**ELEANOR CRAIG BSc Hons MSc**

# AN INVESTIGATION INTO THE EFFECTIVENESS OF MINDFULNESS-BASED INTERVENTIONS FOR INFORMAL CARERS

**Section A: The Effectiveness of Mindfulness-based Programmes for the Psychological Well-being of Informal Carers: A Meta-analysis**

**Word count: 7851 (additional 244 words)**

**Section B: Online Mindfulness-based Cognitive Therapy for Parents of Children with Food Allergies: A Feasibility Randomised Control Trial**

**Word count: 7936 (additional 342)**

**Overall word count: 15,787 (additional 386)**

A thesis submitted in partial fulfilment of the requirements of Canterbury Christ Church University for the degree of Doctor of Clinical Psychology

May 2022

SALOMONS INSTITUTE OF APPLIED PSYCHOLOGY

CANTERBURY CHRIST CHURCH UNIVERSITY

## Acknowledgments

Firstly, I would like to thank all of the parents and carers who generously gave time out of their busy routines to participate in this study. This project would not have been possible without your valuable contributions.

I would also like to thank my supervisors, Dr Fergal Jones and Dr Chrissie Jones, for giving so much of their time, guidance, enthusiasm, knowledge, and support. They were both so inspiring and I am extremely appreciative to have learnt so much from them.

Thank you to my family and friends for their unwavering support, reassurance and encouragement throughout this course. I would particularly like to thank Rachel for her positivity, attention to detail, and generosity.

Lastly, thank you to my partner, Chris, for all his patience, strength and kindness.

# Summary of MRP


## Section A

Section A presents a systematic literature review and meta-analysis exploring the effectiveness of mindfulness-based interventions (MBIs) for psychological well-being in informal carers. Searches yielded 24 controlled trials and quality was appraised using the Effective Public Health Practice Project (EPHPP) tool. Results suggested that stress and depression were significantly reduced at post-intervention, compared to control, with small to large between-group effect sizes. These effects were also maintained at follow-up, with small to large effect sizes. There was also evidence for a reduction in anxiety at post-intervention and improvement in mental health-related quality of life at follow-up. All studies were quality rated ‘weak’ or ‘moderate’. The implications for clinical practice and future research are discussed.

## Section B

Section B presents a feasibility randomised controlled trial exploring the acceptability of online adapted Mindfulness-based Cognitive Therapy for parents and carers of children with food allergy (MBCT-PCCFA), providing a signal of efficacy. Forty-six participants were randomised into either the MBCT-PCCFA intervention arm or treatment-as-usual (TAU) control arm. The recruitment, response, and attrition rates suggested that undertaking an RCT with this population and intervention was feasible. The high overall session attendance, low-dropout rate, engagement with at-home practice, and qualitative feedback, suggested that MBCT-PCCFA is acceptable. Effect size estimates suggested a full scale RCT is worth undertaking and recommendations for this are provided. The implications for clinical practice are also discussed.

# List of Contents

## Section A: Literature Review

**Section B: Empirical Research Paper**

# List of Tables and Figures

## Section A: Literature Review

**Section B: Empirical Research Study**

## Section C: Appendices of Supporting Material

# Section A: Literature Review

## The Effectiveness of Mindfulness-based Programmes for the Psychological Well-being of Family Carers: A Meta-analysis

**Word Count: 7851 (additional 244 words)**

## Abstract

Informal carers face many challenges which can significantly impact their mental wellbeing. The evidence surrounding mindfulness-based interventions for this group is growing. However, the collective efficacy of these interventions on psychological wellbeing is yet to be quantitatively explored. This paper aimed to conduct a meta-analysis exploring how effective mindfulness-based programmes are at improving psychological well-being outcomes in informal carers. A systematic search of four electronic databases yielded 24 papers for review. The standardised mean difference (SMD) was used to measure differences between intervention and comparison groups at post-intervention and follow-up. Analyses were split between passive and active control studies. Results found that stress and depression were both significantly lower at post-intervention, compared to active controls, with 'small to medium' effect sizes for stress (SMD = -0.31, 95% C.I.: -0.50 to -0.13) and 'small to large' effect sizes for depression (SMD = -0.61, 95% C.I.: -0.87 to -0.35). These effects were maintained at follow-up for stress (SMD = -0.38, 95% C.I.: -0.70 to -0.06) and depression (SMD = -0.56, 95% C.I.: -1.00 to -0.12). There was also some evidence for a reduction in anxiety at post-intervention (SMD = -0.48, 95% C.I.: -0.69 to -0.27) and improvement in mental health-related quality of life at follow-up (SMD = 0.30, 95% C.I.: 0.02 to 0.58). All studies were rated as 'weak' or 'moderate' quality. More rigorous trials with longer follow-up periods are needed to confirm these findings. However, there is a clear demand for these programmes and clinicians should consider mindfulness-based interventions to support carers in their roles.


Keywords: mindfulness, informal carers, psychological wellbeing.

## Introduction

Informal carers can be described as people "who provide unpaid support to a partner, child, relative or friend who couldn't manage to live independently or whose health or wellbeing would deteriorate without this help" (Royal College of General Practitioners, 2011, p. 9). They provide physical and emotional support for many conditions, including chronic illnesses, disabilities, neurological conditions, developmental delays, and mental health difficulties (Carers UK, 2021). There are an estimated 6.5 million unpaid carers within the UK (Carers UK, 2021), whose contributions relieve pressure on the NHS by providing annual social care worth £56.9 billion (ONS, 2017). Over the coming years, this contribution will likely increase as the number of older care-receivers requiring support to continue living independently rises (Plöthner et al., 2019).

In a survey of carers, Birtha and Holm (2017) found the emotional bond between the caregiver and care-receiver was the most common reason (57%) for engaging in a caring role. This was followed by a sense of duty (15%) and obligation (13%) to their loved one. As such, many carers report experiencing their caring role as natural, rewarding and virtuous (Lawrence et al., 2008). However, carers often provide complex care with little preparation or training (Van Ryn et al., 2011), with 49% providing over 90 hours of weekly care and 39% continuing with paid work (Carers UK, 2019).

The 2019 Carers UK report highlighted that financial pressure, service closures, and difficulty accessing carer assessments, practical support and respite, were ongoing challenges. They identified that 39% of carers found it hard to make ends meet, whilst 68% used their own income to purchase supportive equipment or services. Only 27% of carers had a carers assessment in the past year, and 12% saw a reduction in social services support. Francis and Hanna (2020) also highlighted that the social inequalities and racism experienced

by many ethnic minority carers further contributes to difficulties receiving diagnoses for their loved ones and accessing necessary support.

**Psychological wellbeing and support**

Given these challenges, it is unsurprising that carers' health is often affected (Hayley et al., 2020), with 22% and 27% rating their physical and mental health as bad to very bad respectively (Carers UK, 2019). Providing a caregiving role can feel stressful, burdensome, and isolating (Roth et al., 2015; William et al., 2019), which may be due to the high levels of unpredictability and responsibility, alongside low levels of control (Schulz & Sherwood, 2008). Consequently, carers often focus less on their health.

Common psychological difficulties include anxiety, stress, and low mood (Watson et al., 2019; Williams et al., 2019). This, alongside reduced quality of life (QoL; Farina et al., 2017), can impact the care they provide. Osborne et al. (2008) found that highly stressed parents of children with disabilities were less able to implement necessary interventions, and Lawrence et al. (2008) found many felt too burdened to 'fight' for help and resources.

Given this impact, it is vital carers have support. Plöthner et al. (2019) found most carers seek support through informal channels, such as family and social systems, however, many highlighted the need for additional formal support. Formal interventions may include NHS or charity-based information and support groups (e.g., Friedman et al., 2018; Chien & Norman, 2009), self-help guidance (e.g., Age UK, 2021), or psychological therapies. Furthermore, with technology developments, many of these interventions are offered virtually, increasing access (Biliunaite et al., 2021; Chi & Demiris, 2015).

Research surrounding psychological therapies for carers has explored various models, including Cognitive Behavioural Therapy (Akkerman & Ostwald, 2004; Kwok et al., 2014), Acceptance and Commitment Therapy (Han et al., 2021), Existential Behavioural Therapy

(Fegg et al., 2013), Brief Psychodynamic Psychotherapy (Gallagher-Thompson & Steffen, 1994), and Compassion Focused Therapy (Collins et al., 2018). Positively, these studies suggest talking therapies can be effective at reducing anxiety, low mood, and stress, and increasing QoL.

**Mindfulness-based interventions (MBIs)**

The evidence base surrounding the use of mindfulness-based interventions (MBIs) for carers has also been expanding in recent years, with many studies reporting positive outcomes (Li et al., 2016). Originating from Eastern traditions, mindfulness is commonly defined as “the awareness that arises from paying attention, on purpose, in the present moment, and non-judgmentally” (Purser, 2015, p.680). It is increasingly popular in Western psychology, with MBSR (Kabat-Zinn, 1982) and MBCT (Segal et al., 2012) most commonly researched and utilised (Gu et al., 2015).

Developed in the 1970s by Jon Kabat-Zinn for stress management in individuals with chronic pain, MBSR is a structured eight to 10-week group programme which focuses on the acquisition of mindful awareness (Grossman et al., 2004). Sessions are typically 2.5 hours, with a day-long retreat. Individuals are invited to practise mindfulness exercises and discuss topics within the context of mindfulness, including stressful situations and social interactions. Individuals are also encouraged to practise at-home daily.

Later, MBCT was developed to support individuals with recurrent low mood (Segal et al., 2002). Based on MBSR, it consists of an eight-week group programme, integrating cognitive therapy for depression (Beck et al., 1979) and aims to protect against depression reoccurring. Individuals complete daily at-home practice and 'enquiries' are led by facilitators within sessions to explore the experience of practices. Table 1 outlines the main assumptions of mindfulness and these programmes (Grossman et al., 2004).

**Table 1.**

*Six assumptions of mindfulness and the MBSR/MBCT programmes (Grossman et al., 2004)*

| Assumption | Details |
|---|---|
| 1 | Individuals often operate in an 'automatic pilot' mode, whereby they are largely unaware of their moment-to-moment experiences. |
| 2 | All individuals are capable of building skills to focus attention on their mental content (including physical sensations, perceptions, emotions, thoughts, and imagery). |
| 3 | The development of this skill is a gradual process that can be achieved through regular practice. |
| 4 | Achieving a moment-to-moment awareness of experience through participation in mindfulness enables individuals to reduce unconscious reactiveness and lead a richer life. |
| 5 | By persisting with this way of observing mental content, individuals can be enabled to view situations from different perspectives. |
| 6 | This way of observing allows individuals to gather more information that can enhance their effective action in the world, leading to an increased sense of control. |

These assumptions parallel Segal's (2012) theory of 'doing' and 'being' mode. 'Doing' mode is a goal-set, discrepancy monitoring, past and future focused mindset, where thoughts and feelings are seen as reality and used to direct change. However, by repeatedly focusing on how things are not as we want them, we can understandably create and perpetuate negative feelings, particularly if we cannot find effective actions to reduce the discrepancy (Segal, 2016). These negative feelings can increase a sense of failure (Hick & Chan, 2010). Contrastingly, 'being' mode is being open to and holding present experience in awareness, without needing to change it. MBIs encourage people to shift towards 'being' mode, which may be why they offer carers a useful tool, as carers may be enabled to live alongside the difficulties, changing their relationship to the difficulties instead. It is theorised that by entering 'being' mode, one disrupts a cycle of rumination on regrets and fears and enhances self-compassion. People learn to intentionally deploy their attention, ultimately

allowing for more flexible cognitive and behavioural responses. By developing metacognitive awareness, distressing cognitions feel less threatening and demand less resources. Ultimately, individuals' experiences of distress and vulnerabilities for future relapse can be reduced (Hick & Chan, 2010).

**Evidence for MBIs**

There is evidence supporting MBSR and MBCT in many populations. MBSR has been applied to numerous health conditions (e.g., hypertension, diabetes, cancer), significantly reducing anxiety, stress and low mood (Niazi & Niazi, 2011). Similarly, MBCT has been adapted for veterans (King et al., 2013) and people with chronic fatigue syndrome (Rimes & Wingrove, 2013), both of which found a reduction in psychological distress (including stress and low mood). Goldberg et al.'s (2018) review concluded MBIs were superior to either no treatment or other active controls and equivalent to other evidence-based treatments (e.g., CBT) at reducing disorder-specific symptoms in clinical populations, and effects appeared long-lasting.

Studies have also started evaluating MBIs in caring populations. Systematic reviews of MBSR have found reduced stress, anxiety, depression, burnout and increased job satisfaction in healthcare professionals (Ghawadra et al., 2019; Kriakous et al., 2021). Focusing on informal carers, Jaffray et al. (2016) reviewed MBIs for palliative caregivers and concluded they were feasible, acceptable and likely reduce low mood and caregiver burden, whilst increasing QoL. Ó Donnchadha (2018) also reviewed MBIs in carers of people with intellectual and developmental disabilities, reporting MBIs increased mindful awareness and cognitive defusion and reduced distress and thought suppression. These effects were maintained and even increased at follow-up. Promising findings were also found within carers of people with cancer (Al Daken & Ahmed, 2018), dementia (Berk et al., 2018), and mild cognitive impairments (Shim et al., 2020).

In 2016, Li et al. conducted a qualitative systematic review of MBIs for family carers generally. They concluded these approaches were feasible, acceptable, and led to improvements in psychological distress, including stress, depression, and anxiety. However, whilst this review provided a useful summary, it did not include a quantitative synthesis of the findings and incorporated uncontrolled trials. Since its publication, the number of controlled trials has increased, such that a meta-analysis is now possible. However, at the time of writing, this has yet to be published.

**Rationale and Aims**

In summary, informal carers face multiple challenges which can lead to increased feelings of stress, anxiety, low mood and reduced QoL. Surveys suggest formal support is required (Plöthner et al., 2019). This may include psychological therapies, and the evidence-base for MBIs in caring populations is increasing (Li et al., 2016). However, there has not yet been a systematic review of controlled studies that meta-analyses findings to quantify the effects of MBIs on measures of psychological wellbeing in the informal carer population.

Therefore, the current review aimed to evaluate the effects of mindfulness-based programmes on measures of psychological wellbeing in informal carers and suggest which areas are most benefited by engagement in these approaches. This was achieved through a systematic search of the literature and a meta-analysis of the evidence-base. Based on these findings, the review aimed to identify implications for future research and clinical practice.

# Method

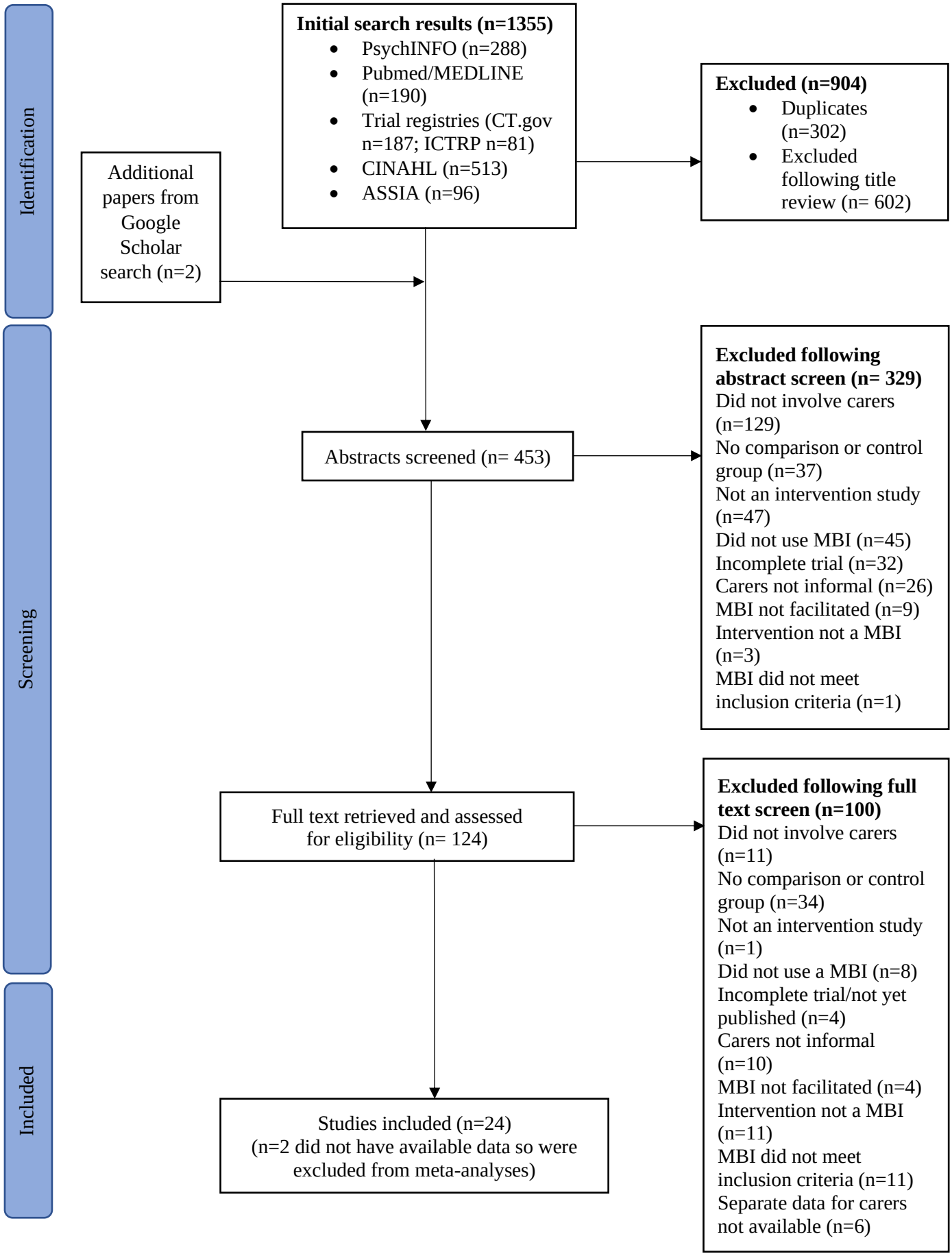
## Search strategy

The review was prospectively registered on Prospero (registration ID: CRD42021269682) in August 2021. All searches were conducted on 8th October 2021. Databases were searched from their inception to the date of the search and included PsychINFO, CINAHL, ASSIA, and the Cochrane Library (Pubmed/MEDLINE and Clincialtrials.gov). Search terms consisted of: (MBCT OR MBSR OR MBI OR MBP OR MBCP OR mindfulness OR mindfulness-based OR MYmind OR "MY Mind" OR MSFP) AND (Carer* OR caregiver* OR parent* OR famil* OR mother* OR father* OR foster carer* OR spous* OR partner* OR sibling* OR "informal care*" OR "unpaid care*") AND (RCT OR "randomi* both ways" OR "randomi* control* trial" OR "randomi* trial" OR "comparison study" OR "comparison trial" OR compari* OR evaluat*). Databases were searched for these terms within titles, keywords, and abstracts.

Figure 1 provides an overview of the screening process (based on PRISMA; Page et al. 2020). Citations from each database were imported into reference management software (Refworks) and duplicates removed. Titles and abstracts were screened for relevance and eligibility, after which, full text versions were reviewed. Reference sections of the final papers were screened and additional papers located through Google Scholar added. A second reviewer, an independent clinical psychologist, separately screened 25% of papers to ensure the quality of the process. A high level of agreement was achieved (99%). Both raters were unclear whether one study met the inclusion criteria and therefore a consensus decision was sought through the project supervisors. Similarly, queries regarding the remaining papers were brought to supervision to decide on their inclusion through consensus (n = 8 in total).

**Figure 1.**

*PRISMA diagram depicting extraction process*



**Eligibility criteria**

The below inclusion criteria were used during the screening process:

1. The paper is published in English language in a peer-reviewed journal.

2. The participant pool included informal carers. This was defined as a person "who provides unpaid support to a partner, child, relative or friend who couldn't manage to live independently or whose health or wellbeing would deteriorate without this help" (Royal College of General Practitioners, 2011, p. 9). Where this was a parent, they were providing additional care due to a condition or difficulty their child was experiencing (e.g., developmental disability or delay, ADHD, ASD, etc.). Where informal carers were a sub-group of participants (amongst other non-informal carers), their data was included if the study's findings for this sub-group were reported separately, or where separate data was provided through subsequent contact with authors.

3. At least one aspect of psychological wellbeing was measured. Psychological well-being was described an individual's emotional health and overall functioning, defined as "the combination of feeling good and functioning effectively" (Huppert, 2009, p.137). This included measures of a person's overall stress, anxiety, depression, burden, worry, rumination, anger, self-compassion, self-efficacy, QoL, satisfaction with life, mood, general mental health and functioning, amongst others.

4. The mindfulness-based intervention was either MBCT (Segal et al., 2012) or MBSR (Kabat-Zinn, 1982; Kabat-Zinn, 1990), or was grounded in these approaches. This included programmes such as Mindful Parenting (Bögels & Restifo, 2013), MYmind (Bögels et al. 2008; De Bruin et al. 2015; Van de Weijer-Bergsma et al. 2012) and Mindfulness-Enhanced Strengthening Families Program (MSFP; Coatsworth et al,.

2014), or a combination of these. Other programmes grounded in MBCT or MBSR were included providing they met Crane et al.'s (2017) definition of an MBI.

5. The intervention was delivered by a facilitator face-to-face, either in person or virtually live online. Self-guided or self-help interventions were excluded.

6. The study design included a control or comparison group which did not receive an MBI. This could be a passive or active, so long as it was not another MBI.

7. Where a study's design met part of the above inclusion criteria, it was only included if data for that relevant part of the study was reported separately.

**Data extraction and sub-grouping**

For both the intervention and comparison groups, the number of participants, mean, and standard deviation for each measure, at the post-intervention time-point, were extracted. Follow-up data were extracted where available. Where more than one follow-up time point was reported, the longest from post-intervention was used. Although this period varied, the analysis aimed to assess the most sustained effect of intervention (i.e., Goldberg et al., 2018). Studies were coded by control group (active or passive). To ensure accuracy, the second rater independently extracted data from 25% of studies (n = 6). A high level of agreement was achieved (94%). All discrepancies were settled in a meeting through consensus. Where studies had relevant unreported data, the corresponding authors were contacted.

**Assessing quality/risk of bias**

As studies consisted of both randomised and non-randomised designs, all were assessed in accordance with the Effective Public Health Practice Project (EPHPP; 2022) Quality Assessment Tool for Quantitative Studies. This tool had 'fair' inter-rater agreement for individual components and 'excellent' global rating agreement (Armijo-Olivo et al.,

2021). It consisted of six methodological components, which were graded and combined to provide a global rating of strong, moderate or weak quality (Table 2).

**Table 2.**

*Description of EPHPP components*

| Component | Description |
|---|---|
| Selection bias | The method used to select individuals to participate and whether this was representative of the target population. Also, the percentage of eligible individuals that agreed to take part. |
| Study design | The design implemented and whether the method of randomisation was outlined and appropriate. |
| Confounders | Important differences between groups prior to the start of the intervention and whether these were controlled for (either through design or analysis). |
| Blinding | Blinding of the assessors/researchers to participant group allocation. Also, whether participants were blind to the research question. |
| Data collection | Validity and reliability of data collection tools. |
| Withdrawals and drop-outs | Reporting of drop-outs, both in terms of numbers and reasons. Also, the total number of participants completing the study. |

The tool's dictionary was adhered to for each component. However, the confounder rating required additional specific criteria for the section to be reliably rated. As such, to assess Question 1 (whether there were differences between groups at baseline), authors needed to have analysed for differences on at least four demographic variables listed and their own outcome measures. If this was not met, a rating of ‘can’t tell’ was applied as authors

may have done this but not reported it in the published version. This ensured a reasonable proportion of typically measured confounders were accounted for.

All studies were provided an overall score (ranging from 6-18, calculated by combining individual component ratings, with higher scores indicating lower quality) and global rating ('strong' if no components rated as 'weak', 'moderate' if one component was 'weak', or 'weak' if ≥2 components were 'weak'). Where studies included a follow-up period, the 'Withdrawal and Drop-outs' domain was rated twice (at post-intervention and follow-up). This did not affect the global rating for any study; however, the total score did vary. To ensure accurate ratings, the second reviewer independently rated 25% of studies (n = 6). A high level of agreement was achieved (92%). All discrepancies were settled in a meeting and a consensus reached.

**Data analysis**

Data were analysed in Jamovi v1.6.23 (The Jamovi Project, 2021). Standardised between group effect sizes (SMDs) were calculated. The estimated pooled effect and its associated 95% confidence interval were generated using a random effects model. This was due to the known heterogeneity in the MBIs and participant pools, meaning studies were not functionally equivalent and therefore we could not assume all studies shared a common effect size (Borenstein et al., 2021). Forest plots were produced for each outcome measure for which there were sufficient data (i.e., a minimum of three studies, in line with previous MBI meta-analyses; Kallapiran et al., 2015). Separate sub-group analyses for active and passive control/comparison groups were conducted where there were a sufficient number of studies. Further analyses were performed on follow-up data. Funnel plots were used to assess the possibility of publication bias, in addition to Egger's regression (Egger et al., 1997). Moderation analysis was conducted using the quality appraisal overall rating to check whether study quality was associated with findings.

# Results

## Results of the search

A total of 1355 references were extracted through the electronic literature searches in October 2021. An additional two references were identified through Google Scholar. Twenty-four studies were deemed eligible, with 22 having the required data for meta-analysis.

## Characteristics of included studies

All study characteristics are detailed in Tables 3 and 4.

### *Study design*

Twenty-two of the 24 studies were RCTs. Of the remaining studies, one was a controlled trial (Petcharat & Liehr, 2021) and the other was described as quasi-experimental (Norouzi et al., 2014). All studies were published between 2010 and 2021. Twenty-three had a single intervention group and control group. Oken et al. (2010) included two active controls, therefore their data was combined (Higgins et al., 2022). Twelve studies collected follow-up measures, with the longest time-point ranging from eight-weeks to six-months.

### *Participant characteristics*

A total of 1644 participants were included in this review. The average age of participants varied from 33 to 61 years. The majority of participants identified as female (56.8% to 100%), and most described their ethnicity as White (69.6% to 98.7%). In 14 studies, participants were the parent of the care-receiver. Other relationships were described as family carers, informal carers and first-degree relatives. Care-receiver characteristics included people with dementia, ADHD, ASD, chronic and functional illnesses, lung cancer, cerebral palsy, substance-use disorders, developmental disabilities and delays, and veterans. Studies were conducted in the USA, Australia, Thailand, Iran, Spain, Netherlands, Sweden, China, and Canada.

### *Mindfulness-based interventions*

Nine studies reported implementing MBSR (Kabat-Zinn, 1990) or a modified version of it. Six studies implemented MBCT (Segal et al., 2012) or a modified version. The remaining studies used a variety of programmes, all based on core principles from MBCT or MBSR, including Mindful Parent Training (Bögels & Restifo, 2013), the MYmind programme (Bögels, 2020; De Bruin et al., 2015; van der Oord et al., 2012), the MiYoga programme (Mak et al., 2018), and a Brief Culturally Tailored Thai Mindfulness Intervention (Petcharat & Liehr, 2021). The number of sessions ranged from six to 10, with the majority (n = 11) offering eight. Sessions lasted between one and 2.5 hours. Five programmes also included an additional day-long retreat. All bar one specified daily at-home practice. The only format that deviated from this was Petcharat and Liehr's (2021), which was facilitated over two weekends and included 14 units. In five studies, care-receivers also attended the programme or attended a concurrent intervention.

### *Outcome measures*

A variety of outcome measures were used to assess psychological wellbeing. The most common was levels of stress (n=19), followed by depression (n=13), mindfulness (n=10), caregiver burden (n=7), anxiety (n=8), self-compassion (n=5), mental and physical QoL (n=5), and wellbeing (n=5). All the measures used were self-reported and are listed in Table 5.

### *Control groups*

Fifteen studies used passive controls (waitlist, treatment as usual (TAU), or no intervention). The remaining 9 with active controls tended to be programmes that matched the time and length of the MBI. They included social support groups, CBT groups, education groups, self-help, respite, and programmes specifically tailored to the target population.

### *Quality Appraisal*

All studies were rated either moderate or weak in quality, with none achieving a strong rating. Selection bias was rated weak for most studies, with several studies (n = 14) opting for a self-referral method (advertising through newspapers, social media, community centres etc.), as opposed to using a comprehensive list of individuals in the target population. Confounder measurement was also lacking in several studies (n = 12), therefore groups may not have been balanced with respect to important variables prior to the intervention. However, given the majority used randomisation, the potential for confounding was reduced (Pourhoseingholi et al., 2012). An overview of ratings is presented in Table 6.

**Table 3.**

*Study characteristics*

| Study | Author(s) | Participant characteristics | Carer relationship (n) | Care-receiver characteristics | Mindfulness intervention | Comparison group details |
|---|---|---|---|---|---|---|
| **1** | Anclair et al. (2018), Sweden | 41.0 (6.1) years; 92.9% female; ethnicity breakdown not reported | Parents (21) | Children, aged <18 years, with chronic conditions (chronic disease and/or functional disabilities) | MBI programme 'Here and Now Version 2.0' (Schenstrom, 2011), derived from MBSR and MBCT. Eight sessions over eight-weeks, 2 h, in-person. 15-minute daily at-home practice using self-instructing material. | Eight-week structured CBT group, 2 h. |
| **2** | Behbahani et al. (2018), Iran | Demographic characteristics (age, gender & ethnicity) not reported for carers | Mothers (60) | Children, aged 7-12 years, with ADHD | Mindful parenting training, based on the Kabat-Zinn protocol (Bögels & Restifo, 2013). Eight sessions over eight-weeks, 1.5 h, in-person. CD with mindfulness exercise for home practice (length unspecified) | No intervention |
| **3** | Brown et al. (2016), USA | 61.14 (10.41) years; 84.2% female; 75.7% Caucasian, 21.6% African American, 2.7% Hispanic/Latino | Family carers (38) | People with Alzheimer's Disease and other dementias (age unspecified) | Adapted MBSR programme (Kabat-Zinn, 1990), eight sessions over eight-weeks, 1.5-2 h, plus a day-long session | Eight-week standard social support (SS) group |
| **4** | Chan & Neece (2017), USA | 37.21 (7.22) years, 96.3% female (ethnicity breakdown not provided) | Parents (80) | Children, aged 2.5-5 years, with a developmental delay | MBSR (Kabat-Zinn, 1990), eight sessions over eight-weeks, 2 h, in-person, plus additional 6-hour retreat. Daily at-home practice of audio-guided exercises. | Waitlist |
| **5** | Dykens et al. (2014), USA | 40.87 (8.92) years 100% female, 69.6% White, 14.7% African American, | Mothers (243) | Children with developmental disabilities (age unspecified) | Modified MBSR (Ludwig & Kabat-Zinn, 2008), six sessions over six-weeks, 1.5 hour. At-home practice consisted of specific exercises from the course. | Six-week Positive Adult Development (positive |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | 9.2% Hispanic, 6.5% Asian/other | | | | psychology practice) group |
| **6** | Ho et al. (2021), China | 46.5 (6.0) years; 76% female; ethnicity breakdown not reported | Parents (37) | Adolescents, aged 10-18 years, with ASD | MY Mind Programme (De Bruin et al., 2015) based on MBCT & MBSR, nine sessions over nine-weeks, 1.5 h, in-person, both child and parents attend. At-home practice included handouts & practising audio-guided mindfulness exercises | Waitlist |
| **7** | Hou et al. (2014), China | 57.49 (8.83) years; 83% female (ethnicity breakdown not provided) | First-degree relatives (141) | People with chronic illness or chronic condition (age unspecified) | MBSR (Kabat-Zinn, 1990), eight sessions over eight-weeks, 2 hr, in-person. At-home practice consisted of audio-guided for 30–45 minutes daily. | Self-help booklet (eight chapters of supportive information and health education) |
| **8** | Kor et al. (2019), China | 57.1 (10.6) years; 83.3% female; ethnicity breakdown not reported | Family carers (36) | People with dementia (age unspecified) | Modified MBCT (Segal et al., 2012). Seven sessions over 10-weeks, 2 h, in-person. Audio-guided daily at-home practice provided. | Usual family care and seven-week brief education programme on dementia care |
| **9** | Kor et al. (2021), China | 61.7 (10.5) years; 61.1% female; ethnicity breakdown not reported | Family carers (113) | People with dementia (age unspecified) | Modified MBCT (Segal et al., 2012). Seven sessions over 10-weeks, 2 h, in-person. Audio-guided daily at-home practice provided. | Usual family care and seven-week brief education programme on dementia care |
| **10** | Lara-Cinisomo et al. (2019), USA | 58.09 (12.43) years; 96% female; 87% White, 13% Black and Native American | Informal caregivers (23) | Veterans (age unspecified) | MBCT (Segal et al., 2012). Eight sessions over eight-weeks, 2 h, in-person. At-home practice included audio-guided mindfulness practice daily for 30-40 minutes and weekly readings. | Waitlist |
| **11** | Lo et al. (2017), China | 38.87 (5.92) years; 93.9% female; ethnicity breakdown not reported | Parents (180) | Children with developmental disabilities (age unspecified) | MBI based on MY Mind & Mindfulness-Enhanced Strengthening Families Program (Bögels & Restifo, 2013; Coatsworth et al., 2014) adapted for Chinese parents of children with developmental disabilities. Six sessions over six-weeks, 1.5 h, in-person. 10-minute at-home practice audio tracks. | No intervention |

| | | | | | | |
|---|---|---|---|---|---|---|
| **12** | Lo et al. (2020), China | 39.21 years, 96% female (ethnicity breakdown not provided) | Parents (100) | Children, aged 5-7 years, with ADHD | Family-based mindfulness intervention based on Mindful Parenting programmes (Bögels & Restifo, 2013; Coatsworth et al., 2014), grounded in MBCT and MBSR, six sessions over six-weeks, 1.5 h, in-person. Children attended a separate "Mindfulness Matters" group, eight sessions, 1 hr. | Waitlist |
| **13** | Lunsky et al. (2017), Canada | 56.6 (8.3) years; 70% female; ethnicity breakdown not provided | Parents (50) | Adults, aged >16, with ASD and Other Developmental Disabilities | Adapted MBCT (Segal, 2013), orientation session plus six sessions over six-weeks, 2 h, in-person. At-home practice included audio-guided brief meditations from Finding Peace in a Frantic World (Williams & Penman, 2012) | Six-week parent support and education group |
| **14** | Mak et al. (2018), Australia | Demographic characteristics (age, gender & ethnicity) not reported for carers | Parents or carers (42) | Children, aged 6-16 years, with unilateral or bilateral cerebral palsy | MiYoga programme (Mak et al., 2018), six weekly sessions in-person, 1.5 hours, then two telephone/Skype consultations, over eight-weeks. At-home practice consisted of >20 minutes practice daily using DVD and poster information. | Waitlist |
| **15** | Neece (2014), USA | 35.28 years, 78.3% female (ethnicity breakdown not provided) | Parents (46) | Children, aged 2.5-5 years, with developmental delays | MBSR (Kabat-Zinn, 1990), eight sessions over eight-weeks, 2-h sessions, plus a daylong 6-h meditation retreat, in-person. Daily at-home practice based on audio CDs with instruction. | Waitlist |
| **16** | Norouzi et al. (2014), Iran | Demographic characteristics (age, gender & ethnicity) not reported for carers | Informal female carers (20) | People with Alzheimer's Disease (age unspecified) | MBCT (Segal et al., 2002) eight sessions over eight-weeks, 2.5 h, in person. At-home practice not described. | Waitlist |
| **17** | Oken et al. (2010), USA | 64.46 years, 80.6% female, 90.3% White, 3.2% African American, 6.5% Asian | Family carers (31) | People with progressive dementia (age unspecified) | Adapted MBCT (Segal et al., 2002) and MBSR (Kabat-Zinn, 1990), six sessions over six-weeks, 1.5h, in-person. Daily at-home practice of audio-guided and written exercises. | (1) Six-week education group (2) Respite only for 3 h per week for seven weeks |
| **18** | Petcharat & Liehr (2021), Thailand | 46.64 (9.41) years, gender not specified, 100% Thai | Parents or carers (24) | Children, aged <18 years, with developmental disabilities | Brief Culturally Tailored Thai Mindfulness intervention (BCTTMi) program, 14 units over 2 weekends, grounded in MBSR (Kabat-Zinn, 2003). | Waitlist |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | Daily at-home practice of exercises (length unspecified). | |
| **19** | Schellekens et al. (2017), Netherlands | 58.7 years, 56.8% female, ethnicity breakdown not provided | Partners or close relatives/friends (44) | People, aged 18 years and over, presenting with cytologically or histologically proven non-small cell or small cell lung cancer | Adapted MBSR (Kabat-Zinn, 1990), eight sessions over eight-weeks, 2.5 h, in-person. Partners/relatives with dementia were also invited to attend if they wanted to. Daily at-home practice of 45 minutes. Alongside care as usual. | Care as usual |
| **20** | Siebelink et al. (2021), Netherlands | 43.4 years; 67.9% female; ethnicity breakdown not provided | Parents (103) | Children, aged 8–16 years, with ADHD | MYmind Programme (Bögels, 2020; van der Oord et al., 2012) based on MBCT & MBSR, eight sessions over eight-weeks with a booster eight-weeks later, 1.5 h, in-person. At-home practice 30-40 minutes daily. Separate child-group led in parallel, with 15 minute daily at-home practice. Plus care as usual. | Care as usual |
| **21** | Smith et al. (2020), Canada | 52.1 (8.1) years; 100% female; 90.7% Caucasian, 9.3% other ethnicities (breakdown not provided) | Informal female carers (43) | Children with substance use disorders (age unspecified) | MBSR (Kabat-Zinn, 1990; Santorelli et al., 2017), 10 sessions over eight-weeks, 2hr, in-person, including an all-day retreat. Daily at-home practice of 45-60 minutes. | Waitlist |
| **22** | Valero et al. (2021), Spain | 46 years, 96.7% female, ethnicity breakdown not provided | Parents (30) | Children, aged 9-14 years, with ADHD | MY Mind Programme (Bögels, 2013) based on MBCT & MBSR, eight weekly sessions over eight-weeks, 1.5 h, in-person. At-home practice included handouts & practising audio-guided mindfulness exercises. Child-only sessions were also facilitated consecutively. | Waitlist |
| **23** | Weitlauf et al. (2020), USA | 33.53 years, 86.9% female, 93.4% White, 3.3% Black or African American, 8.2% Asian American | Parents (61) | Children, aged <3 years, with ASD | Adapted MBSR (Kabat-Zinn, 1990), six individual weekly sessions, 1 hr, in-person. At-home practice consisted of daily formal and informal mindfulness exercises. Plus P-ESDM programme. | 12-week Parent-implemented Early Start Denver Model (P-ESDM) programme |
| **24** | Whitebird et al. (2013), USA | 56.8 (9.9) years, 88.5% female, 98.7% White, 1.3% American Indian | Primary family carer (78) | People with dementia (age unspecified) | MBSR (Kabat-Zinn, 1990), eight sessions over eight-weeks, 2.5 h, in-person, plus additional 5-hour retreat. Daily at-home practice of audio-guided exercises. | 8-week community caregiver education and support |

**Table 4.**

*Additional study characteristics*

| Study | Author(s) | Study design | Control/comparison group category | Follow-up (weeks post intervention) | Intervention (n) | Control/comparison (n) | Quality appraisal rating | Quality appraisal total (post-intervention) | Quality appraisal total (follow-up) |
|---|---|---|---|---|---|---|---|---|---|
| **1** | Anclair et al. (2018) | Pilot RCT | Active | - | 11 | 10 | Weak | 10 | - |
| **2** | Behbahani et al. (2018) | RCT | Passive | Eight weeks post-intervention | 30 | 30 | Moderate | 10 | 10 |
| **3** | Brown et al. (2016) | RCT | Active | Three months post-intervention | 23 | 15 | Moderate | 9 | 9 |
| **4** | Chan & Neece (2017) | RCT | Passive | - | 39 | 41 | Weak | 11 | - |
| **5** | Dykens et al. (2014) | RCT | Active | Six months post-intervention | 116 | 127 | Weak | 11 | 11 |
| **6** | Ho et al. (2021) | RCT | Passive | - | 19 | 18 | Weak | 11 | - |
| **7** | Hou et al. (2014) | RCT | Active | Three months post-intervention | 70 | 71 | Moderate | 8 | 8 |
| **8** | Kor et al. (2019) | Pilot RCT | Active | Three months post-intervention | 18 | 18 | Weak | 11 | 13 |
| **9** | Kor et al. (2021) | RCT | Active | Six months post-intervention | 56 | 57 | Moderate | 9 | 9 |
| **10** | Lara-Cinisomo et al. (2019) | Pilot RCT | Passive | - | 11 | 12 | Moderate | 9 | - |
| **11** | Lo et al. (2017) | RCT | Passive | - | 91 | 89 | Moderate | 9 | - |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **12** | Lo et al. (2020) | RCT | Passive | - | 50 | 50 | Moderate | 9 | - |
| **13** | Lunsky et al. (2017) | RCT | Active | 20 weeks post-intervention (data not available) | 26 | 24 | Weak | 11 | 12 |
| **14** | Mak et al. (2018) | RCT | Passive | - | 21 | 21 | Moderate | 9 | - |
| **15** | Neece (2014) | RCT | Passive | - | 21 | 25 | Moderate | 9 | - |
| **16** | Norouzi et al. (2014) | Quasi-experimental | Passive | - | 10 | 10 | Weak | 13 | - |
| **17** | Oken et al. (2010) | Pilot RCT | Active | - | 10 | 21 | Weak | 11 | 11 |
| **18** | Petcharat & Liehr (2021) | Controlled trial | Passive | - | 12 | 12 | Weak | 11 | - |
| **19** | Schellekens et al. (2017) | RCT | Passive | Three months post-intervention | 21 | 23 | Moderate | 9 | 10 |
| **20** | Siebelink et al. (2021) | RCT | Passive | Six months post-intervention | 55 | 48 | Weak | 11 | 11 |
| **21** | Smith et al. (2020) | Pilot RCT | Passive | - | 21 | 22 | Moderate | 10 | - |
| **22** | Valero et al. (2021) | RCT | Passive | Six months post-intervention | 15 | 15 | Weak | 12 | 12 |
| **23** | Weitlauf et al. (2020) | RCT | Passive | Six months post-intervention | 30 | 31 | Moderate | 10 | 11 |
| **24** | Whitebird et al. (2013) | RCT | Active | Six months post-intervention | 38 | 40 | Moderate | 9 | 9 |

**Table 5.**

*Outcome measures used within selected studies*

| Outcome of interest | Measures used |
|---|---|
| Stress | Perceived Stress Scale (PSS; Cohen et al., 1983), Parenting Stress Index–Short Form (PSI-SF; Abidin, 1990). |
| Depression | Profile of Mood States - depression subscale (PoMS; McNair et al., 1971), The Centre for Epidemiologic Studies Depression Scale/ Chinese Centre for Epidemiologic Studies Depression Scale (CES-D; Radloff, 1977), Patient Health Questionnaire (PHQ9; Kroenke et al., 2001), Beck Depression Inventory (BDI: Beck et al., 1961), Hamilton's Ranking Scale of Depression (Hamilton, 1986), Depression, Anxiety & Stress scale - depression subscale (DASS; Lovibond & Lovibond, 1995), Hospital Anxiety Depression Scale - depression subscale (HADS; Zigmond & Snaith, 1983). |
| Mindfulness | Five Facet Mindfulness Questionnaire (Baer et al., 2006), Mindfulness Attention and Awareness Scale (Brown & Ryan, 2003), Interpersonal Mindfulness in Parenting scale (Duncan et al., 2009). |
| Anxiety | Hospital Anxiety and Depression Scale - Anxiety subscale (Zigmond & Snaith, 1983), State-Trait Anxiety Inventory (STAI; Spielberger et al., 1983), Beck Anxiety Inventory (Steer & Beck, 1997). |
| Caregiver burden | Caregiver Burden Inventory (Preedy & Watson, 2010), Montgomery Borgatta Caregiver Burden Scale (Savundranayagam et al., 2011), Self-Perceived Pressure from Informal Care (Pot et al., 1995), Caregiving Burden 9-item subscale of the Revised Caregiving Appraisal Scales (Bigatti S., Steiner, 2014), Zarit Burden Scale (Zarit et al., 1980). |

| | |
|---|---|
| Self-compassion | Self-Compassion Scale (Neff, 2003). |
| Mental health quality of life | Short Form-36 (Ware, 1993), Short Form-12 (Turner-Bowker & Hogue, 2014). |
| Physical health quality of life | Short Form-36 (Ware, 1993), Short Form-12 (Turner-Bowker & Hogue, 2014). |
| Wellbeing | WHO-5 Well-being Index (World Health Organisation (WHO), 1998), Ryff Scales of Psychological Well-Being (Ryff & Keyes, 1995), Personal Wellbeing Index (International Wellbeing Group, 2006). |

**Table 6.**

*Quality appraisal ratings using the Effective Public Health Practice Project (2022) Quality Assessment Tool for Quantitative Studies*

| Study | Author | Individual components | | | | | | Global rating | Total score (post-intervention) | Total score (follow-up) |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Selection bias | Study design | Confounders | Blinding | Data collections tools | Withdrawals and drop-outs Post-intervention (PI) Follow-up (FU) | | | |
| **1** | Anclair et al. (2018) | Weak | Strong | Weak | Strong | Strong | Strong | Weak | 10 | - |
| **2** | Behbahani et al. (2018) | Moderate | Strong | Weak | Moderate | Strong | Strong (PI), Strong (FU) | Moderate | 10 | 10 |
| **3** | Brown et al. (2016) | Weak | Strong | Strong | Moderate | Strong | Strong (PI), Strong (FU) | Moderate | 9 | 9 |
| **4** | Chan & Neece (2017) | Weak | Strong | Weak | Moderate | Strong | Strong | Weak | 11 | - |
| **5** | Dykens et al. (2014) | Weak | Strong | Strong | Moderate | Strong | Weak (PI), Weak (FU) | Weak | 11 | 11 |
| **6** | Ho et al. (2021) | Weak | Strong | Weak | Moderate | Strong | Strong | Weak | 11 | - |
| **7** | Hou et al. (2014) | Weak | Strong | Strong | Strong | Strong | Strong | Moderate | 8 | 8 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **8** | Kor et al. (2019) | Weak | Strong | Weak | Moderate | Strong | Strong (PI), Weak (FU) | Weak | 11 | 13 |
| **9** | Kor et al. (2021) | Weak | Strong | Strong | Moderate | Strong | Strong (PI), Strong (FU) | Moderate | 9 | 9 |
| **10** | Lara-Cinisomo et al. (2019) | Weak | Strong | Strong | Moderate | Strong | Strong | Moderate | 9 | - |
| **11** | Lo et al. (2017) | Weak | Strong | Strong | Moderate | Strong | Strong | Moderate | 9 | - |
| **12** | Lo et al. (2020) | Weak | Strong | Strong | Moderate | Strong | Strong | Moderate | 9 | - |
| **13** | Lunsky et al. (2017) | Weak | Strong | Weak | Moderate | Strong | Strong (PI), Moderate (FU) | Weak | 11 | 12 |
| **14** | Mak et al. (2018) | Weak | Strong | Strong | Moderate | Strong | Strong | Moderate | 9 | - |
| **15** | Neece (2014) | Weak | Strong | Strong | Moderate | Strong | Strong | Moderate | 9 | - |
| **16** | Norouzi et al. (2014) | Weak | Strong | Weak | Moderate | Strong | Weak | Weak | 13 | - |
| **17** | Oken et al. (2010) | Weak | Strong | Weak | Moderate | Strong | Strong (PI), Strong (FU) | Weak | 11 | 11 |
| **18** | Petcharat & Liehr (2021) | Weak | Strong | Weak | Moderate | Strong | Strong | Weak | 11 | - |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **19** | Schellekens et al. (2017) | Weak | Strong | Strong | Moderate | Strong | Strong (PI), Moderate (FU) | Moderate | 9 | 10 |
| **20** | Siebelink et al. (2021) | Weak | Strong | Weak | Moderate | Strong | Strong (PI), Strong (FU) | Weak | 11 | 11 |
| **21** | Smith et al. (2020) | Weak | Strong | Strong | Moderate | Strong | Moderate | Moderate | 10 | - |
| **22** | Valero et al. (2021) | Weak | Strong | Weak | Weak | Strong | Strong (PI), Strong (FU) | Weak | 12 | 12 |
| **23** | Weitlauf et al. (2020) | Moderate | Strong | Weak | Moderate | Strong | Strong (PI), Moderate (FU) | Moderate | 10 | 11 |
| **24** | Whitebird et al. (2013) | Weak | Strong | Strong | Moderate | Strong | Strong (PI), Strong (FU) | Moderate | 9 | 9 |

**Meta-analyses: Passive Control Groups**

Findings of each meta-analysis is presented below. A summary of all findings is provided at the end of this section.

***Stress***

Figure 2 shows the post-intervention forest plot for passive control studies measuring stress. MBI participants showed significantly lower levels of post-intervention stress compared to passive controls ($Z = -3.32$, $p < .001$), favouring the intervention, with a small to large pooled effect size (standardised mean difference (SMD) = -0.59, 95% C.I.: -0.94 to -0.24). Based on Deeks et al. (2021), the level of heterogeneity in effect sizes between studies was within the range that was appropriate for a random-effects meta-analysis ($Q(9) = 32.56$, $p = 0.0002$, $I^2 = 73.35\%$). There was little evidence of a marked publication bias from the funnel plot (Figure 3) and the publication bias test was insignificant (Egger's Regression = -0.99, p = 0.32).

**Figure 2.**

*Forest plot for studies with passive control groups measuring stress at post-intervention*

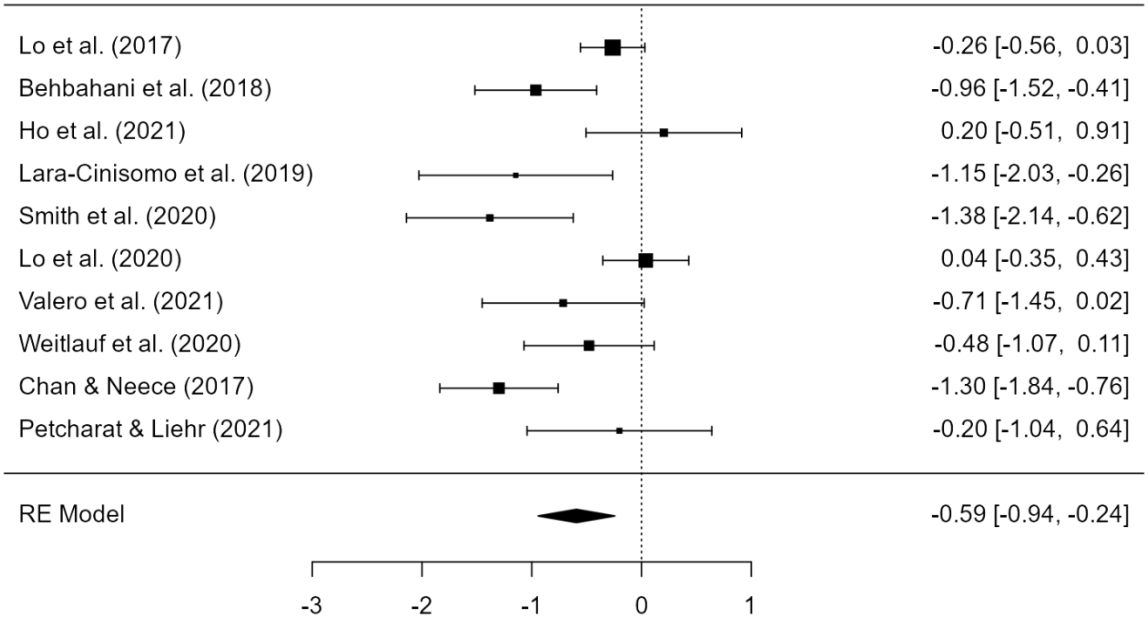
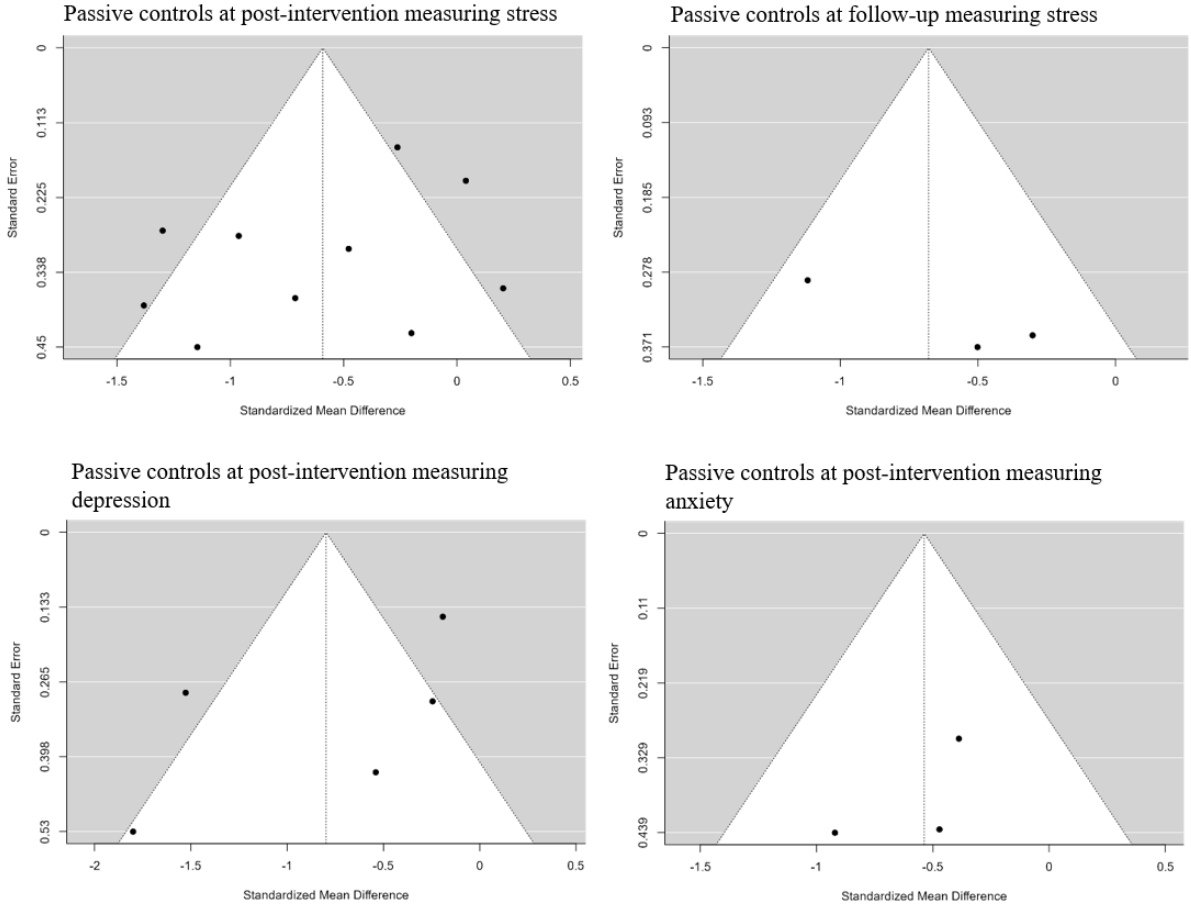


**Figure 3.**

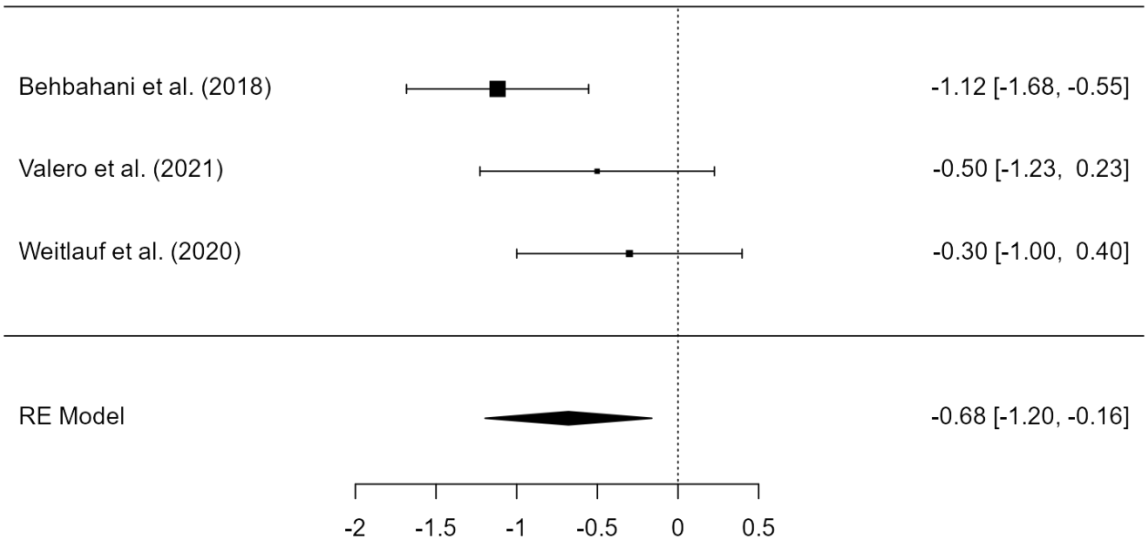
*Funnel plots for the four meta-analyses of passive control studies measuring stress, depression, and anxiety*




As can be seen in Figure 4, these differences were maintained at follow-up. MBI participants showed significantly lower levels of follow-up stress compared to passive controls ($Z = -2.58$, $p = 0.01$), favouring the intervention, with a small to large pooled effect size (SMD = -0.68, 95% C.I.: -1.20 to -0.16). Effect sizes were not significantly heterogeneous ($Q(2) = 3.64$, $p = 0.16$, $I^2 = 45.74\%$). The funnel plot was relatively symmetrical (Figure 3), and the publication bias test was insignificant (Egger's Regression = 1.79, $p = 0.07$).

**Figure 4.**

*Forest plot for studies with passive control groups measuring stress at follow-up*

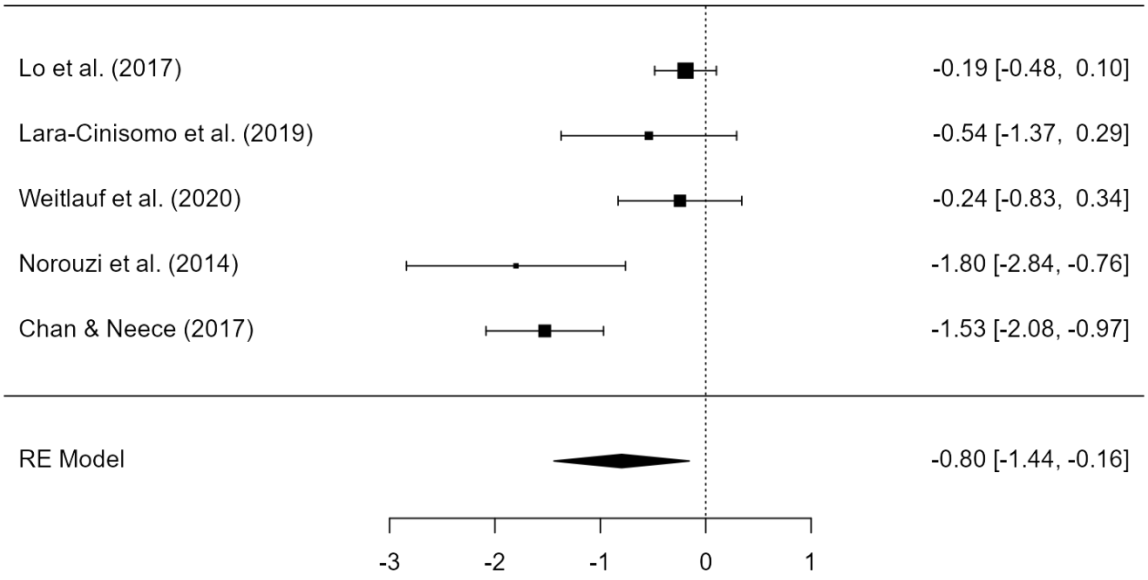



***Depression***

Figure 5 shows the post-intervention forest plot for passive control studies measuring depression. MBI participants showed significantly lower levels of post-intervention depression compared to passive controls ($Z = -2.43$, $p = 0.015$), favouring the intervention, with a small to large pooled effect size (SMD = -0.80, 95% C.I.: -1.44 to -0.16). The level of heterogeneity in effect sizes between studies was within the range that was appropriate for a random-effects meta-analysis ($Q(4) = 24.07$, $p < 0.001$, $I^2 = 83.28\%$). The funnel plot was relatively symmetrical (Figure 3), and the publication bias test was insignificant (Egger's Regression = -1.25, $p = 0.21$).

**Figure 5.**

*Forest plot for studies with passive control groups measuring depression at post-intervention*




Nonetheless, moderator analysis (see ‘Moderation by study quality’ section below) suggested that these findings were possibly biased by study quality, with weaker studies reporting larger effects. As such, this meta-analysis was repeated excluding 'weak' rated studies (i.e., Crombie & Davis, 2009). MBI participants no longer showed significantly lower levels of post-intervention depression compared to passive controls ($Z = -1.83$, $p = 0.07$, SMD = -0.23, 95% C.I.: -0.48 to 0.02; Appendix A). Effect sizes were not significantly heterogeneous ($Q(2) = 0.60$, $p = 0.74$ , $I^2 = 0\%$). Given the small number of studies the funnel plot is difficult to interpret but suggests some asymmetry (Appendix A). However, the publication bias test was insignificant (Egger’s Regression = -0.70, $p = 0.49$). As such, the findings from the meta-analysis incorporating all eligible studies should be interpreted with caution.

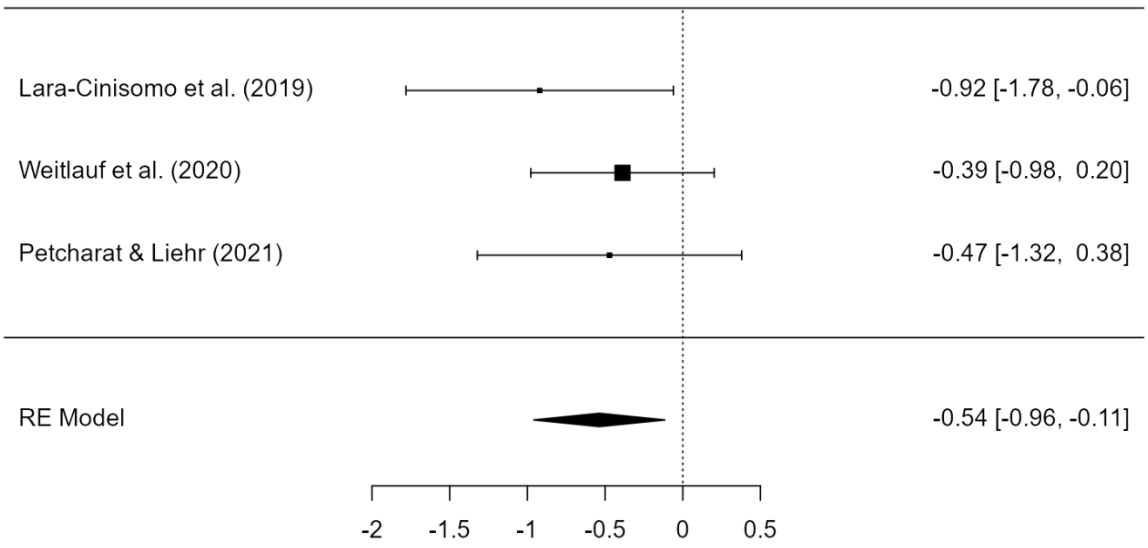
Due to insufficient numbers (n=1), it was not possible to conduct a meta-analysis on depression levels at follow-up in passive control studies. However, Weitlauf et al. (2020) did not find significant differences between groups at follow-up.

***Anxiety***

Figure 6 shows the post-intervention forest plot for passive control studies measuring anxiety. MBI participants showed significantly lower levels of post-intervention anxiety compared to passive controls (Z = -2.49, p = 0.013), favouring the intervention, with a small to large pooled effect size (SMD = -0.54, 95% C.I.: -0.96 to -0.11). Effect sizes were not significantly heterogeneous (Q(2) = 1.03, p = 0.60, $I^2$ = 0%). The funnel plot was relatively symmetrical (Figure 3), and the publication bias test was insignificant (Egger's Regression = -0.73, p = 0.47).

**Figure 6.**

*Forest plot for studies with passive control groups measuring anxiety at post-intervention*




Due to insufficient numbers (n=1), it was not possible to conduct a meta-analysis on anxiety levels at follow-up in passive control studies. However, Weitlauf et al. (2020) did not find significant differences between groups at follow-up.

***Caregiver Burden***

Due to insufficient numbers (n=2) a meta-analysis was not performed for post-intervention caregiver burden measures for passive control studies. The findings from these

two studies were mixed. Whilst Schellekens et al. (2017) did not find a significant difference between groups, Norouzi et al. (2014) did, with those receiving MBCT reporting significantly lower levels of caregiver burden post-intervention compared with passive controls. Only Schellekens et al. (2017) reported follow-up findings, which again did not show any significant differences between groups in caregiver burden levels.

***Self-compassion***

Figure 7 shows the post-intervention forest plot for passive control studies measuring self-compassion. MBI participants did not show significantly higher levels of post-intervention self-compassion compared to passive controls (Z = 1.54, p = 0.12, SMD = 0.35, 95% C.I.: -0.10 to 0.80). Effect sizes were not significantly heterogeneous (Q(2) = 3.70, p = 0.16, $I^2$ = 44.94%). There were no concerns in relation to publication bias (Egger's Regression = 0.93, p = 0.35) and the funnel plot appears relatively symmetrical despite the small number of studies (Figure 8).

**Figure 7.**

*Forest plot for studies with passive control groups measuring self-compassion at post-intervention*

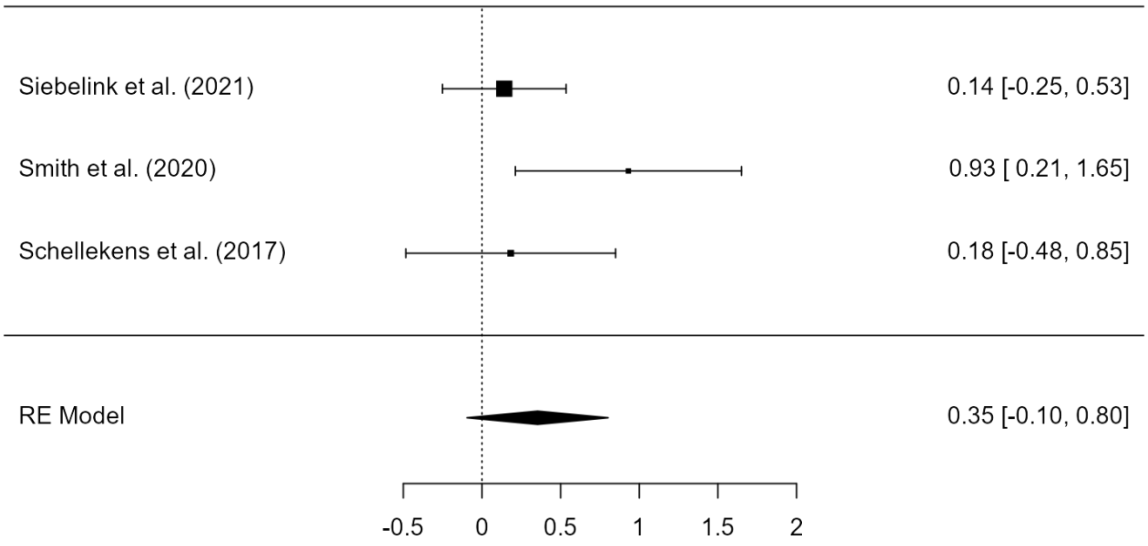
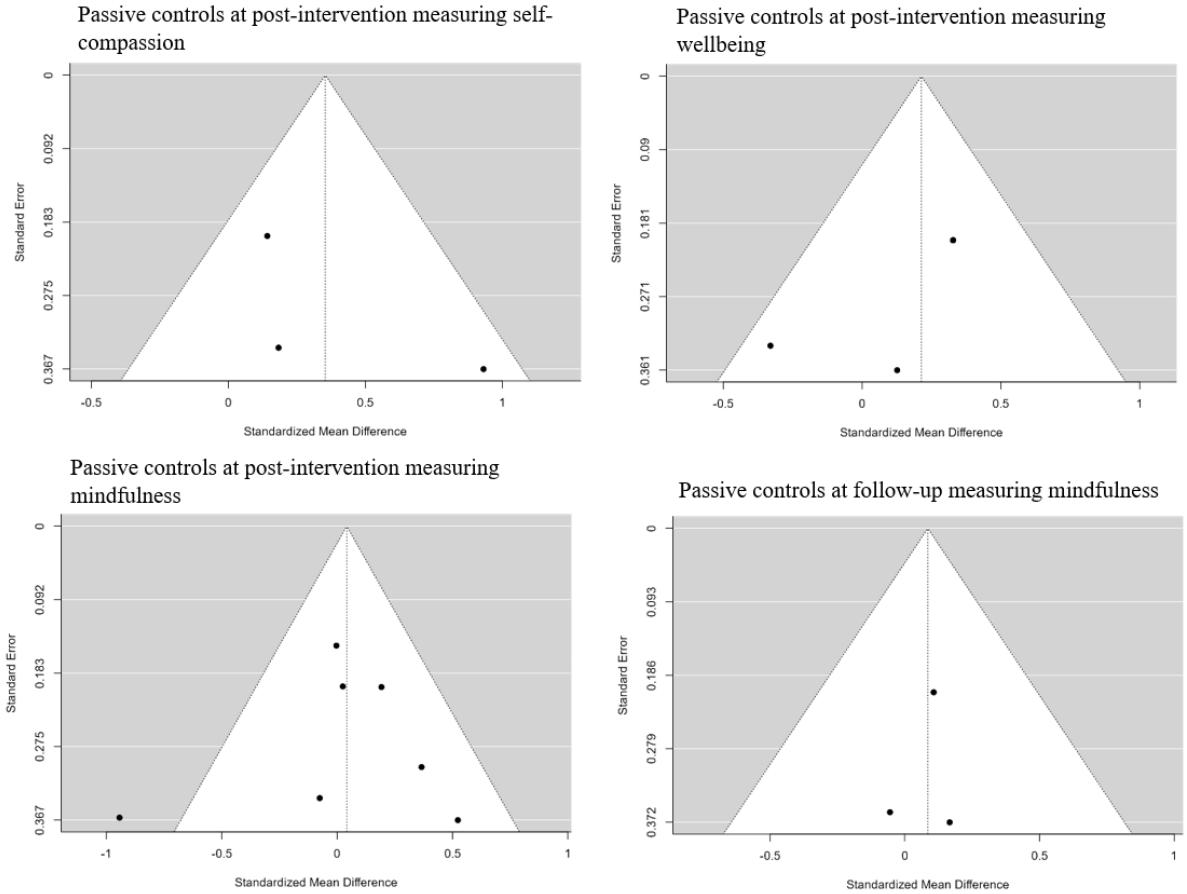


**Figure 8.**

*Funnel plots for the four meta-analyses of passive control studies measuring self-compassion, wellbeing, and mindfulness*




Due to insufficient numbers (n=2) a meta-analysis was not performed on follow-up data for passive control studies measuring self-compassion. The findings from these two studies were mixed. Whilst Schellekens et al. (2017) did not find a significant difference between groups at follow-up, Siebelink et al. (2021) did, with those receiving the MBI reporting significantly higher levels of self-compassion at follow-up compared with passive controls.

### *Mental Health Quality of Life (MH QoL)*

There were no passive control studies exploring MH QoL at post-intervention or follow-up. All studies investigating this outcome (n=5) had an active control group.

***Physical Health Quality of Life (PH QoL)***

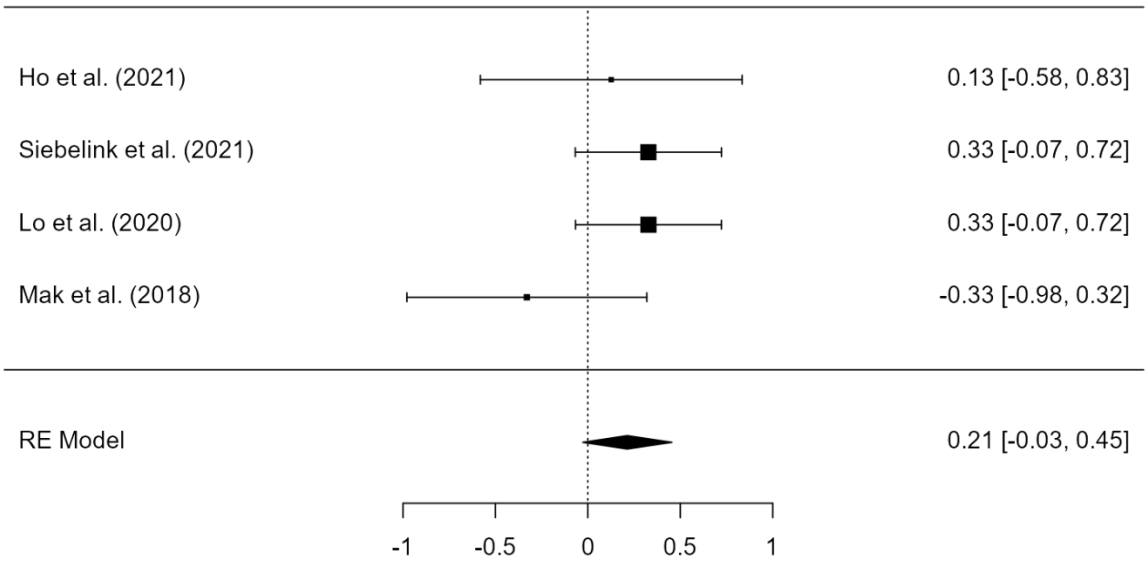
There were no passive control studies exploring PH QoL at post-intervention or follow-up. All studies investigating this outcome (n=5) had an active control group.

***Wellbeing***

Figure 9 shows the post-intervention forest plot for passive control studies measuring wellbeing. MBI participants did not show significantly higher levels of post-intervention mindfulness compared to passive controls, though the findings were close to achieving significance (Z = 1.73, p = 0.08, SMD = 0.21, 95% C.I.: -0.03 to 0.45). Effect sizes were not significantly heterogeneous (Q(3) = 3.39, p = 0.34, $I^2$ = 0%). There were no concerns in relation to publication bias (Egger's Regression = -1.47, p = 0.14) and the funnel plot appears relatively symmetrical (Figure 8).

**Figure 9.**

*Forest plot for studies with passive control groups measuring wellbeing at post-intervention*



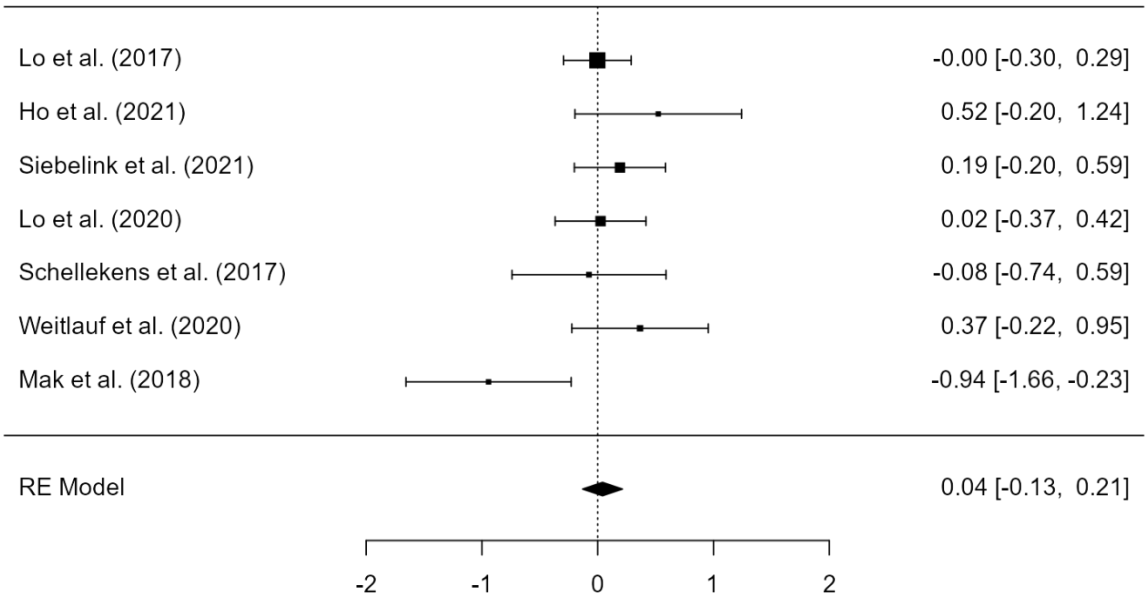

No follow-up data was reported for any of the above passive control studies in relation to measures of wellbeing.

***Mindfulness***

Figure 10 shows the post-intervention forest plot for passive control studies measuring mindfulness. MBI participants did not show significantly higher levels of post-intervention mindfulness compared to passive controls (Z = 0.47, p = 0.64, SMD = 0.04, 95% C.I.: -0.13 to 0.21). Effect sizes were not significantly heterogeneous (Q(6) = 10.98, p = 0.09, $I^2$ = 0%). There were no concerns in relation to publication bias (Egger's Regression = -0.41, p = 0.68) and the funnel plot appears relatively symmetrical (Figure 8).

**Figure 10.**

*Forest plot for studies with passive control groups measuring mindfulness at post-intervention*



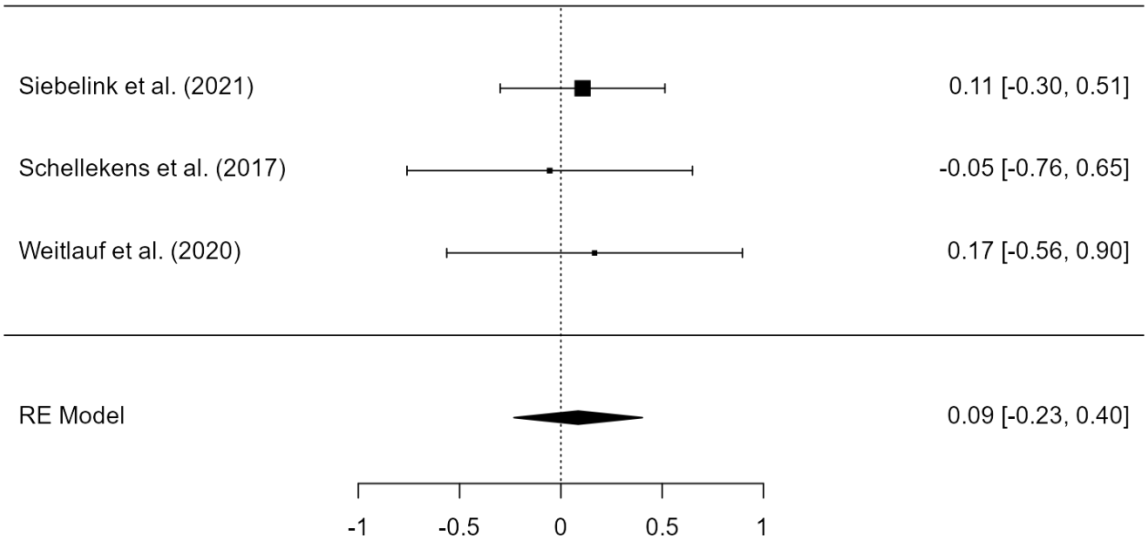

However, moderator analysis (see 'Moderation by study quality' section below) suggested these findings were possibly biased by study quality, with weaker studies reporting larger effects. As such, this meta-analysis was repeated excluding the 'weak' rated studies. MBI participants still did not show significantly higher levels of post-intervention mindfulness compared to passive controls (Z = -0.43, p = 0.67, SMD = -0.07, 95% C.I.: -0.37 to 0.24; Appendix A). Effect sizes were not significantly heterogeneous (Q(4) = 8.15, p =

0.09 , $I^2$ = 48.44%). The funnel plot was relatively symmetrical (Appendix A), and the publication bias test was insignificant (Egger's Regression = -0.88, p = 0.38).

Similarly, at follow-up, MBI participants did not show significantly higher levels of follow-up mindfulness compared to passive controls (Z = 0.53, p = 0.60, SMD = 0.09, 95% C.I.: -0.23 to 0.40; Figure 11). Again, there were no concerns in relation to heterogeneity (Q(2) = 0.21, p = 0.90, $I^2$ = 0%). There were no concerns in relation to publication bias (Egger's Regression = -0.14, p = 0.89) and the funnel plot appears relatively symmetrical despite the small number of studies (Figure 8).

**Figure 11.**

*Forest plot for studies with passive control groups measuring mindfulness at follow-up*




## Meta-analyses: Active Control Groups

### *Stress*

Figure 12 shows the post-intervention forest plot for active control studies measuring stress. MBI participants showed significantly lower levels of post-intervention stress compared to active controls (Z = -3.29, p = 0.001), favouring the intervention, with a small to medium pooled effect size (SMD = -0.31, 95% C.I.: -0.5 to -0.13). Effect sizes were not

significantly heterogeneous (Q(6) = 3.48, p = 0.75, $I^2$ = 0%). There was little evidence of a marked publication bias (Figure 13) and the publication bias test was insignificant (Egger's Regression = -0.12, p = 0.90).

**Figure 12.**

*Forest plot for studies with active control groups measuring stress at post-intervention*

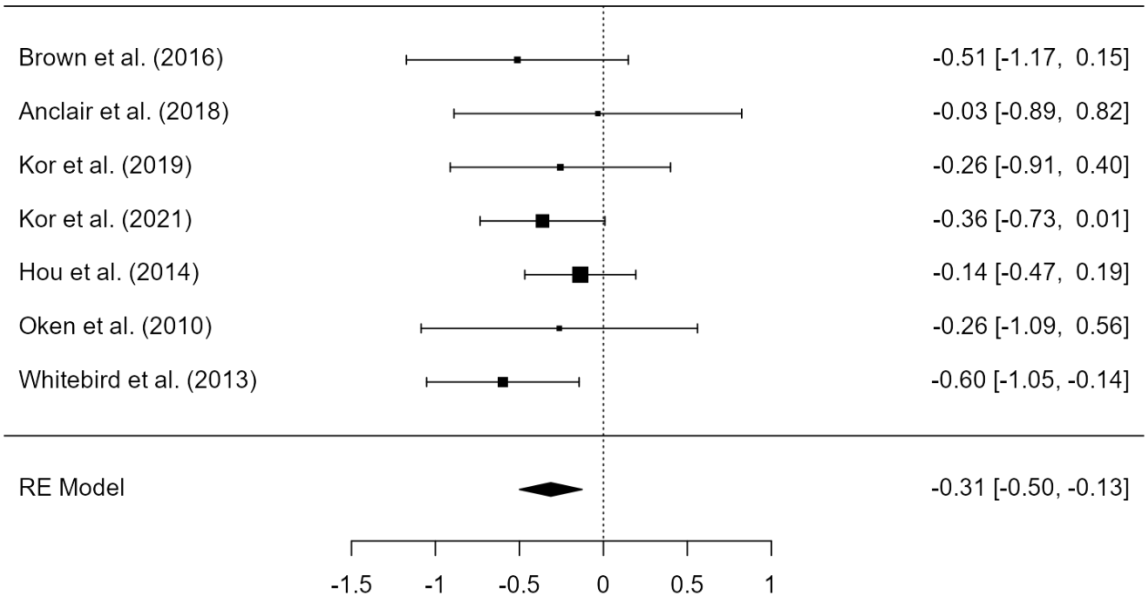
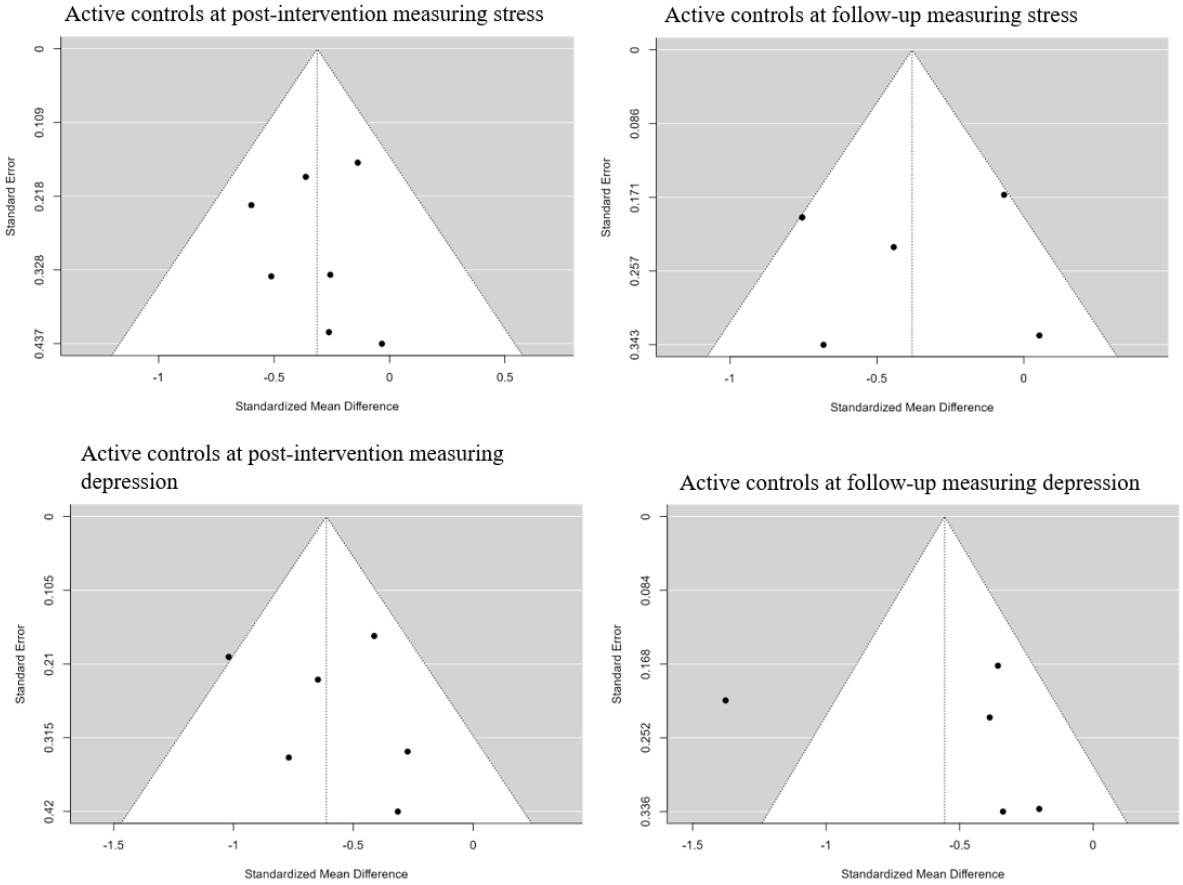


**Figure 13.**

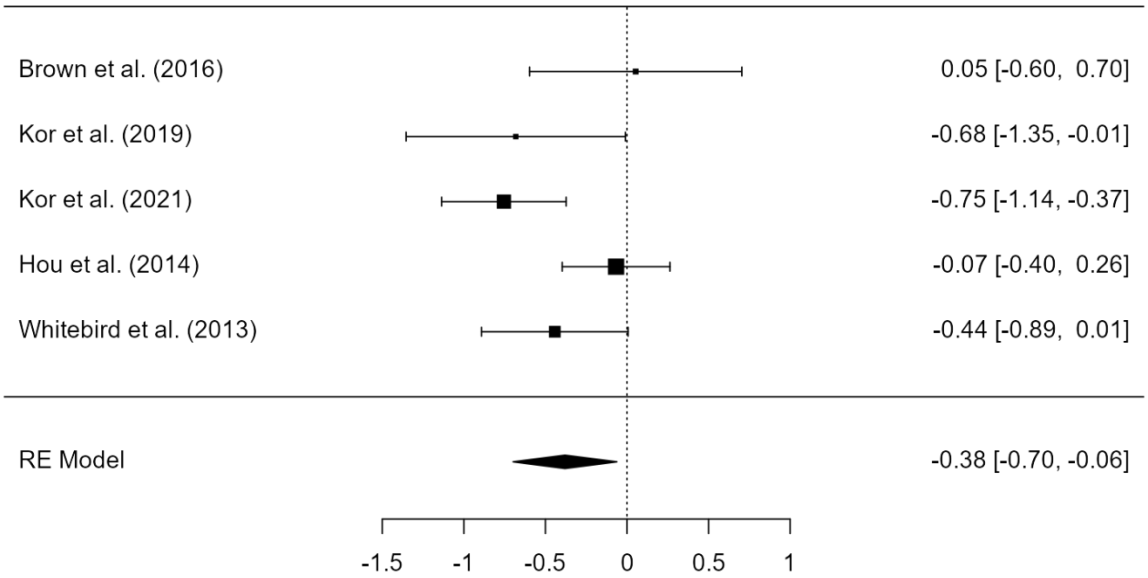
*Funnel plots for the four meta-analyses of active control studies measuring stress and depression*




This significant difference was also found at follow-up for active control studies measuring stress (Figure 14). MBI participants showed significantly lower levels of follow-up stress compared to active controls ($Z = -2.34$, $p = 0.019$), favouring the intervention, with a small to medium pooled effect size (SMD = -0.38, 95% C.I.: -0.70 to -0.06). The level of heterogeneity in effect sizes between studies was within the range that was appropriate for a random-effects meta-analysis ($Q(4) = 9.68$, $p = 0.05$, $I^2 = 56.81\%$). There was little evidence of a marked publication bias (Figure 13) and the publication bias test was insignificant (Egger's Regression = 0.003, $p = 1.00$).

**Figure 14.**

*Forest plot for studies with active control groups measuring stress at follow-up*

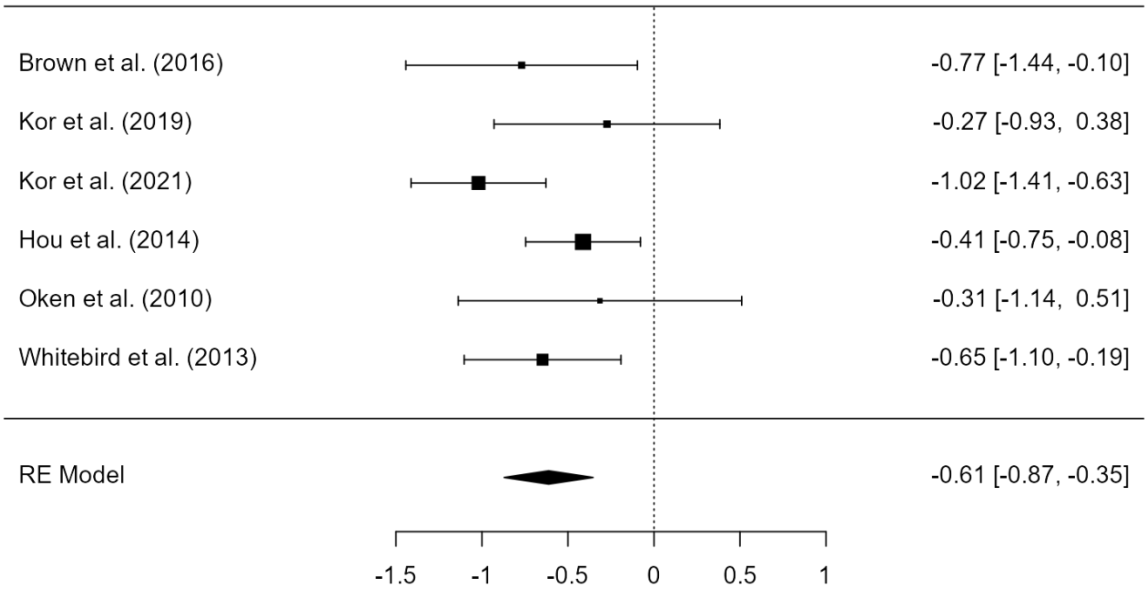



***Depression***

Figure 15 shows the post-intervention forest plot for active control studies measuring depression. MBI participants showed significantly lower levels of post-intervention depression compared to active controls ($Z = -4.64$, $p < 0.001$), favouring the intervention, with a medium to large pooled effect size (SMD = -0.61, 95% C.I.: -0.87 to -0.35). Effect sizes were not significantly heterogeneous ($Q(5) = 7.29$, $p = 0.20$, $I^2 = 36.13\%$). There was little evidence of a marked publication bias (Figure 13) and the publication bias test was insignificant (Egger's Regression = 0.59, $p = 0.55$).

**Figure 15.**

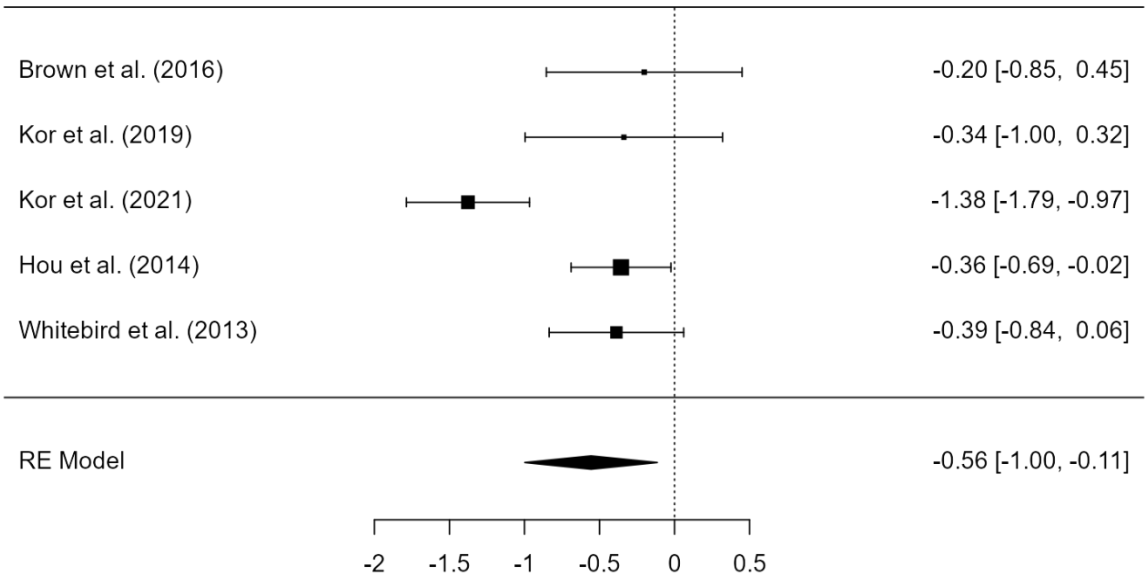
*Forest plot for studies with active control groups measuring depression at post-intervention*




This significant difference was also found at follow-up for active control studies measuring depression (Figure 16). MBI participants showed significantly lower levels of follow-up depression compared to active controls ($Z = -2.47$, $p = 0.014$), favouring the intervention, with a small to large pooled effect size (SMD = -0.56, 95% C.I.: -1.00 to -0.11). The level of heterogeneity in effect sizes between studies was within the range that was appropriate for a random-effects meta-analysis ($Q(4) = 18.73$, $p < 0.001$, $I^2 = 76.96\%$). Given the small number of studies the funnel plot is difficult to interpret but nevertheless there does appear to be some asymmetry (Figure 13), however, the test of publication bias was insignificant (Egger's Regression = 0.70, $p = 0.49$).

**Figure 16.**

*Forest plot for studies with active control groups measuring depression at follow-up*




### *Anxiety*

Figure 17 shows the post-intervention forest plot for active control studies measuring anxiety. MBI participants showed significantly lower levels of post-intervention anxiety compared to active controls ($Z = -4.55$, $p < .001$), favouring the intervention, with a small to medium pooled effect size (SMD = -0.48, 95% C.I.: -0.69 to -0.27). Effect sizes were not significantly heterogeneous ($Q(3) = 2.85$, $p = 0.42$, $I^2 = 0\%$). The funnel plot was relatively symmetrical (Figure 18), and the publication bias test was insignificant (Egger's Regression = 0.59, $p = 0.56$).

**Figure 17.**

*Forest plot for studies with active control groups measuring anxiety at post-intervention*

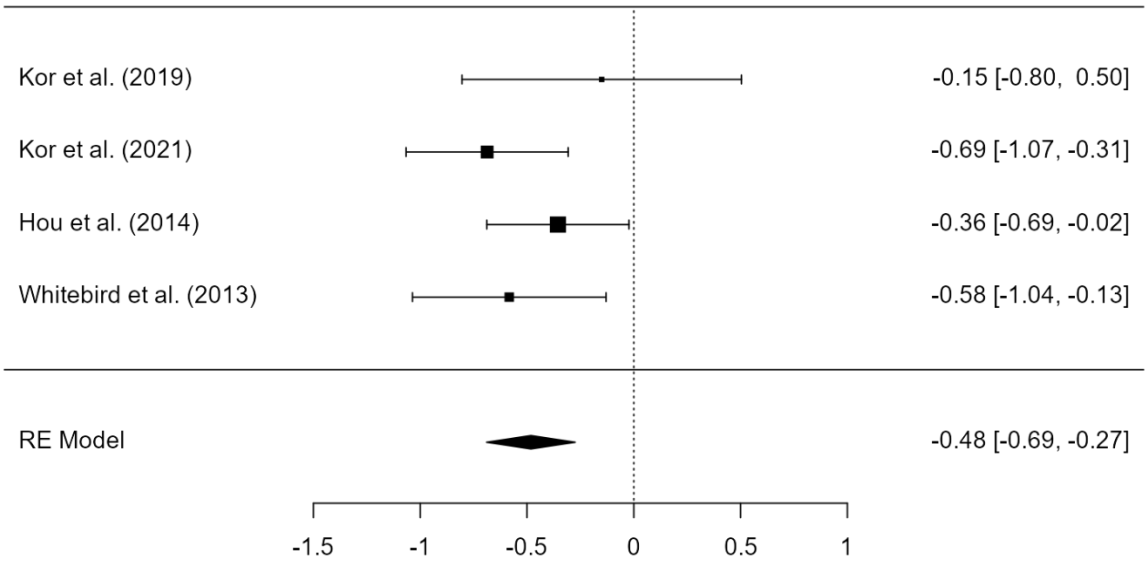
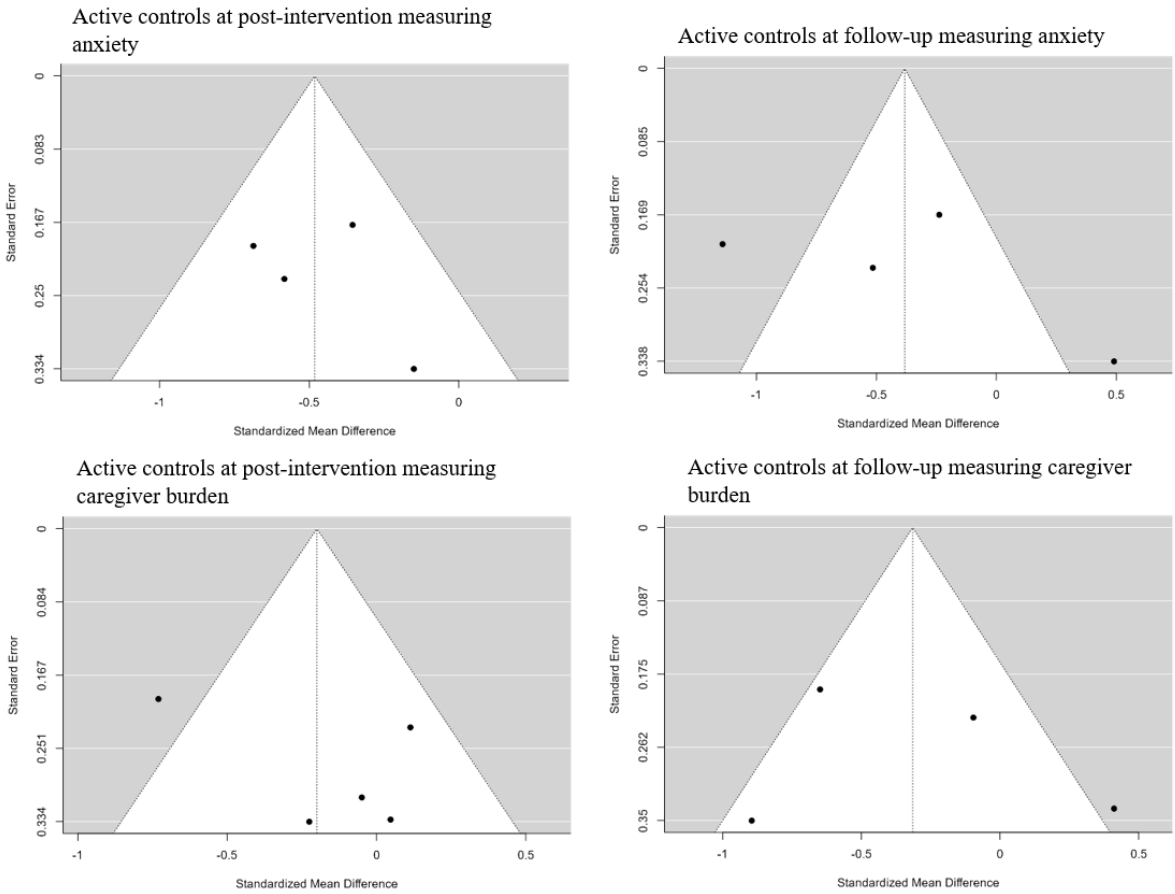



**Figure 18.**

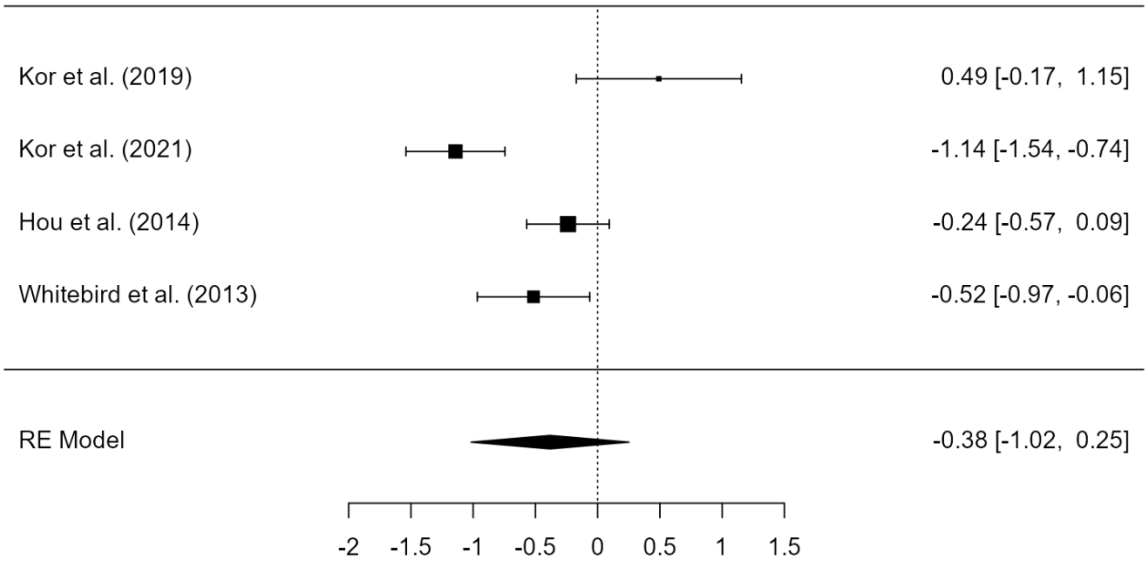
*Funnel plots for the four meta-analyses of active control studies measuring anxiety and caregiver burden*



However, these effects were not found at follow-up. MBI participants did not show significantly lower levels of follow-up anxiety compared to active controls (Z = -1.18, p = 0.24, SMD = -0.38, 95% C.I.: -1.02 to 0.25; Figure 19). The level of heterogeneity in effect sizes between studies was within the range that was appropriate for a random-effects meta-analysis (Q(3) = 20.95, p < 0.001, $I^2$ = 88%). Given the small number of studies the funnel plot is difficult to interpret but nevertheless there does appear to be some asymmetry (Figure 18), however the test of publication bias was insignificant (Egger's Regression = 1.27, p = 0.20).

**Figure 19.**

*Forest plot for studies with active control groups measuring anxiety at follow-up*



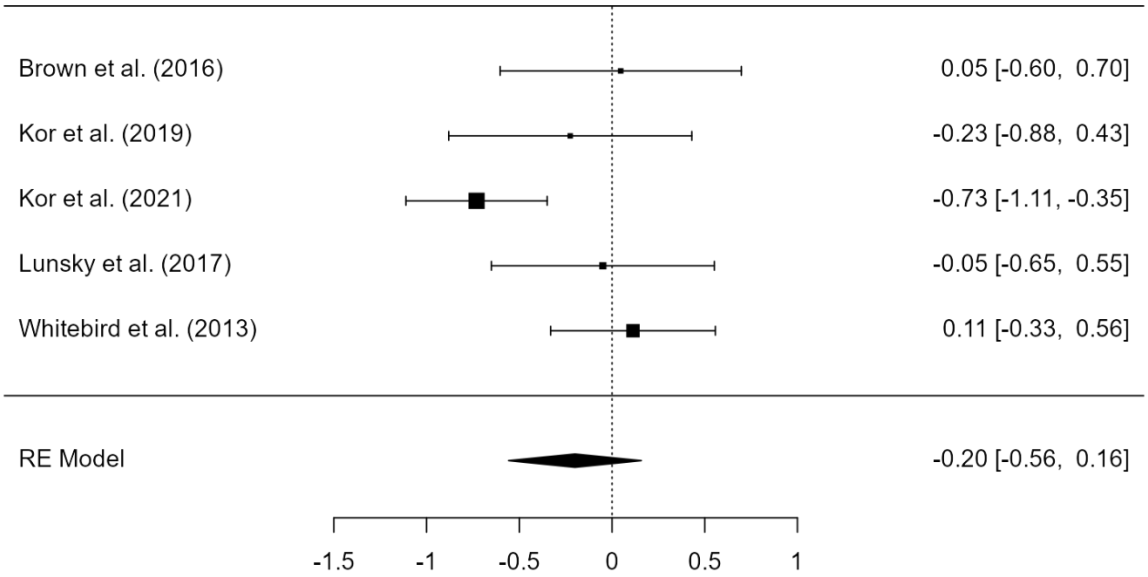

***Caregiver Burden***

Figure 20 shows the post-intervention forest plot for active control studies measuring caregiver burden. MBI participants did not show significantly lower levels of post-intervention caregiver burden compared to active controls (Z = -1.09, p = 0.27, SMD = -0.20, 95% C.I.: -0.56 to 0.16). The level of heterogeneity in effect sizes between studies was within

the range that was appropriate for a random-effects meta-analysis (Q(4) = 9.91, p = 0.04, $I^2$ = 56.38%). The funnel plot was relatively symmetrical (Figure 18), and the publication bias test was insignificant (Egger's Regression = 1.00, p = 0.32).

**Figure 20.**

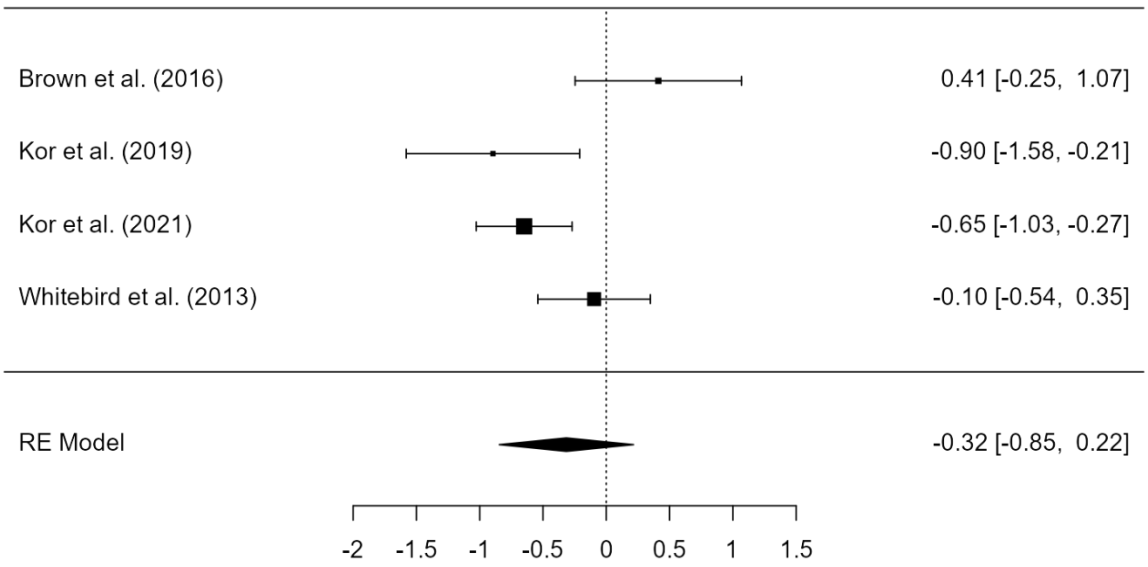
*Forest plot for studies with active control groups measuring caregiver burden at post-intervention*




Similarly, at follow-up, MBI participants did not show significantly lower levels of follow-up caregiver burden compared to active controls (Z = -1.16, p = 0.24, SMD = -0.32, 95% C.I.: -0.85 to 0.22; Figure 21). The level of heterogeneity in effect sizes between studies was within the range that was appropriate for a random-effects meta-analysis (Q(3) = 11.23, p = 0.01, $I^2$ = 75.97%). There were no concerns in relation to publication bias (Egger's Regression = 0.22, p = 0.82) and the funnel plot appears relatively symmetrical despite the small number of studies (Figure 18).

**Figure 21.**

*Forest plot for studies with active control groups measuring caregiver burden at follow-up*




### *Self-compassion*

Due to insufficient numbers (n=2) a meta-analysis was not performed for post-intervention self-compassion measures for active control studies. The findings from these two studies (Hou et al., 2014; Lunsky et al., 2017) both indicated that MBI participants did not show significantly different levels of self-compassion compared to active controls at post-intervention. Hou et al. (2014) also investigated effects at a 3-month follow-up, but again did not find any significant difference between groups.

### *Mental Health Quality of Life*

Figure 22 shows the post-intervention forest plot for active control studies measuring MH QoL. MBI participants did not show significantly higher levels of post-intervention MH QoL compared to active controls ($Z = 1.27$, $p = 0.27$, SMD = 0.18, 95% C.I.: -0.10 to 0.46). Effect sizes were not significantly heterogeneous ($Q(4) = 7.11$, $p = 0.13$, $I^2 = 45.68\%$). The funnel plot was relatively symmetrical (Figure 23), and the publication bias test was insignificant (Egger's Regression = -0.15, $p = 0.88$).

**Figure 22.**

*Forest plot for studies with active control groups measuring MH QoL at post-intervention*

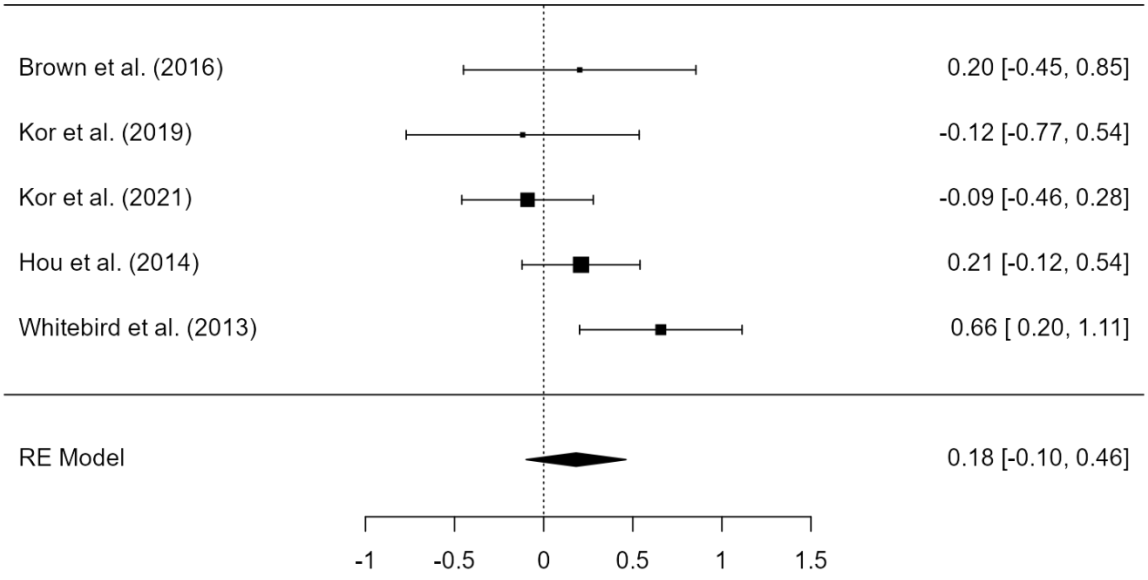
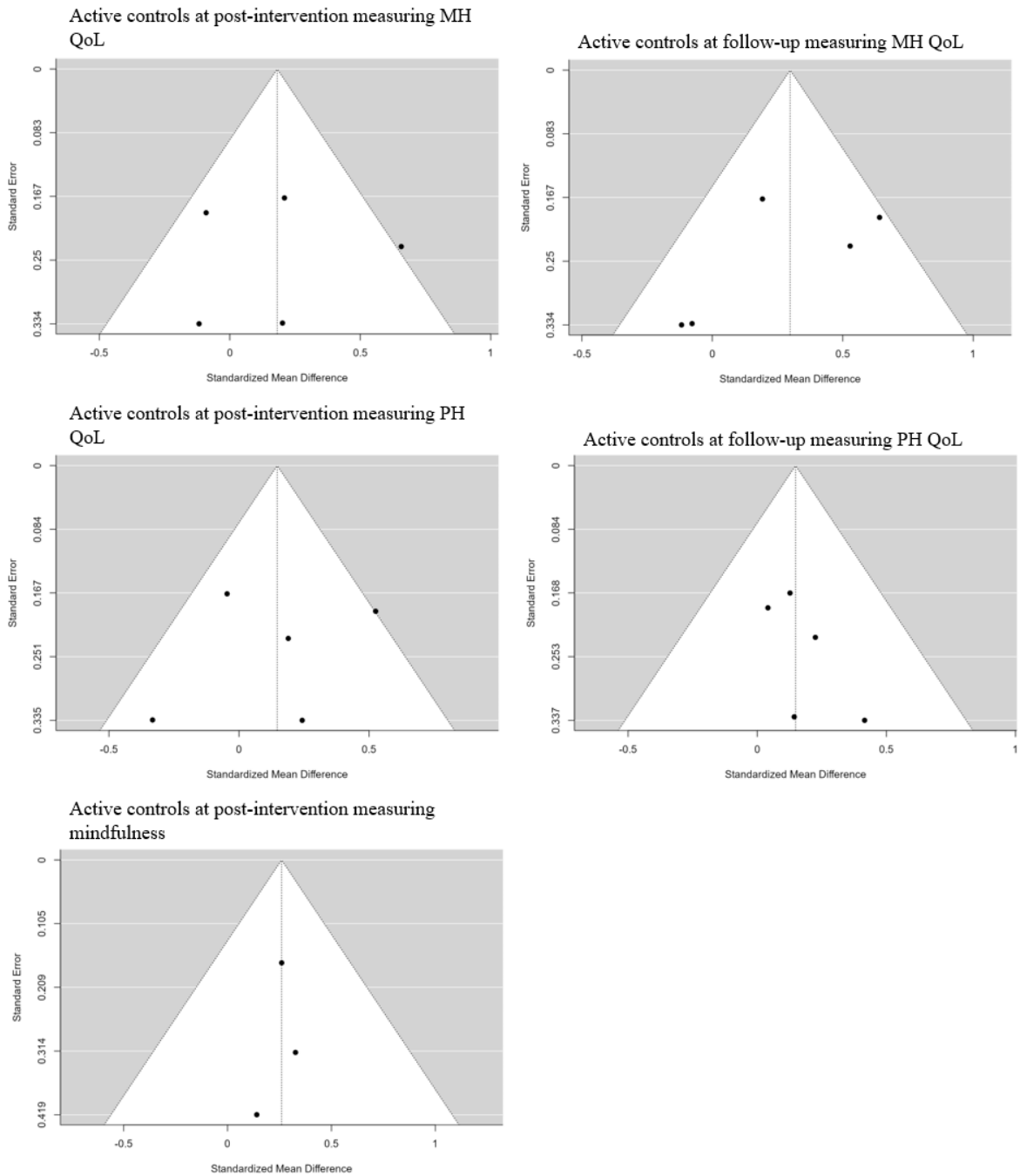


**Figure 23.**

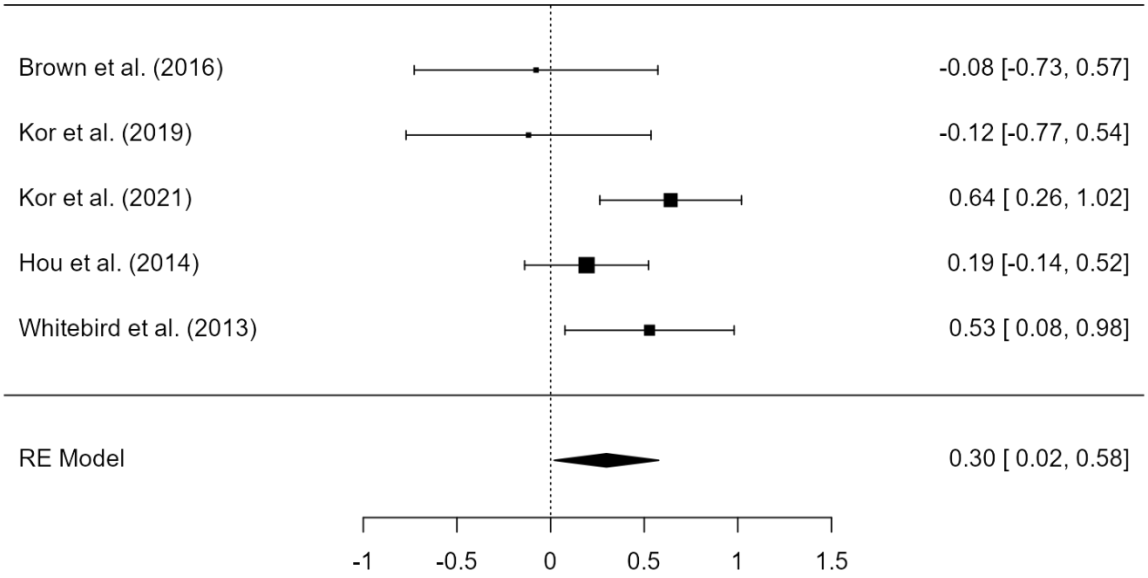
*Funnel plots for the five meta-analyses of active control studies measuring MH QoL, PH QoL, and mindfulness*



Interestingly, a significant effect was found at follow-up. MBI participants did show significantly higher levels of post-intervention MH QoL compared to active controls (Z = 2.09, p =0.04), favouring the intervention, with a small to medium pooled effect size (SMD = 0.30, 95% C.I.: 0.02 to 0.58; Figure 24). Effect sizes were not significantly heterogeneous (Q(4) = 7.31, p = 0.12, $I^2$ = 45.00%). The funnel plot was relatively symmetrical (Figure 23), and the publication bias test was insignificant (Egger's Regression = -1.30, p = 0.19).

**Figure 24.**

*Forest plot for studies with active control groups measuring MH QoL at follow-up*

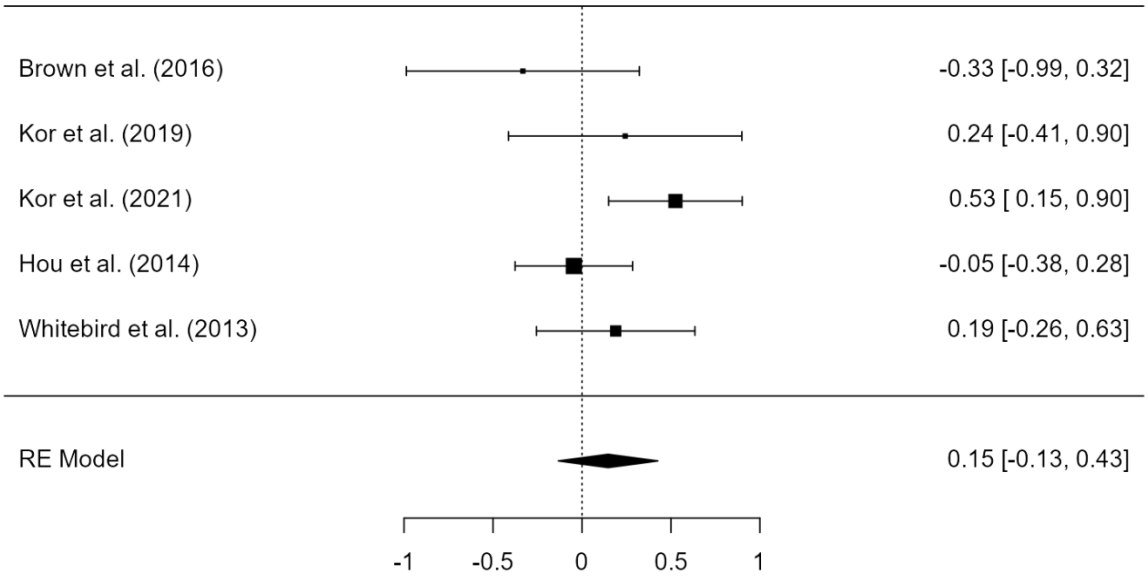



***Physical Health Quality of Life***

Figure 25 shows the post-intervention forest plot for active control studies measuring PH QoL. MBI participants did not show significantly higher levels of post-intervention PH QoL compared to active controls (Z = 1.03, p = 0.30, SMD = 0.15, 95% C.I.: -0.13 to 0.43). Effect sizes were not significantly heterogeneous (Q(4) = 7.38, p = 0.12, $I^2$ = 45.64%). The funnel plot was relatively symmetrical (Figure 23), and the publication bias test was insignificant (Egger's Regression = -0.58, p = 0.57).

**Figure 25.**

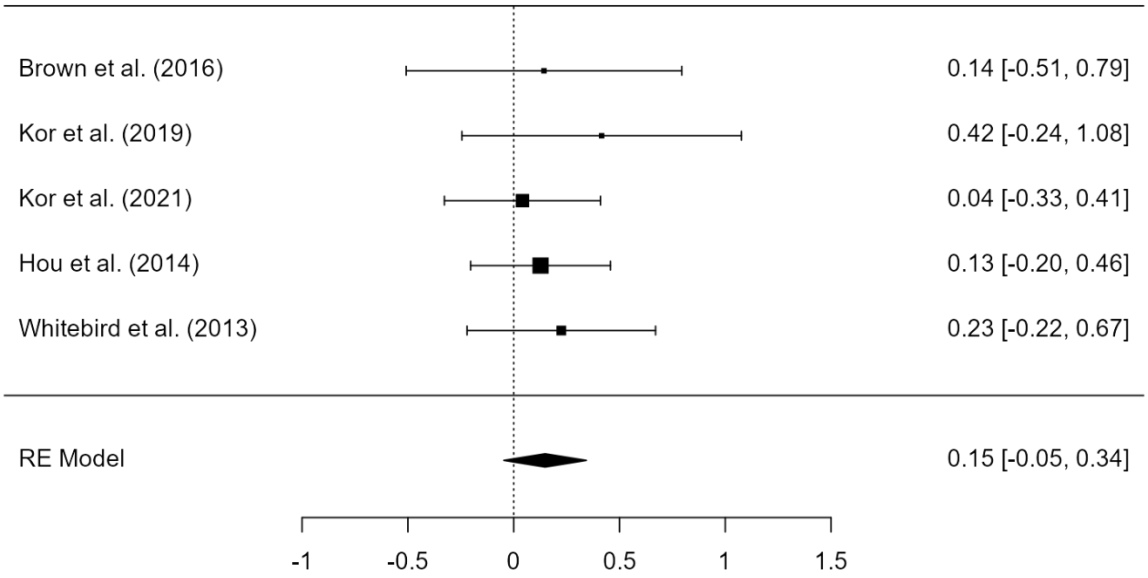
*Forest plot for studies with active control groups measuring PH QoL at post-intervention*




Similarly, no significant effect was found at follow-up. MBI participants did show significantly higher levels of post-intervention PH QoL compared to active controls (Z = 1.49, p = 0.14, SMD = 0.15, 95% C.I.: -0.05 to 0.34; Figure 26). Effect sizes were not significantly heterogeneous (Q(4) = 1.08, p = 0.90, $I^2$ = 45.00%). The funnel plot was relatively symmetrical (Figure 23), and the publication bias test was insignificant (Egger's Regression = 0.70, p = 0.49).

**Figure 26.**

*Forest plot for studies with active control groups measuring PH QoL at follow-up*




### *Wellbeing*

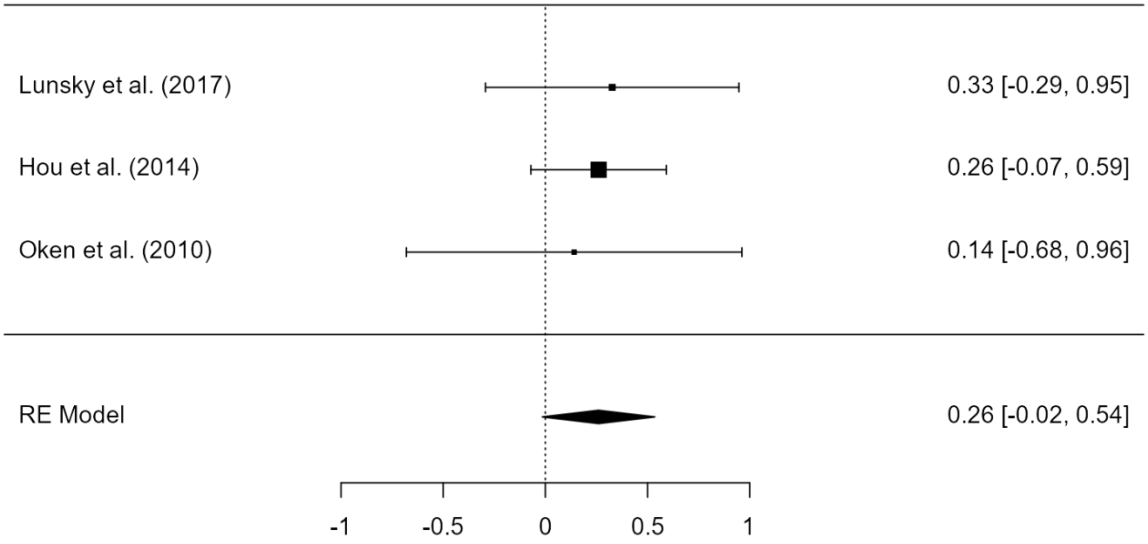
There were no active control studies exploring wellbeing at post-intervention or follow-up. All studies investigating this outcome (n=4) had a passive control group.

### *Mindfulness*

Figure 27 shows the post-intervention forest plot for active control studies measuring mindfulness. MBI participants did not show significantly higher levels of post-intervention mindfulness compared to active controls, but the finding was near to significance ($Z = 1.85$, $p = 0.06$, SMD = 0.26, 95% C.I.: -0.02 to 0.54). Effect sizes were not significantly heterogeneous ($Q(2) = 0.13$, $p = 0.94$, $I^2 = 0\%$). The funnel plot was relatively symmetrical (Figure 23), and the publication bias test was insignificant (Egger's Regression = -0.11, $p = 0.91$).

**Figure 27.**

*Forest plot for studies with active control groups measuring mindfulness at post-intervention*




Due to insufficient numbers (n=1) it was not possible to perform a meta-analysis on follow-up data for active control studies measuring mindfulness. However, the study which did investigate these effects (Hou et al., 2014) reported significant differences between groups at the 3-month follow-up, favouring those who received the MBSR intervention.

**Moderation by study quality**

To examine whether the meta-analyses findings were moderated by study quality, each of the analyses with >3 studies was repeated with their quality rating total scores included as a moderator. As can been seen in Table 7, this moderator was only significant for the analysis of depression levels at post-intervention with passive controls. Findings also approached significance for analysis of mindfulness levels at post-intervention with passive controls. As such, these analyses were repeated excluding the 'weak' rated studies. Doing so resulted in no significant difference between groups. Results of these analyses are provided in their respective sections.

**Table 7.**

*Results of moderator analysis*

| Meta-analysis | Estimate | se | Z | P |
|---|---|---|---|---|
| Passive | | | | |
| Stress post-intervention | -0.07 | 0.19 | -0.39 | 0.70 |
| Stress follow-up | - | - | - | - |
| Depression post-intervention | -0.55 | 0.16 | -3.50 | <.001* |
| Anxiety post-intervention | - | - | - | - |
| Self-compassion post-intervention | - | - | - | - |
| Wellbeing post-intervention | 0.17 | 0.34 | 0.50 | 0.62 |
| Mindfulness post-intervention | 0.19 | 0.10 | 1.86 | 0.06# |
| Mindfulness follow-up | - | - | - | - |
| Active | | | | |
| Stress post-intervention | -0.03 | 0.10 | -0.31 | 0.75 |
| Stress follow-up | -0.33 | 0.22 | -1.50 | 0.13 |
| Depression post-intervention | 0.05 | 0.22 | 0.22 | 0.83 |
| Depression follow-up | -0.02 | 0.41 | -0.04 | 0.97 |
| Anxiety post-intervention | -0.004 | 0.20 | -0.02 | 0.99 |
| Anxiety follow-up | 0.33 | 0.53 | 0.61 | 0.54 |
| Caregiver burden post-intervention | 0.09 | 0.42 | 0.22 | 0.84 |
| Caregiver burden follow-up | -0.74 | 0.65 | -1.15 | 0.25 |
| MH QoL post-intervention | -0.13 | 0.26 | -0.50 | 0.62 |
| MH QoL follow-up | -0.09 | 0.27 | -0.34 | 0.74 |
| PH QoL post-intervention | 0.17 | 0.24 | 0.71 | 0.48 |
| PH QoL follow-up | 0.08 | 0.16 | 0.51 | 0.61 |
| Mindfulness post-intervention | - | - | - | - |

*Note.* * $p < 0.05$, #p value approached significance at 0.05 level

## Summary of findings

A summary of the above findings is provided in Table 8.

**Table 8.**

*Summary of meta-analyses findings*

| Measure | Passive controls post-intervention | | | | | Passive controls follow-up | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Total studies (n) | Total participants (n) | Estimate | CI | P | Total studies (n) | Total participants (n) | Estimate | CI | P |
| Stress | 10 | 584 | -0.59 | -0.94 to -0.24 | <.001* | 3 | 118 | -0.68 | -1.20 to -0.16 | 0.01* |
| Depression | 5 | 332 | -0.80 | -1.44 to -0.16 | 0.015* | 1 | | | Insufficient studies | |
| Anxiety | 3 | 90 | -0.54 | -0.96 to -0.11 | 0.013* | 1 | | | Insufficient studies | |
| Caregiver burden | 2 | | | Insufficient studies | | 1 | | | Insufficient studies | |
| Self-compassion | 3 | 168 | 0.35 | -0.10 to 0.80 | 0.12 | 2 | | | Insufficient studies | |
| MH QoL | 0 | | | Insufficient studies | | 0 | | | Insufficient studies | |
| PH QoL | 0 | | | Insufficient studies | | 0 | | | Insufficient studies | |
| Wellbeing | 4 | 268 | 0.21 | -0.03 to 0.45 | 0.08 | 0 | | | Insufficient studies | |
| Mindfulness | 7 | 525 | 0.04 | -0.13 to 0.21 | 0.64 | 3 | 153 | 0.09 | -0.23 to 0.40 | 0.60 |
| | Active controls post-intervention | | | | | Active controls follow-up | | | | |
| | Total (n) | | Estimate | CI | P | Total (n) | | Estimate | CI | P |
| Stress | 7 | 455 | -0.31 | -0.5 to -0.13 | 0.001* | 5 | 406 | -0.38 | -0.70 to -0.06 | 0.019* |
| Depression | 6 | 434 | -0.61 | -0.87 to -0.35 | 0.001* | 5 | 406 | -0.56 | -1.00 to -0.11 | 0.014* |
| Anxiety | 4 | 368 | -0.48 | -0.69 to -0.27 | < .001* | 4 | 368 | -0.38 | -1.02 to 0.25 | 0.24 |
| Caregiver burden | 5 | 309 | -0.20 | -0.56 to 0.16 | 0.27 | 4 | 265 | -0.32 | -0.85 to 0.22 | 0.24 |
| Self-compassion | 2 | | | Insufficient studies | | 1 | | | Insufficient studies | |
| MH QoL | 5 | 406 | 0.18 | -0.10 to 0.46 | 0.27 | 5 | 406 | 0.30 | 0.02 to 0.58 | 0.04* |
| PH QoL | 5 | 406 | 0.15 | -0.13 to 0.43 | 0.30 | 5 | 406 | 0.15 | -0.05 to 0.34 | 0.14 |
| Wellbeing | 0 | | | Insufficient studies | | 0 | | | Insufficient studies | |
| Mindfulness | 3 | 111 | 0.26 | -0.02 to 0.54 | 0.06 | 1 | | | Insufficient studies | |

*Note.* * $p < 0.05$

**Studies not included in meta-analyses**

Two studies did not have the required data to be included in the meta-analyses (Dykens et al., 2014; Neece, 2014). Neece's study utilised a passive control design without follow-up, whereas Dykens et al. had an active control group with follow-up. Consistent with the meta-analysis findings, both studies found levels of depression were significantly reduced in carers who received the MBI at post-intervention, with Dykens et al. also confirming significant differences at follow-up. Both studies also reported on measures of stress in carers, however only Neece found a significant difference between groups at post-intervention. Dykens et al. also explored anxiety and wellbeing, reporting anxiety levels significantly reduced at both post-intervention and follow-up, and wellbeing levels significantly increased by follow-up.

# Discussion

## Summary of findings

This review aimed to explore the effects of MBIs on measures of psychological wellbeing in informal carers. The meta-analyses found MBIs reduced levels of stress, depression, and anxiety at post-intervention in carers who received an MBI compared to passive and active controls, with small to large effect sizes. Effects on stress were also maintained at follow-up in both passive and active control studies, and for measures of depression at follow-up in studies using active controls (there were insufficient passive control studies). Meta-analyses did not find levels of caregiver burden, self-compassion, MH and PH QoL, or wellbeing were significantly affected in those who received an MBI at post-intervention. However, levels of MH QoL appeared significantly higher at follow-up compared to active controls. Despite the focus on mindfulness techniques within MBIs, participants' levels of mindfulness did not appear to change in those who received the MBI compared to controls. Nonetheless, the active control meta-analysis had a low number of studies and findings were close to significance.

The findings related to reduced levels of stress and low mood quantitatively support Li et al's (2016) narrative review and were expected given they are the primary difficulties MBSR and MBCT were developed to target (Kabat-Zinn, 1990; Segal et al., 2012). As would be expected on the basis of mindfulness theory, by encouraging carers to enter 'being mode' (Segal, 2012), they are enabled to find ways to live alongside some of challenges of caring (Carers UK, 2019). This ultimately reduces their experiences of psychological distress, likely prompted by various discrepancies which are difficult to change but which generate feelings of 'failure', and reduce vulnerabilities for future relapse as indicated by the follow-up data (Hick & Chan, 2010).

The estimated effect sizes varied between control type and were larger in studies using passive controls. This aligns with previous meta-analyses exploring effects of MBIs in non-carer populations which found smaller effects in analyses of active control studies compared to no treatment (Goldberg et al., 2018: Khoury et al. 2013). Nevertheless, the significant findings from active control analyses provide reassuring evidence that MBIs may still offer a useful resource for carers experiencing stress or low mood. Furthermore, MBIs may offer something additional to the interventions typically accessed by carers. MBIs were more successful at alleviating stress and depression compared to social support, educational groups, self-help, and respite. Additionally, MBIs may provide skills which later serve to improve MH QoL when applied over an extended period, compared to other non-MBI treatments. This is not a finding found in past reviews (Li et al., 2016), but may reflect outcomes by Ribeiro et al. (2018) who reported QoL measures continued to increase after the MBI, with the highest levels observed 8-weeks post-intervention.

Overall, estimated effect sizes within this review appear slightly greater than past meta-analyses exploring MBIs in other populations. For example, Goldberg et al. (2018) explored MBIs (versus other specific active treatments) in clinical populations and estimated small to medium effect sizes for depression at post-intervention. This is comparatively less than the medium to large effects estimated with this review. Additionally, effect sizes for stress were small to medium in Burton et al’s (2017) review of MBIs for healthcare professionals, compared to the small to large estimate within this review. However, these differences may be attributed to variations in the population and severity of symptoms at baseline.

Similarly, the effect size estimates within this review appear greater than those in meta-analyses exploring alternative evidence-based interventions. For example, Hopkinson et al. (2017) reviewed CBT for carers, reporting small to medium effects for depression and

stress, compared to the small to large effects estimated with this review. Additionally, no significant effect was found on levels of anxiety in CBT, however small to large effects were estimated in this review. Nonetheless, Hopkinson et al. only reviewed carers of people with dementia. Further research is required to explore if other evidence-based interventions offer greater benefits to informal carers more broadly.

Lastly, an interesting finding relates to absence of effect on mindfulness, despite improvements in stress, depression, and anxiety. Typically, mindfulness is considered a key mechanism of change (Keng et al., 2012; Verhaeghen, 2021). As the p-value approached significance at post-intervention in active control studies, this finding possibly represents a Type II error. Alternatively, improvements may have been brought about by the context of group therapy, independent of the intervention. Newbold et al. (2013) suggested benefits include normalisation, connection, cohesion, and increased hope. Alternatively, other mechanisms of change may be underlying the therapeutic effects of MBIs. Gu et al. (2015) identified cognitive and emotional reactivity as strong mechanisms underlying MBCT and MBSR's effects, however these were not measured.

**Critique**

All studies were rated moderate or weak in quality. Selection bias was rated ‘weak’ in the majority of studies, therefore it is likely their participant pools did not represent the target populations. Confounder measurement was also poorly reported in several studies, therefore groups may not have been balanced with respect to important variables prior to the intervention (Skelly et al., 2012). Nonetheless, the use of randomisation potentially reduced this (Pourhoseingholi et al., 2012), however, this would not have been true for the two non-RCT designs. Furthermore, despite the evidence-base supporting the chosen appraisal tool (EPHPP; Armijo-Olivo et al., 2021), the guidance surrounding confounders was considered

to be open to interpretation, therefore the researcher was required to specify further detail to mitigate against disagreement with the second reviewer.

Whilst the Egger's regression test did not indicate the presence of significant publication bias, some funnel plots appeared to show some asymmetry. As such, there is a risk that unpublished work may exist that did not find significant results, possibly giving a false impression of significance (Clark-Carter, 2010). However, interpretation was imprecise due to the small number of studies, so results should be interpreted with caution until further corroborating research is available.

The significant findings at follow-up on levels of stress and depression are a promising indication that MBIs may have sustained effects. However, the average length of follow-up was four months for stress and depression. As such, we cannot suggest whether benefits continue beyond this, and given the prolonged role of caring, this is a clear limitation of the research.

Finally, several studies did not report on key demographics of participants, most notably ethnic background (n = 16), limiting which groups the results apply to. Those which did report consisted predominantly of white females above 40-years. Results cannot be extrapolated to young carers, males or other gender identities, and many ethnic backgrounds. Additionally, many participants self-referred. Whilst this demonstrates many carers are able and willing to engage in MBIs despite challenges (Carers UK, 2019), we cannot be certain if those who did not participate differed significantly (e.g., in role or background). Lastly, whilst a large number of carer-receiver conditions were explored, it did not include all common conditions/difficulties needing support (e.g., mental health difficulties, children with food allergies, diabetes etc.).

**Clinical implications**

The large pool of research into this area demonstrates that there is a demand for interventions in informal carers. Given the substantial economic contribution carers provide to society (ONS, 2017), clinicians should be aware of and routinely refer them to evidence-based treatments to support them in their roles. The meta-analyses suggest that MBIs may be beneficial to some carers where stress or low mood is problematic, however, given the likely selection bias, they may not offer a good fit for all. Low attrition rates also suggest MBIs offer a feasible treatment for many carers despite their challenging roles. The evidence was largely based on MBCT and MBSR protocols (Kabat-Zinn, 1990; Segal et al., 2012), and therefore these protocols should primarily be used to guide mindfulness treatment programmes. Settings in which carer-based MBI's could be introduced may include specialist NHS health clinics or primary care mental health services (e.g., IAPT). Additionally, some third sector organisations (e.g., City and Hackney Carers Centre) already offer mindfulness sessions and therefore other carer-support charities should consider building these into their support programmes.

**Future research**

Whilst two studies are the minimum requirement for a meta-analysis (Ryan, 2016), some findings may have been impacted by the small number of trials. Mindfulness (active controls; n = 3) and wellbeing (passive controls; n = 4) both approached the 0.05 level of significance and therefore further trials are required to confidently suggest whether effects exist. Additionally, future research should explore extended follow-up periods. Solhaug et al. (2019) suggest benefits of MBIs can be sustained for four years post-intervention, however this is yet to be explored within informal carers. The quality of future research also requires consideration, whereby researchers should aim to recruit from comprehensive lists of the target population, consistently measure for confounders and ensuring blinding where

possible. It is important that future research recruits participants not represented in the current evidence-base, including those from different ethnic backgrounds, genders, and young ages, as research has shown these groups experience the same, if not more, challenges in their caring roles (Children's Society, 2016; Department of Health, 2008; Katbamna et al., 2004). Finally, there were several groups of carers not represented in the evidence-base (e.g., mental health difficulties, children with food allergies, diabetes etc.), therefore further research is warranted to explore the effects of MBIs within these specific populations also.

## Conclusion

To the author's knowledge this is the first review quantitively evaluating the efficacy of MBIs for informal carers. This review has provided further evidence for the therapeutic benefits of these interventions, particularly in relation to levels of stress and depression, at both post-intervention and several months later. There was also some evidence for the reduction in anxiety at post-intervention and MH QoL at follow-up. However, it was not clear which mechanisms of change influenced outcomes. More research is warranted as many studies lack quality, particularly in relation to selection bias. Furthermore, clearer demographic data and longer follow-up periods are necessary, and studies should continue exploring MBIs within carer groups that are yet to be researched.

## References

Abidin, R. R. (1990). *Parenting stress index manual (3rd. edition).* Pediatric Psychology Press.

Age UK. (2021, January 17). *Looking after yourself as a carer.* https://www.ageuk.org.uk/information-advice/care/helping-a-loved-one/getting-support-and-looking-after-yourself/

Akkerman, R. L., & Ostwald, S. K. (2004). Reducing anxiety in Alzheimer's disease family caregivers: the effectiveness of a nine-week cognitive-behavioral intervention. *American Journal of Alzheimer's Disease & Other Dementias*, *19*(2), 117-123. https://doi.org/10.1177%2F153331750401900202

Al Daken, L. I., & Ahmad, M. M. (2018). The implementation of mindfulness-based interventions and educational interventions to support family caregivers of patients with cancer: A systematic review. *Perspectives in Psychiatric Care, 54*(3), 441–452. https://doi.org/10.1111/ppc.12286

Anclair, M., Lappalainen, R., Muotka, J., & Hiltunen, A. J. (2018). Cognitive behavioural therapy and mindfulness for stress and burnout: a waiting list-controlled pilot study comparing treatments for parents of children with chronic conditions. *Scandinavian Journal of Caring Sciences, 32*(1), 389-396. https://doi.org/10.1111/scs.12473

Armijo-Olivo, S., Stiles, C. R., Hagen, N. A., Biondo, P. D., & Cummings, G. G. (2012). Assessment of study quality for systematic reviews: a comparison of the Cochrane Collaboration Risk of Bias Tool and the Effective Public Health Practice Project Quality Assessment Tool: methodological research. *Journal of Evaluation in Clinical Practice, 18*(1), 12-18. https://doi.org/10.1111/j.1365-2753.2010.01516.x

Baer, R. A., Smith, G. T., Hopkins, J., Krietemeyer, J., & Toney, L. (2006). Using self-report assessment methods to explore facets of mindfulness. *Assessment, 13*(1), 27–45. https://doi.org/10.1177%2F1073191105283504

Beck A. T., Rush A. J., Shaw B. F., & Emery G. (1979). *Cognitive therapy of depression*. Guilford Publications.

Beck, A. T., Ward, C. H., Mendelson, M., Mock, J., & Erbaugh, J. (1961) An inventory for measuring depression. *Archives of General Psychiatry, 4*, 561-571. https://doi.org/10.1001/archpsyc.1961.01710120031004

Behbahani, M., Zargar, F., Assarian, F., & Akbari, H. (2018). Effects of mindful parenting training on clinical symptoms in children with attention deficit hyperactivity disorder and parenting stress: Randomized controlled trial. *Iranian Journal of Medical Sciences, 43*(6), 596.

Berk, L., Warmenhoven, F., van Os, J., & van Boxtel, M. P. J. (2018). Mindfulness training for people with dementia and their caregivers: Rationale, current research, and future directions. *Frontiers in Psychology*, *9*, 110–123. https://doi.org/10.3389/fpsyg.2018.00982

Bigatti S., Steiner J. L. (2014). Appraisal of Caregiving Scale. In A. C. Michalos (Ed.) *Encyclopaedia of Quality of Life and Well-Being Research*. Springer. https://doi.org/10.1007/978-94-007-0753-5_101

Biliunaite, I., Kazlauskas, E., Sanderman, R., Truskauskaite-Kuneviciene, I., Dumarkaite, A., & Andersson, G. (2021). Internet-Based Cognitive Behavioral Therapy for Informal Caregivers: Randomized Controlled Pilot Trial. *Journal of Medical Internet Research*, *23*(4), e21466. https://doi.org/10.2196/21466

Birtha, M., & K. Holm. (2017, January 17). *Who Cares? Study on the Challenges and Needs of Family Carers in Europe.* Coface Families Europe. http://www.coface-eu.org/wp content/uploads/2017/11/COFACE-Families-Europe_Study-Family-Carers.pdf.

Bögels, S. M., & Restifo, K. (2013). *Mindful Parenting: A Guide for Mental Health Practitioners.* Springer.

Bögels, S. M., Hoogstad, B., van Dun, L., de Schutter, S., & Restifo, K. (2008). Mindfulness training for adolescents with externalizing disorders and their parents. *Behavioural and Cognitive Psychotherapy*, *36*(2), 193-209. https://doi.org/10.1017/S1352465808004190

Bögels, S.M. (2020). *MYmind. Mindfulness for youth with ADHD, and their parents: A guide for practitioners.* Lannoo Campus.

Borenstein, M., Hedges, L. V., Higgins, J. P., & Rothstein, H. R. (2021). *Introduction to meta-analysis*. John Wiley & Sons.

Brown, K. W., & Ryan, R. M. (2003). The benefits of being present: Mindfulness and its role in psychological well-being. *Journal of Personality and Social Psychology*, *84*, 822-848. https://doi.org/10.1037/0022-3514.84.4.822

Brown, K. W., Coogle, C. L., & Wegelin, J. (2016). A pilot randomized controlled trial of mindfulness-based stress reduction for caregivers of family members with dementia. *Aging and Mental Health*, *20*(11), 1157-1166. https://doi.org/10.1080/13607863.2015.1065790

Burton, A., Burgess, C., Dean, S., Koutsopoulou, G., & Hugh-Jones, S. (2017). How effective are mindfulness-based interventions for reducing stress among healthcare professionals: A systematic review and meta-analysis? *Stress and Health*, *33*(1), 3-13. https://doi.org/10.1002/smi.2673

Carers UK. (2019, January 17). *State of caring report.* http://www.carersuk.org/images/News__campaigns/CUK_State_of_Caring_2019_Report.pdf

Carers UK. (2021, January 17). *Why we're here.* https://www.carersuk.org/about-us/why-we-re-here

Chan, N., & Neece, C. L. (2017). Mindfulness-based stress reduction for parents of children with developmental delays: A follow-up study. *Evidence-Based Practice in Child and*

*Adolescent Mental Health*, *3*(1), 16-29. https://doi.org/10.1080/23794925.2017.1399484

Chi, N. C., & Demiris, G. (2015). A systematic review of telehealth tools and interventions to support family caregivers. *Journal of Telemedicine and Telecare*, *21*(1), 37-44. https://doi.org/10.1177%2F1357633X14562734

Chien, W. T., & Norman, I. (2009). The effectiveness and active ingredients of mutual support groups for family caregivers of people with psychotic disorders: a literature review. *International Journal of Nursing Studies*, *46*(12), 1604-1623. https://doi.org/10.1016/j.ijnurstu.2009.04.003

Children's Society. (2016). *The challenges of estimating the number of young carers and knowing how to meet their needs*. https://www.childrenssociety.org.uk/sites/default/files/CFD094_YoungCarers_Report_V10_LOW%20RES%20SINGLE%20PAGES.pdf

Clark-Carter, D. (2010). *Quantitative psychological research: the complete student's comparison.* Psychology Press.

Coatsworth, J. D., Duncan, L. G., Berrena, E., Bamberger, K. T., Loeschinger, D., Greenberg, M. T., & Nix, R. L. (2014). The mindfulness-enhanced strengthening families program: integrating brief mindfulness activities and parent training within an evidence-based prevention program. In E. Oberle & K. Schonert-Reichl (Eds.), *Mindfulness in Adolescence* (pp. 45–58). Jossey-Bass.

Cohen, S., Kamarck, T., Mermelstein, R. (1983). A global measure of perceived stress. *Journal of Health and Social Behavior*, *24*(4), 385–396. https://doi.org/10.2307/2136404

Collins, R. N., Gilligan, L. J., & Poz, R. (2018). The evaluation of a compassion-focused therapy group for couples experiencing a dementia diagnosis. *Clinical Gerontologist*, *41*(5), 474-486. https://doi.org/10.1080/07317115.2017.1397830

Crane, R. S., Brewer, J., Feldman, C., Kabat-Zinn, J., Santorelli, S., Williams, J. M. G., & Kuyken, W. (2017). What defines mindfulness-based programs? The warp and the weft. *Psychological Medicine*, *47*(6), 990-999. https://doi.org/10.1017/S0033291716003317

Crombie, I. K., & Davies, H. T. (2009). *What is meta-analysis?* Hayward Medical Communications.

Cunningham, J. A., Kypri, K., McCambridge, J. (2013). Exploratory randomized controlled trial evaluating the impact of a waiting list control design. *BMC Medical Research Methodology*, *13*(1), 150. https://www.doi/10.1186/1471-2288-13-150

De Bruin, E. I., Blom, R., Smit, F. M., van Steensel, F. J., & Bögels, S. M. (2015). MYmind: Mindfulness training for youngsters with autism spectrum disorders and their parents. *Autism*, *19*(8), 906-914. https://doi.org/10.1177%2F1362361314553279

Deeks, J. J., Higgins, J. P. T., Altman, D. G. (2021). Analysing data and undertaking meta-analyses. In J. P. T Higgins, J. Thomas, J. Chandler, M. Cumpston, T. Li, M. J. Page, V. A. Welch (Eds.). *Cochrane Handbook for Systematic Reviews of Interventions*. John Wiley & Sons.

Department of Health. (2008). *Carers at the heart of 21st-century families and communities*. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/136492/carers_at_the_heart_of_21_century_families.pdf

Duncan, L. G., Coatsworth, J. D., & Greenberg, M. T. (2009). A model of mindful parenting: implications for parent–child relationships and prevention research. *Clinical Child and Family Psychology Review*, *12*, 255–270. https://doi.org/10.1007/s10567-009-0046-3

Dykens, E. M., Fisher, M. H., Taylor, J. L., Lambert, W., & Miodrag, N. (2014). Reducing distress in mothers of children with autism and other disabilities: a randomized trial. *Pediatrics*, *134*(2), e454-e463. https://doi.org/10.1542/peds.2013-3164

Effective Public Health Practice Project (2022, January 24). *Quality Assessment Tool for Quantitative Studies.* https://www.ephpp.ca/quality-assessment-tool-for-quantitative-studies/

Egger, M., Davey Smith, G., Schneider, M., & Minder, C. (1997). Bias in meta-analysis detected by a simple, graphical test. *BMJ, 315,* 629–634. https://doi.org/10.1136/bmj.315.7109.629

Farina, N., Page, T. E., Daley, S., Brown, A., Bowling, A., Basset, T., & Banerjee, S. (2017). Factors associated with the quality of life of family carers of people with dementia: A systematic review. *Alzheimer's & Dementia*, *13*(5), 572-581. https://doi.org/10.1016/j.jalz.2016.12.010

Fegg, M. J., Brandstätter, M., Kögler, M., Hauke, G., Rechenberg-Winter, P., Fensterer, V., & Borasio, G. D. (2013). Existential behavioural therapy for informal caregivers of palliative patients: A randomised controlled trial. *Psycho-Oncology*, *22*(9), 2079-2086. https://doi.org/10.1002/pon.3260

Francis, N., & Hanna, P. (2020). Informal carer experiences of UK dementia services: A systematic review. *Journal of Psychiatric and Mental Health Nursing*, *29*(1), 116-129. https://doi.org/10.1111/jpm.12698

Friedman, E. M., Trail, T. E., Vaughan, C. A., & Tanielian, T. (2018). Online peer support groups for family caregivers: are they reaching the caregivers with the greatest needs? *Journal of the American Medical Informatics Association*, *25*(9), 1130-1136. https://doi.org/10.1093/jamia/ocy086

Gallagher-Thompson, D., & Steffen, A. M. (1994). Comparative effects of cognitive-behavioral and brief psychodynamic psychotherapies for depressed family caregivers. *Journal of Consulting and Clinical Psychology*, *62*(3), 543-549.

Ghawadra, S. F., Abdullah, K. L., Choo, W. Y., & Phang, C. K. (2019). Mindfulness-based stress reduction for psychological distress among nurses: A systematic review. *Journal of Clinical Nursing*, *28*(21-22), 3747-3758. https://doi.org/10.1111/jocn.14987

Goldberg, S. B., Tucker, R. P., Greene, P. A., Davidson, R. J., Wampold, B. E., Kearney, D. J., & Simpson, T. L. (2018). Mindfulness-based interventions for psychiatric disorders: A systematic review and meta-analysis. *Clinical Psychology Review*, *59*, 52-60. https://doi.org/10.1016/j.cpr.2017.10.011

Grossman, P., Niemann, L., Schmidt, S., & Walach, H. (2004). Mindfulness-based stress reduction and health benefits: A meta-analysis. *Journal of psychosomatic research*, *57*(1), 35-43. https://doi.org/10.1016/S0022-3999(03)00573-7

Gu, J., Strauss, C., Bond, R., & Cavanagh, K. (2015). How do mindfulness-based cognitive therapy and mindfulness-based stress reduction improve mental health and wellbeing? A systematic review and meta-analysis of mediation studies. *Clinical Psychology Review*, *37*, 1-12. https://doi.org/10.1016/j.cpr.2015.01.006

Haley, W. E., Roth, D. L., Sheehan, O. C., Rhodes, J. D., Huang, J., Blinka, M. D., & Howard, V. J. (2020). Effects of transitions to family caregiving on well-being: a longitudinal population-based study. *Journal of the American Geriatrics Society*, *68*(12), 2839-2846. https://doi.org/10.1111/jgs.16778

Hamilton M. (1986). The Hamilton Rating Scale for Depression. In N. Sartorius, T. A. Ban (Eds.). *Assessment of Depression.* Springer. https://doi.org/10.1007/978-3-642-70486-4_14

Han, A., Yuen, H. K., & Jenkins, J. (2021). Acceptance and commitment therapy for family caregivers: A systematic review and meta-analysis. *Journal of Health Psychology*, *26*(1), 82-102. https://doi.org/10.1177%2F1359105320941217

Hick, S. F., & Chan, L. (2010). Mindfulness-based cognitive therapy for depression: effectiveness and limitations. *Social Work in Mental Health*, *8*(3), 225-237. https://doi.org/10.1080/15332980903405330

Higgins, J. P. T., Li, T., & Deeks, J. J. (2022). Choosing effect measures and computing estimates of effect. In J. P. T. Higgins, J. Thomas, J. Chandler, M. Cumpston, T. Li, M. J. Page, V. A. Welch (Eds). *Cochrane Handbook for Systematic Reviews of Interventions (Version 6.3).* Cochrane, 2022. https://training.cochrane.org/handbook/current/chapter-06

Ho, R. Y. F., Zhang, D., Chan, S. K. C., Gao, T. T., Lee, E. K. P., Lo, H. H. M., & Wong, S. Y. S. (2021). Brief Report: Mindfulness training for Chinese adolescents with autism spectrum disorder and their parents in Hong Kong. *Journal of Autism and Developmental Disorders*, 1-13. https://doi.org/10.1007/s10803-020-04729-4

Hopkinson, M. D., Reavell, J., Lane, D. A., & Mallikarjun, P. (2019). Cognitive behavioral therapy for depression, anxiety, and stress in caregivers of dementia patients: A systematic review and meta-analysis. *The Gerontologist*, *59*(4), e343-362. https://doi.org/10.1093/geront/gnx217

Hou, R. J., Wong, S. Y. S., Yip, B. H. K., Hung, A. T., Lo, H. H. M., Chan, P. H., & Ma, S. H. (2014). The effects of mindfulness-based stress reduction program on the mental health of family caregivers: a randomized controlled trial. *Psychotherapy and Psychosomatics*, *83*(1), 45-53. https://doi.org/10.1159/000353278

Huppert, F. A. (2009). Psychological well-being: Evidence regarding its causes and consequences. *Applied Psychology: Health and Well-being*, *1*(2), 137-164. https://doi.org/10.1111/j.1758-0854.2009.01008.x

International Wellbeing Group. (2006). *Personal Wellbeing Index.* Australian Centre on Quality of Life, Deakin University.

Jaffray, L., Bridgman, H., Stephens, M., & Skinner, T. (2016). Evaluating the effects of mindfulness-based interventions for informal palliative caregivers: A systematic literature review. *Palliative Medicine, 30,* 117–131. https://doi.org/10.1177%2F0269216315600331

Kabat-Zinn, J. (1982). An out-patient program in behavioral medicine for chronic pain patients based on the practice of mindfulness meditation: Theoretical considerations and preliminary results. *General Hospital Psychiatry, 4,* 33–47. https://doi.org/10.1016/0163-8343(82)90026-3

Kabat-Zinn, J. (1990). *Full catastrophe living: Using the wisdom of your body and mind to face stress, pain, and illness.* Delacorte Press.

Kabat-Zinn, J. (2003). Mindfulness-based intervention in context: Past, present, and future. *Clinical Psychology: Science and Practice, 10*(2), 144–156. https://doi.org/10.1093/clipsy.bpg016

Kallapiran, K., Koo, S., Kirubakaran, R., & Hancock, K. (2015). Effectiveness of mindfulness in improving mental health symptoms of children and adolescents: a meta-analysis. *Child and Adolescent Mental Health, 20*(4), 182-194. https://doi.org/10.1111/camh.12113

Katbamna, S., Ahmad, W., Bhakta, P., Baker, R., & Parker, G. (2004). Do they look after their own? Informal support for south Asian carers. *Health and Social Care in the Community, 12*(5), 398-406. https://www.doi/10.1111/j.1365-2524.2004.00509.x

Keng, S. L., Smoski, M. J., Robins, C. J., Ekblad, A. G., & Brantley, J. G. (2012). Mechanisms of change in mindfulness-based stress reduction: Self-compassion and mindfulness as mediators of intervention outcomes. *Journal of Cognitive Psychotherapy, 26*(3), 270-280. https://www.doi/10.1891/0889-8391.26.3.270

Khoury, B., Sharma, M., Rush, S. E., & Fournier, C. (2015). Mindfulness-based stress reduction for healthy individuals: a meta-analysis. *Journal of Psychosomatic Research*, *78*(6), 519–528. https://www.doi.org/10.1016/j.jpsychores.2015.03.009

King, A. P., Erickson, T. M., Giardino, N. D., Favorite, T., Rauch, S. A., Robinson, E., & Liberzon, I. (2013). A pilot study of group mindfulness-based cognitive therapy (MBCT) for combat veterans with posttraumatic stress disorder (PTSD). *Depression and Anxiety*, *30*(7), 638-645. https://doi.org/10.1002/da.22104

Kor, P. P. K., Liu, J. Y. W., & Chien, W. T. (2019). Effects of a modified mindfulness-based cognitive therapy for family caregivers of people with dementia: A pilot randomized controlled trial. *International Journal of Nursing Studies*, *98*, 107-117. https://doi.org/10.1016/j.ijnurstu.2019.02.020

Kor, P. P. K., Liu, J. Y., & Chien, W. T. (2021). Effects of a modified mindfulness-based cognitive therapy for family caregivers of people with dementia: A randomized clinical trial. *The Gerontologist*, *61*(6), 977-990. https://doi.org/10.1093/geront/gnaa125

Kriakous, S. A., Elliott, K. A., Lamers, C., & Owen, R. (2021). The effectiveness of mindfulness-based stress reduction on the psychological functioning of healthcare professionals: A systematic review. *Mindfulness*, *12*(1), 1-28. https://doi.org/10.1007/s12671-020-01500-9

Kroenke, K., Spitzer, R. L., & Williams, J. B. (2001). The PHQ-9: Validity of a brief depression severity measure. *Journal of General Internal Medicine*, *16*(9), 606–613. https://doi.org/10.1046/j.1525-1497.2001.016009606.x

Kwok, T., Au, A., Bel Wong, I. I., Mak, V., & Ho, F. (2014). Effectiveness of online cognitive behavioral therapy on family caregivers of people with dementia. *Clinical Interventions in Aging*, *9*, 631. https://doi.org/10.2147%2FCIA.S56337

Lara-Cinisomo, S., Santens, R. L., & Fujimoto, E. M. (2019). A pilot randomized controlled trial of a mindfulness-based intervention for caregivers of veterans. *Mindfulness*, *10*(9), 1855-1869. https://doi.org/10.1007/s12671-019-01131-9

Lavrakas, P. J. (2008). *Encyclopedia of survey research methods.* Sage Publications. https://www.doi/10.4135/9781412963947

Lawrence, V., Murray, J., Samsi, K., & Banerjee, S. (2008). Attitudes and support needs of Black Caribbean, south Asian and White British carers of people with dementia in the UK. *British Journal of Psychiatry*, *193*(3), 240-246. https://www.doi/10.1192/bjp.bp.107.045187

Li, G., Yuan, H., & Zhang, W. (2016). The effects of mindfulness-based stress reduction for family caregivers: Systematic review. *Archives of Psychiatric Nursing*, *30*(2), 292-299. https://doi.org/10.1016/j.apnu.2015.08.014

Lo, H. H. M., Chan, S. K. C., Szeto, M. P., Chan, C. Y. H., & Choi, C. W. (2017). A feasibility study of a brief mindfulness-based program for parents of preschool children with developmental disabilities. *Mindfulness*, *8*(6), 1665-1673. https://doi.org/10.1007/s12671-017-0741-y

Lo, H. H., Wong, S. W., Wong, J. Y., Yeung, J. W., Snel, E., & Wong, S. Y. (2020). The effects of family-based mindfulness intervention on ADHD symptomology in young children and their parents: a randomized control trial. *Journal of Attention Disorders*, *24*(5), 667-680. https://doi.org/10.1177%2F1087054717743330

Lovibond, S. H. & Lovibond, P. F. (1995). *Manual for the Depression Anxiety & Stress Scales (2nd Edition).* Psychology Foundation.

Ludwig, D. S., & Kabat-Zinn, J. (2008). *Mindfulness in medicine. JAMA*, 300(11), 1350-1352. https://doi.org/10.1001/jama.300.11.1350

Lunsky, Y., Hastings, R. P., Weiss, J. A., Palucka, A. M., Hutton, S., & White, K. (2017). Comparative effects of mindfulness and support and information group interventions for parents of adults with autism spectrum disorder and other developmental disabilities. *Journal of Autism and Developmental Disorders*, *47*(6), 1769-1779. https://doi.org/10.1007/s10803-017-3099-z

Mak, C., Whittingham, K., Cunnington, R., & Boyd, R. N. (2018). Effect of mindfulness yoga programme MiYoga on attention, behaviour, and physical outcomes in cerebral palsy: A randomized controlled trial. *Developmental Medicine & Child Neurology*, *60*(9), 922-932. https://doi.org/10.1111/dmcn.13923

McNair, D. M., Lorr, M., & Droppleman, L. F. (1971). *Profile of mood states.* Educational and Industrial Testing Service.

Neece, C. L. (2014). Mindfulness-based stress reduction for parents of young children with developmental delays: Implications for parental mental health and child behavior problems. *Journal of Applied Research in Intellectual Disabilities*, *27*(2), 174-186. https://doi.org/10.1111/jar.12064

Neff, K. D. (2003). The development and validation of a scale to measure self- compassion. *Self and Identity*, *2*(3), 223-250. https://doi.org/10.1080/15298860309027

Newbold, A., Hardy, G., & Byng, R. (2013). Staff and patient experience of improving access to psychological therapy group interventions for anxiety and depression. *Journal of Mental Health*, *22*(5), 456-464. https://doi.org/10.3109/09638237.2013.815333

Niazi, A. K., & Niazi, S. K. (2011). Mindfulness-based stress reduction: A non-pharmacological approach for chronic illnesses. *North American Journal of Medical Sciences*, *3*(1), 20-29. https://doi.org/10.4297%2Fnajms.2011.320

Norouzi, M., Golzari, M., & Sohrabi, F. (2014). Effectiveness of mindfulness based cognitive therapy on the quality of life, depression and burden of demented women caregivers. *Zahedan Journal of Research in Medical Sciences, 16*(9), 5-11.

Ó Donnchadha, S. (2018). Stress in caregivers of individuals with intellectual or developmental disabilities: A systematic review of mindfulness-based interventions. *Journal of Applied Research in Intellectual Disabilities, 31*(2), 181-192. https://doi.org/10.1111/jar.12398

Office of National Statistics (ONS). (2017). Unpaid carers provide social care worth £57 billion. https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandlifeexpectancies/articles/unpaidcarersprovidesocialcareworth57billion/2017-07-10

Oken, B. S., Fonareva, I., Haas, M., Wahbeh, H., Lane, J. B., Zajdel, D., & Amen, A. (2010). Pilot controlled trial of mindfulness meditation and education for dementia caregivers. *The Journal of Alternative and Complementary Medicine, 16*(10), 1031-1038. https://doi.org/10.1089/acm.2009.0733

Osborne, L. A., McHugh, L., Saunders, J., & Reed, P. (2008). Parenting stress reduces the effectiveness of early teaching interventions for autistic spectrum disorders. *Journal of Autism and Developmental Disorders, 38*(6), 1092–1103. https://doi.org/10.1007/s10803-007-0497-7

Page, M. J., McKenzie, J. E., Bossuyt, P. M., Boutron, I., Hoffmann, T. C., Mulrow, C. D., ... & Moher, D. (2021). The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *International Journal of Surgery, 88*, 105906. https://doi.org/10.1016/j.ijsu.2021.105906

Petcharat, M., & Liehr, P. (2021). Feasibility of a brief mindfulness intervention: Examining stress, anxiety and mindfulness for Thai parents of children with developmental

disabilities. *Archives of Psychiatric Nursing*, *35*(5), 418-426. https://doi.org/10.1016/j.apnu.2021.06.002

Plöthner, M., Schmidt, K., De Jong, L., Zeidler, J., & Damm, K. (2019). Needs and preferences of informal caregivers regarding outpatient care for the elderly: A systematic literature review. *BMC Geriatrics*, *19*(1), 1-22. https://doi.org/10.1186/s12877-019-1068-4

Pot, A. M., Van Dyck, R., & Deeg, D. J. (1995). Perceived stress caused by informal caregiving: Construction of a scale. *Tijdschrift voor gerontologie en geriatrie*, *26*(5), 214-219.

Pourhoseingholi, M. A., Baghestani, A. R., & Vahedi, M. (2012). How to control confounding effects by statistical analysis. *Gastroenterology and Gepatology: From Bed to Bench*, *5*(2), 79–83.

Preedy, V. R., & Watson, R. R. (2010). *Handbook of Disease Burdens and Quality of Life Measures*. Springer. https://doi.org/10.1007/978-0-387-78665-0_5254

Purser, R. (2015). The Myth of the Present Moment. *Mindfulness*, *6*, 680–686. https://doi.org/10.1007/s12671-014-0333-z

Radloff, L. S. (1977). The CES-D scale: A self-report depression scale for research in the general population. *Applied Psychological Measurement*, *1*, 385–401. https://doi.org/10.1177/014662167700100306

Ribeiro, L., Atchley, R.M. & Oken, B.S. (2018). Adherence to Practice of Mindfulness in Novice Meditators: Practices Chosen, Amount of Time Practiced, and Long-Term Effects Following a Mindfulness-Based Intervention. *Mindfulness* 9, 401–411. https://doi.org/10.1007/s12671-017-0781-3

Rimes, K. A., & Wingrove, J. (2013). Mindfulness-based cognitive therapy for people with chronic fatigue syndrome still experiencing excessive fatigue after cognitive

behaviour therapy: a pilot randomized study. *Clinical Psychology & Psychotherapy, 20*(2), 107-117. https://doi.org/10.1002/cpp.793

Roth, D. L., Fredman, L., & Haley, W. E. (2015). Informal caregiving and its impact on health: A reappraisal from population-based studies. *Gerontologist 55*(2), 309–319. https://doi.org/10.1093/geront/gnu177

Royal College of General Practitioners. (2011). *Supporting Carers: An action guide for general practitioners and their teams* (2nd ed.). The Princess Royal Trust for Carers.

Ryan, R. (2016). Cochrane Consumers and Communication Group: Meta-analysis. http://cccrg.cochrane.org/sites/cccrg.cochrane.org/files/public/uploads/meta-analysis_revised_december_1st_1_2016.pdf

Ryff, C. D., & Keyes, C. L. (1995). The structure of psychological well-being revisited. *Journal of Personality and Social Psychology, 69*(4), 719–727.

Santorelli, S. F., Meleo-Meyer, F., & Koerbel, L. (2017). Mindfulness-based stress reduction (MBSR) authorized curriculum guide. *Center for Mindfulness in Medicine, Health Care, and Society.*

Savundranayagam, M. Y., Montgomery, R. J., & Kosloski, K. (2011). A dimensional analysis of caregiver burden among spouses and adult children. *The Gerontologist*, *51*(3), 321-331. https://doi.org/10.1093/geront/gnq102

Schellekens, M. P. J., van den Hurk, D. G. M., Prins, J. B., Donders, A. R. T., Molema, J., Dekhuijzen, R., & Speckens, A. E. M. (2017). Mindfulness-based stress reduction added to care as usual for lung cancer patients and/or their partners: A multicentre randomized controlled trial. *Psycho-oncology*, *26*(12), 2118-2126. https://doi.org/10.1002/pon.4430

Schenstrom, O. (2011). *Here & Now: version 2.0.* Pitea Mindfulness Centre.

Schulz, R., & Sherwood, P. R. (2008). Physical and mental health effects of family caregiving. *Journal of Social Work Education, 44*(3), 105-113. https://doi.org/10.5175/JSWE.2008.773247702

Segal, Z. V. (2016, October 27). *The Difference Between "Being" and "Doing".* Mindful. https://www.mindful.org/difference-between-being-and-doing/

Segal, Z. V., Williams, J. M., & Teasdale, J. D. (2002). *Mindfulness-based cognitive therapy for depression: A new approach to preventing relapse (first edition).* The Guilford Press.

Segal, Z. V., Williams, J. M., & Teasdale, J. D. (2012). *Mindfulness-based cognitive therapy for depression: A new approach to preventing relapse (second edition).* The Guilford Press.

Shim, M., Tilley, J. L., Im, S., Price, K., & Gonzalez, A. (2020). A systematic review of mindfulness-based interventions for patients with mild cognitive impairment or dementia and caregivers. *Journal of Geriatric Psychiatry and Neurology, 34*(6), 528-554. https://doi.org/10.1177%2F0891988720957104

Siebelink, N. M., Bögels, S. M., Speckens, A. E., Dammers, J. T., Wolfers, T., Buitelaar, J. K., & Greven, C. U. (2021). A randomised controlled trial (MindChamp) of a mindfulness-based intervention for children with ADHD and their parents. *Journal of Child Psychology and Psychiatry*. https://doi.org/10.1111/jcpp.13430

Skelly, A. C., Dettori, J. R., & Brodt, E. D. (2012). Assessing bias: The importance of considering confounding. *Evidence-based Spine-care Journal*, *3*(01), 9-12. https://doi.org/10.1055/s-0031-1298595

Smith, J. M., Bright, K. S., Mader, J., Smith, J., Afzal, A. R., Patterson, C., & Crowder, R. (2020). A pilot of a mindfulness-based stress reduction intervention for female

caregivers of youth who are experiencing substance use disorders. *Addictive Behaviors*, *103*, e106223. https://doi.org/10.1016/j.addbeh.2019.106223

Solhaug, I., de Vibe, M., Friborg, O., Sørlie, T., Tyssen, R., Bjørndal, A., & Rosenvinge, J. H. (2019). Long-term mental health effects of mindfulness training: A 4-year follow-up study. *Mindfulness*, *10*(8), 1661-1672. https://doi.org/10.1007/s12671-019-01100-2

Spielberger, C. D., Gorsuch, R. L., Lushene, R., Vagg, P. R., & Jacobs, G. A. (1983). Manual for the State-Trait Anxiety Inventory. Consulting Psychologists Press.

Steer, R. A., & Beck, A. T. (1997). Beck Anxiety Inventory. In C. P. Zalaquett & R. J. Wood (Eds.), *Evaluating stress: A book of resources* (pp. 23–40). Scarecrow Education.

The Jamovi Project (2021). Jamovi *(Version 1.6).* Windows. https://www.jamovi.org

Turner-Bowker, D., Hogue, S. J. (2014). Short Form 12 Health Survey (SF-12). In A.C. Michalos (Ed.). *Encyclopedia of Quality of Life and Well-Being Research.* Springer. https://doi.org/10.1007/978-94-007-0753-5_2698

Valero, M., Cebolla, A., & Colomer, C. (2021). Mindfulness training for children with ADHD and their parents: a randomized control trial. *Journal of Attention Disorders*, https://www.doi/10.1177/10870547211027636

Van de Weijer-Bergsma, E., Formsma, A. R., de Bruin, E. I., & Bögels, S. M. (2012). The effectiveness of mindfulness training on behavioral problems and attentional functioning in adolescents with ADHD. *Journal of child and family studies*, *21*(5), 775-787. https://doi.org/10.1007/s10826-011-9531-7

Van der Oord, S., Bögels, S. M., & Peijnenburg, D. (2012). The effectiveness of mindfulness training for children with ADHD and mindful parenting for their parents. *Journal of Child and Family Studies*, *21*(1), 139-147. https://www.doi/10.1007/s10826-011-9457-0

Van Ryn, M., Sanders, S., & Kahn, K. (2011). Objective burden, resources, and other stressors among informal caregivers: A hidden quality issue? *Psycho-oncology, 20,* 44-52. https://doi.org/10.1002/pon.1703

Verhaeghen, P. (2021). Mindfulness as Attention Training: Meta-Analyses on the Links Between Attention Performance and Mindfulness Interventions, Long-Term Meditation Practice, and Trait Mindfulness. *Mindfulness* 12, 564–581. https://doi.org/10.1007/s12671-020-01532-1

Ware, J. E. (1993). Scoring the SF-36. *SF-36. Health Survey: Manual and Interpretation Guide*. Nimrod Press.

Watson, B., Tatangelo, G., & McCabe, M. (2019). Depression and anxiety among partner and offspring carers of people with dementia: A systematic review. *The Gerontologist*, *59*(5), e597-e610. https://doi.org/10.1093/geront/gny049

Weitlauf, A. S., Broderick, N., Stainbrook, J. A., Taylor, J. L., Herrington, C. G., Nicholson, A. G., & Warren, Z. E. (2020). Mindfulness-based stress reduction for parents implementing early intervention for autism: An RCT. *Pediatrics*, *145*(1), S81-S92. https://doi.org/10.1542/peds.2019-1895K

Whitebird, R. R., Kreitzer, M., Crain, A. L., Lewis, B. A., Hanson, L. R., & Enstad, C. J. (2013). Mindfulness-based stress reduction for family caregivers: a randomized controlled trial. *The Gerontologist*, *53*(4), 676-686. https://doi.org/10.1093/geront/gns126

WHO. (1998). *Wellbeing Measures in Primary Health Care/The Depcare Project*. WHO Regional Office for Europe.

Williams, M., & Penman, D. (2012). *Mindfulness: An eight-week plan for finding peace in a frantic world.* Rodale.

Williams, N. A., Burnfield, J. M., Springer, P., Wolf, K., & Buster, T. (2019). Therapeutic massage to enhance family caregivers' well-being in a rehabilitation

hospital. *Complementary Therapies in Clinical Practice*, *35*, 361-367. https://doi.org/10.1016/j.ctcp.2019.03.020

Wong, S. Y. S., Yip, B. H. K., Mak, W. W. S., Mercer, S., Cheung, E. Y. L., Ling, C. Y. M., & Ma, H. S. W. (2016). Mindfulness-based cognitive therapy v. group psychoeducation for people with generalised anxiety disorder: Randomised controlled trial. *The British Journal of Psychiatry*, *209*(1), 68-75. https://doi.org/10.1192/bjp.bp.115.166124

Zarit, S.H., Reever, K. E., & Back-Peterson, J. (1980). Relatives of the impaired elderly: Correlates of feelings of burden. *The Gerontologist*, *20*, 649-655. https://doi.org/10.1093/geront/20.6.649

Zigmond, A. S., & Snaith, R. P. (1983). The hospital anxiety and depression scale. *Acta Psychiatrica Scandinavica*, *67*(6), 361-370. https://doi.org/10.1111/j.1600-0447.1983.tb09716.x.

**Section B: Empirical Research Paper**

# Online Mindfulness-based Cognitive Therapy for Parents of Children with Food Allergies: A Feasibility Randomised Controlled Trial.

**Word Count: 7936 (additional 342)**

For submission to the Journal of Allergy and Clinical Immunology.

## Abstract

Caring for a child with a food allergy can be extremely challenging and can impact a parent's psychological wellbeing. Mindfulness-based Cognitive Therapy (MBCT) has been successfully adapted and applied to several carer populations, and therefore may offer a useful intervention to parents and carers of children with food allergy (PCCFA). However, this has not yet been researched. A feasibility randomised controlled trial explored the acceptability of online, adapted MBCT for PCCFA (MBCT-PCCFA), providing a signal of efficacy. Forty-six participants were randomised to an MBCT-PCCFA group or treatment as usual (TAU) control. Measures of quality of life, anxiety, stress, and low mood were collected at baseline (week 0), post-intervention (week 15), and at follow-up (week 23). The recruitment, response and attrition rates suggested that undertaking an RCT within this population and intervention was feasible. The high overall session attendance, low-dropout rate, engagement with at-home practice, and qualitative feedback, suggested MBCT-PCCFA is acceptable. The MBCT-PCCFA group showed greater improvement in quality of life from baseline than control, with a large between group effect size (Hedges g = 1.34; 95% CI = 0.66 to 2.00). Improvements in levels of stress and anxiety (small to large estimated effect sizes) were also found at post-intervention. These changes were maintained at follow-up. Based on these results, a larger definitive trial is warranted and recommendations for this are provided. Clinical implications are outlined.

## Introduction

Food allergy is defined as "an adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food" (Boyce et al., 2011, p.180), with cow's milk, peanut, tree nuts and egg being the most common allergens (Perkin et al., 2016; Soller et al., 2012). It currently affects 5-8% of children within the United Kingdom (Food Standards Agency, 2016), and research suggests this prevalence will increase as the variety of allergens change (Food Standards Agency, 2016; Tang & Mullins, 2017). Currently, the aetiology of food allergies is not conclusive, however research supports a combination of environmental factors and genetic disposition (Sicherer & Sampson, 2010). Given that food allergies can result in high morbidity and, in some cases, life-threatening anaphylaxis (Muraro et al., 2014), it can understandably have a negative impact on a person's physical and emotional health, and those who care for them (Sicherer et al., 2001).

### Challenges for parents/carers

Being a parent or carer of a child with a food allergy (PCCFA) can often be a difficult experience, not least because of possible fatal food-induced anaphylaxis (Brantlee Broome-Stone, 2012). Food allergies are commonly diagnosed at a young age and parents describe this as a critical transition in family life, whereby they are required to become 'alert assistants', must create 'safe spaces' and negotiate the challenges outside of the home for their children (Pitchforth et al., 2011). As the child ages, they enter a period where they must start self-managing and emergency management is 'handed-over' from the parent (Akeson et al., 2007). This can be stressful for carers, as peer pressure, social embarrassment, inexperience, or inconvenience often leads to children taking greater risks (Sampson et al., 2006). Additional social challenges include managing a lack of sensitivity, misconceptions, alongside the experience of stigma (Pitchforth et al., 2011). Rouf et al. (2012) reported the extreme responsibility parents often feel, including negotiating trust with others, teaching

their child to manage their condition and balancing risk with social inclusion. This is further compounded by the lack of specialist resources available to achieve diagnosis, medical support, and the necessary situation-specific advice (Akeson et al., 2007).

It is unsurprising that research has found increased anxiety and low mood, alongside reduced quality of life (QoL) in PCCFA (Cummings et al., 2010). This is supported by Polloni (2015) who found that 40% of food allergy parents seeking psychological support reported high anxiety, stress, social isolation, and poor self-esteem. Whilst a level of anxiety can be adaptive (e.g., to ensure appropriate precautions are taken), sustained and intense anxiety can lead to increased burden and high distress, impacting quality of life. Cognitive-behavioural theories suggest that the mechanisms underlying the link between psychological distress and food allergy may relate to negatively biased cognitive patterns (Polloni & Muraro, 2020). This may include elevated perceived risk towards situations, the consistent fear of severe reaction and fatality, and complete loss of control. Consequently, adverse effects of the allergy can become exaggerated and the individual's self-esteem and sense of confidence to adapt to threatening situations is undermined, perpetuating experiences of anxiety.

Exploration of these experiences has suggested that parental anxiety can also be transferred to the child in some cases (Akeson et al., 2007). Chow et al. (2015) suggests this may occur vicariously (e.g., modelling of behaviours or restricting a child's ability to explore autonomously), or more directly (e.g., direct verbal communication). It is therefore vital that services are created or adapted to support the specific needs of this population with evidence-based interventions.

**Evidenced-based interventions**

A review by Sugunasingha et al. (2020) found current evidence-based interventions for this population centred on educational, psychological, or peer/professional support. Educational support consisted of programmes, workshops or clinics aimed at increasing food allergy knowledge. Psychological support primarily involved facilitated sessions, with treatment being informed by Cognitive Behavioural therapy (CBT), aiming to reduce psychological distress whilst increasing self-efficacy, self-regulation, and QoL. Lastly, those involving peer/professional support aimed to increase confidence and reduce social isolation and anxiety in participants. Whilst the majority of studies were rated as poor to moderate quality, all demonstrated a high level of acceptability, suggesting a willingness for intervention.

A ‘second wave’ CBT approach was most frequently adopted within the psychological intervention research (Sugunasingha et al., 2020). This model typically involves collaboratively discussing the interaction between a client’s thoughts, feelings, and behaviours, and exploring how making changes to unhelpful behaviours and challenging difficult thoughts can break vicious cycles, subsequently improving mood (Padesky & Greenberger, 1995). However, given the ongoing risk families with food allergies live with and the associated emotional impact (Polloni, 2015), there may also be advantages for parents to find ways to live alongside this. As such, an intervention focused on changing the relationship to experience may also offer something useful, but this is yet to be researched.

‘Third-wave’ cognitive therapies integrate mindfulness, acceptance, decentring, cognitive defusion and values (Hayes & Hofmann, 2017). There are several interventions incorporating these core aspects, with Mindfulness-based Cognitive Therapy (MBCT) considered one of the most evidence-based programmes (Gu et al., 2016). Developed from Jon Kabat- Zinn’s Mindfulness-based Stress Reduction programme (MBSR; Kabat-Zinn,

1982), MBCT aims to support people with recurrent depression (Segal et al., 2018). Research has since suggested its effectiveness at also helping individuals to manage feelings of anxiety and stress (Evans, 2016; Kaviani et al., 2011) with the programme being successfully adapted for several other presentations including post-traumatic stress disorder (King et al., 2013) and generalised anxiety disorder (Wong et al., 2016). Theories regarding the mechanisms underlying the therapeutic effects of MBCT unsurprisingly often cite an increase in mindfulness (Kuyken et al., 2010). More recently, a synthesis of current literature by Gu et al. (2015) also suggested cognitive and emotional reactivity are strong mediators. Cognitive and emotional reactivity involve the extent to which a low-level of distress coupled with stress reactivate negative emotional and cognitive patterns (Scher, Ingram, & Segal, 2005). Consistent with cognitive-behavioural theories of anxiety and food allergy (Polloni & Muraro, 2020), a reduction in cognitive and emotional reactivity may serve to reduce experiences of sustained distress and perseverative cycles.

Research exploring experiences within MBCT groups also found a sense of connectedness amongst participants, where individuals shared a common difficulty, finding the group a normalising and soothing place to address this (Griffiths et al., 2009). Guttmacher & Birk (1971) suggested the sense of cohesion and acceptance often developed enables individuals to withstand higher degrees of anxiety when outside of the group. Given the frequent concerns regarding stigmatization and isolation (Walkner et al., 2015), this may offer something useful to PCCFA.

**Adapting MBCT**

MBCT is typically delivered face-to-face in groups of eight to 12 participants (Schroevers et al., 2016). This allows participants to experience observational learning, wider perspectives, emotional peer support and often increases motivation to complete at-home practices. However, due to geographical distance, work commitments, limited mobility, and

childcare, this mode of delivery is not always viable. Furthermore, the unprecedented changes caused by the Covid-19 pandemic forced many to seek alternative ways to interact, with the internet offering a conceivable solution. A meta-analysis, comparing the effectiveness of psychological interventions delivered face-to-face and via the internet, concluded that results were comparable (Barak et al., 2008). Specifically investigating MBIs online, Spijkerman et al. (2016) reported small to medium effect sizes on measures of psychological wellbeing. As such, it appears that this MBCT may be successfully transferred online with thoughtful consideration.

The original focus on chronic depression (Segal et al., 2018) is another component of MBCT that has been successfully adapted to other populations. This has been achieved by altering the psychoeducational components and taking into consideration the lifestyles of the target audience (Cheung et al., 2020). For example, Rodgers et al. (2019) adapted the protocol for people with Parkinson's Disease by modifying the language, pace, and exercises. Goodman et al. (2014) also adapted MBCT for pregnant women with anxiety, focusing on perinatal anxiety and adapting postures for exercises. Therefore, it seems that MBCT can be effectively adapted with small, careful modifications.

**Summary and rationale**

Given the challenges frequently faced by PCCFA, it appears there is scope for an intervention that enables parents to find ways to live alongside these. Based on the theory and evidence-base, online adapted MBCT may provide a useful intervention for this population, however this has not yet been researched. In line with the NHS values of improving lives and compassion, this intervention aims to improve psychological wellbeing of this population whilst encouraging them to consider their experiences of distress with loving-kindness.

As such, a feasibility randomised controlled trial (RCT) examining the acceptability of online MBCT adapted for PCCFA is proposed (MBCT-PCCFA). Effect size estimates will be calculated to inform the basis of a subsequent larger definitive RCT.

Therefore, the study aimed to examine whether:

1. MBCT-PCCFA will be acceptable to PCCFA as indicated by: (a.) overall session attendance; (b.) engagement with at-home practice; (c.) dropout rates; (d.) qualitative themes derived from post-intervention feedback surveys.
2. Undertaking an RCT of adapted MBCT-PCCFA will be feasible as indicated by the: (a.) number of people recruited to the study; (b.) level of attrition in both the intervention and control groups; (c.) number of people completing screening tools/interview; and (d.) measure response rate/missing data.

In addition, the study aimed to provide effect size estimates for the below hypotheses that could be used both as an indicator of whether there was a sufficient signal of efficacy to justify a definitive trial, and, if so, to provide the basis for a power calculation for that trial. In line with the guidance for feasibility studies (Eldridge et al., 2016), this study was not intended or powered to provide a definitive test of these hypotheses.

Primary hypothesis:

a. The improvement from baseline (Time 1 at week 0) to post-intervention (Time 2 at week 15) in levels of QoL will be greater for the MBCT-PCCFA plus treatment as usual (TAU) group (referred throughout as the MBCT-PCCFA group) compared to the TAU-only control group.

Additional hypotheses:

b. The improvement from baseline (Time 1 at week 0) to post-intervention (Time 2 at week 15) scores will be greater for the MBCT-PCCFA group compared to the TAU control group on the following secondary outcomes: (i.) anxiety; (ii.) low mood; (iii.) stress.

c. The improvement from baseline (Time 1 at week 0) to follow up (Time 3 at week 23) will be greater for the MBCT-PCCFA group compared to the TAU-only control group on all of the above measures.

d. Improvements in the above measures will be statistically mediated by improvements in: (i.) mindfulness; (ii.) emotional reactivity; (iii.) cognitive reactivity.

# Method

## Design

This study used a parallel feasibility RCT to explore the effectiveness of MBCT-PCCFA. There were two arms: (1) MBCT-PCCFA plus Treatment as Usual (TAU) group, and (2) TAU-only control group. The study was pre-registered (https://clinicaltrials.gov; Identifier: NCT04738890) and delivered entirely online.

Self-reported outcome measures were completed at three time points: baseline (Time 1 at week 0), post-intervention (Time 2 at week 15), and at follow-up (Time 3 at week 23). Time 1 was three weeks prior to the start of the intervention. Whilst the duration of intervention was nine weeks, a 12-week post-measure allowed additional time for logistical issues, such as sickness or absence. Participants were not aware of their random group allocation until they had consented to be part of the study and completed the first set of questionnaires. The process of recruitment occurred in waves, with two cohorts recruited.

### *User involvement*

PCCFA were consulted at the design stages of the project. Volunteers were contacts of the second supervisor and facilitated regional support groups for a voluntary allergy organisation. Consultations explored ways to recruit and retain participants throughout the study. Suggestions, including using social media groups, emailing weekly updates and financial incentives, which were built into the study protocol. The length and timing of sessions and at-home practice were also discussed, alongside ways to support participants who were not allocated to the intervention group. It was decided that outlining the study process in the screening meeting whilst also highlighting the important role of the control group would aid this process. The scheduling of sessions was considered the most appropriate time for the majority of parents.

***Treatment as usual***

Both groups continued accessing their existing support (TAU). Therefore, the study examined the additional benefit of MBCT-PCCFA on the top of usual care. This was so participants did not need to stop anything they found helpful (as is usual within an intervention RCT; Freedland et al., 2011). However, those who had engaged in a substantial mindfulness course or were planning another psychological intervention during the study were excluded.

***MBCT-PCCFA***

The MBCT-PCCFA course was facilitated by a Consultant Clinical Psychologist who is a British Association of Mindfulness-Based Approaches (BAMBA) Registered Mindfulness Teacher and a British Association for Behavioural and Cognitive Psychotherapies (BABCP) Accredited Psychotherapist. The researcher also attended all sessions and was available to offer a private space to speak in a breakout room should a participant require during the session. The course predominantly followed the standard MBCT curriculum, with small adaptions to ensure relevance to PCCFA. Whilst the course did not have a specific focus on food allergy, participants were able to share their experiences and difficulties. The facilitator also leant more so into the kindness aspects of the course (i.e., encouraging self-compassion in response to experiences). Unrelated handouts from the original course were removed and shorter at-home practises were offered as an alternative to the original longer recordings, in line with service user suggestions regarding likely time constraints of the target population (see Appendix B for course details). The course consisted of nine, two-hour, weekly sessions including an orientation session. It was delivered using videoconferencing (Zoom). Participants were invited to complete daily at-home practice for approximately 30-50 minutes. The group ran between 19:00 to 21:00 on 6th May 2021 to 1st July 2021 and between 9th September 2021 to 4th November 2021.

**Participants**

The recruitment target was 30-60 participants (15-30 per arm), which was considered appropriate for a feasibility RCT (Bell et al, 2018; Lancaster et al., 2004). No power calculation was conducted as this was a feasibility trial. Participants were recruited over a total of four months via adverts posted on social media and through Allergy UK which advertised on their website, newsletters, mailing list and Facebook page.

Participants were included if they met the following criteria: (1.) they identified as a parent or caregiver of a child under the age of 18 with a food allergy; (2.) their child's allergy had been diagnosed by a qualified physician (e.g. GP or allergy specialist); (3.) they were a resident in the United Kingdom; (4.) their mean score was >2 on the FAQL-PB (obtained through screening meeting, see 'Procedure' section below), indicating they are at least 'somewhat limited/troubled' by their child's allergy (Cohen et al., 2004); (4.) they had access to email, a PC/laptop/tablet with a webcam and microphone and internet access to allow videoconferencing.

Participants were excluded if they met any of the following criteria: (1.) they had consulted on the design and content of the study; (2.) they had already participated in a substantial mindfulness-based course; (3.) they were currently engaged or are planning to engage with another psychological intervention during the course of the study; (4.) they were currently engaged in regular mindfulness-based practice; (5.) they did not have the practical means or time available to be able to attend the intervention during the dates outlined on the information sheet and commit to at-home practice; (6.) their score was >=20 on PHQ-8 indicating 'severe' depressive symptom severity (Kroenke et al., 2009); (7.) their score was >=15 on GAD-7 indicating a 'severe' level of anxiety (Spitzer et al., 2006); (8.) they had a problem with alcohol or recreational drug misuse; (9.) they had experienced thoughts about harming themselves or others in the last 12 months; (10.) they had been given a diagnosis of

psychosis; (11.) they were currently experiencing high levels of distress and/or feeling particularly fragile; (12.) they had experienced a bereavement of someone close to them in the last year or were continuing to experience grief in relation to loosing someone further back in time; (13.) they had had traumatic experiences that they continued to be troubled by (including, but not limited to, receiving a diagnosis of post-traumatic stress disorder); (14.) they experienced significant difficulty being in group with other people. Please see the 'Ethical considerations' section for a rationale pertaining to these criteria.

## Measures

All measures were collected using an online platform, Qualtrics.

### *Primary outcome measure*

The primary outcome, quality of life (QoL), was measured using the Food Allergy Quality of Life-Parental Burden scale (FAQoL-PB; Cohen et al., 2004). This measure is specific to parents of children with food allergies and consists of 17 items (ranging from 'not limited/troubled' to 'extremely limited/troubled'). Total scores range from 17-119, with higher scores indicating reduced QoL and increased parental burden. Questions asked about parents' emotional wellbeing, ability to cope, and health. It has been shown to have good internal consistency and good test-retest reliability ($\alpha$ = 0.93-0.95; Cohen et al., 2004; Flokstra-de Bok & Dubois, 2009), and has been validated within the UK (Knibb & Stalker, 2013). An excellent level of internal consistency was also calculated within the present study's sample ($\alpha$ = 0.92).

### *Secondary outcome measures*

Secondary outcome measured parents' levels of anxiety, stress and depression.

Anxiety was measured using the Generalized Anxiety Disorder screener (GAD-7; Spitzer et al., 2006), which explores a person's feelings of generalised anxiety. The GAD-7

consists of seven items rated on a 4-point Likert scale from ‘not at all’ to ‘nearly every day’. Total scores range from 0-21, with higher scores indicating greater severity. It has been validated in clinical samples and in the general population with good internal consistency in the literature ($\alpha > 0.89$; Löwe et al., 2008; Spitzer et al., 2006) and current study ($\alpha = 0.89$).

Depression was measured using the Patient Health Questionnaire (PHQ-8; Kroenke et al., 2009), which explores a person’s feelings of low mood. The PHQ-8 consists of eight items rated on a 4-point Likert scale from ‘not at all’ to ‘nearly every day’. Total scores range from 0-24, with higher scores indicating greater severity. This measure has been validated in clinical samples and in the general population with high internal consistency ($\alpha = 0.86$-$0.89$; Kroenke et al., 2009; Cameron et al., 2008) and current study ($\alpha = 0.89$). It has also been validated in a UK sample (Gilbody et al., 2007).

Stress was measured using the Perceived Stress Scale (PSS; Cohen et al., 1983), which explores how different situations affect someone’s feelings and their perceived stress. The PSS consists of 10 items rated on a 5-point Likert scale from ‘never’ to ‘very often’. Total scores range form 0-40, with higher scores indicating greater severity. This measure has good internal validity and test-retest reliability ($\alpha > 0.7$; Lee, 2012) and has been validated in a UK sample (Schlotz et al., 2011). An excellent level of internal consistency was also calculated within the present study’s sample ($\alpha = 0.92$).

***Mediating measures***

Process variables assessed mindfulness, cognitive reactivity, and emotional reactivity (Gu et al., 2015).

Mindfulness was measured using the 15-item Five-Facet Mindfulness Questionnaire (FFMQ15; Baer et al., 2008). The FFMQ-15 has adequate internal validity in the literature ($\alpha > 0.64$-$0.8$; Gu et al., 2016), and current study ($\alpha = 0.82$). Emotional reactivity was measured

using the Perth Emotional Reactivity Scale (PERS; Becerra et al., 2019), which explores the typical ease of activation, intensity, and duration of one's emotional responses. This measure has good to excellent internal reliability ($\alpha$ = 0.93-0.94) and strong concurrent validity (Becerra et al., 2019). However, a questionable to satisfactory level of internal consistency was calculated within the present study's sample ($\alpha$ = 0.64-0.74). The implications of this are outlined in the discussion. Finally, cognitive reactivity was measured using the Leiden Index of Depression Sensitivity-Revised (LEIDS-R; Van der Does, 2002), which explores cognitive reactivity to sadness. This measure has good internal validity in the literature ($\alpha$ = 0.92; Himle et al., 2020) and current study ($\alpha$ = 0.90).

### *At-home practice*

Each week the intervention group completed a brief online survey outlining the number of days and minutes of formal mindfulness mediation (formal practice) and mindfulness in everyday life (informal practice; Appendix C).

### *Feedback questionnaire*

Both the intervention and control group completed feedback questionnaires at follow-up (week 23, Appendix D). They were asked about their experience of taking part in the study. The intervention group were also asked about their experience of the intervention.

## Procedure

### *Screening*

During the recruitment period, interested individuals registered their email address via an online survey (Qualtrics). The researcher then sent a copy of the information sheet (Appendix E). If they wished to proceed, the researcher arranged a virtual screening meeting to check their understanding and eligibility. The researcher then emailed a consent form (Appendix F) to the participant which they completed and sent back. The FAQL-PB, PHQ8

and GAD7 was then administered and scored, and individuals were advised of their eligibility. Individuals whose scores did not fall within the specified range were directed to resources to access further support (e.g., IAPT services). Afterwards an email was sent to all participants summarising the conversation, their status within the study, and any recommendations (Appendix G).

***Data collection***

Once a sufficient number of participants had been recruited, a link to the baseline measures was sent (week 0). At the end of the intervention (week 15) and at follow-up (week 23), both groups were emailed further measures. Participant email addresses enabled questionnaire responses to be linked. Those within the intervention group were also sent weekly links to enter their at-home practice totals. If questionnaires were not completed within four days, a reminder email was sent in the first instance, followed by a telephone call/message two days later (Appendix H).

***Randomisation***

Following completion of the baseline measures, participants were randomly assigned to the intervention or control group. Randomisation was completed by a Trainee Clinical Psychologist external to the project using a random number generator in Microsoft Excel. This was so that the researcher was blind to participant group allocation until it had occurred and did not have any influence over the process. Participants were ordered in ascending order based on their randomly generated number. To ensure equal division between groups, the first 50% were allocated to the intervention group and the second 50% to the control group. If there was an odd number of participants, the remaining participant was generated a random number (0-1) and allocated to the intervention group if it was ≤0.5 and to the control group if it was >0.5.

### *Group allocation*

Those within the ‘control group’ were asked to continue with TAU; they did not receive the intervention during this study. They were offered a £10 Amazon voucher and a list of mindfulness-based resources to integrate mindfulness practice into their life at the end of the study. Those within the ‘intervention group’, were asked to complete the MBCT-PCCFA intervention outlined in the ‘Design’ section above.

## Ethical considerations

Ethical approval for this study was granted by the Salomons, Canterbury Christ Church University ethics panel (Appendix I). Participants who received MBCT-PCCFA were asked to sit with difficult feelings associated with their child’s food allergy which had the potential to cause distress. This was not necessarily problematic as part of the approach is to work on changing the relationship with such experiences, such that we suffer from them less. However, to ensure difficult experiences were containable, the following steps were implemented: (1.) participants were made aware of potential distress at the start of the study and consented to this; (2.) participants were offered the option to speak with the researcher/intervention facilitator regarding the appropriateness of the group for them individually before commencing; (3.) information on free services was provided if they required further support in managing their distress; and (4.) in line with typical clinical practice, if a participant became distressed during a group, the first step was for the facilitator to work with that in the group setting (with the agreement of the participant) in a way that fitted with MBCT. However, the researcher was also available to speak to them in a breakout room.

Given that the intervention was facilitated within a group context, there was a possibility for participants to disclose confidential information. Issues of confidentiality were covered at the beginning and participants were reminded of the limits to confidentiality. Intervention participants were asked to engage in mindful movement, and physical difficulties may have meant this was not appropriate for some. This was managed by: (1.) including details on the information sheet and consent form; (2.) asking participants to identify whether they had any physical difficulties and reminding them they did not need to engage with the movement during the intervention; and (3.) reminding participants of this when mindful movement was led during the practice. Participants were also aware that they could contact the researcher or intervention facilitator should they have any concerns about the study and could withdraw at any point without explanation.

**Analysis plan**

Analysis of acceptability consisted of descriptive statistics of retention data (i.e., session attendance, at-home practice completion, time dedicated to at-home practice, and dropout rates). Qualitative experiences of acceptability collected through feedback surveys were also explored through content analysis. Analysis of feasibility consisted of descriptive statistics of recruitment data (i.e., number of people recruited, number of people completing the screening questionnaire/interview, and level of attrition). Response rate and missing data were also described.

Given that this was a feasibility study primarily exploring the viability of conducting a large scale RCT, effect sizes with 95% confidence intervals were calculated for each of the measures and inferential statistics were not reported (Eldridge et al., 2016). While the trial was not aiming to provide a definitive test of efficacy, as with other feasibility studies (i.e., Vreeken-Ross et al., 2021), effect size estimates were examined to see if they indicated an initial signal of efficacy that was suggestive enough of a possible effect to justify

investigation in a future definitive trial. The mean observed change from baseline to post-intervention and from baseline to follow-up was calculated for each group. The mean between group difference in change scores was then calculated along with Hedges g effect sizes (with 95% confidence intervals) at post-intervention and follow-up. To explore change at an individual level, the Reliable Change Index was calculated for each outcome measure using Cronbach's Alpha and mean SD at baseline and used to examine reliably significant change at post-intervention and follow-up (Jacobson & Truax, 1991). This was to compare the overall number of individuals who reliably changed (improved or deteriorated) between groups. Given a non-clinical sample was recruited and the primary outcome was not a clinical measure, clinical significance was not examined. Finally, the Process Macro for SPSS was used to provide a signal of efficacy of process variables on each outcome measure. This mediation analysis explored whether post-intervention scores on mindfulness, emotional reactivity, and cognitive reactivity mediated the effect of group on follow-up outcome measure scores.

# Results

## Demographics of sample

Demographic details for parents are detailed within Table 1. All parents identified as female, with most from White ethnic backgrounds and educated to at least undergraduate university level. Demographic details for their eldest child with a food allergy are detailed within Table 2. In line with the CONSORT guidelines, statistical tests were not used to explore differences in demographic or outcome data between groups at baseline (De Boer et al., 2015). This was because groups were randomly allocated and therefore any differences would have occurred by chance rather than bias. Nonetheless, visual inspection of descriptive data suggests groups were broadly balanced.

**Table 1.**

*Parental demographic characteristics*

| | Intervention group n = 24 | Control group n = 22 | Total sample n = 46 |
|---|---|---|---|
| Gender n (%) | | | |
| Female | 24 (100) | 22 (100) | 46 (100) |
| Age mean (SD) | 37.12 (5.50) | 37.95 (5.92) | 37.52 (5.65) |
| Ethnicity n (%) | | | |
| White British | 22 (91.7) | 17 (77.3) | 39 (84.8) |
| White Irish | 0 (0) | 1 (4.5) | 1 (2.2) |
| Other White background | 0 (0) | 1 (4.5) | 1 (2.2) |
| Asian/Asian British | 1 (4.2) | 1 (4.5) | 2 (4.3) |
| Mixed (Asian and White) | 0 (0) | 1 (4.5) | 1 (2.2) |
| Other mixed background | 1 (4.2) | 0 (0) | 1 (2.2) |
| Other background | 0 (0) | 1 (4.5) | 1 (2.2) |
| Employment n (%) | | | |
| Full time | 4 (16.7) | 5 (22.7) | 9 (19.6) |
| Part time | 16 (66.7) | 10 (45.5) | 26 (56.5) |
| Self employed | 1 (4.2) | 4 (18.2) | 5 (10.9) |
| Homemaker | 5 (20.8) | 4 (18.2) | 9 (19.6) |
| Unemployed | 1 (4.2) | 0 (0) | 1 (2.2) |
| Highest education n (%) | | | |

| | | | |
|---|---|---|---|
| O-levels/GCSEs, N5 qualifications | 2 (8.3) | 2 (9.1) | 4 (8.7) |
| A-levels, Scottish Highers | 1 (4.2) | 2 (9.1) | 3 (6.5) |
| Undergraduate | 11 (45.8) | 9 (40.9) | 20 (43.5) |
| Post-graduate | 8 (33.3) | 7 (31.8) | 15 (32.6) |
| Doctoral | 1 (4.2) | 2 (9.1 | 3 (6.5) |
| Other | 1 (4.2) | 0 (0) | 1 (2.2) |
| Current mental or physical health difficulties n (%) | | | |
| Yes | 3 (12.5) | 3 (13.6) | 6 (13.0) |
| No | 21 (87.5) | 17 (77.3) | 38 (82.6) |
| Prefer not to say | 0 (0) | 2 (9.1) | 2 (4.3) |
| Support for mental or physical health difficulties n (%) | | | |
| Yes | 1 (33.3) | 3 (100) | 4 (8.7) |
| No | 2 (66.7) | 0 (0) | 2 (4.3) |
| Past psychological therapy n (%) | | | |
| Yes | 13 (54.2) | 9 (40.9) | 22 (47.8) |
| No | 10 (41.7) | 12 (54.5) | 22 (47.8) |
| Prefer not to say | 1 (4.2) | 1 (4.5) | 2 (4.3) |
| Past mindfulness-based intervention n (%) | | | |
| No | 24 (100) | 22 (100) | 46 (100) |
| Practiced mindfulness in past n (%) | | | |
| Yes | 9 (37.5) | 4 (18.2) | 13 (28.3) |
| No | 15 (62.5) | 18 (81.8) | 33 (71.7) |
| Access food allergy support group | | | |
| Yes | 12 (50) | 14 (63.6) | 26 (56.5) |
| No | 12 (50) | 8 (36.4) | 20 (43.5) |
| Total children with a food allergy | | | |
| One | 19 (79.2) | 20 (90.9) | 39 (84.8) |
| Two | 5 (20.8) | 2 (9.1) | 7 (15.2) |

**Table 2.**

*Child demographic characteristics*

| | Intervention group n = 24 | Control group n = 22 | Total sample n = 46 |
|---|---|---|---|
| Gender n (%) | | | |
| Female | 18 (75.0) | 11 (50.0) | 29 (63.0) |
| Male | 6 (25.0) | 11 (50.0) | 17 (37.0) |
| Current age mean (SD) | 5.48 (4.27) | 4.96 (3.76) | 5.23 (3.99) |
| Age at diagnosis mean (SD) | 1.17 (1.44) | 1.12 (1.72) | 1.14 (1.56) |
| Total food allergies mean (SD) | 3.83 (2.96) | 4.36 (3.11) | 4.09 (3.01) |
| Last seen by doctor (months) mean (SD) | 8.17 (6.03) | 9.77 (9.91) | 8.93 (8.07) |
| Diagnosed allergen | | | |
| Peanut | 16 (66.7) | 15 (68.2) | 31 (67.4) |
| Tree nut | 13 (54.2) | 11 (50.0) | 24 (52.2) |
| Milk | 13 (54.2) | 11 (50.0) | 24 (52.2) |
| Egg | 16 (66.7) | 13 (59.1) | 29 (63.0) |
| Sesame | 5 (20.8) | 9 (40.9) | 14 (30.4) |
| Soya | 0 (0) | 0 (0) | 0 (0) |
| Wheat | 0 (0) | 0 (0) | 0 (0) |
| Fish | 2 (8.3) | 1 (4.3) | 3 (6.5) |
| Shellfish | 0 (0) | 0 (0) | 0 (0) |
| Comorbid conditions | | | |
| Asthma | 10 (41.7) | 6 (27.3) | 16 (34.8) |
| Eczema | 22 (91.7) | 18 (81.8) | 40 (87.0) |
| Hay fever | 15 (62.5) | 11 (50.0) | 26 (56.5) |
| Medication | | | |
| Antihistamines | 23 (95.8) | 22 (100) | 45 (97.8) |
| Auto-injector (AAI) | 16 (66.7) | 19 (86.4) | 35 (76.1) |
| Hospital required for past reaction | | | |
| Yes | 15 (62.5) | 13 (59.1) | 28 (60.9) |
| No | 9 (37.5) | 9 (40.9) | 18 (39.1) |
| Previous anaphylactic reaction | | | |
| Yes | 9 (37.5) | 11 (50.0) | 20 (43.5) |
| No | 15 (62.5) | 11 (50.0) | 26 (56.5) |

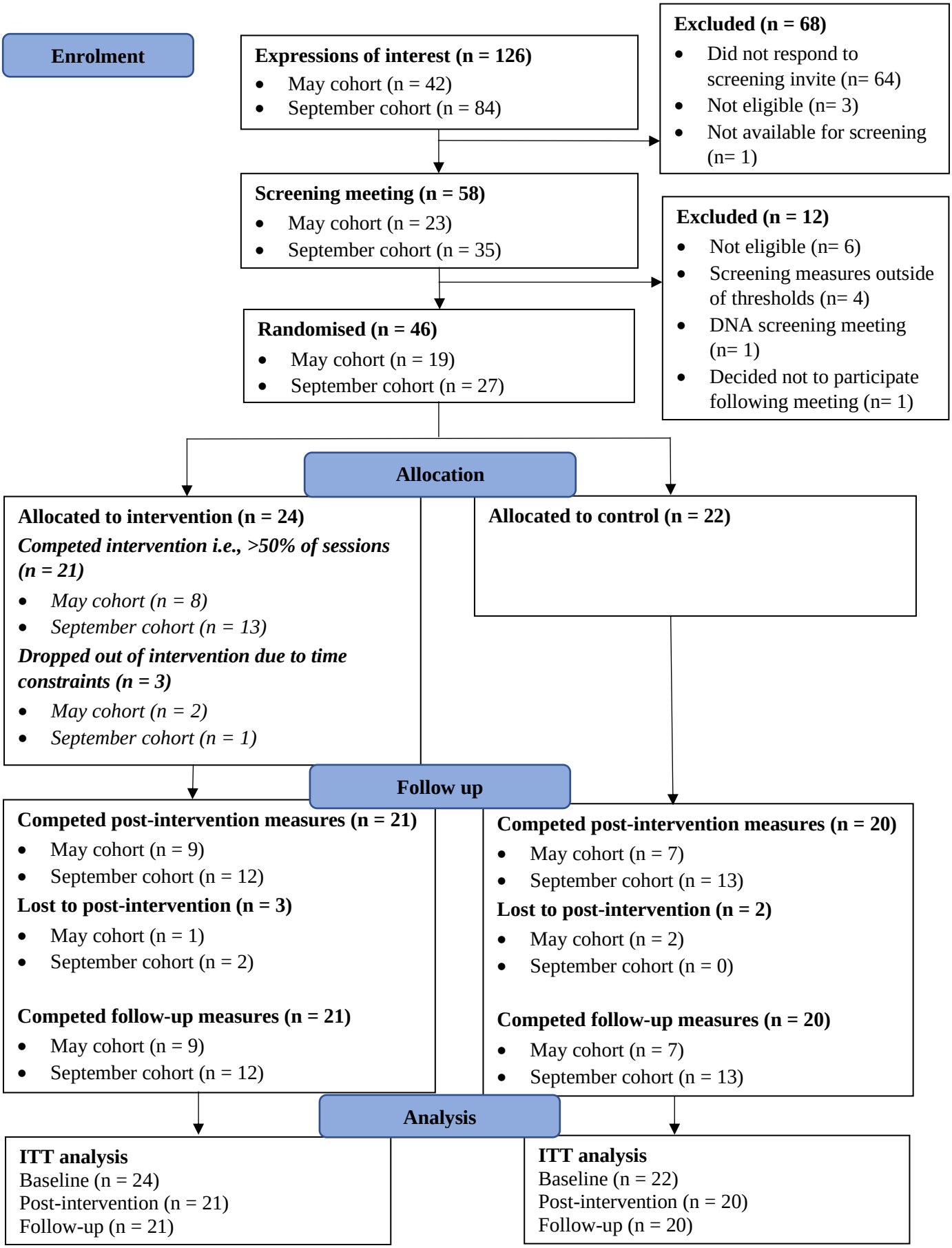
| | | | |
|---|---|---|---|
| Total anaphylactic reactions mean (SD) | 2.38 (1.41) | 1.36 (0.92) | 1.79 (1.23) |
| Anaphylaxis Management plan | | | |
| Yes | 18 (75.0) | 20 (90.0) | 38 (82.6) |
| No | 6 (25.0) | 2 (9.1) | 8 (17.4) |

**Analysis of feasibility**

A total of 126 expressions of interest were received throughout the total recruitment period (four months) and 46% (n = 58) arranged a screening meeting to discuss participation. Of these, 79% (n = 46) met the eligibility criteria and consented to participate. All participants provided baseline measures and were randomised to either the intervention or control group. 89% (n = 41) went on to complete post-intervention and follow-up data, and 11% (n=5) were lost to follow-up. Of the 24 participants allocated to the intervention group, a total of 88% (n = 21) attended >50% of sessions (i.e., Dimidjian et al., 2016). The remaining participants withdrew early due to time constraints. A flow diagram of recruitment and retention at each stage can be found within Figure 1 (based on CONSORT; Eldridge et al., 2016).

**Figure 1.**

*Recruitment and retention flow diagram (based on CONSORT; Eldridge et al., 2016)*



**Analysis of acceptability**

Feedback regarding study acceptability was collected from both the intervention and control groups. Additional feedback relating to MBCT-PCCFA was also sought from the intervention group. Follow-up information was sought if a participant rated an item ‘unacceptable’ or ‘very unacceptable’, however, this rating was only provided on one aspect of the study (at-home practice). An overview of responses is detailed in Table 3.

**Table 3.**

*Ratings of acceptability*

| Aspect of acceptability | Very unacceptable N (%) | Unacceptable N (%) | Acceptable N (%) | Very acceptable N (%) |
|---|---|---|---|---|
| Acceptability of study overall | | | | |
| Intervention (n = 21) | 0 (0) | 0 (0) | 4 (19.0) | 17 (81.0) |
| Control (n = 20) | 0 (0) | 0 (0) | 10 (50) | 10 (50) |
| Acceptability of completing questionnaires | | | | |
| Intervention (n = 21) | 0 (0) | 0 (0) | 8 (38.1) | 13 (61.9) |
| Control (n = 20) | 0 (0) | 0 (0) | 11 (55.0) | 9 (45.0) |
| Acceptability of MBCT-PCCFA | | | | |
| Intervention (n = 21) | 0 (0) | 0 (0) | 4 (19.0) | 17 (81.0) |
| Acceptability of at-home practice | | | | |
| Intervention (n = 21) | 0 (0) | 1 (4.8) | 11 (52.4) | 9 (42.9) |

Regarding overall participation in the study and the completion of the questionnaires, all participants provided either a ‘very acceptable’ or ‘acceptable’ rating. All intervention participants who completed this measure provided a ‘very acceptable’ or ‘acceptable’ rating regarding acceptability of taking part in MBCT-PCCFA. Regarding at-home practice all bar one provided a ‘very acceptable’ or ‘acceptable’ rating. The remaining participant rated at-home practice as ‘unacceptable’. Qualitative feedback indicated that finding time alone to practice whilst being a full-time parent made this aspect of the intervention difficult.

***Attendance and at-home practice completion***

Information regarding the total number of sessions attended and time dedicated to at-home practice (formal and informal) is detailed in Table 4. Overall, participants attended an average of 7.25 (SD = 2.49) out of the nine weekly sessions. Informal at-home practice was more frequently engaged in than formal practice, however, participants spent more time in minutes on formal than informal practice.

**Table 4.**

*Session attendance and at-home practice completion*

| | May cohort M (SD) | September cohort M (SD) | Combined M (SD) |
|---|---|---|---|
| Number of sessions attended | 6.60 (3.31) | 7.71 (1.68) | 7.25 (2.49) |
| Days of formal at-home practice | 3.82 (1.27) | 3.12 (0.97) | 3.38 (1.11) |
| Minutes of formal at-home practice (weekly) | 73.25 (42.77) | 47.76 (22.21) | 57.03 (32.75) |
| Days of informal at-home practice | 5.89 (1.57) | 4.44 (1.66) | 4.96 (1.75) |
| Minutes of informal at-home practice (weekly) | 54.66 (38.10) | 29.57 (18.21) | 38.70 (29.01) |

When asked if they continued to practise mindfulness after the course had ended, 85.7% (n = 18) said they did. These participants practised on average 3.58 days a week (SD = 1.99), and for an average of 25.0 minutes each time (SD = 21.64).

**Effect size estimates**

Graphs displaying the group means (with 95% confidence intervals) at each time point were produced (Figure 2). A summary of estimated effect sizes for each measure is presented within Table 5. This includes the mean observed change from baseline to post-intervention and from baseline to follow-up for each group. The mean between group difference in change scores was also calculated along with Hedges g effect sizes (with 95% confidence intervals) at post-intervention and follow-up. This employed a modified intention-to-treat analysis, whereby all participants for whom there were data were included regardless of how much of the intervention they completed. Five participants did not provide data at post-intervention or follow-up.

**Figure 2.**

*Line graphs displaying the group means (with 95% confidence intervals) at each time point for outcome and mediating measures*

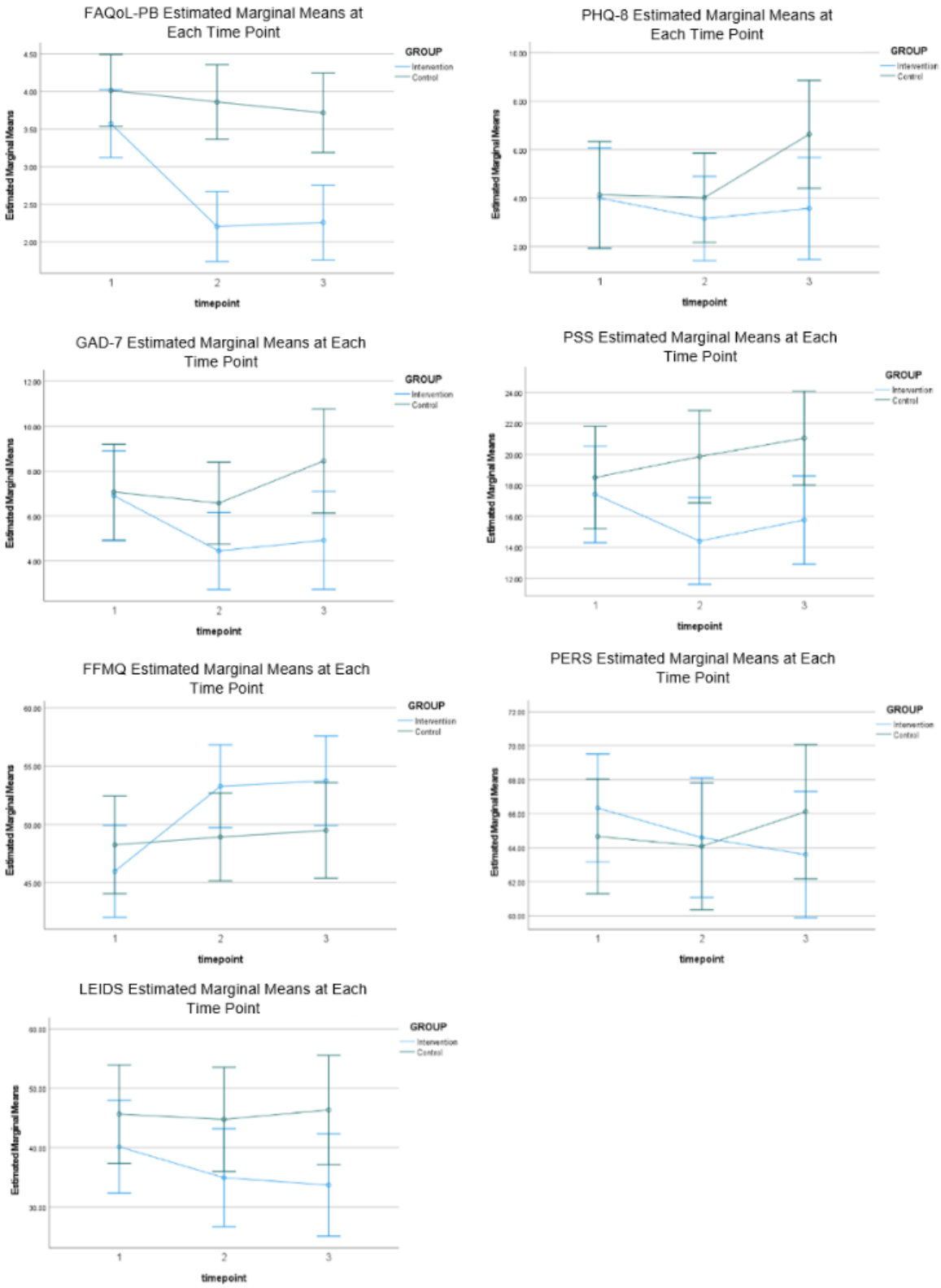


**Table 5.**

*A summary of mean change scores and estimated effect sizes for each measure*

| Measure | Intervention | | | Control | | | Between group comparison of change scores | |
|---|---|---|---|---|---|---|---|---|
| | n | M (SD) | Mean observed change from baseline (SD) | n | M (SD) | Mean observed change from baseline (SD) | Mean between group difference in change scores | Hedges g effect size (95% CI) |
| FAQoL-PB (/6) | | | | | | | | |
| Baseline (week 0) | 24 | 3.64 (0.97) | | 22 | 4.10 (0.97) | | | |
| Post-intervention (week 15) | 21 | 2.19 (1.00) | 1.42 (0.95) | 20 | 3.89 (1.06) | 0.14 (0.92) | 1.28 | 1.34 (0.66 to 2.00) |
| Follow-up (week 23) | 21 | 2.23 (1.05) | 1.38 (0.97) | 20 | 3.75 (1.15) | 0.28 (0.79) | 1.10 | 1.22 (0.56 to 1.87) |
| PHQ-8 (/24) | | | | | | | | |
| Baseline (week 0) | 24 | 4.79 (5.52) | | 22 | 3.77 (3.90) | | | |
| Post-intervention (week 15) | 21 | 3.05 (4.20) | 0.95 (3.44) | 20 | 4.15 (3.41) | -0.15 (2.78) | 1.10 | 0.35 (-0.26 to 0.95) |
| Follow-up (week 23) | 21 | 3.38 (4.52) | 0.62 (3.14) | 20 | 6.40 (4.91) | -2.40 (3.07) | 3.02 | 0.95 (0.31 to 1.59) |
| GAD-7 (/21) | | | | | | | | |
| Baseline (week 0) | 24 | 7.67 (4.96) | | 22 | 6.50 (4.35) | | | |
| Post-intervention (week 15) | 21 | 4.29 (3.41) | 2.76 (3.78) | 20 | 6.45 (4.25) | 0.30 (2.92) | 2.46 | 0.71 (0.09 to 1.33) |
| Follow-up (week 23) | 21 | 4.81 (4.27) | 2.24 (4.27) | 20 | 7.95 (5.53) | -1.20 (3.62) | 3.44 | 0.85 (0.22 to 1.47) |
| PSS (/40) | | | | | | | | |
| Baseline (week 0) | 24 | 18.21 (7.41) | | 22 | 18.18 (6.49) | | | |
| Post-intervention (week 15) | 21 | 14.48 (5.78) | 3.24 (5.79) | 20 | 19.65 (6.49) | -1.45 (3.62) | 4.69 | 0.95 (0.31 to 1.58) |
| Follow-up (week 23) | 21 | 15.48 (5.80) | 2.24 (7.87) | 20 | 20.60 (7.13) | -2.40 (5.59) | 4.64 | 0.66 (0.04 to 1.28) |
| FFMQ-15 (/75) | | | | | | | | |
| Baseline (week 0) | 24 | 45.88 (7.44) | | 22 | 48.45 (9.93) | | | |
| Post-intervention (week 15) | 21 | 53.29 (7.80) | -7.48 (7.37) | 20 | 49.50 (7.90) | -0.75 (5.38) | -6.73 | -1.02 (-1.65 to -0.37) |
| Follow-up (week 23) | 21 | 53.95 (7.55) | -8.14 (8.06) | 20 | 50.45 (9.83) | -1.70 (5.37) | -6.44 | -0.92 (-1.55 to -0.28) |
| PERS (/90) | | | | | | | | |
| Baseline (week 0) | 24 | 66.08 (6.14) | | 22 | 64.64 (7.80) | | | |
| Post-intervention (week 15) | 21 | 64.33 (8.92) | 1.76 (6.74) | 20 | 63.30 (6.82) | 1.05 (4.44) | 0.71 | 0.12 (-0.48 to 0.72) |
| Follow-up (week 23) | 21 | 63.52 (8.13) | 2.57 (5.21) | 20 | 65.60 (8.24) | -1.25 (5.05) | 3.82 | 0.73 (0.10 to 1.35) |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| LEIDS (/136) | | | | | | | | |
| Baseline (week 0) | 24 | 40.96 (16.88) | | 22 | 44.64 (15.69) | | | |
| Post-intervention (week 15) | 21 | 34.86 (18.90) | 5.57 (11.95) | 20 | 45.05 (16.99) | 0.25 (14.68) | 5.32 | 0.39 (-0.22 to 1.00) |
| Follow-up (week 23) | 21 | 33.90 (18.40) | 6.52 (16.30) | 20 | 46.25 (19.35) | -0.95 (15.31) | 7.47 | 0.46 (-0.15 to 1.07) |

Note. *FAQoL-PB* Food Allergy Quality of Life-Parental Burden scale; *PHQ-8* Patient Health Questionnaire; *GAD-7* Generalized Anxiety Disorder screener; *PSS* Perceived Stress Scale; *FFMQ* Five-Facet Mindfulness Questionnaire; *PERS* Perth Emotional Reactivity Scale; *LEIDS* Leiden Index of Depression Sensitivity-Revised

The point estimate for the between group effect size from baseline to post-intervention for change scores in the primary outcome (FAQoL-PB) was ‘large’, with a ‘medium’ to ‘large’ CI that did not include ‘0’. Similar estimated effect sizes were found at follow-up.

For secondary outcomes, the point estimates for the between group effect sizes from baseline to post-intervention for change scores in both levels of anxiety and stress were ‘large’. ‘Large’ and ‘medium’ point estimate effect sizes were found for anxiety and stress at follow-up, respectively. Whilst a ‘small’ point estimate effect size was found for depression at post-intervention, a ‘large’ point estimate was found at follow-up. In all bar one case the CIs did not include ‘0’ and were within ‘small’ to ‘large’ ranges. For depression at post-intervention, the CIs were wider and included ‘0’.

For measures of mindfulness, the point estimate for the between group effect size from baseline to post-intervention for change scores was ‘large’, with ‘small’ to ‘large’ CIs that did not cross ‘0’. Similar results were found at follow-up. ‘Small’ point estimates were found for emotional and cognitive reactivity at post-intervention, and ‘medium’ point estimates at follow-up. However, in all bar one case (emotional reactivity post-intervention), the CIs were wide and included ‘0’.

**Reliable Change Index**

Change on an individual basis was examined using the Reliable Change Index. Findings are presented in Table 6.

**Table 6.**

*Summary of reliable change for each measure*

| | Intervention n = 21 | | | Control n = 20 | | |
|---|---|---|---|---|---|---|
| | Reliably improved n (%) | No change n (%) | Reliably deteriorated n (%) | Reliably improved n (%) | No change n (%) | Reliably deteriorated n (%) |
| Baseline to Post-intervention | | | | | | |
| FAQoL-PB | 15 (71.4) | 6 (28.6) | 0 (0) | 5 (25.0) | 13 (65.0) | 2 (10.0) |
| GAD | 6 (28.6) | 14 (66.7) | 1 (4.8) | 3 (15.0) | 16 (80.0) | 1 (5.0) |
| PHQ | 1 (4.8) | 19 (90.5) | 1 (4.8) | 0 (0) | 20 (100) | 0 (0) |
| PSS | 8 (38.1) | 11 (52.4) | 2 (9.5) | 1 (5.0) | 16 (80.0) | 3 (15.0) |
| PERS | 2 (9.5) | 19 (90.5) | 0 (0) | 0 (0) | 20 (100) | 0 (0) |
| LEIDS | 4 (19.0) | 17 (81.0) | 0 (0) | 3 (15.0) | 13 (65.0) | 4 (20.0) |
| FFMQ | 8 (38.1) | 13 (61.9) | 0 (0) | 1 (5.0) | 18 (90.0) | 1 (5.0) |
| Baseline to Follow-up | | | | | | |
| FAQoL-PB | 15 (71.4) | 6 (28.6) | 0 (0) | 4 (20.0) | 15 (75.0) | 1 (5.0) |
| GAD-7 | 6 (28.6) | 14 (66.7) | 1 (4.8) | 2 (10.0) | 15 (75.0) | 3 (15.0) |
| PHQ-8 | 2 (9.5) | 19 (90.5) | 0 (0) | 0 (0) | 16 (80.0) | 4 (20.0) |
| PSS | 9 (42.9) | 9 (42.9) | 3 (14.3) | 1 (5.0) | 15 (75.0) | 4 (20.0) |
| PERS | 2 (9.5) | 19 (90.5) | 0 (0) | 0 (0) | 18 (90.0) | 2 (10.0) |
| LEIDS | 4 (19.0) | 15 (71.4) | 2 (9.5) | 1 (5.0) | 16 (80.0) | 3 (15.0) |
| FFMQ | 10 (47.6) | 11 (52.4) | 0 (0) | 1 (5.0) | 18 (90.0) | 1 (5.0) |

Note. *FAQoL-PB* Food Allergy Quality of Life-Parental Burden scale; *PHQ-8* Patient Health Questionnaire; *GAD-7* Generalized Anxiety Disorder screener; *PSS* Perceived Stress Scale; *FFMQ* Five-Facet Mindfulness Questionnaire; *PERS* Perth Emotional Reactivity Scale; *LEIDS* Leiden Index of Depression Sensitivity-Revised

**Exploratory analysis of mediation**

A mediation analysis was conducted to provide a signal of efficacy indicating whether there was sufficient tentative evidence for possible mediating effects (of mindfulness, emotional reactivity, and cognitive reactivity) to justify examination within a definitive RCT. The results are summarised in Table 7. The CIs for the indirect effects for the LEIDS do not include '0' for two outcomes (PHQ-8 and PSS) and the remaining outcomes (GAD-7 and FAQoL-PB) came close to not including '0', as such there appears to be a potential signal of efficacy for cognitive reactivity mediating the effect of group on outcomes. Similarly, for the FFMQ, effect size estimate CIs come close to not crossing '0' for most outcomes. There appears to be a less consistent signal for mediation of the PERS.

**Table 7.**

*A summary of mediation analysis*

| | Mediation estimates | | |
|---|---|---|---|
| | FFMQ Indirect effect (95% CI) | LEIDS Indirect effect (95% CI) | PERS Indirect effect (95% CI) |
| FAQoL-PB | 0.04 (-0.04 to 0.40) | 0.06 (-0.03 to 0.39) | -0.03 (-0.27 to 0.03) |
| GAD-7 | 0.60 (-0.05 to 2.01) | 0.85 (-0.02 to 2.95) | -0.09 (-1.24 to 0.34) |
| PHQ-8 | 0.36 (-0.11 to 1.57) | 0.72 (0.01 to 2.42) | -0.02 (-0.27 to 0.08) |
| PSS | 1.09 (-0.07 to 4.09) | 1.78 (0.21 to 4.43) | -0.24 (-1.79 to 0.65) |

Note. *FAQoL-PB* Food Allergy Quality of Life-Parental Burden scale; *PHQ-8* Patient Health Questionnaire; *GAD-7* Generalized Anxiety Disorder screener; *PSS* Perceived Stress Scale; *FFMQ* Five-Facet Mindfulness Questionnaire; *PERS* Perth Emotional Reactivity Scale; *LEIDS* Leiden Index of Depression Sensitivity-Revised

**Content analysis of intervention feedback**

Qualitative feedback regarding MBCT-PCCFA was collected from the intervention group and analysed using content analysis. Categories and sample quotations for each question are provided in Table 8.

In asking about learning points from the intervention, the main categories identified centred on the 'positive effects of mindfulness' and 'noticing and managing emotional responses' (n = 7). Participants reflected on the positive impact it had on their lives when practised regularly and how they had learnt useful strategies to manage difficult feelings (e.g., anxiety). These were then followed by 'coping better with unhelpful thoughts' and increased 'awareness and appreciation of everyday moments (n=4). The remaining categories included 'importance of creating time for self' and learning they were 'not alone in experiences'.

When asked which aspects of MBCT-PCCFA they liked the most, the main category consisted of the 'body scan' (n = 9), closely followed by 'mindfulness of breathing (including three-minute breathing space)' (n = 7). Four participants referenced 'connecting to others with similar experiences'. This was followed by appreciation of the 'online aspect' of the course and learning to apply 'mindfulness to everyday tasks' (n = 3). The last category was 'mindful movement' (n = 2).

When asked about which aspects they liked least, most people referenced 'fitting in at-home practice' (n = 7), in particular, the pressures of trying to schedule this into a busy lifestyle. This was followed by experiencing 'guilt around non-engagement' and 'timing of sessions' (n = 3), particularly due to child care and family commitments. Two participants found the 'focus on allergy' difficult, and one mentioned the 'group setting' and 'online format' as challenging. Four participants did not feel there were any aspects they disliked.

Similar to the aforementioned responses, the main category generated when considering challenges to taking part focused on ‘time commitment to course’ (n = 10). This was followed by ‘session timing’ (n = 4), with some suggesting a later or early time may have been more suitable. Two participants mentioned ‘lacking motivation’ and ‘arranging childcare’ as challenges to engaging. Another two did not feel there were any challenges, and one participant found their ‘internet connectivity’ posed a challenge.

Responses considering what could be improved about the intervention varied. The majority of responses fell into the category of ‘nothing’, however this was followed by suggestions of a ‘different session time’, ‘greater focus on food allergy’, and ‘in-person sessions’ (n=2). Other individuals suggested ‘less sitting practice’, ‘recording sessions’, ‘further breakout opportunities’, and ‘regular check-ins’ as possible ways to improve MBCT-PCCFA (n=1).

Most participants agreed there had been a change in their perspective of parenting a child with a food allergy since starting the course (n = 3 did not). Of those, the main category generated focused on ‘an ability to manage these experiences’ (n = 9), with many feeling more confident and able since completing the course. This was followed by an increased understanding that ‘I am not the only one’ (n = 7) and an ‘increased acceptance of situation’. Others felt they had ‘reduced worry regarding the future’ (n = 2), and a ‘sense of pride’ (n = 1).

Lastly, when considering the differences that the course had made to their lives, the main category generated suggested ‘improved emotional wellbeing’ (n = 9), in particular feeling calmer and happier. This was following by ‘managing difficulties more effectively’ (n = 7) and an ‘increased awareness of experience/emotion’ (n = 4). Others noted having ‘better

self-care’ and ‘better concentration’ as a result of the course. Two participants did not feel the course made any changes to their lives.

**Table 8.**

*An overview of content analysis categories with sample quotations*

| Question | Categories | Frequency (total respondents) | Sample quote |
|---|---|---|---|
| What are the main things you feel you learnt from this intervention? | Importance of creating time for self | 3 | "Take time out of life chaos to concentrate on myself." |
| | Awareness and appreciation of everyday moments | 4 | "[…] and be aware of small things and moments in life." |
| | Positive effects of mindfulness | 7 | "The practice of mindfulness is bigger than I realised. Its effects are wide reaching." |
| | Not alone in experiences | 3 | "That I'm not alone in coping with parenting an allergy child […]" |
| | Noticing and managing emotional responses | 7 | "I felt I learnt how I react when I am anxious and was given techniques to try and react more effectively, less emotionally. I learnt how to explore my emotions in a safe way […]" |
| | Coping better with unhelpful thoughts | 4 | "That thoughts are fleeting and I can stop them and change my thought pattern." |
| What was the aspect of the intervention that you liked the most? What was your favourite activity (or session)? | Body scan | 9 | "The full body scan really made me feel at peace." |
| | Mindfulness of breathing (including three-minute breathing space) | 7 | "[…] the 3-minute breathing spaces […] were easier for me to incorporate into busy life outside of sessions." |
| | Mindful movement | 2 | "My favourite activity was the mindful movement […]" |
| | Mindfulness in everyday tasks | 3 | "Bringing mindfulness into daily life was the most useful - mindful eating, for example." |
| | Online format | 3 | "Loved the zoom sessions." |

| | | | |
|---|---|---|---|
| | Connecting to others with similar experiences | 4 | “Group session as it was great to meet others undergoing similar experiences and feelings.” |
| What did you least like about the intervention? | Fitting in at-home practice | 7 | “Keeping up with the home practice. […] Finding time each day felt like a lot of pressure.” |
| | Guilt around non-engagement | 3 | “[…] then felt bad for not doing it.” |
| | Focus on allergy | 2 | “I didn’t like putting my allergy fears at the front of my thoughts just because of the fear of not being able to control it.” |
| | Timing of sessions | 3 | “The home practise was often difficult to fit in and the time slot was just at bed time so difficult juggle.” |
| | Group setting | 1 | “Found it hard sometimes to talk about my feelings in a group situation, a little shy.” |
| | Online format | 1 | “Having to lie down with the webcam.” |
| | Nothing | 4 | “Nothing it was all great.” |
| Were there any difficulties or challenges to taking part? | Session time | 4 | “Time slot would have been easier if it was half hour later.” |
| | Time commitment to course | 10 | “Finding the time to practice.” |
| | Arranging childcare | 2 | “As a single mum, I had to pay a babysitter to attend. It was worth every penny, but it could be a block to some parents who really need it.” |
| | Internet connectivity | 1 | “Internet quality my end.” |
| | Lacking motivation | 2 | “[…] motivation to practice” |
| | No challenges | 2 | “None.” |
| What do you think could be improved? | Nothing | 9 | “I honestly couldn’t fault the course. I’m so incredibly grateful for the experience and the knowledge I gained and I rave about it to people all the time.” |

| | | | |
|---|---|---|---|
| | Less sitting practice | 1 | “I didn’t enjoy sitting practice so much so less sitting. […]” |
| | Recording sessions | 1 | “Recording the sessions for people to be able to look back at them […]” |
| | Further breakout opportunities | 1 | “[…] I'd have welcomed more chance to share peer support with others in breakout rooms.” |
| | Regular check-ins | 1 | “It would be nice to have regular check in’s.” |
| | Different session time | 2 | “I found the timing of the sessions difficult with a young child.” |
| | Greater focus on food allergy | 2 | “Make it more specific for parents of children with allergies.” |
| | In-person sessions | 2 | “It would have been great to be in a physical class to ensure no interruption, but obviously logistically that couldn't have happened.” |
| Are there any changes in your perspective of being a parent of a child with a food allergy? If the answer is ‘Yes’, what are they? | I am not the only one | 7 | “Yes. Knowing that we are not alone in this.” |
| | An ability to manage the experiences | 9 | “Yes - I try not to dwell on the negative thoughts, instead I now recognise them and refocus my mind on to something more positive.” |
| | Reduced worry regarding future | 2 | “Yes, less worrying about what haven’t happened.” |
| | Increased acceptance of situation | 3 | “Yes - accepting the fact that it’s ok to feel a certain way and not worrying about feeling that way in the first place.” |
| | Sense of pride | 1 | “[…] I've come an awful long way and so has my daughter and I feel proud for that. […]” |
| | No changes | 3 | “Not really.” |
| Have you noticed any differences in your life as a result of taking part in the intervention? If | Improved emotional wellbeing | 9 | “I feel happier, calmer and more resilient.” |
| | Managing difficulties more effectively | 7 | “I have managed to cope better under very stressful situations for example we went to London for the day and forgot our medi bag, where I was very anxious all day I feel I handled it much better than I would have before. […] I used the breathing exercises when I felt myself getting anxious and it really helped.” |

| | | | |
|---|---|---|---|
| ‘yes’, what are these differences? | Better self-care | 1 | “If I invest time in myself, I can make a positive change to me and my family's life.” |
| | Increased awareness of experience/emotion | 4 | “More aware of things surrounding me” |
| | Better concentration | 1 | “Concentration at work is improved.” |
| | No differences | 2 | “Not really.” |

Inter-rater reliability was calculated using Cohen's kappa (Cohen, 1960). All seven questions produced an almost perfect kappa statistic ($\kappa \geq 0.83$; Landis & Koch, 1977; Table 9).

**Table 9.**

*Inter-rater reliability analysis*

| Question | Cohen's kappa (κ) |
|---|---|
| What are the main things you feel you learnt from this intervention? | 1 |
| What was the aspect of the intervention that you liked the most? What was your favourite activity (or session)? | 0.83 |
| What did you least like about the intervention? | 1 |
| Were there any difficulties or challenges to taking part? | 1 |
| What do you think could be improved? | 1 |
| Are there any changes in your perspective of being a parent of a child with a food allergy? If the answer is 'Yes', what are they? | 0.83 |
| Have you noticed any differences in your life as a result of taking part in the intervention? If 'yes', what are these differences? | 0.83 |

**Serious adverse events**

No serious adverse events were reported during the trial (i.e., important harms or unintended effects in either group; Junqueira et al., 2021).

## Discussion

This study consisted of a parallel feasibility trial aiming to explore the acceptability of MBCT-PCCFA and provide a signal of efficacy. The recruitment, attrition, and measure response rates, support the feasibility of undertaking a RCT investigating MBCT-PCCFA. Overall session attendance, low dropout rates, engagement with at-home practice, and qualitative feedback support that adapted MBCT is acceptable to this population. Effect size estimates suggest that MBCT-PCCFA with TAU has a favourable effect on quality of life (‘medium’ to ‘large’ estimated effects), stress, anxiety, and low mood (‘small’ to ‘large’ estimated effects) compared to TAU-only. Estimated effects were also maintained at an 8-week follow-up. In all bar one case the 95% confidence intervals did not include ‘0’, however for measures of low mood at post-intervention, the CIs were wider. Nevertheless, these findings provide a good signal of efficacy to justify a future definitive trial and provide a basis for a power calculation for this.

Overall, the recruitment target to conduct a feasibility study was achieved in the allotted timeframe through two waves of recruitment (Bell et al, 2018; Lancaster et al., 2004). The proportion who expressed interest and subsequently participated in a screening meeting was lower (44%) than other studies with PCCFA (60%; Vreeken-Ross et al., 2021). However, Vreeken-Ross et al’s. study involved a process of invitation by allergy support group leaders and did not include a control group, so all participants knew they were to receive the intervention. Future research may wish to consider building these support groups into recruitment plans and using a waitlist control group. Nonetheless, the rates of those screened for eligibility and then randomised within this study (79%) were comparable to other MBCT trials (78.3%; Kor et al., 2019). Interestingly, only 10.8% were lost to follow-up, which is considerably lower than the average attrition rate seen across pilot RCTs (21.1%;

Cooper et al., 2018) and other MBCT RCTs (12.9-26%; Lunsky et al., 2017; Oken et al., 2010). There was no missing data from the 41 participants who provided questionnaire responses.

Regarding acceptability, session attendance was high (an average of 7.25 out of 9 sessions), with only 12.5% (n = 3) not completing the intervention. This compares favourably to other MBCT pilot trials with carers of different populations (17-23%; Kor et al., 2019; Smith et al., 2020). Whilst participants identified at-home practice as most challenging and the average time spent on formal at-home practice (57.03 minutes) was less than other MBCT studies (180 minutes; Parsons et al., 2017), shorter practices were available to participants, so less practice may have been expected due to this adaptation. At-home practice is also commonly cited as difficult to build into busy schedules (Racey et al., 2018), nonetheless almost all participants in this study still rated it as ‘acceptable’. Overall, although this study did not have defined prospective progression criteria (Mbuagbaw et al., 2019), the recruitment, retention and engagement rates are comparable to other feasibility studies using MBCT which have employed criteria (Pitt et al., 2020).

Categories identified within the content analysis were also consistent with previous research. ‘Connecting to others with a similar experience’, ‘coping better with unhelpful thoughts’ and ‘improved wellbeing’ overlapped with the themes identified within Douglas et al’s (2021) exploration of carers experiences of MBCT. They found that participants appreciated the group facilitating a ‘shared suffering’ as many coped with difficulties alone, they were also more able to manage difficult memories by focusing on the present, and noticed ‘feeling better’ in themselves as result. Interestingly, both Douglas et al. (2021) and Racey et al. (2018) also identified themes around negative emotions at the start (e.g., feeling apprehensive about the intervention) that were not noted by any participants within this study.

This possibly suggests the right level of pre-course information and orientation was provided and should be continued in future research.

In comparison to other evidence-based interventions for PCCFA, the effect size estimates obtained in this study appear promising. Knibb (2015) explored the efficacy of 12-weekly individual CBT sessions, reporting a ‘medium’ effect size improvement in quality of life at post-intervention. This suggests that whilst ‘second wave’ CBT improves QoL, MBCT-PCCFA may be able to offer something over and above this. The estimated effect size for reduction in anxiety is also comparable to those found within Vreeken-Ross et al. (2021) who found a ‘medium’ effect following a brief two-session CBT intervention. However, they did not find any significant effects in relation to levels of stress or depression, therefore lengthier interventions such as MBCT-PCCFA may offer a more suitable treatment when these are the presenting difficulties. Regarding MBI approaches for carers generally, it would appear the effect size reductions in stress and anxiety are comparable, and possibly larger, based on findings in Part A whereby ‘small’ to ‘medium’ effect size estimates at post-intervention were calculated. As such, this trial provides further support that MBIs are useful in supporting carers with these difficulties.

Regarding the process variables, this study supports the feasibility of measuring cognitive reactivity and mindfulness using the LEIDS (Van der Does, 2002) and FFMQ- 15 (Baer et al., 2008) in PCCFA. Effect size estimates provided a potential signal of efficacy that these variables mediated the effect of group on outcome measures. This is consistent with theories regarding mechanisms of change (Gu et al., 2015) and the key theoretical premise underlying MBCT that an increase in mindfulness enables insight and non-reactive acceptance of experiences, ultimately allowing individuals to live alongside difficulties that are not easily changed and reducing distress (Segal et al., 2002). However, findings relating to emotional reactivity should be interpreted with caution as a questionable level of internal

consistency was calculated within this sample. Future research may therefore wish to use the LEIDS and FFMQ but consider an alternative measure of emotional reactivity (e.g., the Emotional Reactivity Scale; Nock et al., 2008).

Alternatively, there may be other mechanisms supporting change, for example levels of rumination and worry, which are often high in parents caring for children with chronic health conditions (Staab et al., 2002; Williams et al., 2009). As such, future research may look to employ measures for these constructs (e.g., Ruminative Response Scale; Treynor et al., 2003, or Penn State Worry Questionnaire; Meyer et al., 1990). Group process theory may also offer some explanation, whereby the interpersonal environment of the group is often considered a vehicle for change (Yalom, 1995). Yalom and Leszcz (2005) identified therapeutic factors for change in groups, some of which directly linked to the feedback of experiences in this study, including ‘universality’ (members recognising that others share similar feelings, thoughts, and difficulties) and ‘cohesiveness’ (feelings of belonging experienced by group members). It is also possible that other factors common in groups, such as ‘instillation of hope’ (members recognising improvement in others and developing optimism for their own), and ‘catharsis’ (releasing strong feelings about past and present experiences) occurred, aiding positive change alongside the intervention itself. To explore this in further detail future research would require an active control group.

**Strengths and limitations**

There are several strengths to this feasibility trial. Firstly, the current evidence base focuses predominantly on ‘second wave’ CBT and this study offers a novel and unique insight into the use of adapted online MBCT for PCCFA, demonstrating its feasibility and acceptability. It also provided evidence supporting the feasibility of recruitment within a limited timeframe and in the context of a pandemic when many faced additional demands (Haleem et al., 2020). Despite using a passive control, engagement levels were high for both

groups. Furthermore, randomisation of participants supported the balance of important variables between groups and blinded outcome assessment at each timepoint eliminated observer bias. While by design it was not possible to definitively measure effects, there were nevertheless promising indications of potential signals of efficacy which warrant examining this intervention in a large-scale funded trial.

Several limitations of this study should be noted. Firstly, the self-referral of participants likely introduces selection bias and therefore the sample may represent a subset of the population for whom such interventions are more accessible or possible. All participants within the sample identified as female and were predominantly university educated and of white ethnic background, which has also been found in other studies reliant principally on social media for recruitment (i.e., Sugunasingha et al., 2022; Vreeken-Ross et al., 2021). As such, it is not possible to generalise findings beyond this population. Given there is research suggesting Black and Asian children are more likely to develop a food allergy (Jiang et al., 2020) and the overall burden of allergic disease being worse for these groups (Jones et al., 2022; McQuaid et al., 2016), it is imperative that this is carefully addressed in future trials to obtain a truly representative sample, including people from minority ethnic backgrounds and other genders. This may be achieved by structuring recruitment through an allergy clinic caseload list, as seen in Boyle et al. (2017). Other ways to ensure MBCT is made accessible to underrepresented populations may include having interventions for specific groups (e.g., a group for fathers of children with food allergies). A good example of tailoring for minority groups is an NHS service in Sussex where there are specific groups for travelling communities. The service has also recruited a MBCT-trained Equality and Diversity lead who supports the tailoring of interventions to specific groups. In a research study, Burnett-Zeigler et al. (2016) found positive outcomes when MBSR was adapted for African-American participants by modifying content to be culturally relevant

(e.g., poems and images). As such, it is important in the planning stages of future trials to consider how MBCT can be adapted to specific groups to ensure the intervention is accessible and relevant.

Another limitation relates to the use of a passive control group, as this limits how much it can be concluded that change was due to the MBCT-PCCFA intervention verses other factors (e.g., group processes). As such, an active control using a group-based intervention over similar time period would be useful in future trials. Moreover, whilst this study included a follow-up period, the effects of MBCT cannot be assumed past 8-weeks. Future research should include a longer period, allowing for firmer conclusions regarding the long-lasting effects of the intervention and therefore the value of the intervention to PCCFA and services supporting them. Finally, whilst a modified intention-to-treat analysis was conducted, there were five participants who did not provide any post-intervention or follow-up data and therefore their views and outcomes could not be included in the results. A larger definitive trial may wish to employ imputation analysis to manage missing values.

**Clinical implications**

As this was a feasibility trial, it would not be appropriate to draw firm clinical implications until a definitive trial has been conducted. However, the ‘medium’ to ‘large’ effect size estimates for the primary outcome and ‘small’ to ‘large’ estimates for secondary outcomes, combined with the additional evidence for this intervention in carer populations (see Part A meta-analysis), promisingly suggests that this type of intervention might offer some useful resources for PCCFA. As such, clinicians may wish to consider integrating or referring to MBCT groups when clients are experiencing difficulties that the evidence is already there for (e.g., stress and low mood). Settings where MBCT groups for PCCFA could be introduced may include paediatric services, specialist NHS allergy centres (some of which already provide parent and carer support services, primary care mental health services, or

third sector allergy organisations. Furthermore, by offering groups online, services can reach a wider number of individuals and save on costs associated with holding in-person sessions.

**Summary of recommendations and conclusions**

To the author's knowledge this was the first feasibility RCT aiming to explore the acceptability of MBCT-PCCFA in order to ascertain whether a definitive trial was warranted. Rates of recruitment, retention and engagement support the feasibility of exploring this intervention with this population using an RCT. Engagement with the intervention and qualitative feedback regarding the study process and intervention supported acceptability of live online MBCT-PCCFA. Effect size estimates provided a promising potential signal of efficacy for MBCT-PCCFA on quality of life and secondary psychological wellbeing outcomes. As such, a definitive trial is warranted and recommendations include: (1.) utilising the findings within the current study to perform a power calculation; (2.) careful consideration of recruitment strategies to obtain a truly representative sample; (3.) using an alternative measure of emotional reactivity; (4.) measuring constructs including rumination and worry as possible process variables; (5.) an active control group; (6.) a longer follow-up period; (7.) imputation analysis; (8.) offering groups at different times to fit with varying routines; (9.) conducting a comprehensive health-economic analysis as an incentive for funding a larger trial (Turner et al., 2021).

## References

Akeson, N., Worth, A., & Sheikh, A. (2007). The psychosocial impact of anaphylaxis on young people and their parents. *Clinical & Experimental Allergy, 37*(8), 1213-1220. https://doi.org/10.1111/j.1365-2222.2007.02758.x

Baer, R. A., Smith, G. T., Lykins, E., Button, D., Krietemeyer, J., Sauer, S., Walsh, E., Duggan, D. & Williams, J. M. G. (2008). Construct validity of the Five Facet Mindfulness Questionnaire in meditating and nonmeditating samples. *Assessment, 15*, 329–342. https://doi.org/10.1177/1073191107313003

Barak, A., Hen, L., Boniel-Nissim, M., & Shapira, N. A. (2008). A comprehensive review and a meta-analysis of the effectiveness of internet-based psychotherapeutic interventions. *Journal of Technology in Human services*, *26*(2-4), 109-160. https://doi.org/10.1080/15228830802094429

Becerra, R., Preece, D., Campitelli, G., & Scott-Pillow, G. (2019). The assessment of emotional reactivity across negative and positive emotions: Development and validation of the Perth Emotional Reactivity Scale (PERS). *Assessment*, *26*(5), 867-879. https://doi.org/10.1177%2F1073191117694455

Bell, M. L., Whitehead, A. L., & Julious, S. A. (2018). Guidance for using pilot studies to inform the design of intervention trials with continuous outcomes. *Clinical Epidemiology, 10*, 153. https://doi.org/10.2147%2FCLEP.S146397

Boyce, J. A., Assa'ad, A., Burks, A. W., Jones, S. M., Sampson, H. A., Wood, R. A., & Schwaninger, J. M. (2011). Guidelines for the diagnosis and management of food allergy in the United States: summary of the NIAID-sponsored expert panel report. *Journal of the American Academy of Dermatology*, *64*(1), 175-192. https://doi.org/10.1016/j.jaad.2010.11.020

Boyle, R. J., Umasunthar, T., Smith, J. G., Hanna, H., Procktor, A., Phillips, K., ... & Hodes, M. (2017). A brief psychological intervention for mothers of children with food allergy can change risk perception and reduce anxiety: outcomes of a randomized controlled trial. *Clinical & Experimental Allergy*, *47*(10), 1309-1317. https://doi.org/10.1111/cea.12981

Brantlee Broome-Stone, S. (2012). The psychosocial impact of life-threatening childhood food allergies. *Pediatric Nursing*, *38*(6), 327-330.

Burnett-Zeigler, I. E., Satyshur, M. D., Hong, S., Yang, A., Moskowitz, J. T., & Wisner, K. L. (2016). Mindfulness based stress reduction adapted for depressed disadvantaged women in an urban Federally Qualified Health Center. *Complementary Therapies in Clinical Practice*, *25*, 59–67. https://doi.org/10.1016/j.ctcp.2016.08.007

Cameron, I. M., Crawford, J. R., Lawton, K., & Reid, I. C. (2008). Psychometric comparison of PHQ-9 and HADS for measuring depression severity in primary care. *British Journal of General Practice*, *58*(546), 32-36. https://doi.org/10.3399/bjgp08X263794

Cheung, D. S. K., Kor, P. P. K., Jones, C., Davies, N., Moyle, W., Chien, W. T., & Lai, C. K. (2020). The use of modified mindfulness-based stress reduction and mindfulness-based cognitive therapy program for family caregivers of people living with dementia: A feasibility study. *Asian Nursing Research*, *14*(4), 221-230. https://doi.org/10.1016/j.anr.2020.08.009

Chow, C., Pincus, D. B., & Comer, J. S. (2015). Pediatric food allergies and psychosocial functioning: Examining the potential moderating roles of maternal distress and overprotection. *Journal of Pediatric Psychology*, *40*(10), 1065-1074. https://doi.org/10.1093/jpepsy/jsv058

Cohen, B. L., Noone, S., Muñoz-Furlong, A., & Sicherer, S. H. (2004). Development of a questionnaire to measure quality of life in families with a child with food allergy.

*Journal of Allergy and Clinical Immunology*, *114*(5), 1159-1163. https://doi.org/10.1016/j.jaci.2004.08.007

Cohen, J. (1960). A coefficient of agreement for nominal scales. *Educational and Psychological Measurement*, *20*(1), 37-46. https://doi.org/10.1177/001316446002000104

Cohen, S., Kamarck, T., & Mermelstein, R. (1983). A global measure of perceived stress. *Journal of Health and Social Behavior*, 385-396. https://doi.org/10.2307/2136404

Connell, J., Brazier, J., O'Cathain, A., Lloyd-Jones, M., & Paisley, S. (2012). Quality of life of people with mental health problems: A synthesis of qualitative research. *Health and Quality of Life Outcomes*, *10*(1), 1-16. https://doi.org/10.1186/1477-7525-10-138

Cooper, C. L., Whitehead, A., Pottrill, E., Julious, S. A., & Walters, S. J. (2018). Are pilot trials useful for predicting randomisation and attrition rates in definitive studies: a review of publicly funded trials. *Clinical Trials*, *15*(2), 189-196. https://doi.org/10.1177%2F1740774517752113

Cummings, A. J., Knibb, R. C., King, R. M., & Lucas, J. S. (2010). The psychosocial impact of food allergy and food hypersensitivity in children, adolescents and their families: a review. *Allergy*, *65*(8), 933-945. https://doi.org/10.1111/j.1398-9995.2010.02342.x

De Boer, M. R., Waterlander, W. E., Kuijper, L. D., Steenhuis, I. H., & Twisk, J. W. (2015). Testing for baseline differences in randomized controlled trials: an unhealthy research behavior that is hard to eradicate. *International Journal of Behavioral Nutrition and Physical Activity*, *12*(1), 1-8. https://doi.org/10.1186/s12966-015-0162-z

Douglas, S., Stott, J., Spector, A., Brede, J., Hanratty, É., Charlesworth, G., & Aguirre, E. (2021). Mindfulness-based cognitive therapy for depression in people with dementia:

A qualitative study on participant, carer and facilitator experiences. *Dementia*, *21*(2), 457-476. https://doi.org/10.1177%2F14713012211046150

Eldridge, S. M., Chan, C. L., Campbell, M. J., Bond, C. M., Hopewell, S., & Thabane, L. (2016). CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ*, *355*, i5239. https://doi.org/10.1136/bmj.i5239

Evans S. (2016) Mindfulness-Based Cognitive Therapy for Generalized Anxiety Disorder. In Eisendrath S. (Ed.) *Mindfulness-Based Cognitive Therapy.* Springer. https://doi.org/10.1007/978-3-319-29866-5_13

Faul, F., Erdfelder, E., Lang, A.-G., & Buchner, A. (2007). G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behavior Research Methods*, *39*, 175-191. https://doi.org/10.3758/BF03193146

Flokstra-de Blok, B. M., & Dubois, A. E. (2009). Quality of life in food allergy: Valid scales for children and adults. *Current Opinion in Allergy and Clinical Immunology*, *9*(3), 214-221. https://doi.org/10.1097/ACI.0b013e32832aa59f

Food Standards Agency. (2016). *Chief Scientific Adviser's Science Report. Issue five: Food allergy and intolerance.* https://www.food.gov.uk/sites/default/files/media/document/fifth-csa-report-allergy%20%281%29.pdf

Freedland, K. E., Mohr, D. C., Davidson, K. W., & Schwartz, J. E. (2011). Usual and unusual care: existing practice control groups in randomized controlled trials of behavioral interventions. *Psychosomatic Medicine*, *73*(4), 323. https://doi.org/10.1097%2FPSY.0b013e318218e1fb

Gilbody, S., Richards, D., & Barkham, M. (2007). Diagnosing depression in primary care using self-completed instruments: UK validation of PHQ–9 and CORE–OM. *British Journal of General Practice*, *57*(541), 650-652.

Goodman, J.H., Guarino, A., Chenausky, K. (2014). CALM Pregnancy: results of a pilot study of mindfulness-based cognitive therapy for perinatal anxiety. *Archives of Women's Mental Health 17*, 373–387. https://doi.org/10.1007/s00737-013-0402-7

Griffiths, K., Camic, P. M., & Hutton, J. M. (2009). Participant experiences of a mindfulness-based cognitive therapy group for cardiac rehabilitation. *Journal of Health Psychology*, *14*(5), 675-681. https://doi.org/10.1177%2F1359105309104911

Gu, J., Strauss, C., Bond, R., & Cavanagh, K. (2015). How do mindfulness-based cognitive therapy and mindfulness-based stress reduction improve mental health and wellbeing? A systematic review and meta-analysis of mediation studies. *Clinical Psychology Review*, *37*, 1-12. https://doi.org/10.1016/j.cpr.2015.01.006

Gu, J., Strauss, C., Crane, C., Barnhofer, T., Karl, A., Cavanagh, K., & Kuyken, W. (2016). Examining the factor structure of the 39-item and 15-item versions of the Five-Facet Mindfulness Questionnaire before and after Mindfulness-Based Cognitive Therapy for people with recurrent depression. *Psychological Assessment*, *28*(7), 791-802. https://doi.org/10.1037/pas0000263

Guttmacher, J. A., & Birk, L. (1971). Group therapy: what specific therapeutic advantages? *Comprehensive Psychiatry*, *12*(6), 546-556. https://doi.org/10.1016/0010-440X(71)90037-X

Hayes, S. C., & Hofmann, S. G. (2017). The third wave of cognitive behavioral therapy and the rise of process-based care. *World Psychiatry*, *16*(3), 245. https://doi.org/10.1002%2Fwps.20442

Haleem, A., Javaid, M., & Vaishya, R. (2020). Effects of COVID-19 pandemic in daily life. *Current Medicine Research and Practice*, *10*(2), 78. https://doi.org/10.1016%2Fj.cmrp.2020.03.011

Himle, A. E., Havik, O. E., & Thimm, J. C. (2020). The Leiden Index of Depression Sensitivity-Revised (LEIDS-R) and its revision (LEIDS-RR): An investigation of the internal structure and conceptual validity in a Norwegian sample. *Nordic Psychology*, *72*(4), 331-345. https://doi.org/10.1080/19012276.2020.1727359

Jacobson, N. S., & Truax, P. (1992). Clinical significance: A statistical approach to defining meaningful change in psychotherapy research. In A. E. Kazdin (Ed.), *Methodological Issues & Strategies in Clinical Research* (pp. 631–648). American Psychological Association. https://doi.org/10.1037/10109-042

Jiang, J., Warren, C. M., & Gupta, R. S. (2020) Epidemiology and Racial/Ethnic Differences in Food Allergy. In Gupta R. (Ed.), *Pediatric Food Allergy* (pp. 3-16). Springer. https://doi.org/10.1007/978-3-030-33292-1_1

Jones, C. J., Paudyal, P., West, R. M., Mansur, A. H., Jay, N., Makwana, N., Baker, S., & Krishna, M. T. (2022). Burden of allergic disease among ethnic minority groups in high income countries. *Clinical and Experimental Allergy: Journal of the British Society for Allergy and Clinical Immunology*, 10.1111/cea.14131. Advance online publication. https://doi.org/10.1111/cea.14131

Junqueira, D. R., Phillips, R., Zorzela, L., Golder, S., Loke, Y., Moher, D., & Vohra, S. (2021). Time to improve the reporting of harms in randomized controlled trials. *Journal of Clinical Epidemiology*, *136*, 216-220. https://doi.org/10.1016/j.jclinepi.2021.04.020

Kabat-Zinn, J. (1982). An outpatient program in behavioral medicine for chronic pain patients based on the practice of mindfulness meditation: Theoretical considerations and preliminary results. *General Hospital Psychiatry*, *4*(1), 33-47. https://doi.org/10.1016/0163-8343(82)90026-3

Kaviani, H., Javaheri, F., & Hatami, N. (2011). Mindfulness-based cognitive therapy (MBCT) reduces depression and anxiety induced by real stressful setting in non-clinical population. *International Journal of Psychology and Psychological Therapy*, *11*(2), 285-296.

King, A. P., Erickson, T. M., Giardino, N. D., Favorite, T., Rauch, S. A., Robinson, E., & Liberzon, I. (2013). A pilot study of group mindfulness-based cognitive therapy (MBCT) for combat veterans with posttraumatic stress disorder (PTSD). *Depression and Anxiety*, *30*(7), 638-645. https://doi.org/10.1002/da.22104

Knibb, R. C. (2015). Effectiveness of cognitive behaviour therapy for mothers of children with food allergy: a case series. *Healthcare*, 3(4), 1194-1211. https://doi.org/10.3390/healthcare3041194

Knibb, R. C., & Stalker, C. (2013). Validation of the food allergy quality of life: Parental burden questionnaire in the UK. *Quality of Life Research*, *22*(7), 1841-1849. https://doi.org/10.1007/s11136-012-0295-3

Kor, P. P. K., Liu, J. Y. W., & Chien, W. T. (2019). Effects of a modified mindfulness-based cognitive therapy for family caregivers of people with dementia: A pilot randomized controlled trial. *International Journal of Nursing Studies*, *98*, 107-117. https://doi.org/10.1016/j.ijnurstu.2019.02.020

Kroenke, K., Strine, T. W., Spitzer, R. L., Williams, J. B., Berry, J. T., & Mokdad, A. H. (2009). The PHQ-8 as a measure of current depression in the general population. *Journal of Affective Disorders*, *114*(1), 163-173. https://doi.org/10.1016/j.jad.2008.06.026

Kuyken, W., Watkins, E., Holden, E., White, K., Taylor, R. S., Byford, S., & Dalgleish, T. (2010). How does mindfulness-based cognitive therapy work?. *Behaviour Research and Therapy*, *48*(11), 1105-1112. https://doi.org/10.1016/j.brat.2010.08.003

Lancaster, G. A., Dodd, S., & Williamson, P. R. (2004). Design and analysis of pilot studies: recommendations for good practice. *Journal of Evaluation in Clinical Practice, 10*(2), 307-312. https://doi.org/10.1111/j..2002.384.doc.x

Landis, J. R., & Koch, G. G. (1977). The measurement of observer agreement for categorical data. *Biometrics, 33*(1), 159-174. https://doi.org/10.2307%2F2529310

Lee, E. H. (2012). Review of the psychometric evidence of the perceived stress scale. *Asian Nursing Research*, *6*(4), 121-127. https://doi.org/10.1016/j.anr.2012.08.004

Löwe, B., Decker, O., Müller, S., Brähler, E., Schellberg, D., Herzog, W., & Herzberg, P. Y. (2008). Validation and standardization of the Generalized Anxiety Disorder Screener (GAD-7) in the general population. *Medical Care, 46*(3), 266-274. https://doi.org/10.1097/MLR.0b013e318160d093

McQuaid, E. L., Farrow, M. L., Esteban, C. A., Jandasek, B. N., & Rudders, S. A. (2016). Pediatric food allergies among diverse children. *Journal of Pediatric Psychology*, *41*(4), 391-396. https://doi.org/10.1093/jpepsy/jsv051

Meyer, T. J., Miller, M. L., Metzger, R. L., & Borkovec, T. D. (1990). Development and validation of the penn state worry questionnaire. *Behaviour Research and Therapy*, *28*(6), 487-495. https://doi.org/10.1016/0005-7967(90)90135-6

Muraro, A., Werfel, T., Hoffmann-Sommergruber, K., Roberts, G., Beyer, K., & Bindslev-Jensen, C. (2014). EAACI food allergy and anaphylaxis guidelines: Diagnosis and management of food allergy. *Allergy*, *69*(8), 1008-1025. https://doi.org/10.1111/all.12429

Mbuagbaw, L., Kosa, S. D., Lawson, D. O., Stalteri, R., Olaiya, O. R., Alotaibi, A., & Thabane, L. (2019). The reporting of progression criteria in protocols of pilot trials designed to assess the feasibility of main trials is insufficient: a meta-epidemiological

study. *Pilot and Feasibility Studies, 5*(1), 1-8. https://doi.org/10.1186/s40814-019-0500-z

Nock, M. K., Wedig, M. M., Holmberg, E. B., & Hooley, J. M. (2008). The emotion reactivity scale: development, evaluation, and relation to self-injurious thoughts and behaviors. *Behavior Therapy*, *39*(2), 107-116. https://doi.org/10.1016/j.beth.2007.05.005

Padesky, C. A., & Greenberger, D. (1995). *Clinician's guide to mind over mood.* The Guilford Press.

Parsons, C. E., Crane, C., Parsons, L. J., Fjorback, L. O., & Kuyken, W. (2017). Home practice in mindfulness-based cognitive therapy and mindfulness-based stress reduction: a systematic review and meta-analysis of participants' mindfulness practice and its association with outcomes. *Behaviour Research and Therapy*, *95*, 29-41. https://doi.org/10.1016/j.brat.2017.05.004

Perkin, M. R., Logan, K., Tseng, A., Raji, B., Ayis, S., Peacock, J., & Lack, G. (2016). Randomized trial of introduction of allergenic foods in breast-fed infants. *New England Journal of Medicine*, *374*, 1733-1743. https://doi.org/10.1056/NEJMoa1514210

Pitchforth, E., Weaver, S., Willars, J., Wawrzkowicz, E., Luyt, D., & Dixon-Woods, M. (2011). A qualitative study of families of a child with a nut allergy. *Chronic Illness*, *7*(4), 255-266. https://doi.org/10.1177%2F1742395311411591

Pitt, K., Feder, G. S., Gregory, A., Hawcroft, C., Kessler, D., Malpass, A., & Lewis, N. V. (2020). The coMforT study of a trauma-informed mindfulness intervention for women who have experienced domestic violence and abuse: a protocol for an intervention refinement and individually randomized parallel feasibility trial. *Pilot and Feasibility Studies*, *6*(1), 1-14. https://doi.org/10.1186/s40814-019-0527-1

Polloni, L., Lazzarotto, F., Bonaguro, R., Toniolo, A., Celegato, N., & Muraro, A. (2015). Psychological care of food-allergic children and their families: an exploratory analysis. *Pediatric Allergy and Immunology*, *26*(1), 87-90. https://doi.org/10.1111/pai.12325

Polloni, L., & Muraro, A. (2020). Anxiety and food allergy: a review of the last two decades. *Clinical & Experimental Allergy*, *50*(4), 420-441. https://doi.org/10.1111/cea.13548

Racey, D. N., Fox, J., Berry, V. L., Blockley, K. V., Longridge, R. A., Simmons, J. L., & Ford, T. J. (2018). Mindfulness-based cognitive therapy for young people and their carers: a mixed-method feasibility study. *Mindfulness*, *9*(4), 1063-1075. https://doi.org/10.1007/s12671-017-0842-7

Rodgers, S. H., Schütze, R., Gasson, N., Anderson, R. A., Kane, R. T., Starkstein, S., & Egan, S. J. (2019). Modified mindfulness-based cognitive therapy for depressive symptoms in Parkinson's disease: a pilot trial. *Behavioural and Cognitive Psychotherapy*, *47*(4), 446-461. https://doi.org/10.1017/S135246581800070X

Rouf, K., White, L., & Evans, K. (2012). A qualitative investigation into the maternal experience of having a young child with severe food allergy. *Clinical Child Psychology and Psychiatry*, *17*(1), 49-64. https://doi.org/10.1177%2F1359104511415636

Sampson, M. A., Munoz-Furlong, A., Sicherer, S. H. (2006). Risk-taking and coping strategies of adolescents and young adults with food allergy. *Journal of Allergy and Clinical Immunology*, *11*(7), 1440-1445. https://doi.org/10.1016/j.jaci.2006.03.009

Scher, C. D., Ingram, R. E., & Segal, Z. V. (2005). Cognitive reactivity and vulnerability: Empirical evaluation of construct activation and cognitive diatheses in unipolar depression. *Clinical Psychology Review*, *25*(4), 487-510. https://doi.org/10.1016/j.cpr.2005.01.005

Schlotz, W., Yim, I. S., Zoccola, P. M., Jansen, L., & Schulz, P. (2011). The perceived stress reactivity scale: Measurement invariance, stability, and validity in three countries. *Psychological Assessment*, *23*(1), 80. https://doi.org/10.1037/a0021148

Schroevers, M. J., Tovote, K. A., Snippe, E., & Fleer, J. (2016). Group and individual mindfulness-based cognitive therapy (MBCT) are both effective: A pilot randomized controlled trial in depressed people with a somatic disease. *Mindfulness*, *7*(6), 1339-1346. https://doi.org/10.1007/s12671-016-0575-z

Segal, Z. V., Williams, J. M., & Teasdale, J. D. (2002). *Mindfulness-based cognitive therapy for depression: A new approach to preventing relapse (first edition).* The Guilford Press.

Segal, Z. V., Williams, J. M., & Teasdale, J. D. (2018). *Mindfulness-based cognitive therapy for depression*. Guilford Publications.

Sicherer, S. H., & Sampson, H. A. (2010). Food allergy. *Journal of Allergy and Clinical Immunology*, *125*(2), 116-125. https://doi.org/10.1016/j.jaci.2009.08.028

Sicherer, S. H., Noone, S. A., & Munoz-Furlong, A. (2001). The impact of childhood food allergy on quality of life. *Annals of Allergy, Asthma & Immunology*, *87*(6), 461-464. https://doi.org/10.1016/S1081-1206(10)62258-2

Smith, J. M., Bright, K. S., Mader, J., Smith, J., Afzal, A. R., Patterson, C., & Crowder, R. (2020). A pilot of a mindfulness-based stress reduction intervention for female caregivers of youth who are experiencing substance use disorders. *Addictive Behaviors*, *103*, e106223. https://doi.org/10.1016/j.addbeh.2019.106223

Soller, L., Ben-Shoshan, M., Harrington, D. W., Fragapane, J., Joseph, L., Pierre, Y. S., & Clarke, A. E. (2012). Overall prevalence of self-reported food allergy in Canada. *Journal of Allergy and Clinical Immunology*, *130*(4), 986-988. https://doi.org/10.1016/j.jaci.2012.06.029

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 randomised controlled trials. *Clinical Psychology Review, 45*, 102-114. https://doi.org/10.1016/j.cpr.2016.03.009

Spitzer, R. L., Kroenke, K., Williams, J. B., & Löwe, B. (2006). A brief measure for assessing generalized anxiety disorder: The GAD-7. *Archives of Internal Medicine, 166*(10), 1092-1097. https://doi.org/10.1001/archinte.166.10.1092

Staab, D., Von Rueden, U., Kehrt, R., Erhart, M., Wenninger, K., Kamtsiuris, P., & Wahn, U. (2002). Evaluation of a parental training program for the management of childhood atopic dermatitis. *Pediatric Allergy and Immunology, 13*(2), 84-90. https://doi.org/10.1034/j.1399-3038.2002.01005.x

Sugunasingha, N., Jones, F. W., du Toit, G., & Jones, C. J. (2022). Evaluating an online self-help intervention for parents of children with food allergies. *Pediatric Allergy and Immunology*, *33*(2), e13731. https://doi.org/10.1111/pai.13731

Sugunasingha, N., Jones, F. W., & Jones, C. J. (2020). Interventions for caregivers of children with food allergy: A systematic review. *Pediatric Allergy and Immunology*, *31*(7), 805-812. https://doi.org/10.1111/pai.13255

Tang, M. L., & Mullins, R. J. (2017). Food allergy: is prevalence increasing? *Internal Medicine Journal*, *47*(3), 256-261. https://doi.org/10.1111/imj.13362

Treynor, W., Gonzalez, R., & Nolen-Hoeksema, S. (2003). Rumination reconsidered: A psychometric analysis. *Cognitive Therapy and Research*, *27*(3), 247-259. https://doi.org/10.1023/A:1023910315561

Turner, H. C., Archer, R. A., Downey, L. E., Isaranuwatchai, W., Chalkidou, K., Jit, M., & Teerawattananon, Y. (2021). An Introduction to the Main Types of Economic Evaluations Used for Informing Priority Setting and Resource Allocation in

Healthcare: Key Features, Uses, and Limitations. *Frontiers in Public Health*, *9*, 722927. https://doi.org/10.3389/fpubh.2021.722927

Van der Does, W. (2002). Cognitive reactivity to sad mood: structure and validity of a new measure. *Behaviour Research and Therapy*, *40*(1), 105-119. https://doi.org/10.1016/S0005-7967(00)00111-X

Vreeken-Ross, S. C., Cartwright-Hatton, S., Harris, S. A., Hanna, P., & Jones, C. J. (2021). Feasibility of an online CBT group intervention for parents of children with food allergy. *Clinical and Experimental Allergy: Journal of the British Society for Allergy and Clinical Immunology*, *52*(1),171-175. https://doi.org/10.1111/cea.13970

Walkner, M., Warren, C., & Gupta, R. S. (2015). Quality of life in food allergy patients and their families. *Pediatric Clinics*, *62*(6), 1453-1461. https://doi.org/10.1016/j.pcl.2015.07.003

Williams, N. A., Parra, G. R., & Elkin, T. D. (2009). Subjective distress and emotional resources in parents of children with food allergy. *Children's Health Care*, *38*(3), 213-227. https://doi.org/10.1080/02739610903038792

Wong, S. Y. S., Yip, B. H. K., Mak, W. W. S., Mercer, S., Cheung, E. Y. L., Ling, C. Y. M., & Ma, H. S. W. (2016). Mindfulness-based cognitive therapy v. group psychoeducation for people with generalised anxiety disorder: Randomised controlled trial. *The British Journal of Psychiatry*, *209*(1), 68-75. https://doi.org/10.1192/bjp.bp.115.166124

Yalom, I. D. (1995). *The theory and practice of group psychotherapy (4th ed.).* Basic Books.

Yalom, I. D., & Leszcz, M. (2005). *The Theory and Practice of Group Psychotherapy (5th ed.).* Basic.

## Section C: Appendices of Supporting Material

### Appendix A: Repeated meta-analyses following significant moderation analysis

**Figure 1.**

*Forest plot for studies with passive control groups measuring depression at post-intervention ('moderate' quality rated studies only)*

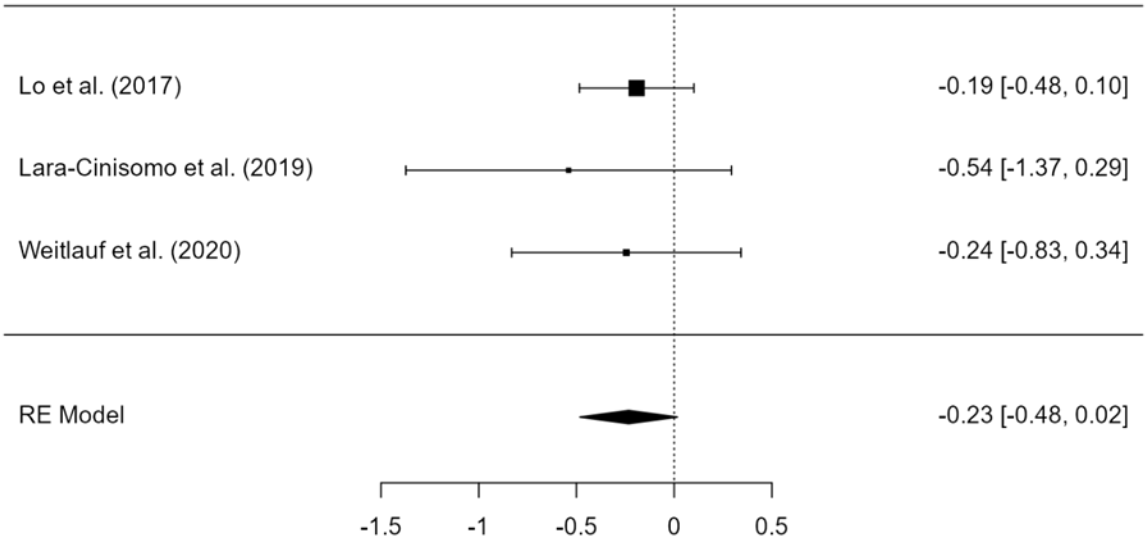



**Figure 2.**

*Funnel plot for meta-analyses of passive control studies measuring depression at post-intervention ('moderate' quality rated studies only)*

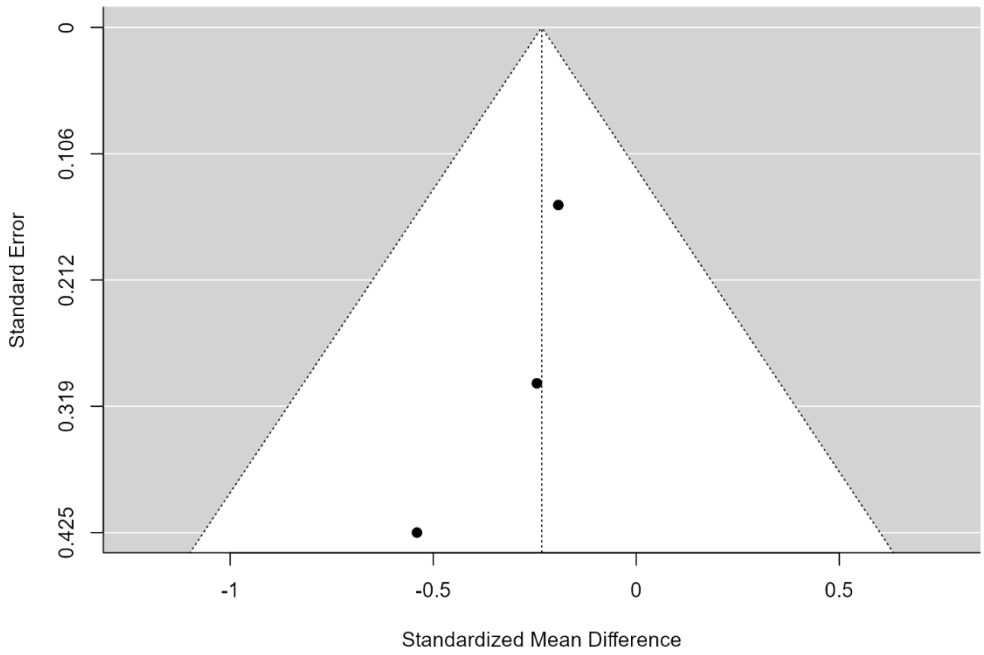


**Figure 3.**

*Forest plot for studies with passive control groups measuring mindfulness at post-intervention ('moderate' quality rated studies only)*

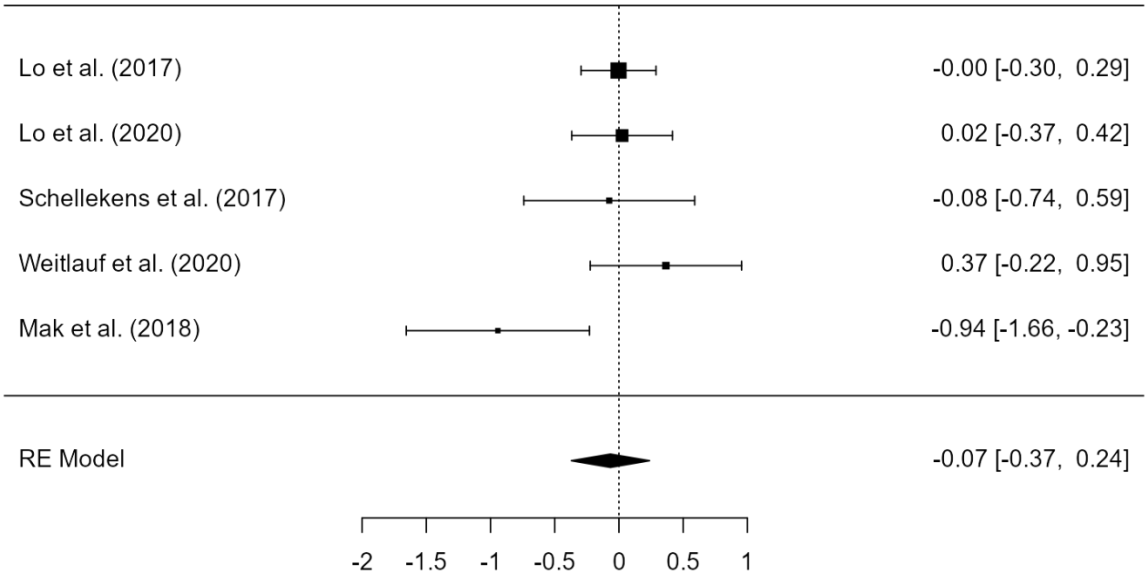
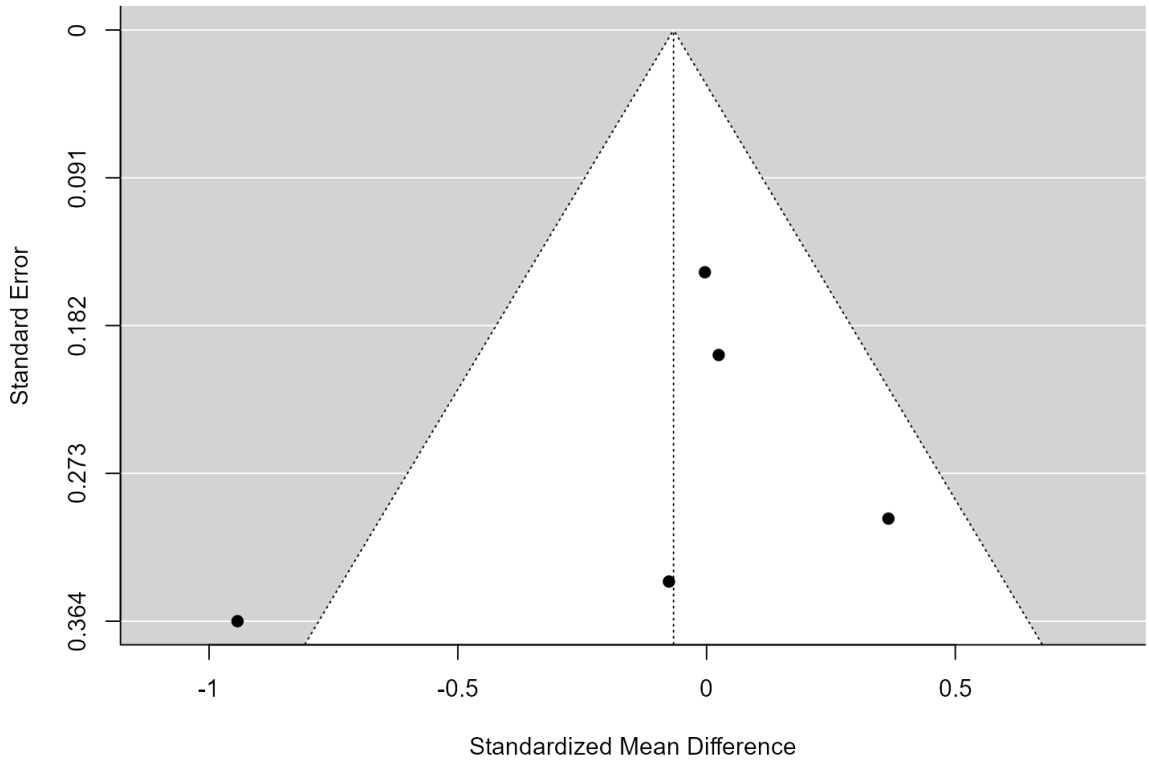



**Figure 4.**

*Funnel plot for meta-analyses of passive control studies measuring mindfulness at post-intervention ('moderate' quality rated studies only)*



## Appendix B: Details of intervention

### What is MBCT?

Mindfulness-based cognitive therapy (MBCT) combines mindfulness techniques, including meditation practice and mindful movement, with elements from cognitive therapy to help people notice and break free of negative cycles of thought and mood.

MBCT consists of nine weekly, two-hour group sessions. Sessions involve mindfulness mediations, exploring the inter-relationship between thoughts, feelings and behaviour, and discussing people's experiences during the mindfulness mediations and exercises. During MBCT, individuals are asked complete daily homework which lasts approximately 30-50 minutes, consisting mainly of mindfulness practice.

### Session-by-session overview

Orientation session: Check technology working, introductions, group rules and confidentiality, tips for working online, participant introductions, hopes for the treatment, information surrounding course (e.g., what is mindfulness, why might it be helpful, session and at-home practice structure, commitment, challenges, when MBCT might not be useful, support in place in sessions), Q&A, brief mindful breathing exercise, time to think in pairs re challenges and how to overcome these, feedback and close.

Session 1: **Awareness and Automatic Pilot** (Focus: On automatic pilot, we are more likely to have our "buttons pressed": Old, unhelpful habits of thinking are more likely to be triggered. This can be managed by becoming more aware of our thoughts, feelings, and body sensations, from moment to moment)

Session 2: **Living in Our Heads** (Focus: A powerful influence taking us away from being "fully present" in each moment is our automatic tendency to judge our experience as being not quite right in some way)

Session 3: **Gathering the Scattered Mind** (Focus: The mind is often scattered and lost in thought because it is working away in the background to complete unfinished tasks from the past and strive for goals for the future. We need to find a reliable way intentionally to "come back" to the here and now. This can be done by resting awareness on the breath and the body in movement)

Session 4: **Recognizing Aversion** (Focus: Difficult things are part and parcel of life itself. It is how we handle those things that makes the difference between whether they control our lives or whether we can relate more lightly to them. Outlines 3 common but unhelpful ways of reacting to these difficult experiences)

Session 5: **Allowing/Letting Be** (Focus: To extend formal practice to begin deliberately turning toward and approach painful experiences with kindness)

Session 6: **Thoughts Are Not Facts** (Focus: Our thoughts can have very powerful effects on how we feel and what we do. By becoming aware, over and over again, of the thoughts and images passing through the mind and letting go of them as we return our attention to the breath and the moment, it is possible to get some distance and perspective on them)

Session 7: **"How Can I Best Take Care of Myself?"** (Focus: By being actually present in more of our moments and making mindful decisions about what we really need in each of those moments, we can use activity to become more aware and alert, and to regulate mood)

Session 8: **Maintaining and Extending New Learning** (Focus: How to bring mindfulness into daily lives)

## Adaptation to course

1. Handouts removed
   - All at-home practice record forms were removed from handout pack as a separate table for the research project was provided (see Appendix C)
   - Session 6 – Handouts 2 (Ways you can see your thoughts differently), 3 (Relapse prevention), 4 (Working wisely with unhappiness and depression I) & 7 (Stepping back from thought)
   - Session 7 – Handouts 2 (When depression is overwhelming), 3 (The exhaustion funnel), & 4 (Working wisely with unhappiness and depression II)
2. The facilitator leant more so into the kindness aspects of the course (i.e., encouraging self-compassion in response to experiences).
3. Shorter at-home practises (e.g., 5–10-minute recordings) were offered as an alternative to the original longer recordings. These were pre-recorded by the facilitator and included in the shared drive along with the original longer practises. Participants were given choice as to which practises they selected that week and encouraged to find something possible for them.
4. Where elements of the session content focused on depression (e.g., The Territory of Depression in session 7), the facilitator generalised this to difficult experiences and explored challenges faced in day-to-day life.

## Appendix C: At-home practice questionnaire

**Please complete the following questions:**

1. Email address:
2. Week being rated: *(choose from drop down e.g. 'Week 1: 01/02/20-07/02/20')*
3. Total number of **days** you completed **formal** at-home practice (i.e. listened to pre-recorded guided meditations, body scans, or mindful movement) this week. *Do* **not** *count the group session.*: *(e.g. 0-7)*
4. Total number of **minutes** of **formal** at-home practice (i.e. listened to pre-recorded guided meditations, body scans, or mindful movement) completed this week (e.g. 180). *Please estimate how many minutes of practice you did each day and then add these together, if you kept the diary sheet please refer to that: (e.g. 0-210)*
5. Total number of **days** you completed **informal** at-home practice (i.e. when you brought mindfulness into everyday activities, such as brushing your teeth or making a cup of tea) this week: *(e.g. 0-7)*
6. Total number of **minutes** of **informal** at-home practice (i.e. when you brought mindfulness into everyday activities, such as brushing your teeth or making a cup of tea) completed this week: *(e.g. 0-210)*

Participants were sent the table below to assist them in recording their at-home practice each day (n.b. only the above information was self-reported to the study team at the end of each week):

| Week dates: e.g., 13/04/2021 – 20/04/2021 | At-home practice completed (Y/N?) | Minutes **formal** practice: | Minutes **informal** practice: |
|---|---|---|---|
| Day 1: e.g., 13/04/20 | | | |
| Day 2: | | | |
| Day 3: | | | |
| Day 4: | | | |
| Day 5: | | | |
| Day 6: | | | |
| Day 7: | | | |
| **Total:** | | | |

## Appendix D: Feedback questionnaire

Feedback survey (for intervention group)

Questions for the feedback survey were informed by the qualitative survey within Saracutu et al's (2018) intervention feasibility and acceptability study. The questionnaire was originally developed to evaluate the satisfaction and perceptions of another acceptance and mindfulness therapy for a long-term health condition (brief Acceptance and Commitment-based Therapy for people with persistent pain). The questions were developed to understand participants' views on acceptability, feasibility, processes of change, suggestions for improvements, barriers, and implementing change. Therefore, it was felt that the aims of the questionnaire were parallel to those within the present study on several levels.

Saracutu, M., Edwards, D. J., Davies, H., & Rance, J. (2018). Protocol for a feasibility and acceptability study using a brief ACT-based intervention for people from Southwest Wales who live with persistent pain. *BMJ open*, *8*(11), e021866.

**1.** Other than the MBCT, have you engaged in or received any other interventions over the last 23 weeks to support your wellbeing (this may include a change in medication or other psychological interventions)?
- **a.** Yes [ ]
- **b.** No [ ]
- ***c.*** *If yes, please provide details:*

**2.** How acceptable did you find participating in this study as a whole?
- **a.** Very acceptable [ ]
- **b.** Acceptable [ ]
- **c.** Unacceptable [ ]
- **d.** Very unacceptable [ ]
- ***e.*** *If unacceptable/very unacceptable, please can you give brief details on this:*

**3.** How acceptable did you find completing the questionnaires?
- **a.** Very acceptable [ ]
- **b.** Acceptable [ ]
- **c.** Unacceptable [ ]
- **d.** Very unacceptable [ ]
- ***e.*** *If unacceptable/very unacceptable, please can you give brief details on this:*

**4.** How acceptable did you find taking part in the intervention?
- **a.** Very acceptable [ ]
- **b.** Acceptable [ ]
- **c.** Unacceptable [ ]
- **d.** Very unacceptable [ ]
- ***e.*** *If unacceptable/very unacceptable, please can you give brief details on this:*

**5.** How acceptable did you find completing the at-home practice?
- **a.** Very acceptable [ ]
- **b.** Acceptable [ ]
- **c.** Unacceptable [ ]

**d.** Very unacceptable [ ]
***e.*** *If unacceptable/very unacceptable, please can you give brief details on this:*

**6.** What are the main things you feel you learnt from this intervention?

**7.** What was the aspect of the intervention that you liked the most? What was your favourite activity (or session)?

**8.** What did you least like about the intervention?

**9.** Were there any difficulties or challenges to taking part?

**10.** What do you think could be improved?

**11.** Are there any changes in your perspective of being a parent of a child with a food allergy? If the answer is 'Yes', what are they?

**12.** Do you practice Mindfulness now? How many days on average per week? For how long in minutes (if no, please enter '0')

**13.** Have you noticed any differences in your life as a result of taking part in the intervention? If 'yes', what are these differences?

**14.** Would you recommend this intervention to someone you care about?

Feedback survey (for control group)

**1.** Have you engaged in or received any other interventions over the last 23 weeks to support your wellbeing (this may include a change in medication or other psychological interventions)?
- **a.** Yes [ ]
- **b.** No [ ]
- **c.** If yes, please provide details:

**2.** How acceptable did you find participating in this study as a whole?
- **a.** Very acceptable [ ]
- **b.** Acceptable [ ]
- **c.** Unacceptable [ ]
- **d.** Very unacceptable [ ]
- ***e.*** *If unacceptable/very unacceptable, please can you give brief details on this:*

**3.** How acceptable did you find completing the questionnaires?
- **a.** Very acceptable [ ]
- **b.** Acceptable [ ]
- **c.** Unacceptable [ ]
- **d.** Very unacceptable [ ]

***e.*** *If unacceptable/very unacceptable, please can you give brief details on this:*

# Appendix E: Information sheet

Canterbury Christ Church University

Participant Information Sheet

**Online Mindfulness-based Cognitive Therapy (MBCT) for parents of children with food allergies: A pilot randomised control trial.**

**Are you a parent or carer of a child with a food allergy? If so, we would like to invite you to take part in our research study.**

**Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Discuss it with friends and relatives if you wish. You are free to decide whether or not to take part in this trial. Please get in contact with us if there is anything that is not clear or if you would like more information.**

My name is Ellie Craig and I am a Trainee Clinical Psychologist at Salomon's Institute for Applied Psychology, Canterbury Christ Church University. This research project forms part of my doctoral thesis and is supervised Dr Fergal Jones (Consultant Clinical Psychologist & Reader in Clinical Psychology).

Part 1 tells you the purpose of this study and what will happen to you if you take part.
Part 2 gives you more detailed information about the conduct of the study. Please ask us if anything is unclear or if you have any further questions.

Part 1

**What is the purpose of the study?**
Mindfulness-based Cognitive Therapy is a therapy that aims to reduce psychological distress in people. We would like to explore how acceptable and feasible an adapted online version of this therapy is for parents of children with food allergies and whether it helps to reduce symptoms of low mood, stress and anxiety.

**What is Mindfulness-based cognitive therapy?**
"Mindfulness is the awareness that emerges through paying attention on purpose, in the present moment, and nonjudgmentally, to things as they are." Williams, Teasdale, Segal & Kabat-Zinn (2007)

Mindfulness-based cognitive therapy (MBCT) combines mindfulness techniques, including meditation practice and mindful movement, with elements from cognitive therapy to help people notice and break free of negative cycles of thought and mood.

MBCT consists of nine weekly, two-hour, live group sessions. Sessions involve mindfulness meditations, exploring the inter-relationship between thoughts, feelings and behaviour, and discussing people's experiences during the mindfulness meditations and exercises. During MBCT, individuals are asked to complete daily homework lasting at least 30 minutes a day, consisting mainly of mindfulness practice.

**What would be involved if I sign up?**
You will be asked to complete an initial questionnaire. If your scores fall with a certain range (please see 'Who can take part?' below), you will be randomly assigned to one of two groups. These two groups will be randomly allocated so that any differences between participants are equally spread between groups. The first will be a 'mindfulness-based course group', where people will receive the therapy outlined under the heading 'What is MBCT?' above, facilitated online and adapted for parents of children with food allergies. The second is a 'control group', where people will not receive the intervention. A control group is really important in

research as it allows the researchers to assess whether there are any benefits of the intervention above those that may have happened anyway.

Both groups will be asked to complete a set of online questionnaires at the start of the study, 15 weeks later and then at a follow-up stage 8 weeks later. The questionnaires are given in order to measure the effect of the intervention and compare any change that happens for the control group over the same time period. These questionnaires will take approximately 20-30 minutes to complete. They will concern peoples' level of stress, quality of life, and feelings of anxiety and low mood.

Within the 'control group' people will not be asked to do anything other than complete the questionnaires mentioned above. Those in the 'control group' would be asked continue to engage in any supportive interventions they already do. They will also be offered a £10 Amazon shopping voucher at the end of the study (contact details will be forwarded to the University's finance team who will issue this). Finally, a list of helpful mindfulness-based resources will be provided, should this group wish to integrate mindfulness practice into their lives after the study.

For those that enter the 'mindfulness-based course group', the study will also involve receiving the MBCT course outlined above. As the study will be conducted online, people will not be required to attend any meetings in person, however the sessions will be at set times and the intervention will run weekly for nine weeks between Thursday 6th May to Thursday 1st July 2021 at 19:00-21:00. The initial week will involve an orientation session, aimed to induct people to the invention and meet other participants. The subsequent sessions will work through the MBCT programme. At the end of the intervention, they will also be asked to complete an online feedback survey, where they will be asked about their experience of the intervention.

**Who can take part?**
We are inviting parents of children (under the age of 18) who have a food allergy diagnosed by a doctor (i.e. GP or allergy specialist) to participate. You will also need to be a resident in the United Kingdom and have access to email, a PC/laptop/tablet with a webcam, microphone and internet access to allow videoconferencing.

If you choose to take part, you will be asked to complete a questionnaire to ensure the intervention is suitable for you. Please note, MBCT is not suitable for everybody, as such, we may ask that you do not participate in the study after reviewing your questionnaire responses.

Because this is the first time were offering this, we need to be cautious about who we offer it to. For some, MBCT may be more unhelpful than helpful. If any of the following apply then we ask that you don't take part in the study because there is a risk that MBCT could be unhelpful or harmful:

a. You have a problem with alcohol or recreational drug misuse
b. You have experienced thoughts about harming yourself or others in the last 12 months
c. You have been given a diagnosis of psychosis (e.g. schizophrenia)
d. You are currently experience high levels of distress and/or currently feeling particularly fragile
e. You have experienced a bereavement of someone close to you in the last year or are continuing to experience continuing grief in relation to loosing someone further back in time
f. You have had traumatic experiences that you continue to be troubled by (including, but not limited to, receiving diagnosis of post-traumatic stress disorder)
g. You experience significant difficulty being in a group with other people.

If you aren't sure whether any of apply to you these or have any questions, please contact the lead researcher at e.craig606@canterbury.ac.uk.

Canterbury Christ Church University

**Do I have to take part?**
It is entirely up to you to decide to participate in the study, you do not have to take part if you do not want to. If you agree to take part, we will ask you to complete an online consent form. You are free to withdraw at any time, without giving a reason.

**What are the possible benefits of taking part?**
To the best of our knowledge, this is the first time this therapy is being offered to parents/carers of children with food allergies, so the aim is to start the process of trying to understand whether it is helpful for this group. For those in the 'intervention group', we cannot promise the intervention will help you, however research suggests that mindfulness has a potential to help people experiencing stress, anxiety and low mood, and to become more aware of the richness of our present moment experience. As mentioned above, those within the 'control group' will not receive the intervention.

Additionally, the information we get from this study may encourage further research in this area. Finally, it may help improve the provision of psychological support for parents of food-allergic children.

**What are the possible disadvantages and risks of taking part?**
All participants (both the 'control group' and 'mindfulness-based course group') will be asked to complete questionnaires. These are frequently used in research without difficultly. However, they do ask about current levels of stress, quality of life and feelings of low mood and anxiety which some people may find potentially distressing or difficult to think about.

If you are randomly allocated to the 'mindfulness-based course group', in addition to the above questionnaires, there is also the possible impact associated with MBCT. Mindfulness practices invite us to be present with our experience, whether that is pleasant or unpleasant. This can sometimes mean experiencing unpleasant bodily sensations, thoughts, emotions or memories. You'll be welcome to stop any meditation activity or session of MBCT at any point. A facilitator will be available to offer you support should you experience difficulties. You will also be given information about where you can seek additional support should this happen outside of the sessions. You should consider this when deciding to take part in the study.

Another consideration for those allocated to the 'mindfulness-based course group' is that we will be asking people to engage in mindful movement (including stretching and yoga style movement). Physical difficulties may mean this is not appropriate for some people. If you do have any physical difficulties that might make this movement difficult, you do not need to engage with the movement during the intervention. However, you are still welcome to take part in the MBCT if this is the case and facilitators will offer an alternative practice that is possible.

If you are unsure about whether to take part or would like to discuss these potential risks further, please contact the researcher, Eleanor Craig, at e.craig606@canterbury.ac.uk.

Canterbury Christ Church University

Part 2

**What will happen if I don't want to carry on with MBCT and/or the study?**
If you are randomly assigned to 'mindfulness-based course group' and decide you would like to stop the therapy, you can do this at any point. If you do stop the therapy, it would still be useful for you to complete the questionnaires at the end, so we would ask if you would be happy to do this but this is your choice and you can still withdraw entirely. Similarly, if you are in the 'control group' you can withdraw at any point.

Please note, if you do withdraw from the study, we will use your data collected up until the point of withdrawal because this is important in evaluating the intervention. If you are not happy with this, please do not take part in the study.

**What if there is a problem?**
If you are unhappy with the study or have an unsatisfactory experience, you would be welcome to direct your concerns towards myself or the MBCT group facilitator. We would be happy to discuss any concerns with you.

Eleanor Craig (researcher): e.craig606@canterbury.ac.uk
Fergal Jones (facilitator of MBCT group, Consultant Clinical Psychologist & Reader in Clinical Psychology): fergaljones@canterbury.ac.uk

If you would like to make a complaint or discuss your concerns with someone independent of the study, you are able to contact the Director of Salomons Institute for Applied Psychology.

Professor Margie Callanan (Director of Salomons Institute for Applied Psychology): margie.callanan@canterbury.ac.uk

**Will information from or about me from taking part in the study be kept confidential?**
All information that is collected from or about you during the course of the research will be kept strictly confidential. We are required to break confidentiality and share information with relevant support services only under specific circumstances, this includes if we feel there is a significant risk of harm to yourself or someone else. We would always endeavour to discuss any such concerns with you prior to taking any action.

Following the completion of the study, data will be stored securely, encrypted and password protected for 10 years. Anonymised, numerical data will be made publicly available so that it can be further analysed by other researchers.

**What will happen to the results of the research study?**
The research will be published as part of a thesis. The researchers will seek to publish the findings in an academic journal. Some comments from feedback questionnaires may be quoted in the completed research article. All data will remain anonymous and identifiable information changed or removed to protect your anonymity.

**Who is organising and funding the research?**
This study is funded and sponsored by the Salomons Institute of Applied Psychology, which is part of Canterbury Christ Church University.

**Who has reviewed the study?**
All research in the University is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and approved by The Ethics Panel at Salomons Institute for Applied Psychology, Canterbury Christ Church University.

**Next steps?**

If you have any questions about anything that you have read, please contact me at e.craig606@canterbury.ac.uk and I will get back to you as soon as possible.

If you are interested in taking part in the study, please contact me on the email address noted above and I will arrange an initial meeting with you.

## Appendix F: Consent form

Consent form

Title of Project: Online Mindfulness-based Cognitive Therapy (MBCT) for parents of children with food allergies: A feasibility randomised controlled trial.

Name of Researcher:

| | Please confirm the following (delete as appropriate) |
|---|---|
| **1.** I confirm that I have read the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. | Yes/No |
| **2.** I confirm I meet the inclusion criteria as follows: | |
| **a.** I am a parent or caregiver of a child under the age of 18 with a food allergy | Yes/No |
| **b.** My child's allergy has been diagnosed by a doctor (e.g. GP or allergy specialist) | Yes/No |
| **c.** I have not previously participated in a substantial mindfulness-based course | Yes/No |
| **d.** I am not currently engaged or planning to engage with another psychological intervention during the course of the research | Yes/No |
| **e.** I do not currently engage in regular mindfulness-based practice | Yes/No |
| **f.** I have the practical means and time available to be able to attend the intervention and commit to at-home practice. This includes having access to email, a PC/laptop/tablet with a webcam and microphone and internet access to allow videoconferencing. | Yes/No |
| **g.** I am a resident within the United Kingdom | Yes/No |
| **3.** I confirm that I: | |
| **a.** do not have a problem with alcohol or recreational drug misuse | Yes/No |
| **b.** have not experienced thoughts about harming myself or others in the last 12 months | Yes/No |
| **c.** have not been given a diagnosis of psychosis | Yes/No |
| **d.** am not currently experiencing high levels of distress and/or currently feeling particularly fragile | Yes/No |
| **e.** have not experienced a bereavement of someone close to me in the last year or am not continuing to experience grief in relation to losing someone further back in time | Yes/No |
| **f.** have not had traumatic experiences that I continue to be troubled by (including, but not limited to, receiving diagnosis of post-traumatic stress disorder) | Yes/No |

**g.** do not experience significant difficulty being in a group with other people Yes/No

**4.** I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected. Yes/No

**5.** I understand that if I withdraw from the study, any data I have provided up until that point will be retained in the study. Yes/No

**6.** I understand that my data may be looked at by people with oversight of the research (e.g. the Project Supervisors, Fergal Jones and Chrissie Jones). Yes/No

**7.** I understand that my anonymised data from the study may be published and this may include anonymous quotations from my feedback survey. Yes/No

**8.** I understand that some sessions may be recorded for use in the facilitator's supervision. These will be deleted as soon as they are used in supervision and will not form any part of the research project. Yes/No

**9.** I agree to take part in the above study. Yes/No

Signature (typed name accepted): _____

## Appendix G: Email text following screening meeting

**Email text for post-screening meeting**

**For those who met all inclusion/exclusion criteria and will be taking part in the study:**

**Subject:** 'Research study: MBCT for parents/carers of children with food allergies'

**Attach:** Information sheet

Dear xxx,

Thank you very much for speaking with me today.

This email is to confirm that following our conversation today, we've agreed you will be taking part in the study.

As discussed, the next step is for the researchers to finalise recruitment. We anticipate this will take approximately another 'X' weeks as we need another 'X' participants before the intervention can start. We spoke about the importance of having both an intervention group and a control group, and once the recruitment process is finalised, we will let you know your group allocation via email. Prior to this, you will be sent a link to complete the initial set of questionnaires.

I will keep you updated with our progress in a fortnightly email.

Thank you again for your participation and for contributing to important research within this area. In case its useful, I've attached another copy of the information sheet should you wish to refer to this at any point during the study. Please remember, you can withdraw at any point without giving a reason.

Best wishes,

XXXX

Lead Researcher

**For those whose scores were within the 'severe' range on either the PHQ8 or GAD7 and are not able to take part in the study:**

N.B. Please note, the content of this email may be adjusted according to the conversations had during the meeting and also where the person is based (i.e. IAPT services are not available in Scotland and Wales)

**Subject:** 'Research study: MBCT for parents/carers of children with food allergies'

Dear xxx,

Thank you again for speaking with me today.

This email is to confirm that after our discussion today and your responses indicted on the questionnaires measuring anxiety, low-mood and stress, we do not feel the intervention we are offering within this study will be suitable for you at this current time.

As we discussed, we would recommend making an appointment with your GP in the first instance to seek help for your feelings of low mood '*and/or* [edit]*'* anxiety. There is also an option of self-referring to an NHS psychological therapies service within your area. Details of your local services can be found at https://www.nhs.uk/service-search/other-services/Psychologicaltherapies(IAPT)/LocationSearch/10008.

I wish you all the best for the future and thank you for taking time to apply to participate in this study.

Best wishes,

XXXX

Lead Researcher

**For those whose scores were not >2 on the FAQL-PB and are not able to take part in the study:**

**Subject:** 'Research study: MBCT for parents/carers of children with food allergies'

Dear xxx,

Thank you again for speaking with me today.

This email is to confirm that after our discussion today and your responses indicted on the questionnaires, we do not feel the intervention we are offering within this study will be suitable for you at this current time.

At this current time, as far as we're aware, there is no research specifically supporting the helpfulness of mindfulness-based interventions for parents of children with food allergies. However, there is some research that suggests that mindfulness can help in relation to low mood or depression more generally. If you are still interested in pursuing a mindfulness-based intervention independent of this study, I have included some potential resources below.

Mindfulness-based resources

https://www.nhs.uk/conditions/stress-anxiety-depression/mindfulness/

https://bamba.org.uk/ (here you can ensure your identified mindfulness-based practitioner is BAMBA registered.)

Please speak with whoever is facilitating these interventions to check they are likely to be helpful for you.

I wish you all the best for the future and thank you for taking time to apply to participate in this study.

Best wishes,

XXXX

Lead Researcher

**For those who did not meet the inclusion/exclusion criteria and are not able to take part in the study or decided after this discussion that they would not like to take part:**

**Subject:** 'Research study: MBCT for parents/carers of children with food allergies'

Dear xxx,

Thank you again for speaking with me today.

This email is to confirm that after our discussion today, we decided that the intervention we are offering within this study will not be suitable for you at this current time.

I wish you all the best for the future and thank you for taking time to apply to participate in this study.

Best wishes,

XXXX

Lead Researcher

## Appendix H: Reminder email text and telephone script

**Email/telephone prompts**

**Initial email prompt (Time 1) to be sent if responses not received within 4 days of emailing the Qualtrics link:**

**Subject:** 'Research study: MBCT for parents/carers of children with food allergies'

Dear xxxx,

We have noticed that you haven't yet submitted your responses to the questionnaires sent on xx/xx/xx.

Please may we ask that you do so by xx/xx/xx so that we are able to progress to the next stage of the study. If we haven't received your response by this date, we will assume you no longer wish to take part in the study and will withdraw you.

If you have any questions or concerns about the study, or are having technical difficulties, please don't hesitate to contact me.

Best wishes,

XXXX

Lead researcher

**Telephone message script to be communicated if no response received following initial reminder email (Time 1):**

*Hello, introduce self*

*I wanted to follow up on my email sent to you on xx/xx/xx as we are yet to receive your questionnaire responses for the MBCT study. Please also note that if you have seen it and no longer want to take part in the study this is also fine and so please disregard this message.*

*However, I am phoning to check that the email hasn't been directed to your junk mailbox. Please do check that if you haven't yet received it.*

*If you are still happy to continue with the study, please could you submit them by xx/xx/xx.*

*If we have not heard from you by this date, we will assume you no longer wish to take part in the study and will withdraw you.*

*If you are still unable to find it, please contact me on xxxxxxxxxx and we will look into this.*

**Follow up email if no further response following email or telephone prompt (Time 1):**

**Subject:** 'Research study: MBCT for parents/carers of children with food allergies'

Dear xxxx,

As we haven't heard from you, we assume you no longer wish to take part in this study and will be withdrawing you.

If the questionnaires drew your attention to any health or wellbeing problems that you may be experiencing, we'd advise you to contact your GP or NHS 111, by dialling 111 or using https://111.nhs.uk.

If you have any questions or feedback about the study, please contact the research team using xxxx.

If you wish to make a complaint about the study, please either contact the study team using the above email address or xxxx, xxxx, via xxxx.

We wish you all the best.

Best wishes,

XXXX

Lead Researcher

**Email prompt (Time 2 & 3) to be sent if responses not received within 4 days of emailing the Qualtrics link:**

**Subject:** 'Research study: MBCT for parents/carers of children with food allergies'

Dear xxxx,

We have noticed that you haven't yet submitted your responses to the questionnaires sent on xx/xx/xx.

Please may we ask that you do so by xx/xx/xx. If we haven't received your response by this date, we will assume you no longer wish to take part in the study and will withdraw you.

Best wishes,

XXXX

Lead researcher

**Telephone message script to be communicated if no response received following initial reminder email (Times 2 & 3):**

*Hello, introduce self*

*I wanted to follow up on my email sent to you on xx/xx/xx as we are yet to receive your questionnaire responses for the MBCT study. Please also note that if you have seen it and no longer want to take part in the study this is also fine and so please disregard this message.*

*However, I am phoning to check that the email hasn't been directed to your junk mailbox. Please do check that if you haven't yet received it.*

*If you are still happy to continue with the study, please could you submit them by xx/xx/xx.*

*If we have not heard from you by this date, we will assume you no longer wish to take part in the study and will withdraw you.*

*If you are still unable to find it, please contact me on xxxxxxxxxx and we will look into this.*

**Follow up email if no further response following email or telephone prompt (Time 2 & 3):**

**Subject:** 'Research study: MBCT for parents/carers of children with food allergies'

Dear xxxx,

As we haven't heard from you, we assume you no longer wish to take part in this study and will be withdrawing you.

If the questionnaires drew your attention to any health or wellbeing problems that you may be experiencing, we'd advise you to contact your GP or NHS 111, by dialling 111 or using https://111.nhs.uk.

If you have any questions or feedback about the study, please contact the research team using xxxx.

If you wish to make a complaint about the study, please either contact the study team using the above email address or xxxx, xxxx, via xxxx.

We wish you all the best.

Best wishes,

XXX

Lead Researcher

## Appendix I: Ethical approval

This has been removed from the electronic copy

# Appendix J: Demographic questionnaire

**Demographic questionnaire**

Participant Information

1. What is your email address:
2. What gender do you identify with:

   **Male [ ]**

   **Female [ ]**

   **Another gender [ ] Please specify:**

   **Prefer not to say [ ]**
3. What is your age (in years):
4. How would you best describe your ethnic background?

| **White** | **Black or Black British** | **Asian or Asian British** | **Mixed** | **Other ethnic groups** |
|---|---|---|---|---|
| British [ ] | African [ ] | Bangladeshi [ ] | Asian & White [ ] | Chinese [ ] |
| Irish [ ] | Caribbean [ ] | Indian [ ] | Black African & White [ ] | Prefer not to say [ ] |
| Any other White background [ ] | Any other Black background [ ] | Pakistani [ ] | Black Caribbean & White [ ] | Any other ethnic background [ ] **Please specify:** |
| | | Any other Asian background [ ] | Any other mixed background [ ] | |

5. What is your employment status (tick all that apply):

**Full time employment [ ]**

**Part time employment [ ]**

**Self-employed**

**Homemaker/carer [ ]**

**Unemployed [ ]**

6. What is the highest degree or level of school you have completed?

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Primary school** | [ ] | **O-levels/ GCSEs, N5 qualifications or equivalent** | [ ] | **A-Levels, Scottish Highers or equivalent** | [ ] | **Specialist trade/apprenticeship** | [ ] |
| **University undergraduate programme** | [ ] | **University post-graduate programme** | [ ] | **Doctoral degree** | [ ] | **Other, please specify:** | |

7. Are you currently experiencing any mental or physical health difficulties?

**YES [ ]** **NO [ ]** **PREFER NOT TO SAY [ ]**

**If yes, please provide brief details: _____**

8. If yes to Q7, are you currently accessing support, therapy or treatment for these?

**YES [ ]** **NO [ ]** **PREFER NOT TO SAY [ ]**

**If yes, please specify what kind of support:_____**

9. Have you ever accessed psychological therapy/support in the past?

**YES [ ]** **NO [ ]** **PREFER NOT TO SAY [ ]**

**If yes, please specify what kind of support:_____**

10. Have you ever accessed a mindfulness-based intervention in the past?

**YES [ ]** **NO [ ]** **PREFER NOT TO SAY [ ]**

**If yes, please specify what kind of mindfulness-based intervention:_____**

11. Have you ever practiced mindfulness in the past?

**YES [ ]** **NO [ ]** **PREFER NOT TO SAY [ ]**

**If yes, please give details:_____**

**Child information**

12. **Do you have more than one child with a food allergy?**

YES [ ] NO [ ]

If yes, please answer the following questions separately for each child.

13. **How old is your child (in years)?_____**

14. **What gender does your child identify as:**

Male [ ]

Female [ ]

Another gender [ ] Please specify:

Prefer not to say [ ]

15. **How many food allergies does your child have? _____**

16. **When was the last time your child was seen a doctor about their food allergy/allergies (in months)?**

17. **How did the doctor test for food allergy?**

Skin prick tests [ ] Blood tests [ ] Food challenge [ ]

Other please state……

18. **How old was your child when their allergy was diagnosed (in years)?**

19. **What is your child allergic to?** *(tick as many as apply)*

| | | | |
|---|---|---|---|
| ▪ Peanut | [ ] | • Fish | [ ] |
| ▪ Tree nuts | [ ] | • Shellfish | [ ] |
| ▪ Milk | [ ] | • Wheat | [ ] |
| ▪ Egg | [ ] | • Soya | [ ] |
| ▪ Other | [ ] | | |
| If other please specify: | | | |

20. **Does your child also have:**

| | | | | |
|---|---|---|---|---|
| ▪ Asthma | Yes | [ ] | No | [ ] |
| ▪ Eczema | Yes | [ ] | No | [ ] |
| ▪ Hay fever | Yes | [ ] | No | [ ] |

21. **What medicine do they have for their food allergy (tick as many that apply)?**

| | |
|---|---|
| ▪ Antihistamines | [ ] |
| ▪ Adrenaline injection (Emerade, Epi-Pen or JEXT) | [ ] |
| ▪ None | [ ] |

22. **Has your child ever been to hospital with an allergic reaction to food?**

    YES [ ] NO [ ]

23. **Has your child ever had an anaphylactic reaction (a severe allergic reaction)?**

    YES [ ] NO [ ]

    **If yes, how many? _____**

24. **Does your child have an anaphylaxis management plan?**

    YES [ ] NO [ ]

25. **Do you belong to a food allergy or anaphylaxis support group?**

    YES [ ] NO [ ]

## Appendix K: Feedback letter to ethics panel

This has been removed from electronic copy