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The efficacy of mindfulness meditation apps in enhancing users' well-being and mental health related outcomes: a meta-analysis of randomized controlled trials

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ABSTRACT

Background: Mindfulness applications are popular tools for improving well-being, but their effectiveness is unclear. We conducted a meta-analysis of randomized controlled trials (RCTs) that employed a mindfulness meditation app as the main intervention to improve users' well-being and mental-health related outcomes.
Methods: A systematic search was conducted in PsycINFO, PubMed, Web of Science, ProQuest Dissertations and Theses Global, the Cochrane Library, Open Grey and ResearchGate through June, 2020. Effects were calculated as standardized mean difference (Hedges' g) between app-delivered mindfulness interventions and control conditions at post-test and pooled with a random-effects model.
Results: From 2637 records, we selected 34 trials (N = 7566). Significant effect sizes were found at post-test for perceived stress (n = 15; g = 0.46, 95% CI [0.24, .68], I^2 = 68%), anxiety (n = 15; g = 0.28, 95% CI [0.16, .40], I^2 = 35%), depression (n = 15; g = 0.33, 95% CI [0.24, .43], I^2 = 0%), and psychological well-being (n = 5; g = 0.29, 95% CI [0.14, .45], I^2 = 0%). No significant effects were found for distress at post-test (n = 6; g = 0.10, 95% CI [-0.02, .22], I^2 = 11%) and general well-being (n = 5; g = 0.14, 95% CI [-0.02, 0.29], I^2 = 14%).
Conclusion and limitations: Mindfulness apps seem promising in improving well-being and mental-health, though results should be interpreted carefully due to the small number of included studies, overall uncertain risk of bias and heterogeneity.

1. Introduction

Mindfulness was introduced to the western psychological world by Jon Kabat- Zinn, who tried to secularize methods from Buddhist practice (Tirch et al., 2015) and developed his Mindfulness- Based Stress Reduction (MBSR) program. The program rapidly became popular, and mindfulness expanded at large-scale (Reibel & McCrown, 2019). Briefly, mindfulness refers to the non-judgmental awareness of the present moment, by observing and accepting our unfolding experiences, emotions, thoughts and physical sensations (Kabat-Zinn, 2003). Mindfulness is conceptualized as a skill that can be improved through formal meditation (e.g., focused attention, awareness of breathing, emotions or thoughts) and informal practices (e.g., open monitoring of experiences, cultivating awareness during regular daily activities, like walking; Mace, 2007; Plaza et al., 2013; Wahbeh & Oken, 2016).

Growing evidence supports the beneficial effects of mindfulness training for clinical and non-clinical populations. Several meta-analyses showed the effectiveness of mindfulness-based interventions (MBIs) in the treatment of somatization disorder (Lakhan & Schoefield, 2013), anxiety (Vollestad et al., 2012), depression (Cavanagh et al., 2014), including relapse prevention (Kuyken et al., 2016). Practicing mindfulness meditation was also associated with enhanced well-being in healthy individuals (Keng et al., 2011; Lomas et al., 2018).

Digital delivery is gaining traction as a way of increasing the accessibility of psychological treatments (Fairburn & Patel, 2017). MBIs have already been successfully adapted to the online context, several meta-analyses confirming that online MBIs are effective (Jaywardene et al., 2017; Spijkerman et al., 2016). Moreover,

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individual RTCs have found comparable effects to face-to-face interventions (Compen et al., 2018) and demonstrated that an online mindfulness course significantly reduced stress and these gains remained stable at follow-up (Krusche et al., 2012). Mobile technology provides a further platform for delivering mindfulness interventions (Garcia et al., 2017), but evidence of effectiveness has been mixed. Two recent meta-analyses on app-supported smartphone interventions for mental health problems found that these outperformed the control conditions for outcomes of distress, quality of life, symptoms of depression and anxiety (Linardon et al., 2019). However, app-delivered interventions conferred no additional benefits for negative affect, panic and post-traumatic stress disorder symptoms (Linardon et al., 2019).

Mindfulness meditation apps are one of the most common in the mental health and well-being app category (Coulon et al., 2016; Pospos et al., 2018), totaling over 260 apps (Mani et al., 2015). Public interest in mindfulness practice is high: around 10% of the individuals included in the National Health Survey between 2002 and 2012 reported practicing mindfulness to improve their health and well-being (Clarke et al., 2015). The number is probably an underestimation, since many more individuals are resorting to mobile apps. According to company reports in 2018, Headspace has over 1 million paid subscribers (Pesce, 2018), while Calm reached over 80 million downloads. Yet the app marketplace is generally characterized by high availability and low evidence base (Leigh & Flatt, 2015), often promoting strategies and exercises lacking evidence or developed without clinical expertise (Coulon et al., 2016; Nicholas et al., 2015; Sucala et al., 2017). Furthermore, providing incorrect information and dishonest advertising is also a common phenomenon (Coulon et al., 2016; Nicholas et al., 2015).

The feasibility of mindfulness training apps has been examined in several populations like employees (Muuraiskangas et al., 2016), students (Donovan et al., 2016) and cancer patients (Mikolasek et al., 2018). Participants generally perceived the apps as useful tools for enhancing well-being. Several randomized controlled trials (RCT) showed a range of benefits for mindfulness meditation apps. Mindfulness meditation apps were found to be efficient in reducing anxiety, depression, fear of recurrence (Lengacher et al., 2018) and distress (Kubo et al., 2019) among cancer patients and compassion fatigue and burnout among hospice and palliative care professionals (Heeter et al., 2017). RCTs using a mindfulness meditation app as the intervention demonstrated significant improvements on well-being, distress (Bostock et al., 2019), life satisfaction (Champion et al., 2018), stress (Smith et al., 2020) depressive (Flett et al., 2019; Fish and Saul, 2019) and anxiety symptoms (van Emmerik et al., 2018). Furthermore, the use of mindfulness meditations apps was shown to exert positive effects on quality of life in unselected sample (Economides et al., 2018; Mak et al., 2018; Yang et al., 2018) or among women diagnosed with breast cancer (Rosen et al., 2018). Studies also showed that improvements in mental health are maintained at 4 (Flett et al., 2019) and 16 weeks (Bostock et al., 2019) after the intervention.

Mobile app-based mindfulness interventions demonstrated similar effects compared to a therapist-led mindfulness group, and performed better than an educational program in terms of reductions in symptoms of depression and anxiety (Cox et al., 2019). Furthermore, app-delivered mindfulness interventions showed comparable effects with app-delivered self-compassion and cognitive-behavioral psychoeducation in improving well-being and reducing distress (Mak et al., 2018). However, when compared to sham meditation, although, a significant increase from pre to post-test in positive and negative affect could be observed, they were not attributable to mindfulness practice since the sham meditation group reported similar improvements (Noone and Hogan, 2018). Several studies yielded mixed results, reporting significant improvements in positive affect (Howells et al., 2016; Lee and Jung, 2018) and mindfulness (Wen et al., 2017), while no differences were found regarding negative affect (Howells et al., 2016; Wen et al., 2017), life satisfaction (Howells et al., 2016), stress, state anxiety, physical and social functioning (Lee and Jung, 2018). Despite the accumulation of trials, systematic reviews and meta-analyses of mindfulness apps for mental health and well-being outcomes are lacking.

As Firth et al. (2017a) have stated, the accessibility of mHealth apps and their large media promotion have created a "duty of care" situation, when informing the public about their usefulness and evidence-base is crucial. Hence, the present meta-analysis, proposes to integrate available research on the effectiveness of mindfulness meditation apps in improving users' well-being and mental health related outcomes (e.g., symptoms of anxiety and depression, perceives stress, psychological well-being, life satisfaction, quality of life, positive and negative emotions).

2. Method

The protocol of this systematic review was registered (PROSPERO registration: CRD42019132276). Changes to the protocol are described in the corresponding sections and in the Supplementary Materials. The PRISMA guidelines (Moher et al., 2009) were followed for reporting.

2.1. Identification and selection of studies

A systematic literature search was conducted in the following electronic databases: PubMed, Web of Science, PsycINFO, ProQuest Dissertations and Theses Global, Cochrane Library from inception until June 10th 2020, using combinations of the following keywords: mindfulness, mindfulness meditation, mindful meditation, intervention, trial, RCT, randomized, randomized, randomized controlled trial, training, effect, impact, app, application, mobile, phone, smartphone, app-delivered, mhealth, m-health, mobile-based, mobile-health, well-being, wellbeing, satisfaction, emotion, affect, quality, mental health, stress, distress, depression, anxiety (see Supplementary Materials for the complete search strings). To identify unpublished studies, besides including theses and dissertations, we also searched two databases (i.e., Open Grey and ResearchGate with mindful* app* as keywords – these sites does not allow for long search strings), which contain conference papers, preprints and unpublished manuscripts as well. Since ResearchGate does not allow for reference exporting, only the first 200 hits were examined for eligibility. When full-text papers were not available (n = 5) a request was sent to the authors (no positive response were obtained). A legacy search was also conducted by reviewing the reference list of the included studies and meta-analyses on mindfulness interventions to identify potential studies. Furthermore, the homepages of the two most popular mindfulness apps (i.e., Headspace and Calm) was also hand-searched.

Eligible studies were RCTs comparing an app for mindfulness meditation/training to a control condition (e.g., waitlist, attention control) or an active psychological treatment (e.g., existing interventions, techniques used to increase well-being or mental health) for outcomes related to well-being and mental health. Mental health outcomes included symptoms of anxiety and depression, burnout, and stress. For well-being, we adopted a broad definition so as to capture its multidimensional nature (Diener, 2000; Khaneman et al. 1999, Ryff & Keyes, 1995), in line with previous meta-analyses (e.g., Lomas et al., 2018). Indicators of eudaimonic (e.g., flourishing, psychological well-being) and hedonic (e.g., positive and negative affect, life satisfaction) were also included. However, state measures of affective states were excluded as they might index only transient variations.

Eligible mindfulness apps could feature different types of meditation and any mindfulness exercises (e.g., guided meditations, breathing awareness, body scan). Studies were included if app-guided mindfulness practice was the main component of the intervention. Studies where mindfulness was an element of a more complex intervention or as adjunctive to a face-to-face one were excluded, as were studies examining one-time (i.e. single session) use of the mindfulness app.

2.2. Data extraction

For each included study, the following data were extracted: first author, year of publication, population (type of sample, mean age, gender distribution, number of participants in each condition, number of drop-outs), intervention (app, whether it was commercially available or developed by the researchers as part of the trial), frequency of instructed use, intervention duration (weeks), session length (minutes), average number of completed sessions, contact with the researchers (no or minimal contact), number of reminders sent to complete mindfulness sessions, type of control condition), outcome (means and standard deviations if available).

Outcomes enclosed a range of mental health and well-being related outcomes assessed at post-test and follow-up (e.g., symptoms of anxiety and depression perceives stress, general and psychological well-being, life satisfaction, quality of life, positive and negative emotions, burnout, distress). Baseline and post-intervention mindfulness scores were also extracted as secondary outcomes. For studies reporting both intent-to-treat (ITT) and per-protocol analysis, both were extracted.

2.3. Risk of bias assessment

Risk of bias was assessed independently by two of the authors (EG, SS) using the Cochrane Collaboration's Risk of Bias (RoB) assessment tool (Higgins & Green 2011). The following six domains were rated: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, and selective outcome reporting. Each domain was ranked as low, high or uncertain for risk of bias. Selection bias was rated as low risk if there was a random component in the allocation sequence generation, while allocation concealment was considered to be a low risk when a clear method that prevented foreseeing group allocation before or during enrollment was described. Blinding of participants was rated as low when a study incorporated an attention control condition or the app-delivered intervention was compared with an active psychological treatment, and consequently, participants could not be sure whether they are in the intervention or control condition. Blinding of outcome assessors was rated as low risk if proper measures were taken to conceal participants' group membership, or if the outcome measures were self-reported, which did not involve a direct interaction with the assessor. The risk for attrition bias was regarded as low, if all randomized participants were included in the analysis (i.e., intent-to-treat analysis or complete data). Selective reporting was evaluated as low risk if all the prespecified outcomes in the trial protocol (identified by trial registration numbers) were reported. When trial protocol was not available, selective reporting was rated as unclear of risk of bias. For each criterion inter-rater agreement was assessed prior to resolving disagreements using the Cohen's kappa coefficient. For each study an overall RoB score was also computed by assigning 1 point for each domain evaluated as having low risk and was used as an indicator of study quality (higher scores indicating lower risk of bias). A sensitivity analysis was performed by excluding studies with a RoB score of 4 or lower.

2.4. Statistical analysis

All analyses were conducted using Comprehensive Meta-Analysis (CMA version 2.2), forest plots were generated using the metan command in STATA (STATA Corp., Inc., College Station, TX).

Between -group standardized mean difference (SMD) were calculated based on post-test means, standard deviations (SDs), and sample size. SMD represents the difference in means between the intervention and control arms divided by the pooled standard deviation (Borenstein et al., 2011). When these were not reported, we computed the SMD from alternative statistics (Borenstein et al., 2011), such as t or p values from independent group comparisons. We used Hedges' g as a standard metric of the effect size, which includes an adjustment for small sample studies. The interpretation is similar to Cohen's d: 0.2 represents small, 0.5 medium, while 0.8 large effect sizes (Cohen, 2013). Prediction intervals (it estimates where the true effects of 95% of future similar studies are to be expected) were also calculated (InHout et al., 2016).

Though initially we planned to also report within (i.e., pre-post) group effects, this analysis was omitted due to methodological considerations. As Cuijpers et al., (2016) point out pre- and post-test scores are not independent and the correlation is generally not reported. Furthermore, change from pre- to post-test can also be influenced by factors unrelated to the intervention (e.g., natural course of the disorder, participant expectations). As suggested by the Cochrane Handbook (Higgins & Green, 2011, sec. 9.1.4), separate analyses were carried out for the different mental-health and well-being outcomes if three or more trials have reported those outcomes.

When studies included multiple subgroups, they were combined to create a single pair-wise comparison (Borenstein et al., 2011). Intent-to-treat (ITT) analyses were preferred over per protocol (PP), where available. A sensitivity analysis by excluding studies with ITT analysis was performed to explore possible differences between studies reporting ITT and PP analyses.

Since there was a considerable diversity in the interventions and population characteristics, a random-effects model was used in all analyses, which assumes that differences between study effect sizes are not only due to random error, but also to real variation in the intervention effect (Hedges & Vevea, 1998). A study was considered to be an outlier when its 95% confidence interval (CI) was outside of the 95% CI of the pooled effect (Cuijipers, 2016). Heterogeneity was examined using the I^2 statistics which determines the percentage of the total variation across studies due to heterogeneity: 0% indicating no, 25% low, 50% moderate, and 70% high heterogeneity (Borenstein et al., 2011). Confidence intervals for the I^2 statistics were computed following the large-sample approximation-based method presented by Borenstein et al. (2009).

2.5. Subgroup, sensitivity and meta-regression analyses

In the protocol, we had planned a range of subgroup and meta-regression analyses for type of control, commercially available apps versus those developed as part of the trial, type of well-being indicator, length of the intervention, frequency of meditation sessions, change in mindfulness from pre- to post-test, average completed session. However, considering the rule of at least 10 studies per characteristics modeled (Higgins & Green, 2011, sec. 9.6.5.1) no such analyses were carried out because none of the outcomes passed this threshold. To test the robustness of the results, we employed several sensitivity analyses (when there were multiple studies available for an outcome): (i) type of control condition (i.e., attention, waitlist or active psychological treatment), (ii) whether participants had minimal or no contact with the researchers, (iii) excluding outliers, (iv) considering only studies using Headspace, (v) and for studies reporting PP analysis.

2.6. Small study effects

Small study effects, a potential indicator of publication bias was examined by visually inspecting the funnel plot and by Egger's test of the intercept for outcomes where at least ten studies were available (Egger et al., 1997; Higgins & Green, 2011, sec. 10.4.3.1). The protocol included additional analyses for detecting publication bias (i.e., Rosenthal's fail-safe N, the trim and fill procedure), but due to their methodological weaknesses and unreliability of their estimates (Higgins & Green, 2011, sec.10.4.4.2 and sec. 10.4.4.3), these were not carried out.

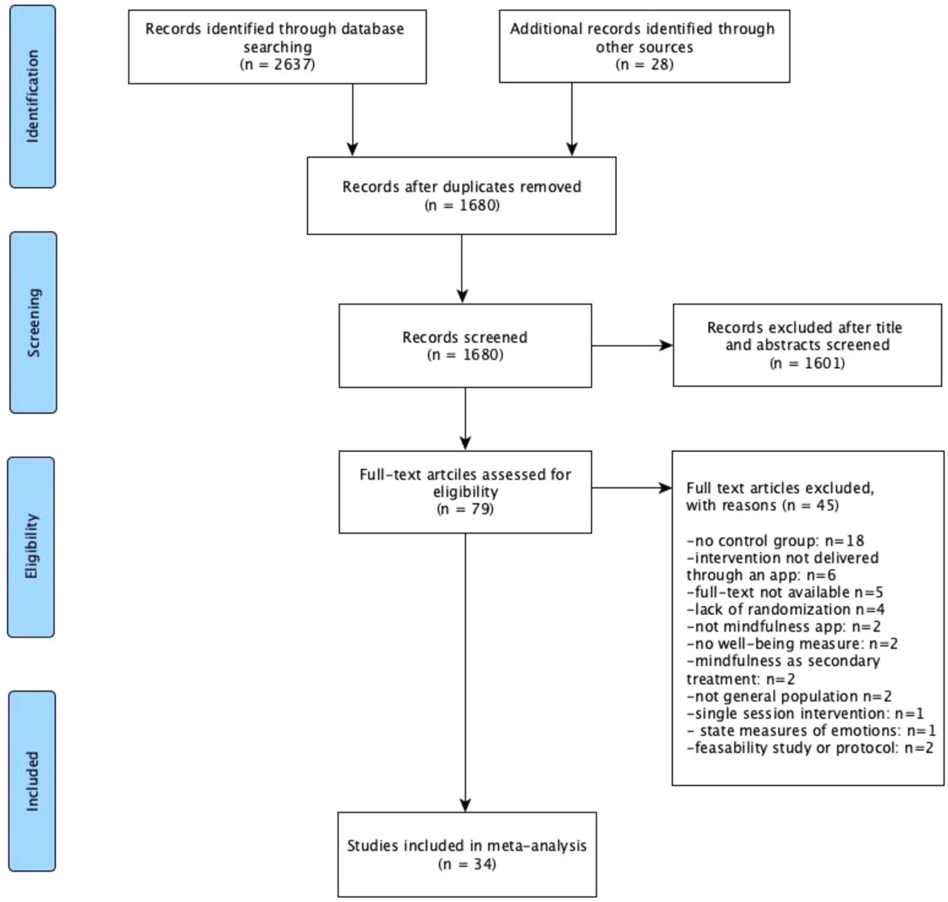

Figure 1. PRISMA flow chart of study selection.

3. Results

3.1. Identification and selection of studies

The initial search yielded 2637 records, (1680 after removing duplicates). A further 1601 records were removed following title and abstract screening. Seventy-nine full-texts were retrieved and examined for eligibility, out of which 45 were excluded, leaving 34 included RCTs. A PRISMA flow diagram of the study selection process is shown in Figure 1.

3.2. Study characteristics

Characteristics of the included studies are presented in Table 1. The 34 RCTs included 7,612 participants, from which 3,260 received a mindfulness app, and 4,352 a control intervention. Study sample sizes were highly variable ranging from 12 to 2,283. Studies included diverse samples: unselected sample (n = 3,270), employees (n = 600), students (n = 1,436), adults with elevated symptoms of depression or anxiety (n = 500) and signs of compulsive internet use (n=994), women approaching childbirth (n = 78), foster parents (n = 150), intensive care unit patients (n = 80), or women diagnosed with breast cancer (n = 240), chronic pelvic pain (n = 90) or myeloproliferative neoplasm (n = 128). Women accounted for 64% of all participants and mean ages ranged from 17 to 58 years.

The majority of the studies included only one control condition (n = 27). A few studies which had two control conditions (both waitlist/attention and active psychological treatment; n = 4) or used two mindfulness apps (n = 3). Most trials used waitlist (n = 21), or attention (n = 9) control conditions (e.g., note taking, cognitive training game, sham meditation). Seven RCTs used active psychological treatments as comparators (e.g., self-compassion or telephone-based mindfulness training). Only 9 studies included a follow-up assessment, 5 comparing a mindfulness app with a waitlist or attention control condition, and 4 with an active psychological treatment. Most studies (n = 29) used a commercially available app, whereas the remaining ones (n = 5) developed the app as part of the study. Overall, 13 distinct commercially available apps were used (see Table 1), with the most common ones being Headspace (n = 16) and Calm (n = 4).

Interventions lasted between 10 days and 8 weeks and in most cases (n = 17) participants were advised to use the app once a day. Follow-up period ranged between 1 and 24 weeks, the most common being a 12-week follow-up period. Across the included studies, session duration ranged from 3 to 37 minutes, with the most frequent session duration being 10 minutes. Participants had no contact with the researchers in 17 trials, and had one introductory in-person session or call in 14 (3 studies did not mention this aspect). On average, participants completed around 43% of the recommended sessions. Detailed information about the content of the mindfulness applications and the type of control conditions are presented in Table S1 in Supplementary Materials.

3.3. Outcome measures

The most frequently assessed mental health and well-being related outcomes were symptoms of depression (n = 15) and anxiety (n = 15), perceived stress (n= 15), psychological and general well-being (n = 9), life satisfaction (n = 4), quality of life (n = 5). Eleven studies also measured mindfulness skills. A complete list of the instruments for well-being indicators is presented in the Supplementary Materials (Table S2). Outcomes measured at follow-up varied considerably, the most common being stress (n = 6), anxiety (n = 4), depression (n = 3), and

Table 1
Characteristics of the included studies

Study	N	N of drop-out	Mean age	Population characteristics	Mindfulness application	Control condition	Length of the intervention	Follow-up time	Advised frequency of app use/week	Average completed sessions	Indicators of WB	Type of analysis
Abbott (2018)	163	-	24	Students (elevated worry)	Headspace	Waitlist	4 weeks	-	7-14	-	anxiety, worry	ITT
Bhayee et al. (2016)	26	10	32.65	General population	Muse, Calm	Math training	6 weeks	-	5	-	anxiety, depression, QOL	PP
Borjalilu et al. (2019)	68	-	24.29	Students	Aramgar	MBSR	3 weeks	-	-	-	stress, anxiety, depression	-
Bostock et al. (2019)	238	9	35.5	Employee	Headspace	Waitlist	8 weeks	16 weeks	7	16.6	PWB, depression, anxiety	PP
Carissoli et al. (2015)	56	0	38.1	Employee	Developed	Relaxing music	3 weeks	-	14	16.8	stress	PP
Carissoli et al. (2017)	78	-	33.2	Pregnant women	Developed	Childbirth class	4 weeks	-	5	11.9	PWB	-
Champion et al. (2018)	62	12	39.13	General population	Headspace	Waitlist	4 weeks	-	7	8.93	SWL, stress, PWB	ITT, PP
Cox et al. (2019)	80	14	49.5	ICU patients	Developed	Mindfulness; Education*	4 weeks	12 weeks	1	3.87	QOL, anxiety, depression, distress	ITT
Economides et al. (2018)	69	19	30	General population	Headspace	Audiobook	2 weeks	-	5	10	stress, PA, NA, irritability	PP
Fish & Saul (2019)	91	19	21	Students	Headspace	Waitlist	2 weeks		5	-	depression	PP
Flett et al. (2019)	208	16	20.8	Students	Headspace SmilingMind	Evernote app	10 day	-	7	8	stress, depression, anxiety, flourishing	PP
Flett et al., (2020)	250	55	17.87	Students	Headspace	Waitlist	12 weeks	-	-	-	distress	ITT
Forbes et al. (2020)	90	25	35.1	Women with chronic pelvic pain	Headspace	Muscle relaxation; Waitlist control	8.5 weeks	24 weeks	-	-	QOL, depression, anxiety	ITT
Howells et al. (2016)	194	73	40.7	General population	Headspace	Catch Notes app	10 days	-	7	-	PA, NA, depression, SWL, flourishing	PP
Huberty et al. (2019a)	109	21	20.4	Students	Calm	Waitlist	8 weeks	12 weeks	7	3.8	stress	PP
Huberty et al. (2019b)	128	34	58	Patients with myeloproliferative neoplasm	10% Happier Calm	Educational control	4 weeks	-	7	-	depression, anxiety	-
Kubo et al. (2019)	128	30	57.9	Cancer patients	Headspace	Waitlist	8 weeks	-	7	-	distress, QOL, anxiety, depression	
Lanz et al. (2019)	105	23	-	General population	Smiling Mind	Waitlist	8 weeks	-	5	35	burnout	-
Lee & Jung. (2018)	206	41	20.6	Students	DeStressify	Waitlist	4 weeks	-	5	-	WB, anxiety, depression	PP
Levin et al. (2020)	23	7	20.4	Students	Stop Breathe & Think	Waitlist	4 weeks	-	7	7.44	anxiety, depression, distress, WB	PP
Loree (2018)	27	110	-	Foster parents	Calm	Thought Diary	1 week	1 week	1		stress	PP
Mak et al. (2018)	2282	1653	33.6	General population	Developed	Self-compassion; CBT psychoed.	4 weeks	12 weeks	7	9	WB, distress	ITT, PP
Moberg et al. (2019)	500	296	30.2	Adults with elevated symptoms of depression and anxiety	Pacifica	Waitlist	4 weeks	8 weeks	-	19	depression, depression	ITT
Möltner et al. (2018)	306	-	42.8	Employees	7mind	Waitlist	2 weeks	-	-	-	burnout, SWL	-
Nolan (2019)	95	29	21	Students	Headspace	Waitlist	10 days	-	7	6	stress, SWL, depression, anxiety, stress	PP
Noone & Hogan (2018)	91	20	20.5	Students	Headspace	Sham meditation	6 weeks	-	5	15	WB, PA, NA	ITT
Quinones & Griffiths (2019)	994	631	40	Individuals with sign of compulsive internet use	Headspace	Arousal decentering; Waitlist	2 weeks	-	-	-	depression	PP
Robinson (2018)	12	-	35	General population	Headspace	Waitlist	4 weeks	4 weeks	7	-	stress, PA, NA, burnout	PP
Rosen et al. (2018)	112	48	52.3	Cancer patients	Headspace	Waitlist	8 weeks	4 weeks	7	18	QOL	ITT
Siembor (2017)	21	3	20.89	Students	Mindfulness App	Waitlist	4 weeks	-	7	-	stress	PP

(*continued on next page*)

Table 1 (*continued*)

Smith et al. (2020)	215	46	33.2	General population	Spire	Waitlist	4 weeks	4 weeks	1	2.6	Stress, anxiety, PA, NA	PP
vanEmmerik et al. (2018)	377	156	44.7	General population	VGZ Coach	Waitlist	8 weeks	12 weeks	7	-	distres, QOL	ITT, PP
Walsh et al. (2019)	108	23	20	Students	Wildflowers	2048 app	3 weeks	-	7	20.7	stress, PWB	PP
Yang et al. (2018)	88	7	25.1	Student	Headspace	Waitlist	4 weeks	4 weeks	7	11.97	WB, stress	ITT, PP

Note. * the control conditions were telephone-based mindfulness training and web-based education about illness; WB well-being, PWB psychological well-being; PA positive affect, NA negative affect, SWL satisfaction with life, QOL quality of life, PP per-protocol analysis, ITT intent-to-treat analysis; anxiety and depression were measured as symptoms.

quality of life (n = 3).

3.4. Attrition

All but five studies (Abbott, 2018; Borjalilu et al., 2019; Carissoli et al., 2017; Möltner et al., 2018; Robinson, 2018) reported the number of drop-outs (mean = 31.56%; range 0%- 73.3%). Drop-out rates were slightly higher in the mindfulness meditation groups (mean = 42%; range 0%- 77%) than in the control conditions (mean = 34%; range 0% -79%). Drop-out rates largely driven by the largest study (Mak et al., 2018), where, from the total 2,283 randomized participants, only 24% completed the study.

3.5. Risk of bias

According to the Cochrane Risk of Bias assessment, 8 studies (23%) had low RoB in five domains and four studies (11%) were rated as low risk in all six domains. Ten RCTs had high or unclear RoB in 2 domains, while 7 studies in 3 and another 5 in 4 domains. Studies generally provided little information regarding the process of randomization (n = 12) and allocation concealment (n = 20). All studies used self-report scales for outcome assessment, thus were rated as low RoB. Fifteen studies explicitly mentioned lack of blinding procedures of participants and personnel and another five were rated unclear in this domain due to lack of information. Eleven studies reported ITT analysis and for 5 studies it was unclear whether all participants were included in the analyses. Five studies were rated as unclear of RoB in selective reporting due to the lack of pre-specified analytical method or insufficient information (e.g., reducing subscales into factors). Inter-rater agreement, based on the detailed risk of bias evaluation of the two authors, was substantial for random sequence generation (Cohen's kappa = .86), allocation concealment (Cohen's kappa = .67), blinding of participants and personnel (Cohen's kappa = .89), blinding of outcome assessment (Cohen's kappa = .96), incomplete outcome data and selective reporting (Cohen's kappa = .98). Figure 2 provides the general risk of bias, while for each study's detailed risk of bias evaluation, see Figure S1 in Supplementary Materials.

3.6. Meta-analysis

3.6.1. Anxiety symptoms

Between-group effect sizes were small and significant at post-test (n = 15; g = 0.28, 95% CI [0.16, 0.40]), and follow-up (n = 4; g = 0.23, 95% CI [0.02, 0.44]) (see also Table 2 and Figure 3A). Heterogeneity was medium at post- test (I^2 = 35%, 95% CI [0, 78]) and absent at follow-up (I^2 = 0%, 95% CI [0, 0]). Excluding one outlier slightly reduced effects at post-test (n = 14; g = 0.23, 95% CI [0.13, 0.32]), as well as heterogeneity (I^2 = 0%, 95% CI [0, 23]). Sensitivity analysis indicated comparable effects for studies using waitlist controls (n = 10; g = 0.31, 95% CI [0.17, 0.46], I^2 = 48%, 95% CI [0, 99]) and when only PP analyses (n = 8; g = 0.23, 95% CI [0.10, 0.37], I^2 = 0%, 95% CI [0, 43]) were considered. Effects were not significant when a mindfulness app was compared to an active psychological treatment (n = 4; g = 0.26, 95% CI [-0.00, 0.52], I^2 = 00 %; 95% CI [0, 18]). The analysis restricted to studies where there was no contact between participants and researchers yielded slightly higher ES with high heterogeneity (n = 6; g = 0.32, 95% CI [0.12, 0.54], I^2 = 67%, 95% CI [20, 85]). However, slightly lower ES was found for studies using Headspace (n = 6; g = 0.21, 95% CI [0.06, 0.35], I^2 = 0%, 95% CI [0, 75]). Sensitivity analyses excluding studies with total RoB scores of 4 or lower led to similar estimations (n = 6; g = 0.40, 95% CI [0.20, 0.60], I^2 = 38 %, 95% CI [0, 74]).

3.6.2. Depressive symptoms

Between-group effect sizes were significant at post-test (n = 15; g = 0.33, 95% CI [0.24, 0.43]) (Figure 3B). Effects were not maintained

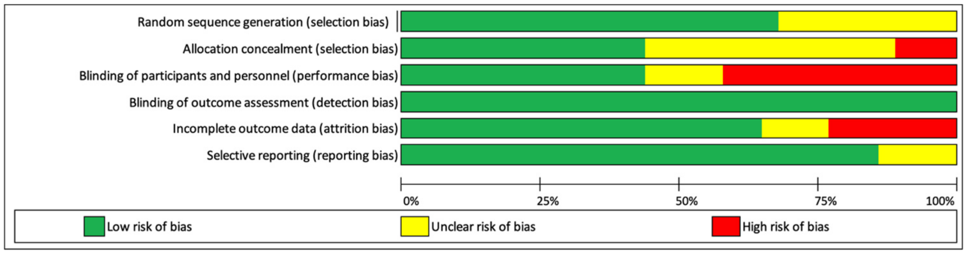

Figure 2. General risk of bias: review authors' judgements about each risk of bias item presented as percentages across all included studies

at follow-up (n = 3; g = 0.10, 95% CI [-0.18, 0.38]). Heterogeneity was zero but with large confidence intervals at post- test (I^2 = 0%, 95% CI [0, 83]) and follow-up (I^2 = 0%, 95% CI [0, 51]). Sensitivity analyses indicated comparable effects for studies using waitlist controls (n = 8; g = 0.35, 95% CI [0.24, 0.47], I^2 = 9%, 95% CI [0, 0]) or active psychological treatments as comparators (n = 5; g = 0.28, 95% CI [0.09, 0.48], I^2 = 00 %; 95% CI [0, 92]), and when only PP analyses (n = 10; g = 0.34, 95% CI [0.22, 0.46], I^2 = 0%, 95% CI [0, 60]) and studies using Headspace (n = 8; g = 0.36, 95% CI [0.23, 0.49], I^2 = 0%, 95% CI [20, 85]) were considered. The analysis restricted to studies with no contact between participants and researchers also yielded unchanged effect sizes (n = 6; g = 0.33, 95% CI [0.21, 0.46], I^2 = 0%, 95% CI [0, 85]). Sensitivity analyses excluding studies with total RoB scores of 4 or lower led to similar estimations (n = 6; g = 0.36, 95% CI [0.20, 0.53], I^2 = 0 %, 95% CI [0, 98]).

3.6.3. *Perceived stress*

Between-group were significant at post-test at post-test (n = 15; g = 0.46, 95% CI [0.24, 0.68]) with high heterogeneity (I^2 = 68%, 95% CI [48, 80]) (Figure S4 in the Supplementary Materials). Excluding one outlier considerably reduced the effects at post-test (n = 14; g = 0.32, 95% CI [0.21, 0.44]), and well as heterogeneity (I^2 = 0%, 95% CI [0, 70]). Results indicate that these effects were maintained at follow-up (n = 5; g = 0.35, 95% CI [0.17, 0.55], I^2 = 0%, 95% CI [0, 14]). Sensitivity analyses indicated higher effect sizes for comparisons using waitlist controls (n = 8; g = 0.62, 95% CI [0.24, 1.01], I^2 = 80%, 95% CI [63, 89]) and for studies with no contact between participants and researchers (n = 8; g = 0.53, 95% CI [0.16, 0.89], I^2 = 84%, 95% CI [73, 92]). However, when one outlier was excluded these effects were considerably reduced both in the case of studies with waitlist controls (n = 7; g = 0.38, 95% CI [0.22, 0.54], I^2 = 0%, 95% CI [0, 78]) and with no contact between researchers and participants (n = 7; g = 0.29, 95% CI [0.14, 0.43], I^2 = 0%, 95% CI [0, 0]). Comparisons with active psychological treatment showed similar estimations to the main analysis for app-delivered mindfulness interventions (n = 3; g = 0.34, 95% CI [0.02, 0.68], I^2 = 00 %; 95% CI [0, 87]), while slightly lower ES was found for studies using Headspace when the same outlier as in the main analysis was excluded (n = 5; g = 0.24, 95% CI [0.05, 0.44], I^2 = 0%, 95% CI [0, 80]). Only three studies had a RoB score higher than four including an outlier, a sensitivity analysis was not carried out.

3.6.4. *Other well-being indicators*

Due to the limited number of available studies, only the mean effect size was calculated separately for each outcome and no sensitivity analyses were carried out (for the different well-being outcomes, except general well-being and quality of life, figures are presented in Supplementary Materials; Figures S2 – S8). Results revealed significant small to medium effect sizes in the case of burnout (n = 3; g = 0.54, 95% CI [0.36, 0.74], I^2 = 0%, 95% CI [0, 96]), life satisfaction (n = 4; g = 0.41, 95% CI [0.24, 0.57], I^2 = 0%, 95% CI [0, 84]), quality of life (n = 5; g = 0.36, 95% CI [0.11, 0.60], I^2 = 39%, 95% CI [1, 53]) (Figure 4B), psychological well-being (n = 5; g = 0.29, 95% CI [0.14, 0.45], I^2 = 0%, 95% CI [0, 61]) small effects sizes were obtained in the case of positive (n = 5; g = 0.26, 95% CI [0.08, 0.44], I^2 = 0%, 95% CI [0, 63]) and negative emotions (n = 5; g = 0.21, 95% CI [0.03, 0.39], I^2 = 0%, 95% CI [0, 46]). In contrast, app-delivered mindfulness interventions showed no benefits in reducing distress (n = 6; g = 0.10, 95% CI [-0.02, 0.22], I^2 = 0%, 95% CI [0, 88]) and improving general well-being (n = 5; g = 0.14, 95% CI [-0.02, 0.29], I^2 = 14%, 95% CI [0, 82]) (Figure 4A). However, if only studies with waitlist or attention controls were considered app-delivered mindfulness interventions seem to have small to medium effects on improving well-being (n = 4; g = 0.31, 95% CI [0.05, 0.56], I^2 = 0%, 95% CI [0, 85]).

Table 2
App-based mindfulness interventions compared to control conditions

Variable	N	g (95% CI)	I^2 (95% CI)	Predictive interval 95% CI
Post-test				
Anxiety	15	0.28 (0.16-0.40)	35 (0-78)	-0.03 to 0.59
Outlier excluded	14	0.23 (0.13-0.32)	0 (0-23)	0.13 to 0.33
Depression	15	0.33 (0.24-0.43)	0 (0-0)	0.23 to 0.49
Stress	15	0.46 (0.24-0.68)	68 (48-80)	-0.33 to 1.25
Outlier excluded	14	0.32 (0.21-0.44)	0 (0-70)	0.18 to 0.45
General well-being	5	0.14 (-0.02-0.29)	0 (0-82)	-0.23 to 0.85
Psychological well-being	5	0.29 (0.14-0.45)	0 (0-61)	0.04 to 0.53
Life satisfaction	4	0.41 (0.24-0.57)	0 (0-84)	0.02 to 0.77
Quality of life	5	0.36 (0.11-0.60)	39 (1-53)	-0.23 to 0.95
Positive affect	5	0.26 (0.08-0.44)	0 (0-63)	-0.03 to 0.55
Negative affect	5	0.21 (0.03-0.39)	0 (0-46)	-0.08 to 0.50
Distress	6	0.10 (-0.02- 0.22)	11 (0-82)	-0.13 to 0.31
Burnout	3	0.54 (0.36-0.74)	0 (0-96)	-0.69 to 1.77
Follow-up				
Quality of life	3	0.31 (0.00 - 0.63)	20 (0-97)	-2.12 to 2.74
Anxiety	4	0.23 (0.02-0.44)	0 (0-0)	-0.23 to 0.69
Depression	3	0.10 (-0.18-0.38)	0 (0-51)	-1.71 to 1.91
Stress	5	0.36 (0.17-0.55)	0 (0-14)	0.05 to 0.66

Note. N, number of studies; g, Hedges' g using random effects model; 95% CI, 95% confidence interval.

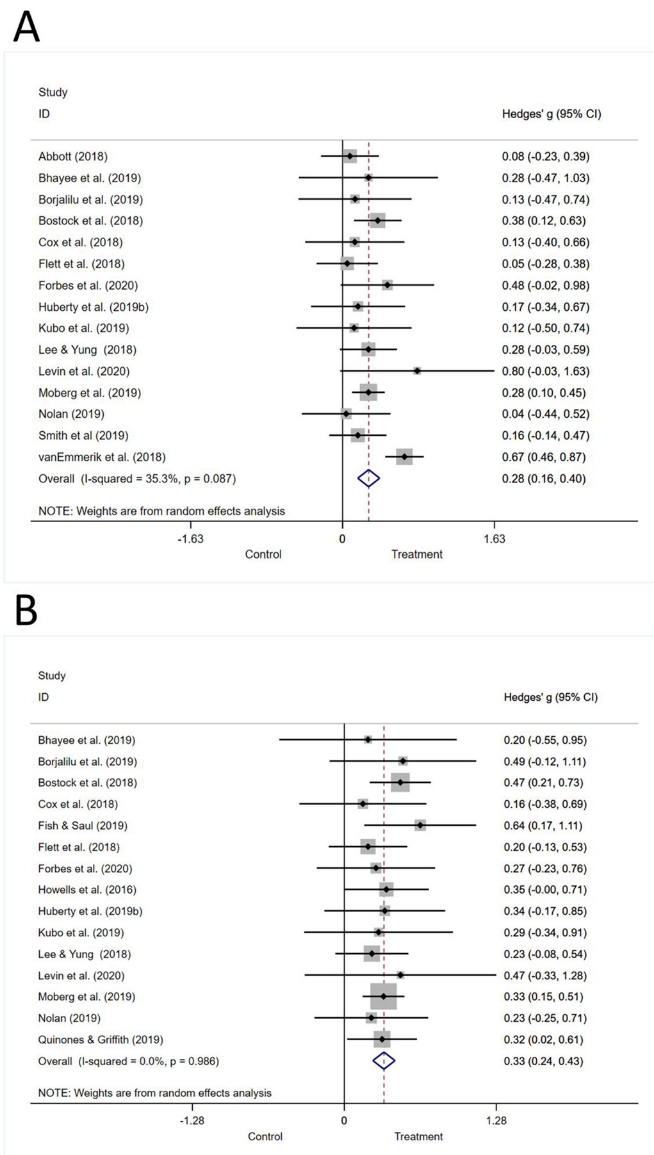

Figure 3. Forest plot of standardized mean differences for symptoms of anxiety (A) and depression (B)

3.7. Small study effects

The funnel plot appeared to be asymmetrical (see Figure S9 in Supplementary Materials) for anxiety symptoms. However, Egger's test was not significant (intercept = -0.79, 95% CI [-2.42, 0.84]). For depressive symptoms neither the funnel plot (Figure S10 in Supplementary Materials), nor Egger's test suggested publication bias (intercept = -0.04, 95% CI [-0.88, 0.79]). For perceived stress, the funnel plot was asymmetrical due to an outlier (Figure S11 in Supplementary Materials), but Egger's test was not significant (intercept = 1.61, 95% [CI -1.10, 4.77). All the outcomes had less than 10 studies and small study effects were not assessed.

4. Discussion

Mindfulness meditation apps are becoming increasingly popular as tools to improve well-being and mental health among the general population (Crandall et al., 2019). Thus, assessing their effectiveness is crucial. The present meta-analysis included 34 randomized trials evaluating the effectiveness of an app-delivered mindfulness intervention on a wide range of mental-health and well-being outcomes.

Results indicated significant small or medium effects of mindfulness apps compared to control conditions for perceived stress, symptoms of depression and anxiety, life satisfaction, quality of life, burnout, psychological well-being and positive and negative affect. Heterogeneity was generally low, though often with large confidence intervals. Effects maintained at follow-up for anxiety symptoms, stress and quality of life, but not for depressive symptoms. Nonetheless, owing to the small number of studies reporting follow-up assessments, conclusion about the long-term utility of mindfulness meditation apps cannot be drawn. Although, the obtained effects sizes are close to the tentative cut-off point (0.24) for clinically relevant effects proposed by Cuijpers et al., (2014), prediction intervals of the interventions' effect generally included zero suggesting that future studies could also yield non-significant effects. There was no evidence of small study effects in the case of anxiety, depression and stress.

Effects were comparable in sensitivity analyses restricted to intent-to-treat or per-protocol findings and for studies using Headspace as the intervention, but reduced in studies where participants had no contact with researchers. Studies using waitlist controls resulted in slightly higher effect sizes (a 0.02-0.05 increase in SMD) across all outcomes, adding to the evidence that waitlist comparisons overestimate effects (Cristea, 2019; Firth et al., 2017a, 2017b). Comparisons restricted to trials using other active psychological treatments as controls resulted in slightly lower effects (with a 0.02-0.05 decrease in SMD) compared to the main analysis for perceived stress and depression, and non-significant ESs for anxiety. However, these analyses are based on a small number of studies with active control conditions and results could be unreliable.

Our findings confirm those of previous meta-analyses, which also found small to moderate effect sizes for online mindfulness interventions in improving mental health (g = 0.23, 95% CI [0.09, 0.38]) (Spijkerman et al., 2016) and reducing perceived stress (g = -0.43, 95% CI [-0.20, -0.66]) (Jaywardene et al., 2017). Similar effects were found in the case of other (i.e., non-mindfulness) app-delivered interventions in decreasing the symptoms of anxiety (g = 0.32, 95% CI [0.17- 0.48]) and depression (g = 0.38, 95% CI [0.24- 0.52]) (Firth et al., 2017a, 2017b). Key differences between the present meta-analysis and previous works relate to the type of app investigated (mindfulness apps exclusively vs. all types of apps), delivery method (smartphone apps vs online) and outcomes (mental health and well-being outcomes vs. mental health, stress, depression or anxiety only). Our results indicate that the effects of app-based mindfulness interventions depend on the type of control condition. Previous meta-analyses have also evidenced similar patterns when comparing app-based interventions with active control conditions (Firth et al., 2017a, 2017b). Similarly, though Bamber & Morpeth (2018) found large effect sizes when comparing MBIs to no-treatment controls, small to moderate effects were reported in another meta-analysis that included studies with active control conditions (Zoogman et al., 2015).

Non- adherence is a common issue in online psychological interventions (Linardon & Fuller- Tyszkiewics, 2020), also reflected by our findings showing that participants completed on average 43% of the mindfulness meditation sessions, with rates of session completion varying between 24- 100%. Similarly, Spijkerman et al. (2016) found that adherence ranged from 39% to 92% in studies on mindfulness-based online interventions. Low user engagement is consistently reported in other mental health app studies as well (Firth et al., 2017b). Furthermore, participants' motivation to engage in app-use might be especially low in the absence of severe problems or diagnosed conditions (Jaywardene et al., 2016). Adherence appears to impact the effectiveness of the interventions, especially for mindfulness, as regular practice is viewed as key for the development of mindfulness skills (Carmody & Baer, 2008).

Attrition rate, the proportion of participants dropping out before post-test, was 31% overall, but it was considerably influenced by one

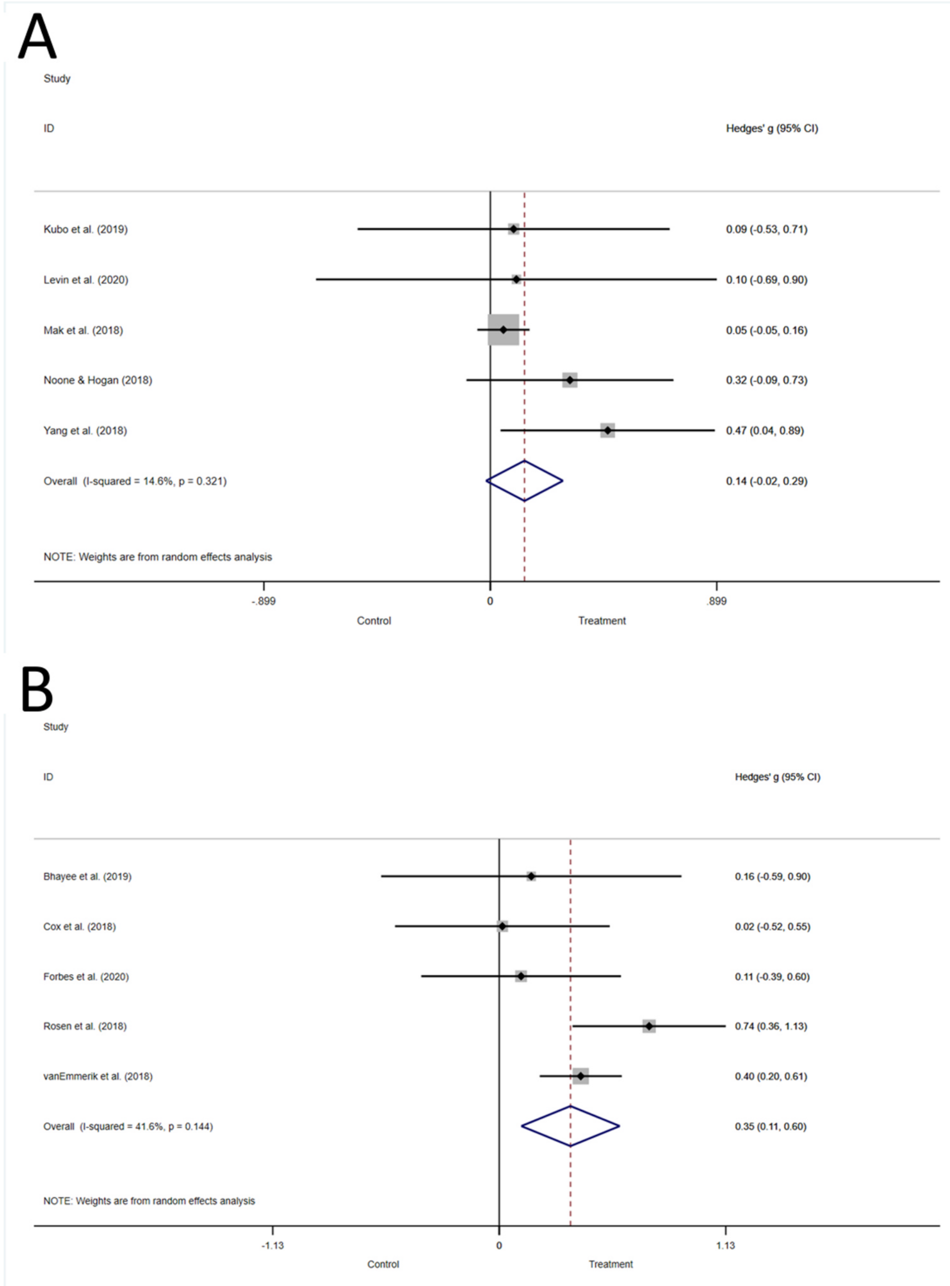

Figure 4. Forest plot of standardized mean differences for general well-being (A) and quality of life (B)

large trial (Mak et al., 2018), in which 547 out of 2,283 participants completed the intervention (23%). The rate is similar to the one (42%) reported by a meta-analysis examining attrition in smartphone-delivered interventions (Linardon & Fuller- Tyszkiewics, 2020). Nonetheless, owing to considerable attrition, estimates of effectiveness might be biased. Given the pragmatic nature of the trials, where researchers had no control over participant engagement, it is likely that adherent participants were more motivated to complete the intervention, possibly because they were also experiencing benefits. To account for the biasing effects of drop-out, we used intent-to-treat data, when available. In a meta-analysis on attrition rates in smartphone-delivered intervention studies Linardon and Fuller- Tyszkiewics (2020) found that reminding participants to engage in app use, offering monetary incentives or including at least one in-person contact with the researchers significantly reduced attrition. Crandall et al. (2019) propose that creating more favorable subjective norms regarding mindfulness meditation and increasing intentions by emphasizing attitudes and perceived behavioral control could be potential methods for increasing mindfulness app engagement.

The prevalence of mental health problems is rising, however, in the same time the accessibility of evidence-based treatments is limited, and only a small portion of those in need receive care (Bijl et al., 2003). According to the World Health Organization mental health promotion by building up personal strengths, tackling risk factors and improving the quality of life has an important role in mental illness prevention (Mak et al., 2018). Though, for most outcomes, findings were based on a limited number of trials, our findings offer a promising signal for the benefit of mindfulness apps for symptoms of anxiety and depression, perceived stress, life satisfaction, psychological well-being, burnout, quality of life, positive and negative emotions. Smartphone interventions could serve as low-cost, scalable and easily accessible tools which could empower individuals to manage their own mental health

(Carissoli et al., 2015), however, when facing mental health problems other approaches might be more beneficial.

5. Limitations

The present meta-analysis has several limitations. Comparisons for some of the well-being and mental health outcomes (i.e., life satisfaction, burnout, general and psychological well-being, quality of life, positive and negative emotions) and comparisons at follow-up, or with active control conditions, were based on a small number of studies, which might make estimations unreliable. Estimations for comparisons with active control conditions were heavily influenced by a single trial, which might question reliability. Furthermore, almost half of the included studies used Headspace as the mindfulness intervention, thus, limiting the generalizability of the conclusions. However, sensitivity analysis indicated that effects sizes for studies using Headspace approximate the effect found in the main analysis. Non-adherence was high among the included studies and as Baumel et al. (2019) suggested, the trial setting, especially the proactive recruitment of users, has considerable impact on user engagement in e-mental health programs. The authors showed that the median program usage in trials was four times higher than real-world usage. Hence, the real-world generalizability of our findings might be further constrained, though, most of the included trials were pragmatic ones where researchers did not influence participant engagement.

Few included studies assessed the intervention's effect on mindfulness skills, making it impossible to ascertain if observed effects are due to changes in the purported mechanism of change (i.e., mindfulness skills) or to other non-specific components or expectancies. Participant adherence (i.e., average number of completed sessions), as well attrition are ubiquitous problems for unguided app- based interventions (Linardon & Fuller- Tyszkiewics, 2020), and could have also influenced our findings. Risk of bias might have also biased estimates. Most trials did not report sufficient information for assessing potential bias due to randomization or allocation concealment. One third of the studies did not report ITT analyses, with some excluding participants from the analysis if their engagement was not adequate. While this choice can be justified, in the presence of high attrition rates, it raises questions about the effectiveness of the intervention, which might only bring benefits to a select group of participants who stayed engaged, possibly because they were experiencing benefits. Yet for app-based interventions to be scalable, we need to be able to gauge whether there are benefits for the entire pool of users, not just a selected sample.

6. Conclusions

Although tentatively, the findings of the present meta-analysis suggest that mindfulness meditation apps are promising self-management tools for improving mental health and well-being. Nonetheless, due to small number of studies conclusions regarding their long-term utility cannot be drawn. They are easily accessible, scalable and, if proven cost-effective, could constitute a feasible alternative to promote mental health and enhance well-being at a large scale.

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CRediT authorship contribution statement

Éva Gál: Conceptualization, Methodology, Writing - original draft. **Simona Ștefan:** Methodology, Writing - review & editing. **Ioana A. Cristea:** Methodology, Writing - review & editing.

Declaration of competing interest

The authors have no conflict of interest to declare.

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Supplementary materials

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