrophe living: using the wisdom of your body and mind to face stress, pain, and illness*. Random House.
- Khoury, B., Lecomte, T., Fortin, G., Masse, M., Therien, P., Bouchard, V., ... Hofmann, S. G. (2013). Mindfulness-based therapy: A comprehensive meta-analysis. *Clinical Psychology Review*, 33(6), 763–771.

- Klein, R. A., Vianello, M., Hasselman, F., Adams, B. G., Adams, R. B., Alper, S., Aveyard, M., Axt, J. R., Babalola, M. T., Bahník, Š., Batra, R., Berkics, M., Bernstein, M. J., Berry, D. R., Bialobrzeska, O., Binan, E. D., Bocian, K., Brandt, M. J., Busching, R., ... Nosek, B. A. (2018). Many labs 2: Investigating variation in replicability across samples and settings. *Advances in Methods and Practices in Psychological Science*, 1(4), 443–490.
- Landis, J. R., & Koch, G. G. (1977). The measurement of observer agreement for categorical data. *Biometrics*, 33(1), 159–174.
- Lazarus, R. S., & Folkman, S. (1984). *Stress, appraisal, and coping*. Springer.
- Lehrer, P. M., Vaschillo, E., & Vaschillo, B. (2000). Resonant frequency biofeedback training to increase cardiac variability: Rationale and manual for training. *Applied Psychophysiology and Biofeedback*, 25(3), 177–191.
- Lehrer, P., Vaschillo, B., Zucker, T., Graves J., Katsamanis, M., Aviles, M., & Wamboldt F., (2013). Protocol for heart rate variability biofeedback training. *Biofeedback*, 41(3), 98–109.
- Lehrer, P. M., & Gevirtz, R. (2014). Heart rate variability biofeedback: How and why does it work? *Frontiers in Psychology*, 5, 756.
- Lin, I. M., Fan, S. Y., Yen, C. F., Yeh, Y. C., Tang, T. C., Huang, M. F., Liu, T. L., Wang, P. W., Lin, H. C., Tsai, H. Y., & Tsai, Y. C. (2019). Heart rate variability biofeedback increased autonomic activation and improved symptoms of depression and insomnia among patients with major depression disorder. *Clinical Psychopharmacology and Neuroscience*, 17(2), 222–232.
- MacCoon, D. G., Imel, Z. E., Rosenkranz, M. A., Sheftel, J. G., Weng, H. Y., Sullivan, J.

- C., Bonus, K. A., Stoney, C. M., Salomons, T. V., Davidson, R. J., & Lutz, A. (2012). The validation of an active control intervention for Mindfulness Based Stress Reduction (MBSR). *Behaviour Research and Therapy*, 50(1), 3–12.
- Maggio, L. A., Tannery, N. H., & Kanter, S. L. (2011). Reproducibility of literature search reporting in medical education reviews. *Academic Medicine*, 86(8), 1049–1054.
- Maxwell, S. E. (2004). The Persistence of underpowered studies in psychological research: causes, consequences, and remedies. *Psychological Methods*, 9(2), 147–163.
- Maxwell, S. E., Lau, M. Y., & Howard, G. S. (2015). Is psychology suffering from a replication crisis? What does “failure to replicate” really mean? *American Psychologist*, 70(6), 487–498.
- May Barry, K., Woods, M., Martin, A., Stirling, C., & Warnecke, E. (2018). A randomized controlled trial of the effects of mindfulness practice on doctoral candidate psychological status. *Journal of American College Health*, 67(4), 299–307.
- McFarland, C., Buehler, R., von Rüti, R., Nguyen, L., & Alvaro, C. (2007). The impact of negative moods on self-enhancing cognitions: The role of reflective versus ruminative mood orientations. *Journal of Personality and Social Psychology*, 93(5), 728–750.
- McShane, B. B., Böckenholt, U., & Hansen, K. T. (2016). Adjusting for publication bias in meta-analysis. *Perspectives on Psychological Science*, 11(5), 730–749.
- Moreau, D., & Gamble, B. (2020). Conducting a meta-analysis in the age of open science: Tools, tips, and practical recommendations. Available via *PsyArXiv* <https://psyarxiv.com/t5dwg/>.
- Nyklíček I., & Irmischer M. (2017). For whom does mindfulness-based stress reduction work? Moderating effects of personality. *Mindfulness*, 8, 1106–1116.
- Olfson, M., King, M., & Schoenbaum, M. (2015). Benzodiazepine use in the United States. *JAMA Psychiatry*, 72(2), 136–142.

- Open Science Collaboration. (2015). Estimating the reproducibility of psychological science. *Science*, 349(6251), 943–952.
- Ouzzani, M., Hammady, H., Fedorowicz, Z., & Elmagarmid, A. (2016). Rayyan—a web and mobile app for systematic reviews. *Systematic Reviews*, 5(1), 210–220.
- Perez, S. (2020). *Meditation and mindfulness apps continue their surge amid pandemic*. TechCrunch. <https://techcrunch.com/2020/05/28/meditation-and-mindfulness-apps-continue-their-surge-amid-pandemic/>.
- Pessoa, L. (2008). On the relationship between emotion and cognition. *Nature Reviews Neuroscience*, 9(2), 148–158.
- Phelps, E. A. (2006). Emotion and cognition: Insights from studies of the human amygdala. *Annual Review of Psychology*, 57(1), 27–53.
- Prinsloo, G. E., Rauch, H. G. L., Lambert, M. I., Muench, F., Noakes, T. D., & Derman, W. E. (2010). The effect of short duration heart rate variability (HRV) biofeedback on cognitive performance during laboratory induced cognitive stress. *Applied Cognitive Psychology*, 25(5), 792–801.
- Pustejovsky, J. E., & Tipton, E. (2020). Meta-Analysis with robust variance estimation: Expanding the range of working models. *MetaArXiv*, <https://osf.io/preprints/metaarxiv/vyfcj/>.
- Ratanasiripong, P., Ratanasiripong, N., & Kathalae, D. (2012). Biofeedback intervention for stress and anxiety among nursing students: A randomized controlled trial. *ISRN Nursing*, 2012, 827972.
- Rich, R.M., Ogden, J. & Morison, L. (2021). A randomized controlled trial of an app-delivered mindfulness program among university employees: effects on stress and work-related outcomes. *International Journal of Workplace Health Management*. 14 (2), 201-216.

- Rosenthal, R. (1979). The file drawer problem and tolerance for null results. *Psychological Bulletin*, 86(3), 638–641.
- Russell, J. A. (1980). A circumplex model of affect. *Journal of Personality and Social Psychology*, 39(6), 1161–1178.
- Sanada, K., Montero-Marin, J., Alda Díez, M., Salas-Valero, M., Pérez-Yus, M. C., Morillo, H., Demarzo, M. M., García-Toro, M., & García-Campayo, J. (2016). Effects of mindfulness-based interventions on salivary cortisol in healthy adults: A meta-analytical review. *Frontiers in Physiology*, 7, 471.
- Schardt, C., Adams, M. B., Owens, T., Keitz, S., & Fontelo, P. (2007). Utilization of the PICO framework to improve searching PubMed for clinical questions. *BMC Medical Informatics and Decision Making*, 7, 16.
- Schneider, T. R., Rench, T. A., Lyons, J. B., & Riffle, R. R. (2012). The influence of neuroticism, extraversion and openness on stress responses. *Stress and Health: Journal of the International Society for the Investigation of Stress*, 28(2), 102–110.
- Schneiderman, N., Ironson, G., & Siegel, S. D. (2005). Stress and health: Psychological, behavioral, and biological determinants. *Annual Review of Clinical Psychology*, 1, 607–628.
- Segal Z. V., Williams J. M. G., & Teasdale J. D. (2002). *Mindfulness-based cognitive therapy for depression: A new approach to preventing relapse*. Guilford Press.
- Selye, H. (1956). *The stress of life*. McGraw-Hill.
- Simmons, J., Nelson, L., & Simonsohn, U. (2011). False-positive psychology: Undisclosed flexibility in data collection and analysis allows presenting anything as significant. *Psychological Science*, 22(11), 1359–1366.
- Simonsohn, U., Nelson, L. D., & Simmons, J. P. (2014). P-curve: A key to the file-drawer. *Journal of Experimental Psychology: General*, 143(2), 534–547.

- Spijkerman, M. P. J., Pots, W. T. M., & Bohlmeijer, E. T. (2016). Effectiveness of online mindfulness based interventions in improving mental health: A review and meta-analysis of randomized controlled trials. *Clinical Psychology Review*, 45, 102–114.
- Sparacio, A., Ropovik, I., Jiga-Boy, G. M., Lağap, A. C., & IJzerman, H. (2023). Stage 2 Registered Report: Stress regulation via being in nature and social support in adults, a meta-analysis. *Available via PsyArXiv* <https://psyarxiv.com/a4zmj>.
- Stanley T.D. & Doucouliagos C.H. (2014). Meta-regression approximations to reduce publication selection bias. *Research Synthesis Methods*, 5(1), 60–78.
- Stephens, M. A. C., & Wand, G. (2012). Stress and the HPA axis: Role of glucocorticoids in alcohol dependence. *Alcohol Research: Current Reviews*, 34(4), 468-483.
- Sterne, J., Savović, J., Page, M. J., Elbers, R. G., Blencowe, N. S., Boutron, I., A., ... Higgins, J. (2019). RoB 2: A revised tool for assessing risk of bias in randomised trials. *The BMJ*, 366, 14898.
- Sutton, A. J., Duval, S. J., Tweedie, R. L., Abrams, K. R., & Jones, D. R. (2000). Empirical assessment of effect of publication bias on meta-analyses. *The BMJ*, 320(7249), 1574–1577.
- Tang, R., & Braver, T. S. (2020). Towards an individual differences perspective in mindfulness training research: Theoretical and empirical considerations. *Frontiers in Psychology*, 11, 818.
- Taylor H., Strauss C., Cavanagh K., (2021). Can a little bit of mindfulness do you good? A systematic review and meta-analyses of unguided mindfulness-based self-help interventions. *Clinical Psychology Review*. 89, 102078.
- Teasdale, J. D., Segal, Z. V., & Williams, J. M. G. (2006). Mindfulness Training and Problem Formulation. *Clinical Psychology: Science and Practice*, 10(2), 157–160.
- Thayer, J. F., & Friedman, B. H. (2002). Stop that! Inhibition, sensitization, and their

- neurovisceral concomitants. *Scandinavian Journal of Psychology*, 43(2), 123–130.
- Tsuji, S., Bergmann, C., & Cristia, A. (2014). Community-augmented meta-analyses. *Perspectives on Psychological Science*, 9(6), 661–665.
- Van Gordon, W., Shonin, E., & Garcia-Campayo, J. (2017). Are there adverse effects associated with mindfulness? *Australian & New Zealand Journal of Psychiatry*, 51(10), 977–979.
- Vaughan-Johnston, T. I., Jacobson, J. A., Prosserman, A., & Sanders, E. (2021). Mind-body practices and self-enhancement: direct replications of gebauer et al.'s (2018) experiments 1 and 2. *Psychological Science*, 956797621997366. Advance online publication.
- Vaschillo, E. G., Vaschillo, B., & Lehrer, P. M. (2006). Characteristics of resonance in heart rate variability stimulated by biofeedback. *Applied Psychophysiology & Biofeedback*, 31, 129–142.
- Viechtbauer, W. (2010). Conducting meta-analyses in R with the metafor package. *Journal of Statistical Software*, 36(3), 1–48.
- Watson, D., Clark, L. A., & Carey, G. (1988). Positive and negative affectivity and their relation to anxiety and depressive disorders. *Journal of Abnormal Psychology*, 97(3), 346–353.
- Yang, L., Zhao, Y., Wang, Y., Liu, L., Zhang, X., Li, B., & Cui, R. (2015). The effects of psychological stress on depression. *Current Neuropharmacology*, 13(4), 494–504.

Appendix A: Protocols and deviations

Any changes with respect to the choices established in this pre-registration will be fully disclosed in the osf page, and will be noted in this template.

https://docs.google.com/spreadsheets/d/12rPtK6CPPFiVG7dImGgF7rBKAb0ykSBWkC9_0XwjNvk/edit#gid=331821920

Appendix B: Call for unpublished data

Subject: Call for unpublished data for a meta-analysis: “**Stress regulation via self-administered mindfulness and biofeedback intervention for adults: A pre-registered meta-analysis**”

Dear [Prof/Dr/Ms/Mr XXXX](#),

I am Alessandro Sparacio, PhD student in social psychology, at the University of Grenoble-Alpes and I’m conducting a meta-analysis on stress regulation, along with my co-authors Hans IJzerman, Ivan Ropovik, Gabriela Jiga-Boy & Patrick Forscher.

The pre-registered protocol for this meta-analysis is publicly available on the Open Science Framework (OSF) at [\[link\]](#) and on PROSPERO [\[link\]](#) with protocol number [\[NUMBER\]](#)

Our meta-analysis aims to address whether self-administered mindfulness and Heart-Rate Variability biofeedback have any demonstrated efficacy in reducing stress levels.

As you have published studies relevant to this topic, we are getting in touch to see if you have any unpublished/file-drawer data, or papers in-press, which we may have missed through database searching, and which you would like to have included in the meta-analysis.

Feel free to email either the raw data (from which we will calculate summary scores) or the summary scores themselves. While any raw data emailed to us will of course remain confidential, please know that summary scores included in the meta-analysis will be made publicly available in a dataset on the OSF.

We are hoping to include as many relevant studies as possible, so any additional data is greatly appreciated.

Sincerely (also on behalf of my co-authors),

Alessandro Sparacio

This template was provided by Moreau and Gamble (2020)

Appendix C: Requesting for specific data

Subject: Requesting data for a meta-analysis, from your paper: ‘XXXX’

Dear [Prof/Dr/Ms/Mr XXXX](#),

I am Alessandro Sparacio, PhD student in social psychology, at the University of Grenoble-Alpes and I’m conducting a meta-analysis on stress regulation, along with my co-authors Hans IJzerman, Ivan Ropovik, Gabriela Jiga-Boy & Patrick Forscher.

The pre-registered protocol for this meta-analysis is publicly available on the Open Science Framework (OSF) at [\[link\]](#) and on PROSPERO [\[link\]](#) with protocol number [\[NUMBER\]](#)

We think your study ‘XXXX’ meets inclusion criteria for our meta-analysis. However, the effect size we’re interested in (i.e., the [correlation/difference](#) between [XXX](#) and [XXX](#)) does not seem to be reported in the published paper.

We would be grateful if you could send either the summary scores or the raw data themselves (from which we can calculate the effect size). While any raw data emailed to us will of course remain confidential, please know that summary scores included in the meta-analysis will be made publicly available in a dataset on the OSF.

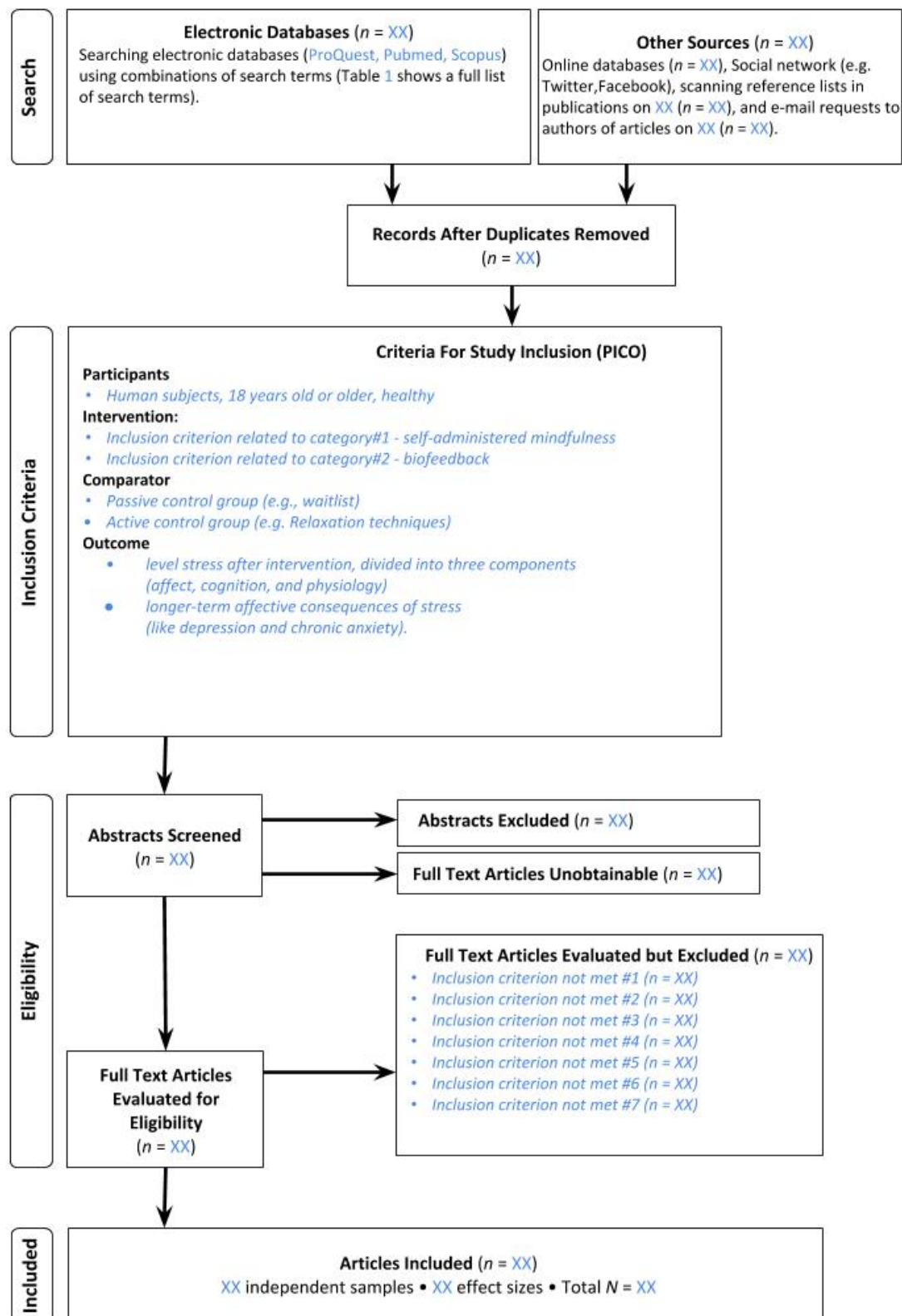
The latest we will be able to accept your data for inclusion is [XXth of XXX, XXXX](#).

We are hoping to include as many relevant studies as possible, so any additional data is greatly appreciated.

Sincerely (also on behalf of my co-authors),

Alessandro Sparacio

Appendix D: Search criteria



This template was provided by Moreau and Gamble (2020)

Appendix E: Search strategy

SELF-ADMINISTERED MINDFULNESS (SAM) MEDITATION

PUBMED

mindful* AND (online OR web* OR self-help OR self-administered OR e-health OR video* OR audio OR computer* OR application* OR app) AND stress AND (affect* OR emotion* OR cogniti* OR ruminati* OR physiological* OR cortisol OR heart_rate)

PROQUEST (APA PsycArticles, APA Psycinfo, ProQuest Dissertations & Theses Global)

mindful* AND (online OR web* OR self-help OR self-administered OR e-health OR video* OR audio OR computer* OR application* OR app) AND stress AND (affect* OR emotion* OR cogniti* OR ruminati* OR physiological* OR cortisol OR heart_rate)

SCOPUS

mindful* AND (online OR web* OR self-help OR self-administered OR e-health OR video* OR audio OR computer* OR application* OR app) AND stress AND (affect* OR emotion* OR cogniti* OR ruminati* OR physiological* OR cortisol OR heart_rate)

HEART-RATE VARIABILITY (HRV) BIOFEEDBACK

PUBMED

(heart rate variability biofeedback OR HRVB OR respiratory sinus arrhythmia biofeedback OR RSA biofeedback OR resonance frequency feedback OR RFF) AND stress AND (affect* OR emotion* OR cogniti* OR ruminati* OR physiological* OR cortisol OR heart_rate)

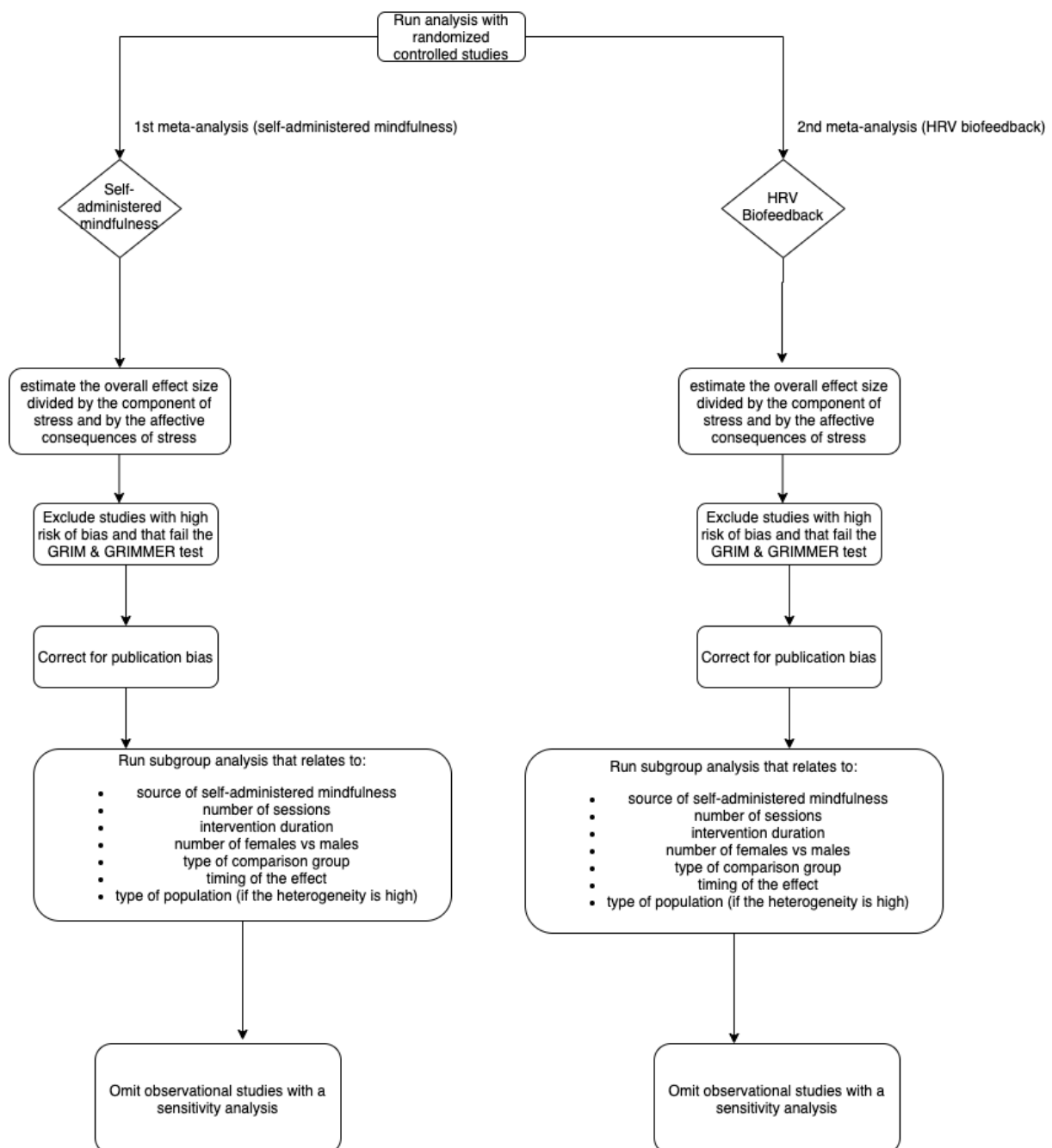
PROQUEST (APA PsycArticles, APA Psycinfo, ProQuest Dissertations & Theses Global)

(heart rate variability biofeedback OR HRVB OR respiratory sinus arrhythmia biofeedback OR RSA biofeedback OR resonance frequency feedback OR RFF) AND stress AND (affect* OR emotion* OR cogniti* OR ruminati* OR physiological* OR cortisol OR heart_rate)

SCOPUS

(heart_rate_variability_biofeedback OR HRVB OR
respiratory_sinus_arrhythmia_biofeedback OR RSA_biofeedback OR
resonance_frequency_feedback OR RFF) AND stress AND (affect* OR emotion* OR
cogniti* OR ruminati* OR physiological* OR cortisol OR heart_rate)

Appendix F: Subgroup analysis workflow



Appendix G: Correction for publication bias

1. Conversion of effect sizes, calculation of variances and p-values
2. Data screening and outlier diagnostics
3. Test of evidential value → p-curve analysis using a permutation procedure
4. Estimation of a naive meta-analysis effect and effect heterogeneity: Hierarchical random-effect meta-analytic model using RVE
5. Correction for publication bias
6. Bias-adjusted test for the presence of an effect: 4-parameter selection model (4PSM) acting as a conditional estimator for PET-PEESE
 - 4PSM significant: Biased-adjusted estimation on the effect → Estimation by hierarchical implementation of PEESE using the RVE
 - 4PSM non significant: Biased-adjusted estimation on the effect → Estimation by hierarchical implementation of PET using the RVE