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MINDFULNESS SELF-HELP FOR HEALTH CARE PROFESSIONALS.

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Summary of MRP

SECTION A

Section A critically reviews the current relevant theoretical literature and empirical studies exploring the impact of mindfulness-based interventions on healthcare professionals. The review includes a meta-review of mindfulness-based interventions and the impact on staff mental health. It then considers the primary recourses and the potential to improve work related performance and outcomes, including patient outcomes. A meta-analysis looks at impact of MBI on empathy. Clinical and theoretical implications are discussed, and what the findings mean for clinical practice and future directions for research are presented.

SECTION B

Interventions have been called for to help stress and wellbeing in health care professionals in the NHS. Mindfulness based interventions have been identified as a promising resource. This full powered randomised control trial evaluated mindfulness based cognitive behavioural self-help, intervention for health care professionals using Williams and Penman's book (2011). Health care professionals in two trusts in the South-East of England (N = 133) participated in a randomised controlled trial. The intervention group showed significantly greater reductions in stress, anxiety and depression, increases self-compassion and in psychological well-being compared to controls. Improvement in self-compassion statistically mediated the change in well-being. Findings are discussed and recommendations for future research are made.

Table of Contents

List of tables

List of Figures

List of Appendices Page number

Section A

Effects of mindfulness for health care professionals: A meta-review, systematic review and meta-analysis

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Abstract

As demand for health care services continues to rise with increased pressure placed on staff, NHS employers need effective, evidence-based workplace interventions, that will help to support and protect their staff.

In the context of supporting the mental health workforce, recent systematic reviews have indicated that psychological interventions show promise and, in recent years, mindfulness-based interventions (MBIs) have gained particular research interest. Many randomised controlled trials (RCTs) of MBIs for healthcare staff have been undertaken and systematic reviews/meta-analyses of these, but there is variation between reviews in terms of staff group, outcomes etc. A systematic literature search was undertaken and a meta-review of seven systematic reviews was carried out to help to consolidate the research in this field (review 1). Research to date has focused on the potential of MBIs to reduce healthcare staff stress but there is also the potential for benefit beyond the individual member of staff; MBIs have the potential to improve work related performance and outcomes, including patient outcomes. A systematic search of the literature found13 primary resources which were included in the systematic review and meta-analysis (review 2). Whilst there is little evidence to support MBIs for work related performance and patient outcomes, there is evidence to suggest that MBIs are helpful for decreasing stress and mental health outcomes in health care professionals.

1.Introduction

Stress and anxiety are amongst the most significant reasons for health care practitioners (HCP)/NHS staff sickness absence (NHS Audit Commission, 2011). The provision of psychological support for staff may have the potential to improve staff job satisfaction, and reduce staff turnover and burnout (Shapiro, Astin, Bishop, & Cordova, 2005; Ruotsalainen, Serra, Marine & Verbeek, 2008). Moreover, improving staff wellbeing has the potential to improve the quality of patient care, which is at the heart of the NHS (Garman, Corrigan & Morris, 2002).

As demand for health care services continues to rise with increased pressure placed on staff, NHS employers need effective, evidence-based workplace interventions, in line with the Five Year Forward View, that will help to support and protect their staff.

The Five Year Forward View for Mental Health (2016, p.48) made recommendations for developing and supporting the mental health workforce in the UK. One recommendation stipulated that "NHS England should ensure current health and wellbeing support to NHS organisations extends to include the management of mental health in the work place...and effective workplace interventions from 2016 onwards.p.48" It also recommended that "NHS England should introduce a Commissioning for Quality and Innovation (CQUIN)…relating to NHS staff wellbeing." These recommendations were not unexpected as ten million NHS working days are lost each year to staff sickness absence. Healthcare sector employees in the UK have the highest sickness absence rates of any sector and sickness rates are rising (NHS Sickness Absence Rates, 2015).

In the context of supporting the mental health workforce, psychological interventions showed promise in a recent Cochrane review (Panagioti et al., 2017) and mindfulness-based interventions (MBIs) have gained particular research interest in recent years. This is supported by a meta-analysis of mediation studies that showed that MBIs appear to work, at least in part, through reducing rumination and worry (Gu, Strauss, Bond & Cavanagh, 2015). Based on theory (Segal, Williams & Teasdale, 2013) and evidence from studies looking at the impact of face-to-face MBCT (e.g. Kuyken et al., 2010), it is suggested that MBCT has an important role in improving wellbeing by increasing mindfulness and compassion (Gu et al., 2015) supported mindfulness as a mediator and provided preliminary evidence for self-compassion.

Mindfulness based interventions in particular could help improve healthcare staff wellbeing by reducing time spent ruminating and worrying about work-related concerns that would otherwise lead to increased stress or mental health problems, and increasing self-compassion. It may be that MBIs offer the potential to improve staff well-being and this review examines MBIs and staff well-being in more detail.

Aims of this review:

1. Many randomised controlled trials (RCTs) of MBIs for healthcare staff have been undertaken and systematic reviews/meta-analyses of these but there is variation between reviews in terms of staff group, outcomes etc., so a meta-review of these would help to consolidate what we know to date in this field.
2. Research to date has focused on the potential of MBIs to reduce healthcare staff stress but there is also the potential for benefit beyond the individual member of staff – MBIs have the potential to improve work related performance and outcomes,

including patient outcomes. The mechanisms for these include: staff being able to give greater present moment attention to the client/patient, staff having a greater focus on decision making rather than reacting automatically, and staff being better able to manage their own heightened emotions in challenging situations.

1.2. Mindfulness Based Interventions

Mindfulness can be defined as "the awareness that emerges through paying attention on purpose, in the present moment, and nonjudgmentally to the unfolding experience moment by moment" (Kabat-Zinn, 2003, p 144). In secular, healthcare settings, mindfulness can be learned through mindfulness-based interventions (MBIs) including mindfulness-based stress reduction (MBSR; Kabat-Zinn,1979) and mindfulness-based cognitive therapy (MBCT; Segal, Williams &Teasdale, 2002). MBSR aims to cultivate awareness of present-moment experiences and guides the individual to not get caught up in automatic thoughts, feelings and patterns of behaviour. This is learnt through meditation practices such as breathing exercises, sitting meditation, body scans and movement. MBCT follows a similar course, with the addition of CBT for depression elements. Crane et al. (2017) defines what constitutes an MBI (See Table 1). MBIs appear to work, at least in part, by reducing rumination/worry. In practice, this may benefit healthcare staff wellbeing by reducing the time spent ruminating/worrying about work-related concerns that would otherwise lead to increased stress or mental health problems. (Segal, Teasdale & Williams, 2004). Indeed, based on this theory, as may be expected, a meta-analytic review showed that MBIs were moderately effective for reducing anxiety and mood symptoms in clinical populations (Hofmann, Sawyer, Witt & Oh, 2010). A meta-analysis also has shown that MBIs are effective at reducing stress in non-clinical populations (Chiesa & Serretti, 2009). Further to this, a pilot

study, (Rabb, Sogge, Parker & Flament, 2015) found that MBIs increased self-compassion in HCPs.

There are two areas of particular interest when considering the effectiveness of MBIs for healthcare staff, namely outcomes in terms of staff wellbeing and outcomes in terms of their effectiveness as HCPs[1]. The impact of MBIs on health care staff, particularly in relation to staff well-being, has been well studied, including several systematic reviews and meta-analyses. However, existing reviews address slightly different questions as they use different populations of health care workers and examine different outcomes. There is value in pooling findings from these reviews and providing a meta-review (a review of reviews). A synthesis across the reviews would help to consolidate the research evidence to date in this area.

There are a few emerging studies that have looked at the effects of MBIs and their potential benefit beyond the individual member of staff. MBIs may have the potential to improve work related performance and outcomes, including patient outcomes. This may happen by enabling staff: to be more present in the moment, pay greater attention to the client/patient, and put more emphasis on decision making rather than reacting automatically. Also, MBIs may help staff to better manage heightened emotions in challenging situations. However, there are no recent reviews that examine this area so the second aim of this review is to conduct a systematic review and meta-analysis of primary research of healthcare staff effectiveness (including but not limited to effects on patient outcomes).

Table 1. The essential and flexible ingredients of MBIs taken from ‘What defines mindfulness-based programs? The warp and the weft’ (Crane, 2017)

[1] To measure HCP effectiveness, psychometric measures are used for assessing the quality of care, patient outcomes or staff performance. These could be direct measures i.e. patient outcomes or indirect measures i.e. staff empathy, and compassion.

Essential	Flexible
1. Is informed by theories and practices that draw from a confluence of contemplative traditions, science, and the major disciplines of medicine, psychology and education 2. Is underpinned by a model of human experience which addresses the causes of human distress and the pathways to relieving it 3. Develops a new relationship with experience characterized by present moment focus, decentring and an approach orientation 4. Supports the development of greater attentional, emotional and behavioural self-regulation, as well as positive qualities such as compassion, wisdom, equanimity. 5. Engages the participant in a sustained intensive training in mindfulness meditation practice, in an experiential inquiry-based learning process and in exercises to develop insight and understanding	1. The core essential curriculum elements are integrated with adapted curriculum elements, and tailored to specific contexts and populations 2. Variations in program structure, length and delivery are formatted to fit the population and context
MBP teacher 1. Has particular competencies which enable the effective delivery of the MBP 2. Has the capacity to embody the qualities and attitudes of mindfulness within the process of the teaching 3. Has engaged in appropriate training and commits to ongoing good practice 4. Is part of a participatory learning process with their students, clients or patients	1. Has knowledge, experience and professional training related to the specialist populations that the mindfulness-based course will be delivered to 2. Has knowledge of relevant underlying theoretical processes which underpin the teaching for particular contexts or populations

2. Aims

To summarise, the aims of this review are as follows:

The first aim is to provide a meta-review of systematic reviews and meta-analyses of RCTs of mindfulness-based interventions (MBIs) for healthcare staff.

The second aim is to provide a systematic review of primary research examining effects of MBIs on health care staff workplace effectiveness.

3. Method- Review 1- Meta-review

The method for the meta-review of systematic reviews and meta-analyses (review 1) examining effects of MBIs on healthcare staff stress and mental health outcomes will be outlined below.

3.1 Search strategy

With the intention of capturing all relevant review articles in the search, the search string included additive three concepts: Health care professionals + mindfulness term + review term.

To maximise the scope of the search, a filter was not applied for the time period. Searches were conducted from inception of those databases to 21 November 2017. PsycInfo, Web of Science and PubMed databases were searched for articles containing the following search terms in their title or 'key concepts.': (healthcare OR nurse* OR doctor* OR clinician* OR psychologist* OR NHS OR therapist* OR professional* OR medical staff OR medical student* OR counsellor* OR counsellor* OR health care OR social worker* OR trainee* OR dentist* OR paramedic* OR ambulance* OR emergency OR intensive care OR primary care OR hospital*OR anaesthetists or art therapists OR Biomedical scientists OR Cardiac physiologists OR Cardiographers OR Cardiologists OR Children's nurses OR Counsellors OR Dietitians OR Doctors OR Gynaecologists OR Health support workers OR Health visitors OR Mental health nurses OR Midwives OR Nurses OR Nursing assistants OR Occupational therapists OR Ophthalmologists OR Paediatricians OR Pathologists OR Pharmacists OR Physiotherapists OR Psychiatrists OR Speech and language therapists OR Psychotherapists OR Radiographers OR Radiologists) AND (mindfulness OR MBCT OR MBSR OR MBI) AND (Systematic review OR Meta-analysis OR review).

3.2. Inclusion and exclusion criteria

Inclusion criteria were that studies: (1) were a literature review, systematic review or meta-analysis; (2) recruited only qualified healthcare staff or healthcare staff in training; (3) were published in English; (4) were in a peer reviewed journal; (5) reviewed MBI(s) that were grounded in mindfulness principles and included mindfulness practice; (6) included RCTs; (7) had a stress or mental health outcome.

3.3. Selection process

The reviews' titles and abstracts were screened against the inclusion/exclusion criteria described above. The full texts of the remaining reviews were then screened.

3.4. Methodological and Reporting Quality

To maintain methodological rigour, the Assessment of Multiple Systematic Reviews (AMSTAR) tool (Shea et al. 2007b) (Appendix A) was used to assess the methodological quality of each review selected for inclusion. The AMSTAR has been shown to have excellent reliability and construct validity (Shea et al. 2007a). AMSTAR uses a checklist which consists of 11 questions. Scoring is given for 'yes,' 'no,' 'can't answer', and 'not applicable' responses. To test a review's methodological rigour, questions are asked about the way the systematic literature review was conducted, for example, if the methods used to combine the findings of the studies were appropriate and whether a scientific quality assessment of the studies was included and used appropriately in formulating conclusions. The scores are then totalled and are interpreted as follows: A score of 0–4 reflects low-quality research, 5–8 moderate and 9–11 high quality. As this tool has two questions which are specific to meta-analysis, it was decided to adjust the scores of the reviews that did not undertake a meta-analysis. This meant that the questions that they could not receive points for

were taken into account. For systematic reviews, the two points were taken into account and adjusted appropriately giving a possible maximum total score of nine. For systematic reviews, a score of 0–3 was deemed low quality, 4–7 moderate and 8– 9 high quality. This score adjustment has been used as a way to include systematic reviews without meta-analysis by other reviewers, for example (Joyce et al., 2015).

4. Results of Review 1 – Meta-review

As above, this meta-review aims to examine the effects of MBIs on healthcare staff stress and mental health. The initial systematic search identified 52 reviews. Of these, seven met the inclusion criteria and were reviewed in detail[2]. All seven reviews met the quality assessment criteria, three were deemed to be of moderate quality and four rated as high quality. Together, these reviews analysed 145 primary research studies. Out of these 145, 42 were controlled studies. The complete selection process is summarized in Figure 1 in a Preferred Reporting Items for Systematic Reviews and Meta-Analyses diagram (PRISMA) (Moher, Liberati, Tetzlaff & Altman, 2009) with included reviews outlined in Table 2.

[2] Another meta-analysis, looking at burnout (Strauss, Jones, Mundy, Strohmaier, O'Hanlon, Cavanagh, under review) was not included in detail here because it is still under review.

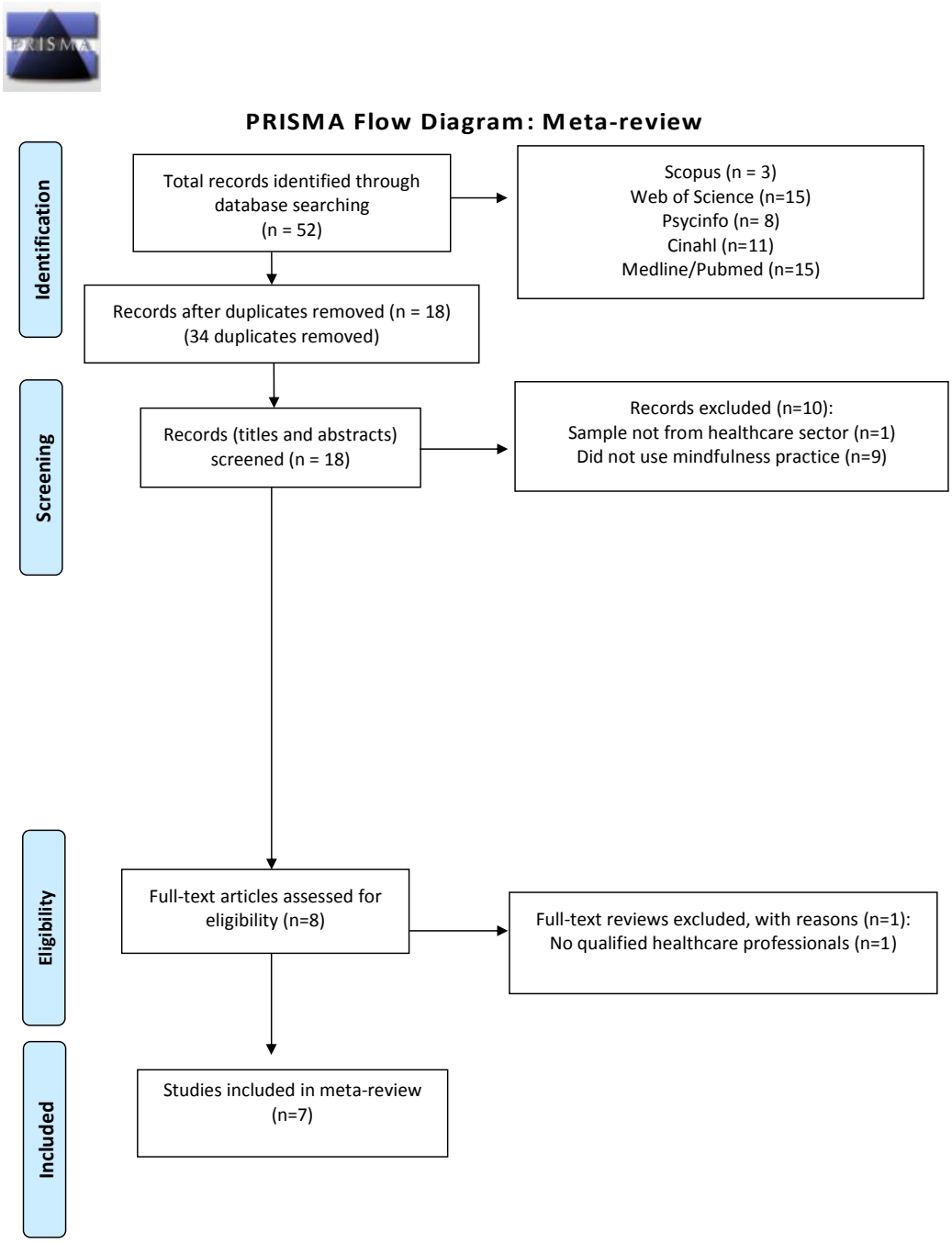

Figure 1. PRISMA diagram

Table 2. Reviews examining the effects of MBIs on health care professionals

Author (year)	Intervention examined	Sample (N RCT)	No Studies included (of which RCT)	Type of review	Quality score and descriptor*	Outcome
Burton et al., (2016)	MBIs on stress	Health care professionals (n=380)	9 (2)	Systematic review and meta- analysis	9 High	Stress Depression and anxiety
Escuriex et al, (2011)	MBIs psychosocial functioning	Health care providers (n=70)	20 (2)	Systematic review	4 Moderate	Psychological wellbeing, , stress, burnout.
Daya et al., (2017)	MBIs Wellbeing	Medical students (n = 511)	12 (4)	Systematic review	8 High	Stress, depression and anxiety.
Gilmartin et al., (2017)	MBIs Wellbeing	Health care providers (n=340)	14 (7)	Systematic review	7 Moderate	Stress, anxiety, depression, burnout
Guillaumie et al., (2016)	MBIs on mental health	Nurses (n=885)	32 (17)	Systematic review	8 High	Stress, anxiety, depression, wellbeing, burnout psychological distress.
Lemothe et al., (2016)	MBIs on empathy and mental health	Health care providers (n=554)	39 (14)	Systematic review	6 Moderate	Stress, anxiety, depression, burnout
McCoville et al., (2017)	MBIs on mental health	Health care professional students (n = 920)	19 (12)	Systematic review and meta- analysis	9 High	Stress, anxiety, depression, burnout

**A score of 0–4 reflects low-quality research, 5–8 moderate and 9–11 high quality. For systematic reviews, a score of 0–3 was deemed low quality, 4–7 moderate and 8– 9 high quality*

4.1. Overview of the narrative review of systematic reviews and meta-analyses

This section gives a narrative review of the systematic reviews and meta-analyses that met the inclusion criteria. The meta-review considers the effects of MBIs on stress in qualified healthcare professionals (HCPs), and then looks more broadly at other measures of mental health and wellbeing. Following the recommendations from Smith (2014) that there are differences between qualified staff and students, it then considers the effects on student HCPs. Review findings of RCTs are given more attention as these are considered more methodologically robust. More recent systematic reviews with high quality assessment ratings are discussed in more depth. Escuriex et al. (2011) and Guilmartin et al. (2017) are not considered in as much detail because they had a lower score on the quality rating tool. In addition, Escuriex et al. (2011) is a relatively older review.

4.2. Effects of MBIs on stress in qualified health care professionals

Burton, Burgess, Dean, Koutsopoulou, and Hugh-Jones (2016) scored 'high' on the quality rating tool. Their systematic review and meta-analysis included nine studies and looked at the effect of MBSR on HCPs' stress levels. Out of these, six studies used pre-post intervention designs, one used a quasi-experimental design and two were RCTs that included pre-measures and post-measures. The authors completed a meta-analysis on the pre-post data studies using stress as an outcome measure. Data were extracted from seven of the nine papers and the authors found a combined medium effect size, r=0.342 (CI=0.202 – 0.468). Their meta-analysis included data from uncontrolled studies so this result has to be treated with caution as causation cannot be assumed. Their systematic review of the RCTs showed that mindfulness-informed interventions improve stress, anxiety and depression outcomes in HCPs relative to passive controls.

The authors rated the RCTs with a quality assessment tool and found fidelity issues. Only one study measured state mindfulness. In studies that do not include a measure of mindfulness, it may be difficult to conclude that the reported changes in stress were as a result of increased levels of mindfulness rather than another aspect of the intervention. Several methodological limitations were reported. Other variables that may impact on the effectiveness of MBIs on health care workers were not routinely measured, such as readiness to change (Lyubomirsky, Dickerhoof, Boehm, & Sheldon, 2011). Their systematic review and meta-analysis concluded that MBIs could be a potential way to reduce stress in HCPs. However, only two RCTs were included whilst the rest were uncontrolled studies, so the conclusions that can be drawn are limited. Further research, using RCTs, may help to draw firmer conclusions on the effectiveness of MBIs in reducing stress.

4.3. Wider effects of MBIs on mental health

Another review that scored 'high' on the rating tool was Guillaumie, Boiral and Champagne (2016). Guillaumie et al. (2016) reviewed literature that looked at the wider effects of MBIs on nurses, regarding anxiety and depression. In their review, a total of 32 studies included 17 RCTs, 11 pre–post designs and four qualitative designs. The meta-analysis was completed on nurses' depression, anxiety and stress outcomes. The data were extracted from the standard mean difference data from intervention and control groups from the RCTs. The meta-analysis suggested that mindfulness-based interventions are effective in reducing state anxiety. Significant mean reductions were observed in the RCTs looking at state anxiety at post-intervention (−0·78, 95% CI −1·39 to −0·18) and at follow-up (−0·80, 95% CI −0·12 to −0·18). Also, significant mean reductions were found in depression at post-intervention (−0·51, 95% CI −0·78 to −0·18). However, inconclusive results were found in the RCTs looking at stress with respect to reductions relative to controls, as the confidence interval

crossed zero −0·34 [−2·67, 1·99]. The results for stress should be considered with some caution due to the small number of studies contributing to the individual meta-analysis and the heterogeneity between the results of some studies.

Their review concluded that mindfulness training may be an effective intervention for organisations wishing to improve nurses' mental health. The methodological quality of the studies was evaluated. Although the individual ratings of the risk of bias for each study were not given by the authors, they stated that no study was excluded on the basis of not reaching the quality threshold. The authors concluded that the results from the RCTs suggest that MBIs are effective in reducing staff stress, anxiety and depression, also, that future research should further explore the long-term impacts of mindfulness on performance using more robust methodological designs. Although this review was highly rated, its quality would have been further improved if the authors had correlated the risk of bias for the individual studies included.

Lemothe, Rondeau, Malboeuf-Hurtbise, Duval and Sultan (2016) included an examination of the effects of MBIs on stress, burnout and depression. Lemothe et al. (2016) reviewed 39 studies. Out of the 39 studies identified, 14 were RCTs, 10 were quasi-experimental studies with controls but no random allocation and 15 studies were pre-post designs with no control group. Intervention length ranged from one to 12 weeks. Eleven different mental health outcomes across the studies were measured, including burnout, perceived stress, anxiety and depression. All of the reviewed studies, except two, measured at least one mental health outcome. The most commonly measured outcome in this category was HCPs' perceived stress, appearing in nineteen studies. Eighteen of these found that MBSR decreases HCPs' perceived stress. Burnout was the second most measured outcome, appearing in 17 studies.

Nine studies found that MBSR reduces HCPs' burnout. Ten studies concluded that MBSR was effective in reducing anxiety in HCPs. Six studies found MBSR to be effective in improving HCPs' mental well-being. Overall, these results suggest that MBSR may favourably impact on HCPs' mental health difficulties and levels of mindfulness. However, the results from all the studies were grouped together in this review. It was not clear whether the results were from the pre-post intervention or between-group findings. An additional limitation of this review was that they did not assess the risk of bias for the studies that looked at mental health outcomes. The authors justified this by saying that other studies, that looked at mental health outcomes, had been reviewed for bias in another, recent review. The conclusions reached in their review is in keeping with other reviews which suggest that MBIs may favourably impact upon HCPs. There appears to be stronger evidence for the effectiveness of MBIs for nurses as reviewed by Guillaumie et al. (2016), compared to Burton et al. (2016) where the results were more ambiguous as fewer RCTs were included. Undertaking another literature review will not help to clarify the evidence for the effectiveness of MBIs as several highly rated reviews have been published, as discussed above. More robust RCTs are needed that look at different samples of HCPs.

4.4. Lower quality rated reviews

Three other systematic reviews considered the effects of MBIs on health care workers, however, their quality was not as highly rated as the other systematic reviews. Escuriex, and Labbe (2011) reviewed 11 primary resources: three pre-post, two RCTs, four qualitative, one correlational, and one non-randomised study. Both of the RCTs included in this study were included in the reviews discussed later. The results of the RCTs supported MBIs for stress. However, the studies were not assessed with a quality rating tool. There may also be

reporting bias of MBI literature. Other, more up to date systematic reviews considered above are arguably more useful.

Gilmartin, Goyal, Hamati, Mann, Saint and Chopra (2017) reviewed a total of 14 studies looking at brief mindfulness practices for HCPs. Out of the studies that met their inclusion criteria, seven were RCTs. The authors concluded that brief mindfulness interventions may be effective in improving HCPs' stress and anxiety. They found that all seven RCTs reported decreased stress and anxiety. However, the authors did not report effect sizes so it is difficult to draw conclusions on how effective the interventions were. The authors concluded that the risk of bias suggested moderate quality. However, all of the RCTs scored poorly on measures of internal validity/bias due to a lack of attempt to blind study subjects or measure the main intervention outcomes. In addition, intervention adherence as part of group or independent practice was not reported in most studies. While these reviews are weaker, they do not contradict the reviews above.

4.5. Effects of MBIs on HCP student sample

McCoville, McAleer and Hahne (2017) considered the impact of MBIs on HCP students. Their systematic review included a meta-analysis examining mindfulness interventions and a meta-analysis that evaluated the effect of mindfulness training on stress, anxiety and depression. The review scored highly using the quality assessment tool. McCoville et al. (2017) reviewed 19 studies of which 12 were RCTs. The meta-analysis that looked at MBIs and depression only used RCTs whereas the other meta-analysis used both uncontrolled and controlled studies. Seven RCTs were included in the meta-analysis evaluating depression post-intervention. This meta-analysis showed a significant effect of mindfulness on depression (SMD= −0.54; 95% CI: −0.83 to −0.26; $p < .01$). Eleven studies evaluated anxiety

post-intervention. The meta-analysis showed a significant effect of mindfulness on anxiety (SMD = −0.44; 95% CI: −0.59 to −0.28; $p < .01$). However, three of the studies were uncontrolled therefore it is difficult to know with certainty whether the results were due to the intervention. Eleven studies evaluated stress post-intervention. The meta-analysis showed a significant effect of mindfulness on stress (SMD = −0.44; 95% CI: −0.57 to −0.31; $p < .01$). However, two of the studies included were uncontrolled therefore it is difficult to be sure that the results were due to the intervention.

This review identified positive outcomes of mindfulness training in HCP students, but the results may be overly positive as uncontrolled studies were included in the analysis alongside RCTs. In addition, these studies used a student population, and therefore the results may not be generalisable to qualified HCPs.

Daya and Heath Hearn (2017) reviewed 12 studies looking at the effects of MBIs on medical students on stress depression, fatigue and burnout. Four of the studies included were RCTs. The RCTs included in this review were also reviewed by McCoville et al. (2017). In this review, the authors did not distinguish between design and grouped the studies together in their analysis. They concluded that 57% of studies reporting on stress demonstrated significant reductions and 67% of those studying depression found significant reductions, as seen in the review above. However, differences in the methodology of the included studies may limit the generalisability of the results.

5. Summary

This review of systematic reviews and meta-analyses suggest that MBIs are helpful for HCPs to improve stress, anxiety and depression. Total sample sizes included in the reviews of

RCTs ranged from 38 to 920. Five reviews used samples from HCPs and two used samples from healthcare student populations. Some studies did not measure mindfulness, so casual links maybe difficult to establish. MBIs for stress were discussed in all the reviews and the majority found a reduction in stress from pre- to post- intervention. However, some of the reviews also included studies that were not controlled and therefore the results should be viewed with caution. Five out of the seven reviews looked at the effects of MBIs on anxiety and found reductions in anxiety, and four looked at depression and found reductions in depression. However, again, the findings were based on the inclusion of studies without controls. The only meta-analysis that used only RCTs found reductions in anxiety and depression but inconclusive results for the effect on stress (Guillaumie et al., 2017).

Using the AMSTAR quality rating scale, none of the reviews had low scores. However, some reviews scored more highly than others. Four were scored as high-quality: Burton et al. (2016), Daya et al. (2017), Guillaumie et al. (2017), and McCoville et al. (2017) while Escuriex et al. (2011) scored the lowest. The majority of reviews failed to discuss the status of publication used as inclusion criterion appropriately and to make an assessment of publication bias.

Many of the systematic reviews identified a few quality issues in the pool of studies examined for risk of bias. For example, some of the studies had limited sample sizes, making the identification of small-size changes difficult and limiting external validity. One review (Burton et al., 2016) did not report on the number of participants in the RCT which would bring the results into question because it is not possible to establish if it was adequately powered. There were also many variations in the MBIs used in the reviewed studies. The length of programs and classes varied considerably and it is not clear whether abbreviated

versions are as effective as the standard MBI. Moreover, a proportion of participants were still in training, which makes it difficult to generalise the findings to practising professionals (Smith, 2014).

The reviews discussed above, suggest that MBIs, particularly for nurses, help reduce anxiety and depression. The reviews' results are more tentative for stress, and although the evidence looks promising, the mixture of designs means that it is difficult to make any definitive conclusions. More robust RCTs that look at the effects of stress and consider different samples of HCPs are needed. Further critical evaluation of these reviews, along with the primary sources will be considered in the discussion.

6. Method Review 2 – review and meta- analysis of primary resources

This paper also aimed to review the primary resources examining effects of MBIs on HCPs' workplace effectiveness. A meta-analysis was planned for any outcome with at least four studies per subgroup.

6. 1. Search Strategy

Studies were identified by searching five electronic databases (PsycInfo, Web of Science, Cinahl, Medline and Scopus) and checking reference lists of retrieved articles, systematic reviews and meta-analyses. Searches were conducted from inception of those databases to 21 November 2017.

With the intention of capturing all relevant primary resources, the search string included two additive concepts: health care professionals + mindfulness term. The research was then hand searched for quality of care outcomes.

To maximise the scope of the search, a filter was not applied for the time period. PsycInfo, Web of Science and PubMed databases were searched for articles containing the following search terms in their title or 'key concepts.' Healthcare OR nurse* OR doctor* OR clinician* OR psychologist* OR NHS OR therapist* OR professional* OR medical staff OR medical student* OR counsellor* OR counsellor* OR health care OR social worker* OR trainee* OR dentist* OR paramedic* OR ambulance* OR emergency OR intensive care OR primary care OR hospital*OR anaesthetists or art therapists OR Biomedical scientists OR Cardiac physiologists OR Cardiographers OR Cardiologists OR Children's nurses OR Counsellors OR Dietitians OR Doctors OR Gynaecologists OR Health support workers OR Health visitors OR Mental health nurses OR Midwives OR Nurses OR Nursing assistants OR Occupational therapists OR Ophthalmologists OR Paediatricians OR Pathologists OR Pharmacists OR Physiotherapists OR Psychiatrists OR Speech and language therapists OR Psychotherapists OR Radiographers OR Radiologists AND mindfulness OR MBCT OR MBSR OR MBI

In addition, the reference sections of all the research articles listed in this paper were checked.

6.2 Eligibility criteria

Inclusion criteria were that studies: (1) recruited healthcare staff or healthcare staff in training; (2) have undertaken a mindfulness based intervention – (i) where mindfulness is undertaken in each session, (ii) where daily practice is undertaken, (iii) where mindfulness is the core part of the intervention; (3) were of any research design that examined the effectiveness of an intervention, or examined change over the course of a mindfulness

intervention, including RCTs, quasi-experimental studies, uncontrolled pre-post designs, and single case studies, (4) measures are used for assessing the quality of care or psychometric measures are used for assessing the quality of care, patient outcomes or staff performance. These could be direct measures i.e. patient outcomes or indirect i.e. empathy, and compassion (6) available in English language (6) Peer reviewed

Papers were excluded if they: (1) only included psychometric measures of mental health wellbeing such as stress, depression, anxiety, as these aren't clear indicators of quality of care; (2) were cross sectional study.

The titles were screened followed by the abstracts. Full texts were then screened and checked against the inclusion/exclusion criteria. See Figure 2 for a PRISMA (Moher, Liberati, Tetzlaff & Altman, 2009) flow diagram showing the flow of the search results and screening processes. Following screening for suitability, 13 studies were included.
A meta-analysis was planned for any outcome with at least four studies per subgroup (Fu et al, 2011) and the remainder were narratively reviewed.

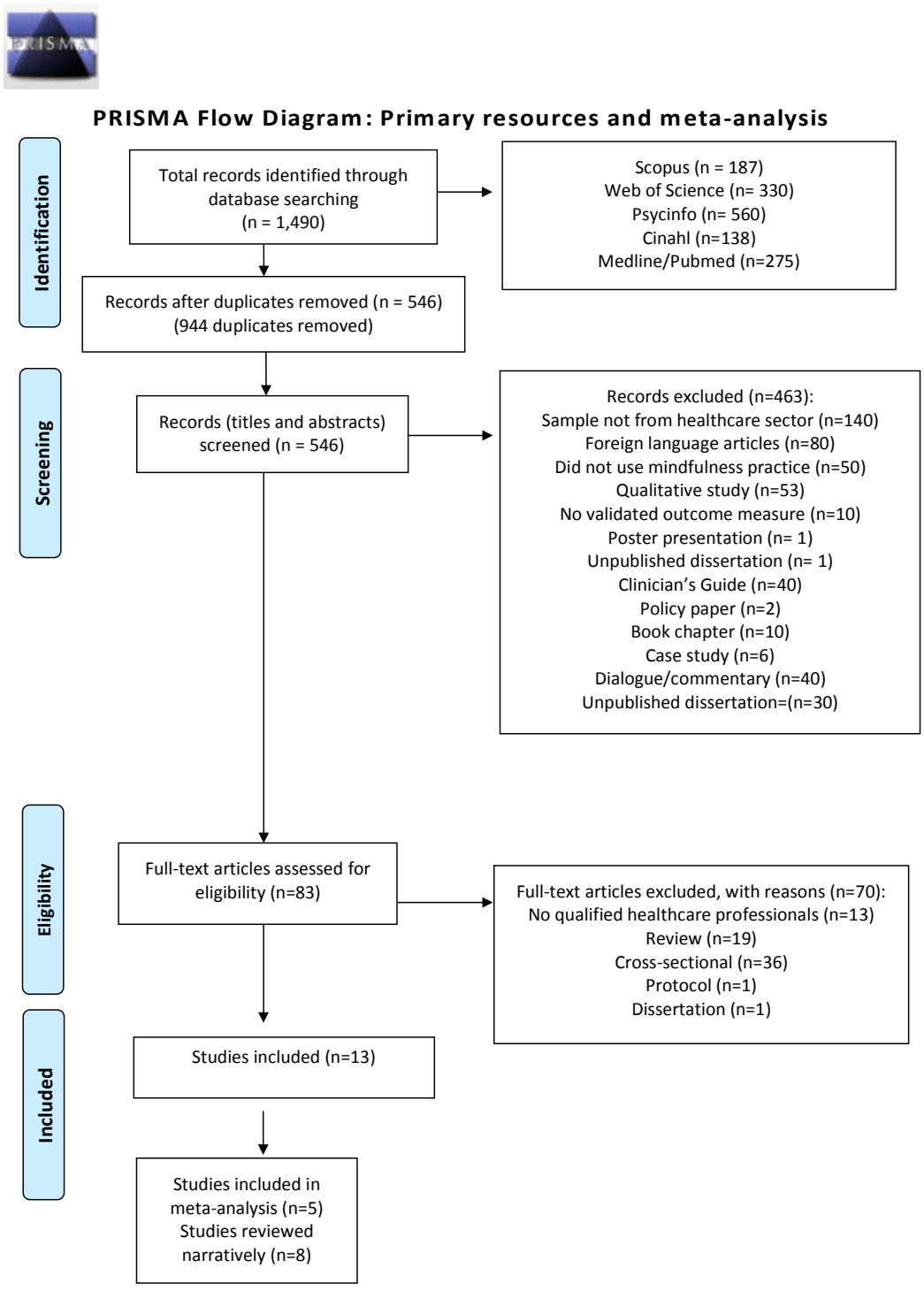

Figure 2. PRISMA diagram

6.3 Data Extraction for meta-analysis

Where available, post-intervention and follow-up means and standard deviations were extracted for each outcome for each condition (MBI and control group). If a study included more than one control group, the inactive control group was selected in order to reduce heterogeneity in design types across the studies. Where available, follow-up data were extracted for the longest available follow-up period. Additional information was extracted to allow a detailed description of each study: participant characteristics, length of intervention, outcome measures used, intervention engagement and attrition rates.

6.4 Methodological and Reporting Quality

The Jadad rating scale (1996) (Appendix B) was used to independently assess the methodological quality of the primary studies included. Bias is assessed by allocating one point for each item on the scale. The points are then totalled to give a total score from 0 to 5. The items assess the quality of the studies by reporting whether the study includes: an adequate randomisation procedure; a description of the randomisation procedure; the use and description of a double blind experimental design; a detailed description of the number and reason of participant withdrawals.

Clarity of study reporting was rated used the CONSORT checklist (2010) (Appendix C) for RCT reporting. The CONSORT guidelines consist of 25 main items (but with 37 items/sub-items in total). One point was allocated for each criterion, giving a total score ranging from 0 to 5. Studies that met inclusion criteria were scored against the 37 checklist items/sub-items. Each checklist item was scored zero (no) or one (yes) depending on whether the criterion was met, giving a total score from 0 to 37.

6.5 Planned methods of analysis for the meta-analysis

Post-intervention and follow-up means, standard deviations and number of participants per group were extracted for each measure and entered into Review Manager (RevMan) version 5.2. Standardised mean differences (SMDs), measuring the size of the intervention effect between groups, were calculated by RevMan using a random effects model. RevMan also produced heterogeneity statistics in order to assess variability in effect sizes across studies, in addition funnel plots were looked at and Rosenthal Failsafe N was calculated.

7. Results for review 2 – meta-analysis and primary resources

Following the initial search of primary resources of the effect of MBIs on staff efficacy and patient outcomes, 486 studies were identified after duplications were removed. A total of 83 full text articles were assessed for eligibility and 56 of these were excluded. Thirteen primary research papers met the inclusion criteria (see Table 3). The research on empathy and closely related constructs allowed for five studies to be included in a meta-analysis. The other constructs that were not included in the meta-analysis were narratively reviewed.

Table 3. Table of primary resources included in meta-analysis and narrative review

Study	MBI format as described by authors (Details if not standard MBSR/MBCT)	Control condition	Measures included in present study	Country	Sample size	Sample type	Follow up	Mean age and/or age range (gender
Asuero et al. (2014) *	Mindfulness education program (8 weekly sessions of 2.5 hours each, 1 full day sessions, home practice)	Waitlist	Mindfulness (FFMQ); Work place effectiveness(JSE)	Spain	68	Primary health care professionals	None	47 years (92% female)
Barbosa et al. (2013)	MBSR	Paid matched control	Mental health symptoms (BAI); Workplace effectiveness (JSE)	US	33	Graduate healthcare students	None	21-65
Burnett and Pettijohn (2015)	MBST 5 week	Waitlist Passive intervention	Workplace effectiveness (EI)Emotional intelligence Salovey and Mayer (1990)	US	55	Healthcare employees	None	Female 63.6%
Danilewitz et al. (2016) *	Adapted MBSR (8 weekly sessions of 1-1.5 hours per session with home practice)	Waitlist	Stress (DASS); Workplace effectiveness (JSE); Mindfulness (FFMQ)	Canada	30	Medical students	None	Not provided (73.3% female)
Duarte et al. (2016)	abbreviated mindfulness-based intervention for nurses	Waitlist	Stress (DASS-21); Workplace effectiveness (AAQ-II) Mindfulness (FFMQ)	Portugal	94	Nurses	3 month	Female (90.1%) with a mean age of 41 range 25 to 56 years

Grepmair et al. (2007)	Zen mindfulness training (9 weeks of daily (five sessions per week) 1 hour sessions involving meditation and mindfulness practices	Waitlist	Workplace effectiveness (STEP),	Germany	142 (18 therapist s, 124 patients)	Psychotherapists and their patients	None	29.3 years (100% female) (therapists only)
Horner et al. (2014)	10-week mindfulness training program	Control condition	Workplace effectiveness Patient satisfaction; Mindfulness MAAS	US	43	staff nurses, nurse aides, and clinical secretaries as well as the unit manager and supervisor Nurses	None	Unknown
McConachie et al. (2014)	Acceptance and mindfulness workshop 1.5 days	Waitlist	Workplace effectiveness (AAQ-II)	UK	120	Support staff	12 week follow up	Mean age 43 74.2% female
Paholpak et al. (2012)	Adapted MBSR (4 weeks involving up to 28 20-minute sessions)	Waitlist	Mental health symptoms (SCL-90); Workplace effectiveness (academic achievement)	Thailand	58	Medical Students	None	23.43 years 21-33 years (50% female)
Phang et al. (2015)	Mindfulness-based stress management (Based on MBCT/MBSR, 5 weekly sessions of 2 hours each, 10-15 minute home practice)	Waitlist	Stress (PSS); Mental health symptoms (GHQ-12); Mindfulness MAAS); Work place effectiveness (SES)	Malaysia	78	Medical students	6 months	21.14 years (70% female [MBI]; 20.95 years 83% female control
Pipe et al. (2009) *	Four week MMC	Control	Workplace effectiveness (CES)	US	33	Nurse Leaders	None	Mean age intervention 50.2 control 49.4 Female 100%

								intervention 94.1% control
Shapiro et al. (1998) *	Adapted MBSR (7 weekly sessions of 2.5 hours each, home practice)	Waitlist	Mental health symptoms (SCL-90); Workplace effectiveness (ECRS)	US	78	Premedical and medical students	None	Mean age not specified. 56% Female
West et al. (2014) *	19 facilitated physician discussions incorporating elements of mindfulness, reflection	Waitlist	Work place effectiveness (JSE)	US	74	Physicians	3 and 9 months	Intervention 32.4% women control 35.1%

**Studies included in meta-analysis*

MBI=Mindfulness Based Intervention; MBCT=Mindfulness-Based Cognitive Therapy; MBSR=Mindfulness-Based Stress Reduction Measures: BDI=Beck's Depression Inventory; BSI=Brief Symptom Inventory; CES-D= Centre for Epidemiology Studies - Depression Scale; DASS= Depression, Anxiety and Stress Scale (DASS-21=21 item version); ECRS= Empathy Construct Rating Scale; Emotional Intelligence; FFMQ= Five Facet Mindfulness Questionnaire; GHQ-12= General Health Questionnaire; JSE= Jefferson Scale of Physician Empathy; JSS= Job Satisfaction Scale; MAAS= Mindful Attention Awareness Scale; MBI=Maslach Burnout Inventory; PHQ-9= Primary Health Questionnaire; PSS= Perceived Stress Scale; RS= Resilience Scale; SCL-90= Symptom Checklist; SDS= Self-Rating Depression Scale

7.1. Study characteristics

7.1.1. Mindfulness measures used in studies

Of the primary sources reviewed, five reported at least one measure of mindfulness. Two studies reported measures of mindfulness adherence. Additionally, four studies reported the average length of meditation practice, four studies reported the mean level of classroom attendance and three studies reported the percentage of participants who practised mindfulness at home during the MBI course.

7.1.2. Outcome measures

Four studies included measures of empathy. The Jefferson Scale of Physician Empathy was most frequently used (n=3). Also used were: the empathy construct rating scale (ECRS), the Caring Efficacy Scale (n=1) and Acceptance and Action Questionnaire-II (AAQ-II) (n=1). Other measures in the studies included: Emotional intelligence Salovey and Mayer (1990) (n=1), Session Questionnaire for General and Differential Individual Psychotherapy (STEP) (n=1), Patient satisfaction (academic achievement) (n=1), The caring efficacy scale (CES) (n=1), Self-efficacy scale (SES) (n=1).

7.2. Details of Included Studies in the meta-analysis

7.2.1. Sample size and characteristics.

Five studies were included in the meta-analysis. 262 participants were recruited in total, of which 141 were randomly allocated to an MBI condition, while 121 were randomly assigned to a control group. Study sample sizes at post-intervention ranged from 13 to 37. Participants were healthcare professionals or support staff (n=1), medical, psychology or nursing students/residents (n=2), nurses (n=1), doctors (n=1). Studies were undertaken in the USA (n=3) Spain (n=1) or Canada (n=1). Four studies included a measure of empathy. The

Jefferson Scale of Physician Empathy was most frequently used (n=3). Also used was the Empathy construct rating scale (ECRS) The Caring Efficacy Scale (n=1).

7.2.3. Drop out and follow up time periods

Four studies reported on the number of participants completing post-intervention measures. Study attrition ranged from 0% to 44.4%. Follow up periods were included in four studies and ranged from one month to nine months.

7.2.4. Meta-analysis findings

The only outcome with at least four studies was empathy (and related constructs) and therefore was the only outcome where a meta-analysis was run. These constructs were combined due to the similarity in how they are measured. The caring efficacy scale was used as it assesses belief in one's ability to express a caring orientation and to develop caring relationships with clients or patients. The empathy scale assesses a cognitive attribute that involves an ability to understand the patient's pain, suffering and perspective combined with a capability to communicate this understanding and an intention to help.

Figure 3 shows the forest plot for the five studies included in the meta-analysis. A significant between-group difference was found between MBI and control group on empathy and closely related constructs at post intervention ($Z=2.33$, $p=.02$), with a small effect size in favour of MBI ($g=0.29$, 95% C.I: 0.05 to 0.54). Effect sizes were not significantly heterogeneous ($\chi^2(4)=2.87$, $p=.58$, $I^2=0\%$). This would support grouping together the different measures and types of MBIs included in the meta-analysis.

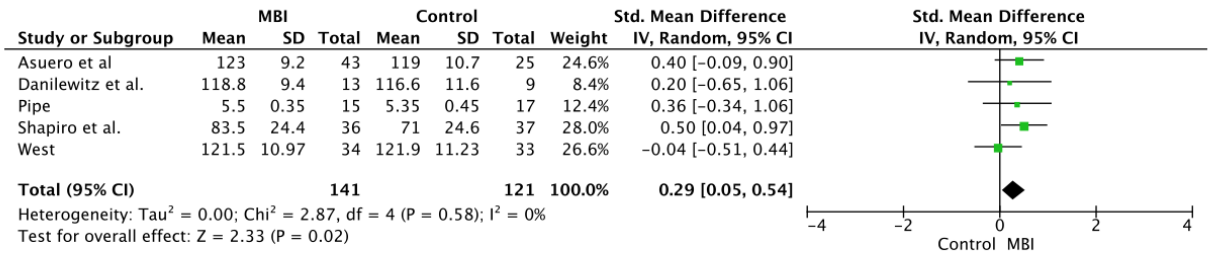

Figure 3. the forest plot for the five studies included in the meta-analysis.

Testing for publication bias, using a funnel plot, was not performed in the meta-analysis as fewer than 10 studies meant that there are not enough data points to make sense of the funnel plot (Higgins & Green, 2011).

Rosenthal's Failsafe N was computed using an SPSS macro.35. Failsafe N value shows the number of additional studies with null results required to produce a non-significant overall outcome for the meta-analysis. Here, Rosenthal fail-safe N=4. The findings of a meta-analysis are considered to be stable if a Failsafe N greater than 5k+10 is obtained, where k is the number of included studies (Tang, Eslick, Nowson, Smith, & Bensoussan, 2007). However, the correlation between effect size and standard error was also computed: Kendall's tau-b correlation coefficient, τb, is -.400. As this was not significant, it suggests that there is no publication bias. Although there is no indication from Kendall's tau-b that there is publication bias, Rosenthal fail-safe N suggests that another four studies would be needed to be published with a nil effect for this to make the effect not significant.

7.3. Narrative review of studies not included in the meta-analysis

Other outcomes had fewer than four studies and so were not included in the meta-analysis. Instead, these were narratively reviewed separately for each outcome type.

7.3.1. Empathy

Barbosa, Raymond, Zlotnick, Toomey and Mitchell (2013), looked at the effects of MBIs on empathy using a quasi-experimental design. Only the pre-post scores for the intervention group were reported and full data were not obtainable from the authors so it was not possible to add these data to the meta-analysis. This study looked at MBSR on graduate mental health workers and the results show that there was a significant increase in empathy scores at post-intervention in comparison to baseline although these effects were not sustained at follow up. Unfortunately, the authors did not report the effect sizes. It should be noted that even though it was not significant, there was also a decrease in empathy scores for the control groups at post intervention. There were several methodological flaws, for example, participants were not randomised and between-group differences were not reported. Results should be considered with caution due to low sample size and so there may be the possibility of Type 2 error in the follow-up findings.

7.3.2. Psychological inflexibility

Two studies used the AAQ-II to measure experimental avoidance/ psychological inflexibility. Psychological flexibility is defined as the ability to fully contact the present moment and the thoughts and feelings it contains without needless defence and, depending upon what the situation affords, persisting or changing in behaviour in the pursuit of goals and values (Hayes, Luoma, Bond, Masuda & Lillis, 2006). This may be considered to aid staff effectiveness by being present and following values, even if situations are uncomfortable.

In an RCT (McConachie, McKenzie, Morris, & Walley, 2014) the intervention consisted of a one-day work shop containing mindfulness. The results showed no interaction between group

and time effect (MBI versus control group) and time (pre- and post-intervention) on measures of experiential avoidance and psychological inflexibility. The study showed that the mindfulness intervention had no effect on psychological flexibility. However, no mindfulness measure was used and therefore it would be difficult to conclude that mindfulness was learnt in the one-day workshop.

Duarte and Pinto-Gouveia (2016) used a non-randomised, waitlist comparison design using an abbreviated mindfulness-based intervention for nurses. The results suggested that there were significant interactions between group and time for experimental avoidance, meaning that the participants in the intervention arm of the study reported larger decreases in psychological inflexibility than participants in the control condition. McConachie et al. (2014) and Duarte and Pinto-Gouveia (2016) found differing results for the effect of mindfulness on psychological inflexibility. One explanation may be the intervention offered. Another may be that that the measures were not sensitive enough to detect change or, perhaps more research needs to be done to see whether robust results can be produced and the AAQ-II can be used as a process measure. The AAQ-II has recently been revised due to concerns regarding its psychometric properties (Bond et al., 2011).

Although a mindfulness measure was used to show significant effects between group and time, there were several methodological flaws. The sample used only nurses from one unit. As well as being homogenous, the sample was not randomised and therefore before any conclusions can be drawn further research should be done on a randomised and wider sample.

7.3.3. Emotional intelligence

Burnett and Pettijohn (2015) completed a RCT looking at the effects of MBSR. The authors found no significant change in emotional intelligence from pre- to post-intervention in the MBSR group compared to the control group. Authors conducted a univariate regression analysis and found that across the groups, individuals with higher emotional intelligence had lower stress levels. This study used a modified MBSR programme with fewer sessions, which may mean that there was not enough time for participants to benefit. It also used a small sample from the same organisation and, therefore, the results would not necessarily be generalisable.

7.3.4. Academic achievement

Paholpak et al. (2012) conducted a RCT looking at the effects of a four-week course of breathing, meditation-based stress reduction intervention on academic achievement in a sample of medical students. Researchers found no significant benefit of the intervention on cognitive ability or academic achievement in comparison to control groups. Several limitations to the study means that conclusions should be drawn with caution. The course was short and did not allow sufficient time and practice for change.

7.3.5. Patient outcomes

Using the patient satisfaction session questionnaire (STEP), Grepmair, Mitterlehner, Loew, and Nickel (2007) found that the clients of psychotherapists who had been randomised to undertake an MBI showed greater symptom reduction and provided more satisfaction with their therapy compared to clients of psychotherapists randomised to the control group. It was found that these clients indicated superior progress in the understanding of their own

psychodynamics, difficulties and goals. Results showed that they made better assessments of their progress in overcoming their difficulties and symptoms, as well as developing new behaviours and transferring them into daily life, than clients of control therapists. This study is the only full RCT to look at direct patient outcomes.

7.3.6. Patient satisfaction

Horner, Piercy, Eure and Woodward (2014), looked at the effects of a 10-week mindfulness training program on nursing staff. They conducted a pilot study using a quasi-experimental design with results that suggest that patient satisfaction scores in the intervention group increased in comparison to the control group. However, this was a pilot study with a small sample size and not fully powered. There were several methodological flaws: the sample used was not randomised, nursing staff on one unit were compared to staff on another, similar unit that served as the control group. It should also be noted that participants were included if they attended just one of the ten sessions. Although the results are encouraging, a full RCT is required before definitive conclusions can be drawn.

7.3.7. Methodological and reporting quality

CONSORT rating of the 13 published studies was 23.5 (sd=3.43) out of a maximum possible score of 37.

The mean Jadad rating of the 13 published studies was 2.61 (sd=1.38) out of a maximum possible score of five, with only one study scoring the maximum score of five.

The CONSORT checklist revealed there were methodological inconsistencies in reporting of the studies. Some of the studies scored highly on the checklist while others revealed

inadequate reporting. The Jadad (1996) checklist to assess risk of bias tool suggested that many of the studies failed to report on the randomisation procedure. Only one study was described as double-blinded, however, this is not surprising considering the nature of the interventions. Only six of the 13 studies gave reasons for drop-out. Describing drop-out is important to further understand the acceptability and appropriateness of the interventions. Therefore, it would be helpful to have a more thorough analysis and understanding of why some of the participants dropped out of the interventions. This means that some of the results should be considered with caution. Future studies should aim to address methodological issues and follow guidelines to make sure that findings are adequately reported.

8. Discussion

The aim of this review was first, to provide a meta-review of systematic reviews and meta-analyses of MBIs for healthcare staff on stress and mental health outcomes; secondly, it was to provide a systematic review and meta-analysis of RCTs of MBIs on healthcare effectiveness outcomes. The results and their implications are discussed below.

8.1. Review 1 – meta-review

First, the meta-review will be considered. This review of previous systematic reviews shows that there may be tentative evidence for MBIs to reduce stress, depression and anxiety in healthcare staff (Escuriex et al., 2011; Burton et al., 2017; Daya et al, 2017; Gilmartin et al., 2017; Guillaumie et al., 2017; Lemothe et al., 2016; McCoville et al., 2017). The size of effect on stress, anxiety and depression was reported in the medium range, similar in magnitude to those observed for other individually-focused, stress-reducing interventions in healthcare staff, as shown in a recent Cochrane review (Panagioti et al., 2017). This meta-review found that MBIs have a moderate effect on HCP stress levels. This finding lends

support to others (Khoury, Sharma, Rush, & Fournier, 2015) who have reported that MBSR is a moderately effective intervention leading to lower levels of stress in non-clinical populations.

The improvements reported in the meta-review on wellbeing are in line with other interventions that have been tried to support staff in occupational settings such as CBT-based stress management (Joyce et al., 2015). However, some findings were grouped together in terms of design and therefore it may be difficult to draw conclusions on causation.

One review (Burton et al., 2017), competed a meta-analysis which suggested that regardless of the dosage and length of the intervention, MBIs had a medium effect on stress outcomes for health care staff. However, the authors combined different methodological designs in the meta-analysis. In addition to this, the authors found a number of fidelity issues with the included studies means that the results should be looked at with caution. The systematic review conducted by Gilmartin et al. (2017) on the effect of brief mindfulness interventions, found that MBIs were effective in reducing stress and anxiety, however the authors did not report effect sizes.

Given that MBIs usually need considerable time commitment, these findings are encouraging as stressed HCPs, with limited time and resources, are likely to find brief interventions more acceptable.

Two of the reviews concentrated their samples specifically on students in health care professions (McCoville et al., 2017; and Daya et al., 2017). It has been suggested that students do not represent HCPs and that the effects of MBSR interventions may, potentially, vary when applied to students versus HCPs (Smith, 2014).

8.2. Review 2 – meta-analysis and primary resources

In the review of MBIs on staff effectiveness, findings showed a mixed pattern. Results from the meta-analysis on staff empathy tentatively suggest that MBIs may have a small, positive effect on staff empathy. There is some tenuous evidence that MBIs can improve other constructs relating to staff efficacy, such as patient satisfaction. However, the findings are mixed and there needs to be more evidence before firm conclusions can be drawn. This is in line with the findings from Lemothe et als. (2016) systematic review. Although Lemothe et al. (2016) did not conduct a meta-analysis, the authors concluded that evidence regarding the effects of MBSR in HCPs suggests that MBIs are associated with improvements in stress, anxiety and depression. One explanation for the pattern of mixed findings could be that the measures used may not be sensitive enough to measure what they were intending to measure. Another explanation may be that the interventions were different in length and content and contained varying amounts of mindfulness. In addition, little is known about the mechanisms underlying the constructs and the effects of MBIs on these constructs. Further research could help to uncover the wider effects of MBIs, including how staff can adapt to complex situations, increase their capacity for complexity and reflexivity, interpersonal resonance and empathetic connections (Baron & Cayer, 2011).

8.3. Practice implications

The meta-review suggests that mindfulness-based interventions may be helpful for staff in reducing stress, anxiety and depression. However, there may be ethical concerns about providing interventions to staff to reduce their stress as this may place the responsibility on the individual and locates the stress in the individual instead of encouraging organisations to look at the factors which lead to stress and to take better care of their staff. However, it need not be one or the other, instead, organisations can be encouraged to take better care of their

staff and look at the factors leading to stress and burnout, as well as offering MBIs to foster wellbeing.

Looking at the primary resources on staff efficacy, it would seem that there are few studies which look specifically at changes in this area. There is scant evidence on the effect of MBIs on, for example: patient satisfaction, improvement in relationships, staff turnover and communication. These changes would be pertinent to HCPs in the NHS where jobs involve client relationships and emotional regulation (Glomb et al., 2011; Hülsheger et al. 2013; Grégoire & Lachance, 2015). Further research needs to be undertaken before MBIs are used to increase patient satisfaction and staff efficacy.

8.4. Research implications

Research suggests that MBIs may help staff wellbeing. However, there is still limited research on how MBIs may be delivered in organisations. Further research may be helpful to look at ways that MBIs can be delivered in busy environments to staff with time constraints and limited resources. Further research, using robust methodological design is needed on workplace effectiveness outcomes.

8.5. Conclusion

Based on the analysis in this paper of previous systematic reviews, there is some evidence for MBIs leading to improvements in staff wellbeing and stress. More robust RCTs studies which look at the effects of stress and also consider a wider sample of health care professionals are needed.

The review of MBIs on staff effectiveness produced mixed results. The results from the meta-analysis suggest that MBIs can have a small effect on improving staff empathy. There is some tentative evidence that MBIs can improve other constructs relating to staff efficacy, such as patient satisfaction, however, the findings were mixed and there needs to be more evidence before firm conclusions can be drawn.

It would be unwise to make sweeping judgements on the use of MBIs to improve patient satisfaction and patient outcomes as this could lead to an inflated notion of MBIs' effectiveness. It maybe that MBIs are helpful for staff wellbeing and stress but more research is needed on the wider effects. Some studies are beginning to explore the wider impact of MBIs in healthcare settings e.g. on patient experience (Horner et al., 2014). However, caution is needed before trying to over-claim the cascading effects of MBIs in healthcare settings without first being able to establish the most effective intervention content and implementation model. Without this, there is the risk that over-claiming the potential effects of MBIs, before they have been fully investigated, may lead to premature disillusionment with them. There is an opportunity following further research, to define a model of best practice using knowledge of how MBIs work and a full understanding of their potential for both primary and secondary gains.

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Section B

A randomised control trial of a mindfulness-based self-help intervention for NHS staff.

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Abstract

Stress and anxiety are among the most significant reasons for staff sickness absence in the NHS. The provision of psychological support for healthcare staff may have the potential to improve staff job satisfaction and reduce staff stress and burnout. Mindfulness-based interventions (MBIs) are one type of psychological approach that has gained particular research interest in recent years. MBIs may have the potential to reduce stress and improve staff wellbeing. A fully powered randomised control trial, followed on from a pilot study, aimed to look at the effects of the effectiveness of a mindfulness-based self-help intervention for healthcare staff and the factors that may mediate any effects found. A total of 133 participants were recruited for the study. The results showed that participants in the intervention arm of the study reported a decrease in stress, anxiety and depression and an increase in wellbeing compared to controls. Further to this it was found that mindfulness is a mediator for self-compassion which increased wellbeing.

1.Introduction

Approximately ten million NHS working days are lost each year to staff sickness absence and UK healthcare sector employees have the highest sickness absence rates of any sector, with sickness rates still rising (NHS Sickness Absence Rates, 2017). *The Five Year Forward View for Mental Health* (2016, p. 48) made recommendations for developing and supporting the mental health workforce in the UK. One recommendation stipulated that "NHS England should ensure current health and wellbeing support to NHS organisations extends to include the management of mental health in the work place…and effective workplace interventions from 2016 onwards." It also recommended that "NHS England should introduce a Commissioning for Quality and Innovation (CQUIN)…relating to NHS staff wellbeing."

Stress and anxiety are among the most significant reasons for staff sickness absence in the NHS (NHS Audit Commission, 2011). The provision of psychological support for healthcare staff may have the potential to improve staff job satisfaction and reduce staff stress and burnout (Shapiro, Astin, Bishop, & Cordova, 2005; Ruotsalainen, Serra, Marine & Verbeek, 2008). Moreover, improving staff wellbeing has the potential to improve the quality of patient care, which is at the heart of the NHS (Garman, Corrigan & Morris, 2002). As demand for health care services continues to rise with increased pressure placed on staff, NHS employers need effective, evidence-based workplace interventions, in line with the Five Year Forward View, that will help to support and protect their staff.

A recent Cochrane review (Panagioti et al., 2017), evaluated interventions to reduce burnout in physicians. This systematic review and meta-analysis considered 19 studies including both randomised control trials (RCTs) and uncontrolled pre-post studies. The authors used burn-out as the main outcome, as it is suggested that burn-out is the most recognised, serious

consequence of work place stress in physicians (Montgomery, 2014). The meta-analysis findings suggested that psychological interventions for health care staff could help improve wellbeing and reduce burnout. Mindfulness-based interventions (MBIs) are one type of psychological approach that has gained particular research interest in recent years. MBIs may have the potential to improve staff well-being. A recent meta-analysis of RCTs suggested that mindfulness training seems to be effective in lowering anxiety and depression in health care staff (Guillaumie, Boiral & Champagne, 2016).

Mindfulness can be defined as "the awareness that emerges through paying attention on purpose, in the present moment, and nonjudgmentally to the unfolding of experience moment by moment" (Kabat-Zinn, 2003, p.144). In secular, healthcare settings, mindfulness can be learned through MBIs including mindfulness-based stress reduction originally developed by John Kabat-Zinn in 1979 (MBSR; Kabat-Zinn,1998) and mindfulness-based cognitive therapy (MBCT; Segal, Williams, Teasdale, 2002). MBSR aims to cultivate awareness of present-moment experiences and guides the individual to not get caught up in automatic thoughts, feelings and patterns of behaviour. This is learnt through meditation practices, such as breathing exercises, sitting meditation, body scans and mindful movement. MBCT follows a similar course, with the addition of some CBT exercises relevant to depression. Research has shown positive results for MBCT in reducing psychological distress and improving wellbeing in both clinical (Hofmann & Gomez, 2017), and non-clinical populations (Janssen, Heerkens, Kuijer, van der Heijden & Engels, 2018).

Rumination and worry are implicated in the onset and maintenance of a broad range of mental health problems, for example anxiety and depression (Raes, Hermans, Williams, Beryers, Brunfaut & Eelen, 2006; Hofman, Sawyer, Witt & Oh, 2010). Segal, Teasdale and

Williams (2004) theorise that mindfulness-based cognitive therapy (MBCT) helps to reduce rumination and worry by cultivating the ability of participants to attend to present-moment experience non-judgementally, and hence disengage from unhelpful thinking that is focussed on the past or future. This is supported by a meta-analysis of mediation studies that showed that MBIs appear to work, at least in part, through reducing rumination and worry (Gu, Strauss, Bond & Cavanagh, 2015).

Based on theory (Segal, Williams & Teasdale, 2013) and evidence from studies looking at the impact of face-to-face MBCT (e.g. Kuyken et al., 2010), it is suggested that MBCT has an important role in improving wellbeing by increasing mindfulness and compassion. Preliminary evidence also suggests that mindfulness may help to increase self-compassion. A systematic review by Gu et al., (2015) supported mindfulness as a mediator and provided preliminary evidence for self-compassion.

All the above-mentioned mechanisms of action could help improve healthcare staff wellbeing by reducing time spent ruminating and worrying about work-related concerns that would otherwise lead to increased stress or mental health problems, and increasing self-compassion.

After participating in MBCT groups, NHS staff reported perceived improvements in the quality of care they were able to provide their patients (Marx, Strauss, Williamson, Karunavira, & Taravajra, 2014). However, such staff groups are time consuming, have a cost that is unlikely to be sustainable in the NHS, and only can be offered to a small proportion of staff at a time. Furthermore, healthcare staff indicate that concerns about stigma remain a significant barrier to accessing support (Knaak, Mantler, & Szeto, 2017) MBCT self-help maybe able to address these limitations and a meta-analysis of RCTs has revealed that mindfulness can be learnt through self-help leading to reductions in stress, depression and

anxiety, in clinical and non-clinical populations (Cavanagh, Strauss, Forder & Jones, 2014). Self-help interventions may be acceptable to busy healthcare practitioners (Lange, Van De Ven & Schrieken, 2003) who would not otherwise seek psychological support.

In 2014, an unpublished pilot study of Mindfulness Based – Self-help (MBCT-SH) on health care professionals' wellbeing was conducted in the same setting as the current study, with promising results (ISRCTN16486066: Is self-help mindfulness-based cognitive therapy beneficial for healthcare staff? A pilot randomised controlled trial, 2014). However, as a pilot study it had an insufficient sample size to be adequately statistically powered and to support a robust mediation analysis. A fully powered RCT was therefore needed to robustly examine the effectiveness of MBCT-SH for healthcare staff and the factors that may mediate any effects found. To date, no such RCT has been published. In addition to this, no other study has looked at the mechanisms that mediate the effects of MBCT-SH. Therefore, the current RCT breaks new ground in these two respects.[3].

2. Aims:

This study aimed to test the hypotheses that:

1. NHS staff who receive MBCT-SH will show a pre- to post-intervention reduction in stress, in comparison to NHS staff in a waitlist control condition (the primary hypothesis);
2. MBCT-SH participants, in comparison to waitlist control participants, will show pre- to post-intervention improvements in secondary outcomes, including mindfulness, self-compassion, anxiety, depression, burnout and mental well-being; and

[3] The fully powered RCT and the mediation analysis were viewed by the clinical psychology research panel as sufficient in making an original contribution to the research literature.

3. changes in self-compassion and mindfulness will mediate the effects of MBCT-SH on stress, depression, anxiety, wellbeing and burnout. As decreased rumination and worry have already been researched and are established in their mediation mechanisms (as detailed above), this study aimed to look at self-compassion as it has not been as widely researched. The choice of self-compassion and mindfulness as the mediators in the third hypothesis was based on Segal, Williams and Teasdale (2013) theory and Gu et al, (2015) findings that mindfulness may increase self-compassion, both of which have been covered in more detail above.

3. Method

3.1. Design

This study was a superiority randomised controlled trial (RCT) with 1:1 allocation to two conditions: self-help mindfulness-based cognitive therapy (MBCT-SH) and a waitlist control condition. There were two independent variables - one between-group variable with two levels (group: intervention versus control), and one within-group variable with two levels (time: pre-intervention and post-intervention[4]).

3.2. Medical Research Council guidelines on RCTs

The Medical Research Council (MRC) intervention development guidelines recommend using a phased approach, starting with pilot studies that look at any key uncertainties in the design and intervention, before moving onto definitive RCTs; Medical Research Council, (Craig et al., 2013).

[4] Three-month follow-up data are also due to be collected. However, due to time limitations these data are not included in this study, but they will be included in any publication.

This study was a definitive RCT following an internal pilot RCT. The internal pilot RCT was conducted in 2014 in the host NHS trust. The author of this submission was a member of the research team involved in collecting the data for this pilot. In line with MRC guidelines, the internal pilot was carried out to estimate the between-group effect size between the two interventions on the primary outcome (stress) so that the number of participants required for the full trial could be established.

It was decided to adopt the same design for this study as for the pilot RCT, so that the latter could be treated as an ‘internal pilot’ and its data included within the full trial. In this way, pilot data were not 'lost', in line with recommendations for internal pilot trials (Avery et al., 2017). Participants in the pilot gave consent for their anonymised data to be used as part of the full trial. The Jadad Scale (Olivio et al., 2008) was used to ensure that the study adhered to robust RCT guidelines and CONSORT criteria (Schulz, Altman & Moher, 2010; see Appendix C) were used when writing up the findings. The RCT was registered on clinical trials website ("A Randomised Controlled Trial of Self-help Mindfulness-based Cognitive Therapy for Health Workers - Full Text View - ClinicalTrials.gov", 2018).

3.3. Sample size

To test the hypothesis that staff who receive MBCT-SH will show a pre- to post-intervention reduction in stress, in comparison to NHS staff in a waitlist control condition, the stress sub-scale of the Depression Anxiety Stress Scale (DASS), was used, based on the effect size observed in the internal pilot study for the group by time interaction. An a priori power calculation for the group by time interaction in an ANOVA, indicated that 74 participants across both conditions would be needed to achieve 90% power for detecting an observed

medium sized effect (which was found in the pilot study) of (d=0.5), when employing .05 criterion of statistical significance[5].

3.4. Participants

A total of 133 NHS health care workers participated in the study. All participants met the inclusion criteria of:

- being adults who were currently employed by one of two NHS mental health trusts in the South East of the UK in a healthcare role, and who had at least one day per week of direct contact with service users;
- being willing to refrain from engaging in another form of psychological therapy during the course of the study;
- having not previously undertaken 50% or more of a face-to-face delivered mindfulness-based intervention;
- having self-reported sufficient English language reading ability to read and understand the self-help book; and
- not having completed 50% or more of an MBCT self-help book.

Exclusion criteria:

- Participants could not participate if they were currently on leave of absence from work.

[5]The follow up post-treatment between group t-test a priori power analysis indicated that 94 participants would be needed. To account for attrition rates, 25% was added to the larger of the two power calculations, making 130 to be the total number of participants required, N=130. However, as mentioned above, follow-up data are not included in this study, but will be included in any journal publication.

Table 1, provides a summary of the demographic characteristics of participants.

3.5. Ethics

University ethics and Health Research Authority applications were completed by the author, and approval received from both bodies (see Appendix D for approval letters). Participants were emailed a written information sheet by the author prior to taking part (Appendix E). This provided details of the study, set out the eligibility criteria, included brief details about mindfulness (adapted from the intervention book's associated website), and informed them that they were free to choose not to participate or to withdraw at any time without adverse consequences. Participants provided informed consent to take part in the study online/by post (Appendix F). They were encouraged to approach this service or their GP instead of taking part if they felt they were in need of professional help. Participants were also given the contact details of the author and her supervisors to whom they could address any concerns they had about the way they were treated during the study. On completion of their participation, participants were debriefed.

Data were kept strictly confidential. Participants' contact details (i.e. email addresses) were stored in a password-protected file that was held separately from their responses to the assessment measures. They were allocated a unique code to use when completing the measures in the study and this was how they were identified in the study database. While the measures used did not include risk items, participants were informed of the limits of confidentiality and made aware that, should any significant risk issues come to light, these would need to be shared by the research team with the appropriate authority. During the study, there was an adverse event when this procedure was used: this will be covered in more detail in the discussion.

The proposed study was designed to meet the requirements of the Declaration of Helsinki (World Medical Association Declaration of Helsinki: Ethical principles for medical research involving human subjects, 2014).

4. Procedure

A consort diagram of participants flow through the study is shown in Figure 1.

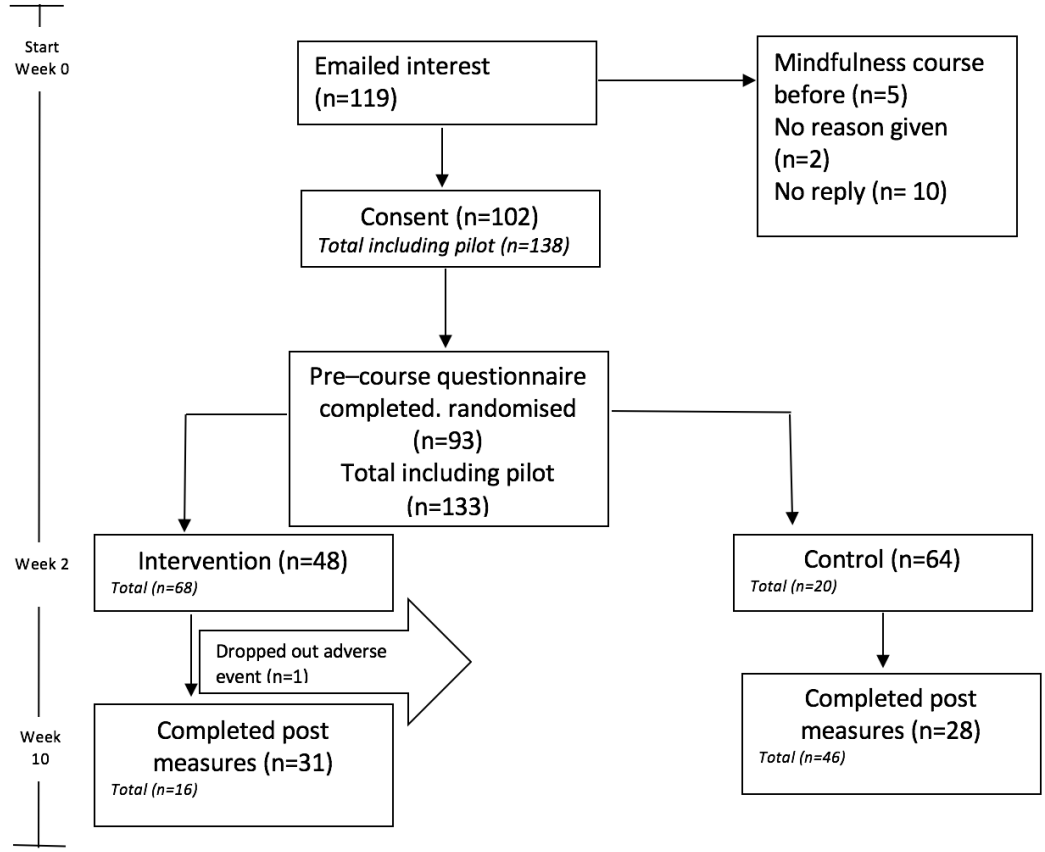

Figure 1. Consort diagram showing participant flow through study

4.1. Recruitment

All participants were recruited between January and December 2017 by the author, via advertisements posted on the trust intranet (Appendix H) as well as emails circulated around

teams (Appendix H); pilot data collection had occurred between November 2014 and February 2015. Participants were invited to express their interest by contacting the author via telephone or email. On receipt of expressions of interest, the author sent potential participants a copy of the study information sheet and consent form, using a link to Bristol Online Surveys (BoS; www.survey.bris.ac.uk/). Participants were run on individual schedules. On receipt of consent, the author sent the participant by email a unique identifier code with a link to the host website for the pre-intervention questionnaires, which was administered via Bristol Online Surveys (BoS; www.survey.bris.ac.uk/). When the author received the pre-course questionnaire, a participant was randomised into intervention or control condition.

4.2 Randomisation

Randomisation occurred after participants had consented to take part to reduce participant allocation bias (Schulz, Altman, & Moher, 2010). Participants were randomly allocated to either the intervention or control group using computer-generated block randomisation to eliminate the risk of researcher bias (https://www.sealedenvelope.com/). An independent researcher, not involved in the project, carried out the randomisation. This researcher was blinded to which group was the intervention arm and which was the control arm. The researcher also ensured that the author was blinded to the block sizes. Neither the independent researcher nor the author or her supervisors knew what group a participant would be randomly allocated to prior to them being allocated. Due to the inactive nature of the control arm, double-blinding was not possible.

4.3. Intervention group

The MBCT-SH intervention was unguided self-help using the book *Mindfulness: A practical guide to finding peace in a frantic world* (Williams & Penman, 2011). The book is based

closely on the evidence-based group intervention MBCT and was lead-authored by one of the originators of MBCT (Mark Williams). The book teaches mindfulness principles and practices through the text, and an accompanying CD containing mindfulness practices. It begins with an introduction to the course followed by eight chapters. Each chapter relates to the equivalent weekly session in the group MBCT course.

In the two-week period following completion of the pre-intervention measures, participants were sent a copy of the book. Participants were asked to read the four introductory chapters before starting the course. After two weeks, participants were asked to start the intervention, which starts at Chapter Five. The first four intervention chapters teach readers to attend to their internal and external world and to use the 'Three-minute Breathing Space' meditation to ground themselves whenever they feel stressed. The remaining four chapters provide practical ways to see thoughts as mental events and to cultivate an attitude of acceptance, compassion and empathy. Each chapter also includes two pieces of 'homework': a 20-30 minutes meditation from the book's accompanying CD; and a 'Habit Releaser', which is a challenge designed to help readers break down ingrained habits (e.g. changing the chair they normally sit on). Readers were asked to practice each meditation six times per week and to carry out one Habit Releaser per week, but the book's author acknowledges that this level of commitment may not always have been possible. Each week, participants were sent a standard weekly email by the author (see Appendix I for an example). Readers were advised to follow one chapter and the exercises that accompany the chapter per week. A total of eight, weekly emails were sent. The emails provided information about mindfulness and encouraged participants to engage with the course materials. They provided an opportunity for participants to ask for clarification if needed. The emails also asked participants to complete the very brief engagement questionnaire by following a link to BoS. Participants were able to keep the book after the study ended.

In keeping with Newman, Szkodny, Llera and Przeworski (2011) criteria for what constitutes minimum guided self-help, contact with participants did not exceed a total of 40 minutes (five minutes per participant per week). Following the eight-week intervention period, participants were sent the post intervention measures to complete via BoS. A further ten weeks after sending them the post-intervention measures, they were sent a link to the follow-up measures. On completion of the follow-up measures, intervention participants were thanked for their participation and debriefed. (Note that, as detailed above, follow-up data collection were not complete at the time of submission and therefore are not included in this MRP, but will be included in any subsequent publication.)

4.4. Control group

Participants in the control group were informed directly after the pre-assessment that they had been randomly allocated to receive the book on completion of follow-up measures. Outcome measures at the post-intervention and follow-up time-points were administered in an identical manner to the intervention group. Following this, the control participants were provided with a copy of the self-help book and sent one standardised email thanking them for their participation in the trial and encouraging them to read the book as advised over the following eight weeks. Participants who had not completed the end of intervention questionnaires within a four-week period after the intervention had ended were considered to have dropped out of the study.

5. Measures

The outcome and process measures were given at baseline (week 0), post-intervention (week 9) and follow-up (week 21) Demographic information was measured at baseline with any demographic information liable to change, for example if they still worked as an employee of

the trust, measured over the intervention and follow up period and also measured at the other two-time points. Participant engagement was measured weekly and at post-intervention.

5.1. Primary Outcome Measures

The stress subscale of the Depression Anxiety Stress Scales (DASS-21; Lovibond & Lovibond, 1995).

The stress subscale of the DASS-21 (Appendix J) was used as a primary outcome measure. The DASS-21, is a set of three, seven-item self-report scales designed to measure stress, depression, and anxiety. Each of the 21 items describes a negative state and participants were asked to use a 0-3-point Likert-type scale to rate the extent to which they had experienced this state over the past week with a maximum score of 21. Ratings on each of the three scales are multiplied by two so scores range from 0 to 42 for each scale. The DASS-21 subscales have been found to validly measure stress, anxiety and depression in non-clinical populations (Henry & Crawford, 2010). A score of <15 is considered "normal" levels of stress, 15-18 equated with "mild" levels of stress, 19-25 "moderate" and 26-33 "severe" and >33 "extremely severe." The internal consistency and concurrent validity of the scale and subscales have been reported to be in the acceptable to excellent ranges (Antony, Bieling, Cox, Enns & Swinson, 1998). In the current study, the internal consistency was in the good range. The stress subscale consisted of seven items ($\alpha = .82$).

5.2. Secondary Outcome Measures

The Compassion Scale (Pommier, 2011)

The compassion scale (Appendix K) was used as a secondary outcome measure. An adapted version of Neff and Pommier's (2011) scale was used. This 24-item scale measures compassion directed towards others and is based upon a definition of compassion adopted from Neff's (2003) model of self-compassion. Participants were asked to use a 5-point Likert-type response scale, with a total maximum score of 108. Neff's (2003) model proposed that compassion entails kindness, common humanity, and mindfulness. The compassion scale is composed of six subscales based on six factors: kindness vs indifference, common humanity vs separation, and mindfulness vs disengagement. The internal consistency, concurrent and convergent validity of the scale have been reported to be good (Pommier, 2011). The adapted version includes 10 additional questions. For the current study, internal validity was in the good range items ($\alpha = .82$).

The anxiety and depression subscales of the Depression Anxiety Stress Scales (DASS-21; Lovibond & Lovibond, 1995).

The anxiety and depression subscales of the DASS-21 (see above) were used as a secondary outcome measure with a maximum score of 21 on each sub-scale. The internal consistency and concurrent validity of the scale and these subscales have been reported to be in the acceptable to excellent ranges (Anthony et al., 1998). In the current study, internal consistency was in the good range for the seven-item anxiety subscale ($\alpha = .76$), and good for the seven-item the depression subscale ($\alpha = .88$). A score of <10 is considered "normal" range of levels of depression, 10-13 equated with "mild," 14-20 "moderate" and 21-27 "severe" and >33 "extremely severe." For anxiety; "normal" <8, "mild" 8-9, "moderate" 10-14, "severe" 15-19 and >19 "extremely severe."

Short Warwick-Edinburgh Mental Well-being Scale (SWEMWS; NHS Health Scotland, University of Warwick & University of Edinburgh, 2007)

The short version of the Warwick-Edinburgh Mental Wellbeing Scale (Appendix M) is a 7-item measure of wellbeing. Participants use a 5- point Likert-type response scale, with a maximum total score of 35. This was used to evaluate the effects of the intervention beyond changes in symptoms of psychological distress. It has been found to have good reliability, validity and internal consistency (Stewart-Brown et al., 2011). For the current study, internal consistency was in the good range ($\alpha = .85$).

The Maslach Burnout Inventory (MBIN; Maslach & Jackson, 1986)

The MBIN (Appendix L) is a 22-item self-report inventory using a Likert-type response scale that measures three facets of job-related burnout: emotional exhaustion (EE), depersonalisation (DP), and reduced personal accomplishment (PA). Participants were asked to use a 7-point Likert-type response scale, with maximum scores for EE of 54, DP of 30 and PA of 30. Several studies have found mindfulness-based interventions to be effective in decreasing job burnout as measured using the MBIN (Shapiro, Astin, Bishop & Cordova, 2005; Cohen-Katz, Wiley, Capuano, Baker & Shapiro, 2005; MacKenzie, Poulin & Seidman-Carlson, 2006). The MBIN is the most widely used measure of burnout in the field and its psychometrics and validity are well evidenced (see Schaufeli, Leiter, Maslach & Jackson, 1996). For the current study the internal validity was moderate or good for each scale: the EE sub-scale consisted of nine items ($\alpha = .92$), DP sub-scale consisted of eight items ($\alpha = .73$), and PA subscale consisted of five items ($\alpha = .77$).

5.3. Process measures

Five-Facet Mindfulness Questionnaire – (Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006).

This 22-item scale assesses five facets of mindfulness (Appendix N). The FFMQ was used to assess whether the MBCT-SH intervention had the intended effect of increasing mindfulness skills. Participants were asked to use a five-point Likert-type response scale. The FFMQ has five sub-scales: describe (max score 40), observing (max score 40), acting with awareness (maximum 40), non-judgemental (maximum score 40), and non-reactivity (max score 35). It has been reported to have good indices of reliability and validity (Bohlmeijer, Klooster, Fledderus, Veehof & Baer, 2011). For the current study, the internal consistency was moderate or good for each sub-scale: the depersonalisation sub-scale consisted of five items ($\alpha = .82$), the observe sub-scale consisted of four items ($\alpha = .86$), the acting with awareness sub-scale consisted of five items ($\alpha = .88$), the non-judgemental sub-scale consisted of five items ($\alpha = .86$), and the non-reactivity sub-scale consisted of five items ($\alpha = .77$).

Self-compassion Scale – Short Form (SCS-SF; Raes, Pommier, Neff, & Gucht, 2011).

The 12-item SCS-SF (Appendix O) yields a total self-compassion score, with a score from 12-60, with higher scores indicating higher levels of self-compassion. Participants were asked to use a five-point Likert-type response scale. It has been reported to have good reliability, validity, and internal consistency (Raes et al., 2011). Furthermore, it has been found to have the same factor structure and to correlate almost perfectly with the longer form of the SCS ($r = 0.98$). For the current study, internal consistency was in the good range ($\alpha = .87$).

5.4. Intervention adherence

The number of participants in the MBCT–SH intervention group who sufficiently completed the intervention was recorded, via self-report questions, at the post-intervention time-point. Sufficient completion of the intervention was defined in line with the MBCT literature as at least 50% adherence to the intervention, which was operationalised as:

(a) reading at least 50% of the MBCT-SH book; and
(b) engaging with at least four mindfulness practices during the intervention.

5.5. Participant Engagement.

Participant engagement was measured using a brief questionnaire that participants in the intervention group were asked to complete weekly (see Appendix P). The questionnaire asked participants to indicate the duration and frequency of their engagement with the intervention materials in the past week (for example, time spent reading the book, number of chapters/pages read) and mindfulness exercises and practices (for example, duration and frequency of practice) on a Likert-type response scale. After the intervention had ended, all participants were asked the same questions, but in reference to the entire duration of the intervention.

6. Analysis strategy

Statistical analyses were conducted using the Statistical Package for Social Sciences (SPSS) version 24.

6.1. Baseline comparisons

Participants' demographic characteristics and pre-assessment scores were compared between groups to check if randomisation had been successful by using two-tailed chi-squared and independent t-test. Missing data were not replaced as steps were taken to account for missing data beforehand as indicated in the protocol, such as making sure that the power calculation pre-empted missing data (Kang, 2013). This was also discussed with an independent statistician, and it was felt that replacing missing data would not be beneficial.
To determine whether there were differences between study completers and non-completers comparisons were made on all demographics and baseline variables.

In this study, Levene's test of homogeneity of variances confirmed equality of variances between groups for all outcome and process measures. The Shapiro-Wilk tests ($p>.05$) (Shapiro & Wilk, 1965; Razai & Wah, 2011) and review of the histograms and Q-Q plots showed the for the waitlist and control conditions the data were approximately normally distributed for both groups in relation to the majority of the process measures. However, significant deviations from normality were revealed for anxiety and depression for the non-judgemental subscale of the FFMQ, the compassion scale, the depersonalisation subscale on the MBIN and for participant age. Nevertheless, Sawilowsky and Blair (1992) found that the independent t-test is robust to violations of normality when: i) variances are equal; ii) sample sizes are equal between groups; iii) sample sizes are 25 or more per group; and iv) tests are two-tailed. As these four conditions were met, t-tests were used rather than relying on alternative, less powerful non-parametric tests. Comparisons for the main analyses were interpreted with a significance of $p<.05$. For within-group t-tests, to control for inflation of the alpha level, Holm's (1979) correction was used. Effect sizes for the main analysis were calculated using partial Eta Squared. The MRC suggests following Kraemer and Thiemann

(1987) criteria, by which an effect size of 0.14 or over is considered to be large, 0.06 medium, and 0.01 small. The exception was participant age, where the Mann-Whitney U-test was used as variances were not equal and each group deviated significantly from normality. Cronbach's alpha (α) was calculated for each outcome and process measure to check their internal consistency at baseline.

6.2. Outcome of intervention

The main analysis used an ANCOVA to examine the change scores from baseline to post intervention whilst controlling for differences at baseline between the intervention and control groups. ANCOVA assumes that the data are normally distributed. An ANCOVA was used instead of an ANOVA as ANOVA assumes homogeneity of variances between groups and normally distributed residuals. The assumption homogeneity of regression slopes was tested using the steps laid out in Field (2015) and showed that they did not significantly differ. This showed that homogeneity of the regression slopes was not violated. In addition, within-group t-tests were planned to examine change within each intervention arm on each outcome measure. Following Fisher, Dixon, Herson, Frankowski, Hearron and Peace (1990), the analyses were conducted for both an intention-to-treat sample and a per protocol sub-sample. The former was the main analysis and included all participants who were randomised and had completed the outcome measures, regardless of how much of the intervention the intervention group participants had completed. The latter sample included all control participants with data, but only those intervention participants who met the above-mentioned criteria for intervention completion.

6.3. Mediation analysis

Mediation analysis was planned to examine whether pre-post intervention changes in mindfulness and/or self-compassion mediated any relationship found between group allocation and change scores on the outcome measures.

Mediation analysis followed Hayes (2009) approach. This approach follows a non-parametric 'bootstrapping' method. This method makes no assumptions about the indirect effect being normally distributed as it uses 95% confidence intervals to estimate the likelihood of the indirect effect being zero. The bootstrapping method was used in the current study, using the macro developed by Hayes (2012; PROCESS macro). The direct pathway is pathway c, and the indirect pathways are pathways a and b (see Figure 2). This method produces a confidence interval for each. If intervals cross zero, then it suggests their true indirect effect could have been zero (i.e. non-significant). If confidence intervals did not cross zero, it suggests that the true indirect effect of the mediator was unlikely at the p=.05 level to be nil (i.e. that mediation paths (ab) were significant). Here, the IV was group; the DV was the pre-post change in scores on the relevant outcome measure (i.e. DASS-21, SEWEMS or MBIN or CS); and the proposed mediators were the pre-post changes in scores on the relevant process measures (i.e. the FFMQ or SCS).

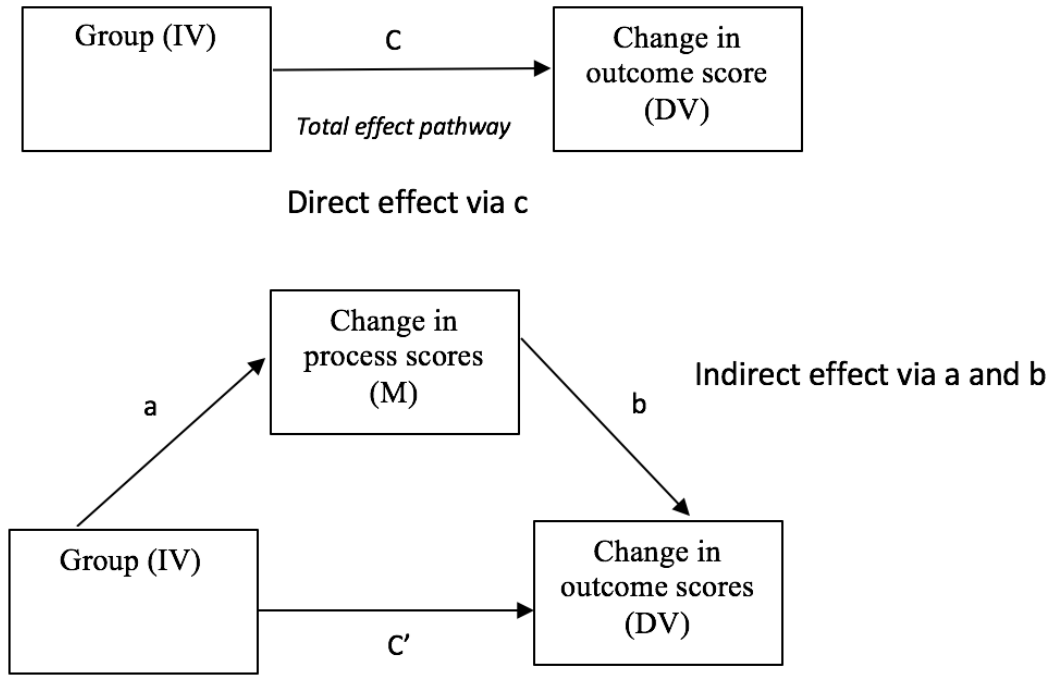

Figure 2. Mediation analysis

Because mindfulness and self-compassion have conceptual overlap, the mediators were entered singly to investigate individual mediation effects as where there is theoretical overlap between mediators, spurious findings can emerge (Hayes, 2012).

Unstandardised regression coefficients were reported as Hayes (2013) suggests that these are the preferred metric in causal modelling, rather than using standardised regression coefficients. Effect sizes were not included as Hayes (2009) suggests that there is no adequate way to report effect sizes for mediation analysis.

Mediation analysis requires that data conform to the assumptions of regression for all four paths (a, b, c, c'). In this study, all assumptions were met except in the case of the DASS

depression scale, where residual errors deviated significantly from normality for paths b, c and c'. The sensitivity of estimates in mediation analysis to violations of assumptions has not yet been firmly established (MacKinnon, 2008) and therefore results for depression should be viewed with caution. The residual errors must be normally distributed, variables should show a linear relationship, and Cook's distance should be <1. As the bootstrapping method does not use standard errors (Preacher & Hayes, 2008) the assumptions of collinearity and homogeneity of variance do not need to be met.

7. Results

Table 1 shows the demographic characteristics of participants. There were no significant demographic differences between intervention and control participants. As can be seen from Table 1, the sample were predominantly female and white.

Table 1. Demographic characteristics of participants

	Intervention group *n* (%)	**Control group *n* (%)**	**Total *N* (%)**
Gender			
Female	56 (82.4)	44 (68.0)	101 (75.9)
Male	12 (17.6)	20 (31.3)	32 (24.1)
Total	40 (100.0)	40 (100.0)	133 (100.0)
Ethnicity			
White	62 (91.2)	53 (82.8)	116 (87.2)
Non-white	4 (17.5)	4 (10.0)	11 (13.8)
Total	68 (100.0)	64 (100.0)	133 (100.0)
Age			
	42.53 (9.84)	41.83 (9.42)	41.95 (9.67)

The results showed that there were significant pre-intervention between-group differences on the non-judgement subscale and the observing sub-scales of the FFMQ and self-compassion scale (see Table 2). As the groups were randomised after competition of the baseline data, and blind to that data, this is interpreted as a random difference between the groups and the planned ANCOVA analyses take account of baseline data. Some of these may represent Type

1 errors due to multiple statistical comparisons, however when the Holm's (1979) correction is applied these differences did not remain significant. Table 2 also shows Cronbach's alpha for each measure.

Table 2. Summary statistics for pre-intervention measures

	Intervention group (*n*=68)		**Control group (*n*=64)**		**Total (*N*=133)**		**Between-group *t*-test**		
Measure	**M**	**SD**	**M**	**SD**	**M**	**SD**	***t*-value**	**sig. (*p*-value)**	**Cronbach's alpha (α)**
DASS-21									
Stress	15.00	6.92	17.21	7.45	16.06	7.21	-1.77	.078	.82
Anxiety	6.41	6.36	7.03	5.81	6.67	6.07	-.583	.561	.76
Depression	8.41	7.28	10.75	7.91	9.49	7.65	-1.77	.079	.88
SWEMWS									
Full scale	24.25	3.84	23.28	4.05	24.25	3.84	1.86	.066	.85
MBIN									
Emo Exhast	23.74	11.57	22.47	11.63	23.74	11.57	.627	.532	.92
Depersonal	5.78	5.87	5.03	3.74	5.78	5.87	.878	.382	.73
Personal Acc	35.53	7.39	35.08	6.48	35.52	7.39	.374	.709	.77
FFMQ									
Observing	13.62	3.34	12.16	4.09	12.23	3.78	2.26	.026*	.86
Describing	17.40	4.13	17.59	3.77	17.50	3.92	-.286	.775	.82
Acting	14.72	4.14	14.00	4.10	14.40	4.12	1.01	.317	.88
Non-judging	16.74	4.19	15.28	3.48	16.05	3.90	2.05	.031*	.80
Non-reacting	14.56	3.32	14.05	3.63	14.35	3.49	.844	.400	.77
SCS									
Full scale	36.31	8.02	32.27	7.09	34.39	7.80	3.07	.003*	.87
CS									
Full scale	130.9	13.39	131.5	11.49	130.9	13.39	-.286	.775	.82

* = p<.05

7.1. Outcome of intervention

Table 2 displays intervention and control group mean pre- and post-scores on the outcome and process measures, and within group *t*-tests along with the results of the ANCOVAs (Table 3).

Table 3. Results of ANCOVA examining between-group differences in pre- to post-intervention change scores for study completers

	Intervention group (*n*=48)		**Control group (n=43)**				
Measure	**Improvement score = baseline – post score**		**Improvement score = baseline – post score**		**Group**		
	M	**SD**	**M**	**SD**	***F*-value**	***Sig***	***P eta*^{2}**
DASS-21							
Stress	4.58	7.22	1.46	7.22	13.03	.001*	.123
Anxiety	3.75	5.07	.09	5.07	24.34	<.001*	.217
Depression	4.17	6.34	.14	8.27	29.32	.<.001*	.250
SWEMWS							
Full scale	2.73	3.84	.09	3.77	26.24	<.001*	.230
MBIN							
DP	1.35	3.64	-.33	3.6	8.64	.004*	.089
EE	4.10	8.90	-.51	8.22	9.41	.003*	.097
PA	3.33	6.14	.7	5.48	9.94	.002*	.101
FFMQ							
Observing	2.79	3.42	.58	2.37	22.84	<.001*	.206
Describing	2.44	3.9	.40	3.45	8.38	.005*	.087
Acting	3.60	3.84	.30	3.46	28.34	<.001*	.244
Non-judging	2.63	3.69	-.023	2.94	26.78	<.001*	.233
Non-reacting	3.35	3.78	-.047	3.68	27.73	<.001*	.240
SCS							
Full scale	6.48	7.78	.58	5.16	26.02	<.001*	.228
CS							
Full scale	14.13	13.87	5.7	12.79	11.50	.001*	.173

7.1.1. Primary outcome measures

When controlling for baseline differences between the groups, ANCOVA found that MBCT-SH participants showed significantly larger pre- to post-intervention improvements in stress compared to control participants, with a large effect size for the stress subscale on the DASS in the hypothesised direction [$F(2, 89)= 13.03$, $p<.001$], (the partial Eta Squared value indicates 0.14 or over was considered to be large, 0.06 medium, and 0.01 small) as can be seen from Table 3. This suggests that the intervention led to greater improvement in stress in the intervention group than the control group. Within-group *t*-tests (Table 4) showed intervention participants improved significantly with large effect sizes. Improvements were greater in the intervention group than the control group across all measures (hence the significant group by time interactions).

On the DASS stress subscale, the mean score at pre-assessment for stress in both intervention and control participants fell into the 'moderate' severity range. At post-assessment, the mean score for intervention participants fell into the 'mild' range on the stress scale, while the mean score for controls remained in the 'moderate' range.

Table 4. Results of within-group *t*-tests for study completers (n=91)

	Intervention group (*n*=48)						**Control group (*n*=43)**					
Measure	**Pre-score**		**Post-score**		**Within-group *t*-test**		**Pre-score**		**Post-score**		**Within-group *t*-test**	
	M	**SD**	**M**	**SD**	***t***	***d*[a]**	**M**	**SD**	**M**	**SD**	***t***	***d*[a]**
DASS-21												
Stress	14.83	6.22	10.25	6.49	4.40*	1.04	17.96	8.05	16.7	7.80	1.24	1.01
Anxiety	6.04	6.11	2.29	2.77	4.47*	.84	6.60	6.00	6.51	5.73	.120	.77
Depression	7.92	6.81	3.75	3.39	4.56*	.91	11.58	7.83	11.44	7.97	.11	.1.26
SWEMWS												
Full scale	24.58	3.81	27.31	3.55	-4.93*	.55	23.05	4.05	23.13	3.70	-.16	.58
MBIN												
EE	22.9	11.29	18.79	10.4	3.19*	1.29	24.63	11.08	25.14	11.82	-.41	1.25
DP	5.25	5.12	3.9	4.12	2.58*	.53	5.7	3.84	6.02	3.28	-.59	.55
PA	36.00	6.98	39.31	5.79	-3.76*	.89	35.33	6.08	36.02	4.78	-.84	.83
FFMQ												
Observing	13.45	3.63	16.25	3.21	-5.65*	.49	11.96	4.28	12.53	4.21	-1.61	.36
Describing	17.23	4.28	19.67	4.02	-4.33*	.56	17.4	3.88	17.79	3.88	-1.46	.53
Acting	14.13	4.28	17.73	3.69	-6.50*	.55	13.95	3.79	14.26	3.5	-0.57	.53
Non-judging	16.98	4.24	19.60	3.73	-4.92*	1.08	15.23	3.85	15.21	4.03	-0.05	.45
Non-reacting	14.46	3.52	17.81	3.47	-6.18*	.97	13.93	3.67	13.88	4.07	-.08	.56
SCS												
Full scale	36.83	8.74	43.31	8.55	-5.77*	1.12	32.00	6.96	32.58	8.778	-.74	.79
CS												
Full scale	131.8	12.56	145.8	12.7	-7.06*	2.00	130.7	10.29	136.4	15.39	*-2.92	1.95

[a]=Effect size (Cohen's *d*) for within-group post-hoc *t*-tests calculated with Dunlap et al.'s (1996) formula.
[b]=Effect size (Cohen's *d*) based on between-group post-intervention differences and pooled standard deviation
*Significant *p*-value ($p<.05$ for interaction effect; Holm's (1979) correction applied for within- and between-group post-hoc *t*-tests).

7.1.2. Secondary outcome measures

ANCOVA found that MBCT-SH participants showed significantly larger pre- to post-intervention improvements compared to control participants for secondary outcome measures (DASS anxiety [$F(2, 89)= 24.34$, $p<.001$], depression [$F(2, 89)= 29.32$, $p<.001$], SWEMWS [$F(2, 89)= 26.24$, $p<.001$] and MBIN EE [$F(2, 89)= 9.41$, $p<.001$],MBIN DP [$F(2, 89)= 8.64$, $p<.001$], MBI PA [$F(2, 89)= 9.94$, $p<.001$] and the compassion scale [$F(2, 89)= 11.50$, $p<.001$]) with a large effect size in the hypothesised direction when controlling for baseline differences between the groups. This suggests that the intervention led to greater improvement in the intervention group than control group. Within-group *t*-tests showed intervention participants improved significantly on all measures. Improvements were significantly greater in the intervention group than the control group across all measures (hence the significant group by time interactions) except compassion.

For the scores on the anxiety subscale of the DASS, both the intervention and control group stayed in the 'normal' range. For the depression subscale, the intervention group remained in the 'normal' range, and the control group remained in the 'mild' range. The other scales did not have qualitative descriptors and therefore were not included.

7.1.3. Process measures

Significant interactions between the intervention and process measures (FFMQ and self-compassion) FFMQ-NJ [$F(2, 89)= 26.78$, $p<.001$], FFMQ-NR [$F(2, 89)= 27.73$, $p<.001$], FFMQ-D [$F(2, 89)= 8.38$, $p<.05$], FFMQ-O [$F(2, 89)= 22.84$, $p<.001$], FFMQ-AA [$F(2, 89)= 28.34$, $p<.001$] and self-compassion [$F(2, 89)= 26.02$, $p<.001$]. These results suggest that the intervention led to greater improvement in mindfulness and self-compassion in

intervention participants than controls. Within-group *t*-tests showed that intervention participants improved significantly on all process measures. Improvements were greater in the intervention group than the control group across all measures.

7.2 Mediation analysis

Table 5 displays the results of the single mediation analyses examining whether mindfulness and/or self-compassion mediated the relationship between group and outcome.

In line with results from the ANCOVA, group significantly predicted change on the outcome measures (c path) and process measures (a path). Change on the process measures significantly predicted change on the outcome measures controlling for group (b path), on the DASS stress, depression, anxiety subscales, SWEMWS, with the exception of the *acting with awareness* subscale of the FFMQ (which only significantly predicted change in DASS stress scale, and the SWEMWS) and *non-judgemental* (which did not predict change in SWEMWS), and *describe* (which did not predict change in DASS depression subscale); and *observe and non-react* (which did not predict change in the compassion scale). Only self-compassion predicted change on all the MBIN subscales. On the measures that showed process measures predicted change, bootstrap confidence intervals crossed zero in these models, suggesting their true indirect effect could have been zero (i.e. non-significant). In all other cases, confidence intervals did not cross zero, suggesting that the true indirect effect of the mediator was unlikely at the p=.05 level to be nil (i.e. that mediation paths (ab) were significant).

Table 5. Results of bootstrapped (5000 interactions) single mediation analyses with group as the independent variable (*N*=91)

Independent variable	**Dependent variable**	**Mediating variable**	**Effect of IV on M**	**Effect of M on DV**	**Direct Effect**		**Indirect Effect**	**Total Effect**
(IV)	(DV)	(M)	(a)	(b)	(c')	(a x b)	95% CI	(c)
Group	DASS Stress[a]	SCS[a]	-5.63*	-.04*	-.73	0.12	-3.85, -1.03*	-3.12*
		FFMQ-NR[a]	-3.45*	.76*	-.48	-1.83	-4.71, -1.00*	
		FFMQ-NJ[a]	-2.53*	.81*	-1.07	-2.19	-4.02, -.59*	
		FFMQ-O[a]	-2.16*	.56*	-1.92	-0.24	-2.58, -.12*	
		FFMQ-AA[a]	-3.07*	.86*	*-.47	-0.43	-4.05, -1.29*	
		FFMQ-D[a]	-2.17*	.73*	-3.12	-0.56	-2.80, -.47*	
	DASS Depression[a]	SCS[a]	-5.63*	.31*	-1.90	-2.06	-.44, -.07*	-3.68*
		FFMQ-NR[a]	-3.45*	-.56*	-1.74	.50	-3.72, .53	
		FFMQ-NJ[a]	-253*	.42*	-2.63	-2.06	-2.44, -.054*	
		FFMQ-O[a]	-2.16*	.48*	-2.64	-1.64	-2.48, -.43*	
		FFMQ-AA[a]	-3.07*	.71	-1.51	-.35	-4.03, .72	
		FFMQ-D[a]	-2.17*	.55	-2.49	-0.56	-2.42, .05	
	DASS Anxiety[a]	SCS[a]	-5.63*	.24*	-2.05	-1.35	-2.42, -.55*	-3.41*
		FFMQ-NR[a]	-3.45*	.27*	*-2.39	-0.93	-2.33, -.04*	
		FFMQ-NJ[a]	-2.53*	.57*	*-1.97	-1.44	-3.22, -.38*	
		FFMQ-O[a]	2.16*	.22	*-2.94	-0.48	-1.28, .28	
		FFMQ-AA[a]	-3.07*	.14	*-2.98	-0.43	-1.37, .76	
		FFMQ-D[a]	-2.17*	.40*	*-2.54	-0.89	-1.67, -.17*	
	SWEMWS[a]	SCS[a]	-5.90*	.20*	-1.48	-1.18	-2.12, -.30*	-2.64*
		FFMQ-O[a]	-2.21*	.40*	*-1.74	-0.88	-1.82, -.14*	
		FFMQ-A[a]	-3.30*	.38*	-1.37	-1.25	-2.23, -.42*	
		FFMQ-NJ[a]	-2.65*	.18	*-2.17	-0.48	-1.35, .18	
		FFMQ-NR[a]	-3.40*	.38*	-1.35	-1.29	-2.21, -.52*	
		FFMQ-D[a]	-2.04*	.43*	*-1.75	-0.88	-1.63, -.20*	

MBIN DP[a]	SCS[a]	-5.90*	.18*	-1.18	-1.06	-2.41, -.06*	-1.68*
	FFMQ-O[a]	-2.21*	.11	-2.40	-0.24	-1.08, .36	
	FFMQ-A[a]	-3.30*	.18	-1.09	-0.59	-1.39, .24	
	FFMQ-NJ[a]	-2.65*	.25*	-1.01	-0.66	-1.75, -.01*	
	FFMQ-NR[a]	-3.40*	.15	-2.53	-0.51	-1.28, .05	
	FFMQ-D[a]	-2.04*	.15	-1.38	-0.31	-1.00, .08	
EE[a]	SCS[a]	-5.90*	.29	-2.90	-1.71	-4.12, .40	-4.62*
	FFMQ-O[a]	-2.21*	.57	-3.35	-1.26	-3.01, .07	
	FFMQ-A[a]	-3.30*	.25	-3.80	-0.86	-2.87, .78	
	FFMQ-NJ[a]	-2.65*	.69*	-2.78	-1.83	-3.95, -.33*	
	FFMQ-NR[a]	-3.40*	.40	-3.29	-1.36	-3.24, .18	
	FFMQ-D[a]	-2.04*	.24	-4.12	-0.49	-2.07, .55	
PA	SCS[a]	-5.90*	.25*	-1.13	-1.48	-2.83, -.31*	-2.64*
	FFMQ-O[a]	-2.21*	.14	-2.37	-0.31	-1.27, .72	
	FFMQ-A[a]	-3.30*	.13	-2.20	-0.43	-1.63, .80	
	FFMQ-NJ[a]	-2.65*	.30	-1.85	-0.80	-2.07, .37	
	FFMQ-NR[a]	-3.40*	.20	-1.97	-0.68	-1.69, .21	
	FFMQ-D[a]	-2.04*	.30	-2.02	-0.61	-1.70, .05	
Compassion Scale	SCS[a]	-5.63*	.90*	-3.82	-5.07	-9.33, -1.57*	-8.86*
	FFMQ-O[a]	-2.21*	.44	*-7.46	-0.97	-3.60, 1.03	
	FFMQ-A[a]	-3.30*	1.01*	-5.12	-3.33	-7.37, -.35*	
	FFMQ-NJ[a]	-2.65*	.96*	*-5.88	-2.54	-6.09, -.15*	
	FFMQ-NR[a]	-3.40*	.73	-5.94	-2.48	-5.00, -.32*	
	FFMQ-D[a]	-2.04*	.80*	*-6.79	-1.63	-4.47, .00	

[a]=pre-post change in score FFMQ-O=Observing; FFMQ-A=Acting; FFMQ-NJ=Non-judging; FFMQ-NR= Non-reactivity; MBIN – EE = Emotional exhaustion; MBIN – PA = Personal accomplishment, MBIN – DP = Depersonalisation

*Where 95% CIs do not cross zero is taken as indication of significant mediation effect at p<05 level

7.3. Engagement and adherence with the intervention

In participants who had completed the MBCT-SH intervention, Table 6 shows correlations between the adherence measures and pre to post intervention changes on the outcome/process measures. Participants reported listening to the mindfulness tracks and engaging with the material on average 4.09 days per week (SD=1.85). A correlation indicates that greater adherence was associated with an improvement on the relevant measure.

For the outcome measures, based on Cohen's (1988) criteria, 'days spent listening to the mindfulness tracks' showed significant medium positive associations with improvement in stress (r=0.43).

For the process measures, only the non-judgmental subscale of the FFMQ was significantly positively correlated with a medium association 'days spent listening to the mindfulness tracks' (r=0.31). However, these did not remain significant when Bonferroni correction for multiple comparisons was applied. Which could mean that this was because Type 1 error occurred.

Table 6. Spearman's correlations between adherence measures and changes in outcome measures (N=44)

Measure	Days week listened to mindfulness tracks and engaged in practice
DASS-21	
Stress change [a]	.43*
Anxiety change [a]	.21
Depression change [a]	.08
SWEMWS	
Full scale change [a]	.27
MBIN	
D change [a]	.01
PA change [a]	-.18
EE change [a]	.07

FFMQ	
Observing change[a]	.23
Describing change [a]	.03
Acting change [a]	.03
Non-judging change [a]	.31*
Non-reacting change [a]	.17
SCS	
Full scale change [a]	.23
CS	
Full scale change [a]	-.02

Significant at p<05 level

7.4. Satisfaction

Overall, participants rated the book highly. The 46 intervention participants who read at least some of the book gave it a mean rating of 7.30 out of 9 for helpfulness (SD=1.72).

8. Discussion

This RCT sought to examine the efficacy of MBCT-SH in HCPs. In line with the hypotheses, intervention participants demonstrated significantly greater improvements than wait-list control participants on measures of depression, stress, and wellbeing directly after a self-help mindfulness intervention. There were large post-intervention effects on stress, compassion, anxiety, depression and wellbeing.

8.1 Comparison to other self-help interventions

These results add to meta-analysis findings that self-help MBIs were effective at reducing psychological distress (Cavanagh et al., 2013). This meta-analysis found small, significant post-intervention between-group effects of MBCT-SH on depression and anxiety. However,

in comparison, the results from this study showed that the MBCT-SH intervention had large effects. The results from this study build on the findings from the meta-analysis by also showing improvements in wellbeing. This difference may be due to the MBCT programme itself as some MBCT programmes maybe more effective than others. It also maybe that differences in the sample could play a role. Further research, looking into which components of MBCT courses are particularly helpful, may help to discover why some programmes are more effective than others.

This study showed similar effect sizes to those reported for CBT self-help. For example, a meta-analyses of CBT self-help showed large overall effect sizes (Coull & Morris, 2011), with an overall post-intervention between-group large effect size for anxiety and depression immediately post-treatment. However, this was found in a clinical population where we might expect the effect sizes to be larger than a non-clinical one, as the baseline scores will be worse and therefore there is more room for improvement.

Although MBCT was originally designed to be taught in a group, the effect sizes identified in the current study are comparable to those reported in meta-analyses of face-to-face MBCT. For example, Strauss et al. (2013) found a significant post-intervention between-group medium effect of face-to-face MBIs on depression. The current study showed medium and large effects for reducing stress, and depression respectively which were comparable to the findings from a meta-analysis of RCTs of mindfulness training for health care staff which found medium effect sizes for lowering anxiety and depression (Guillaumie et al, 2016).

The current study is also comparable to other studies which have looked at the effectiveness of interventions on HCPs' wellbeing. The results from the current study of HCPs' wellbeing

are in line with other interventions that have been tried to support staff in occupational settings, such as CBT-based stress management (Joyce et al., 2015). In their meta-review, Joyce et al. (2015) looked at 20 moderate and high-quality reviews examining the effectiveness of workplace mental health interventions to prevent, treat or rehabilitate a worker with a diagnosis of depression, anxiety or both. Authors were in support of empirically based interventions and found medium effect sizes for CBT to aid the prevention and treatment of common mental health problems in the work force. It should be noted that in Joyce et al.'s (2015) meta-review, all the interventions that were looked at were face-to-face. If, as the current study suggests, self-help interventions can be of similar benefit to face-to-face interventions, there may be advantages in using self-help interventions. For example, they may be more accessible to a wider number of people, they are cheaper to run and can be completed when it is convenient. The comparability of effectiveness would need to be more robustly examined in an RCT that compares self-help and face to face interventions.

8.2. Adverse event

One of the potential harms of mindfulness that has been researched is the paying attention to thoughts, and the way an individual may interpret this (Lindahl, Fisher, Cooper, Rosen, & Britton, 2017). This was considered in the ethics application and was explicitly addressed in the participant information sheet as a potential 'side effect' of mindfulness. During the study, one participant sent an email to the author to say that following the first two sessions of practice she experienced unwanted effects. The participant said that paying attention to her thoughts had left her feeling tearful and she had become tearful at work. She described becoming aware of past issues that she didn't know were still affecting her. Following consultation with the project's supervisors and the Centre's Research Director, the participant was immediately advised to stop the intervention and to seek advice from her GP and mental

health services. The Sponsor, the relevant NHS Trust R&D Department and Chair of the approving Ethics Committee were all notified. After a thorough investigation by the Sponsor, it was found that although this was distressing for the participant, the research had been conducted appropriately and in accordance with the protocol. In follow up contact from the study team, the participant reported that she had sought help. This event highlights an important concern about the use of self-help as a means of delivering mindfulness. Although the results suggest that the large majority found the intervention helpful, it may not be suitable for everyone. Undertaking mindfulness with a teacher present, with the ability to discuss difficult issues as they inevitably come up, might be a more suitable approach for certain individuals. There would be value in future research examining the circumstances in which such interventions may not be suitable.

8.3. Mediation analysis

This study adds to the literature on the mechanisms behind mindfulness and compassion. Mediation analyses supported the hypothesis that self-compassion and aspects of mindfulness mediated the effects of the intervention on outcome. This is consistent with the possibility that participants in the intervention arm improved on the outcome measures because of changes in their mindfulness and self-compassion, (Segal, Williams & Teasdale, 2013). The theoretical implications, as supported by preliminary research (Gu, et al., 2015), is that mindfulness may work in part through the development of self-compassion. More specifically, self-compassion, and the *acting with awareness* and *non-judging* subscales of the FFMQ showed evidence of significant mediation effects for all outcomes (aside, of course, from anxiety). *Non-reactivity* showed evidence of mediation effects for stress, positive affect and satisfaction with life. However, the *observing* subscale of the FFMQ only mediated positive affect.

8.4. Limitations

Although measures were taken to try to decrease bias as much as possible, one limitation of the current study was that double-blinding was not possible.

Another limitation was that because no additional measurements were taken between pre- and post-assessment, it was not possible to determine whether scores on the process measures changed before those on the outcome measures. This meant that the mediation analysis was limited with regard to interpretations of causality. Another limitation is that the study used an inactive control group. In order for clearer interpretations of causality, the study needs to be replicated with an active control.

A limitation may be that although this study's intention was to look at the effect of MBCT-SH on HCPs, the results are not generalisable to other samples, for example clinical populations. This is important especially in light of the adverse event, as research to date is not able to tell us why some people may have an adverse reaction to mindfulness.

Another limitation may be that the self-report measures may have a desirability effect. For example, the self-report measure of mindfulness may be affected by participants having a better understanding of what mindfulness is after completing an MBI. In addition, there was no reported validity for the adherence and self-report measures included in the post questionnaires. This may also account for the correlation not remaining significant once a correction for multiple corrections were applied.

8.5. Clinical implications

The results from this study suggest that MBCT-SH may be one potential way to decrease stress in HCPs. However, it would be unethical to suggest that this intervention is a panacea for stress in the work place, that all employees should be fully accountable for their own stress, and that all employees would benefit.

Rather, emphasis should also be placed on the need for employers to look at systems as a whole and the underlying mechanisms that cause stress and burnout in the work place. For example, in the NHS, waitlist pressures are increasing, services report understaffing and it is likely that that pressures on the NHS will continue to increase given the demographic and resourcing pressures (Health Education England, 2017). A systematic review and meta-analysis suggested that organisation-based interventions were associated with medium significant reductions in burnout (SMD=-0.45) when compared with a control group (Panagioti et al., 2016). Nevertheless, the current study suggests that offering MBCT-SH could be a helpful component of programmes that NHS Trusts could adopt to support staff wellbeing.

8.6. Research implications

Further research should look further at what works for whom, especially to look at other samples who may benefit from MBCT-SH. Future research should also look at different types of MBIs as the findings are mixed on their effectiveness. More robust RCTs could look at the comparability between self-help and face-to-face interventions.

Overall, this RCT suggests that MBCT-SH could be helpful for HCPs in reducing stress and increasing wellbeing. However, this intervention should not be used as a panacea for staff stress and burnout, and caution should be taken over the generalisability of the sample.

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APPENDICES

Appendix A – AMSTAR appraisal tool

AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both

1. Did the research questions and inclusion criteria for the review include the components of PICO?

For Yes:	Optional (recommended)	
Population Intervention Comparator group Outcome	Timeframe for follow-up	Yes No

2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?

For Partial Yes:	For Yes:	
The authors state that they had a written protocol or guide that included ALL the following:	As for partial yes, plus the protocol should be registered and should also have specified:	Yes Partial Yes No
review question(s) a search strategy inclusion/exclusion criteria a risk of bias assessment	a meta-analysis/synthesis plan, if appropriate, *and* a plan for investigating causes of heterogeneity justification for any deviations from the protocol	

3. Did the review authors explain their selection of the study designs for inclusion in the review?

For Yes, the review should satisfy ONE of the following:	
Explanation for including only RCTs OR *Explanation for* including only NRSI OR *Explanation for* including both RCTs and NRSI	Yes No

4. Did the review authors use a comprehensive literature search strategy?

For Partial Yes (all the following):	For Yes, should also have (all the following):	
searched at least 2 databases (relevant to research question) provided key word and/or search strategy justified publication restrictions (e.g. language)	searched the reference lists / bibliographies of included studies searched trial/study registries included/consulted content experts in the field where relevant, searched for grey literature conducted search within 24 months of completion of the review	Yes Partial Yes No

5. Did the review authors perform study selection in duplicate?

For Yes, either ONE of the following:	
at least two reviewers independently agreed on selection of eligible studies and achieved consensus on which studies to include OR two reviewers selected a sample of eligible studies and achieved good agreement (at least 80 percent), with the remainder selected by one reviewer.	Yes No

	No: authors stated that they excluded studies from the review (or did not search for studies) based on publication status, or language. **Can't answer:** no information are provided and no grey literature studies are included in the review
Q5.	**Was a list of studies (included and excluded provided)?** **Yes**: a list with the references of the included studies was provided AND a list with the references of the excluded studies (references) was provided either in the article or in a supplementary source (e.g. Appendix, online). The term excluded studies refers to those studies seriously considered by the review authors on the basis of title and/or abstract, but rejected after reading the body of the text. **No:** only the references of included studies provided; number of excluded studies along with a justification provided but reader can't link the justification with the exact reference/study that was excluded. **Can't answer:** partial information (e.g. all or some of the excluded studies were listed in the article's references but not in the text to allow the reader identify all of them)
Q6.	**Were the characteristics of the included studies provided?** **Yes**: data on participants, interventions and outcomes were provided, and the range of relevant characteristics reported either in a table or as narrative text. **No:** no information about the characteristics of the included studies provided. For example, review provided information about the interventions but not about the number of participants and the outcomes of interest of the study. **Can't answer:** partial information (e.g. only year of publication and intervention reported, or only some of the included studies described)
Q7.	**Was the scientific quality of the included studies assessed and reported?** **Yes:** predetermined methods of assessing quality were reported i.e. a risk of bias or methodological quality assessment instrument/tool was used to critically appraise each study against the instrument's criteria with some kind of result reported for each study. **No:** no quality assessment performed on the actual features of the individual studies (e.g. randomization, concealment of allocation, blinding of assessors, attrition, and/or other study design and implementation characteristics). **Can't answer:** the authors stated that a quality assessment was done, but did not describe how it was performed (e.g. what instruments or criteria were used) and/or do not present the results of the assessment.
Q8.	**Was the scientific quality of the included studies used appropriately in formulating conclusions?** **Yes:** the quality (and limitations) of included studies was considered in the analysis (e.g.

	use of the GRADE system to rate the quality of evidence for each outcome) and/or the conclusions of the review (i.e. in making inferences about the effectiveness of home telemonitoring). For example, authors might say "the results should be interpreted with caution due to the poor quality of the included studies". **No**: quality assessment was not performed or was but the results were not considered throughout the analysis of the findings and/or at the end in formulating conclusions. **Can't answer**: impact of quality of studies on results unclear or not used for conclusions.
Q9.	**Were the methods used to combine the findings of studies appropriate?** **Yes:** In SRs that pooled the results using meta-analysis, if statistical heterogeneity was assessed by means of a formal test (e.g., Chi-squared and/or I^2) and the results of these tests - along with other study aspects such as the clinical heterogeneity between the interventions - were used to inform the decision of the statistical model used (i.e. random or fixed). If statistical heterogeneity was present, (given the nature of home telemonitoring interventions) a random effects model was used and/or the appropriateness of combining data was considered by the review authors. Yes, also, if in SRs that did not conduct meta-analysis, the authors made a statement regarding the inappropriateness of pooling data (e.g. highlighted issues about heterogeneity/variability between the studies) and thus, a qualitative synthesis was performed appropriately. That is, the authors summarized and synthesized the available evidence narratively according to a defined analysis plan and/or using appropriate qualitative methods and techniques (e.g. construction of common rubrics, content analysis, tabulation, groupings and clustering). **No:** In SRs that pooled the results using meta-analysis, heterogeneity was present, but not discussed, fixed-effect model was used by default, and/or meta-analytic methods were used inappropriately (double counting of studies occurred, count data were treated as dichotomous, etc.). **Note**: if there is no heterogeneity present (e.g. I^2=0% or chi-square is non-significant, P is greater than 0.10), and review used fixed-effect model, score Yes because both fixed and random effects models yield the same results in this case. No, also, in SRs in which the authors did not attempt to combine findings into a meta-analysis and did not provide a statement regarding heterogeneity or the inappropriateness of combining findings. **Can't answer:** heterogeneity test result not reported or model (random vs. fixed) used to combine studies not specified.
Q10.	**Was the likelihood of publication bias assessed?** **Yes:** publication bias was explicitly considered and assessed. Funnel plots or other methods used (e.g. egger regression tests). (Note: if funnel plots are not presented as figures, but authors explicitly state that a publication bias assessment was performed and an interpretation of that test is provided, then score Yes.) **No:** In SRs that pooled the results using meta-analysis, publication bias was not assessed or no information about it was provided.

	Can't answer: mentioned or discussed it vaguely only in conclusions. **Not applicable:** SR was narrative/qualitative not a meta-analysis
Q11.	**Was the conflict of interest stated?** **Yes:** conflict of interest and sources of support were clearly acknowledged in both the systematic review AND the included studies. **No:** conflict of interest and sources of funding were reported for the systematic review but not for the included primary studies or vice versa.

Appendix B – JADAD quality rating tool

Quality assessment

A commonly used three-item, five-point quality scale was used to rate the quality of the trials [Jadad et al,1996]. The minimum score possible for inclusion of a study in the review was 2 (one point each for randomisation and double blinding). The maximum score possible was 5 (2 points for descriptions of randomisation, 2 points for descriptions of double blinding, and 1 point for descriptions of withdrawals).

Jadad AR, Moore RA, Carroll D *et al*. Assessing the quality of reports of randomized clinical trials: is blinding necessary? Control Clin Trials 1996; 17:1-12.

How points are awarded:

1) Is the study randomised? If yes, + 1 point.

Is the randomisation procedure appropriate and reported in the study?

If yes, +1 point. If no, delete all points awarded for randomisation.

2) Is the study double blind? If yes, + 1 point.

Is the double blinding method appropriate and reported in the study?

If yes, +1 point. If no, delete all points awarded for double blinding.

3) Are the reasons for patient withdrawals and dropouts described, for each treatment group?

If yes, +1 point.

Appendix C – CONSORT tool

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	
	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Appendix D – Ethics letter

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Appendix E- PIS

Sussex Partnership NHS
NHS Foundation Trust
A teaching trust of Brighton and Sussex Medical School

Canterbury Christ Church University

PARTICIPANT INFORMATION SHEET

A Randomised Control Trial of mindfulness-based self-help for NHS employees.

Invitation

Hello. My name is Emily Ironmonger and I am a trainee clinical psychologist at Canterbury Christ Church University. I would like to invite you to take part in a research study. Before you decide, 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 to help you decide whether or not you wish to take part. Please ask me if there is anything that is not clear or if you would like more information (my contact details are at the end of this document). Please take time to decide whether or not you wish to take part. Please note that this study is only funded for 90 participants and recruitment to the study is on a 'first-come, first-served' basis.

Brief summary

I am the principal investigator on a research team based at Canterbury Christ Church University, The team (Dr Fergal Jones, Dr Clara Strauss, Dr Kate Cavanagh and Dr Kim Griffiths and me) is investigating a mindfulness-based cognitive therapy (MBCT) self-help course with 90 Oxleas and Sussex Partnership NHS Foundation Trust staff members. Half of these staff members will be randomly allocated to receive the MBCT course at the beginning of the study, and half will be randomly allocated to wait for 21 weeks before receiving the MBCT book and CD.

The MBCT course uses a book and a CD as a guide. Participants will have 8 weeks to complete the course, and are advised to spend 1-2 hours per week engaging with course materials and exercises. Participants allocated to start the course at the beginning of the study will receive emails over the 8 weeks encouraging them to keep following the guides during the course. Participants allocated to receive the course materials 21 weeks later will receive an email encouraging them to start the course and follow the 8 week course guide. All participants will be asked to complete three questionnaires, one at the beginning of the study, one at 9 weeks, and one at 21 weeks.

There is more information about the study on the next few pages. If you have any questions you can call or email me (see my contact details on the last page).

What is Mindfulness-Based Cognitive Therapy?

Mindfulness is the capacity to notice and accept our current experience (thoughts, feelings, body sensations) and respond to our experiences in a way that is helpful. Mindfulness-based cognitive therapy (MBCT) adds mindfulness meditation practice and principles to cognitive therapy. A substantial body of evidence supports the effectiveness of group MBCT in reducing symptoms of psychological distress and improving wellbeing.

What is this study about?

Evidence also suggests that participation in group mindfulness-based interventions is associated with a number of beneficial outcomes among healthcare workers and that staff participation in these therapies may improve outcomes for patients. However, demand for group mindfulness-based interventions outstrips supply and group mindfulness-based interventions can present challenges for staff in terms of the demands on their time.

Self-help interventions have the potential to increase access to mindfulness-based interventions and to allow more flexible use of staff time. Emerging evidence suggests that the use of mindfulness-based self-help materials might be helpful for improving wellbeing and for people experiencing mild or moderate symptoms of stress, anxiety, and/or depression. However, to date, there is no high quality research evaluating the benefits of self-help MBCT for healthcare staff. This study aims to investigate whether a self-help mindfulness-based intervention is acceptable and potentially beneficial for NHS staff.

If the results of the study show that mindfulness-based self-help is beneficial for NHS staff, the research team will support the provision of the intervention for NHS employees.

Am I eligible to take part in this study?

The only requirements for participation are that you:

1. are currently employed by Oxleas or Sussex Partnership NHS Foundation Trust in a role that involves direct delivery of healthcare and that you have at least one day per week of direct contact with service users;

2. are currently in work;

3. have not previously completed 50% or more of a mindfulness-based intervention;

4. have sufficient English Language reading ability to undertake a course that is taught through materials written and spoken in English.

You do not need to be experiencing distress or mental health difficulties to take part in this study.

Please note that self-help interventions have been found to be helpful for people experiencing mild to moderate symptoms of psychological distress and may not be helpful for people who are currently experiencing more severe forms of psychological distress. If you are currently experiencing mental health problems and are unsure whether the course would be useful for you, you may wish to discuss the study with your GP or mental health professional. Alternatively, you can contact the research team to discuss any concerns you might have.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide not to take part this will not affect terms and conditions of your employment.

If you decide to take part you will be asked to fill in a consent form. You will be free to withhold any personal information or to withdraw at any time without giving a reason and without this affecting the terms and conditions of your employment.

If you do decide to take part you will be asked not to use any other psychological interventions during the course of the study. This will help me to evaluate mindfulness-based self-help intervention.

What would taking part involve?

If you decide that you want to take part in this study, you will need to complete an online consent form.

The consent form will ask you to give permission for me to access your sickness absence records for the three months prior to your taking part in the study and the three months following the study intervention period. This is because I am interested in whether taking part in a mindfulness-base intervention has an impact on staff sickness absence. Sickness absence information will be coded and your name and contact details will be removed so that you cannot be recognised from it. However, if you do not agree to the release of your sickness absence records, you can still take part in the study.

When I have received your consent form, I will ask you to provide an address to which the MBCT book and CD will be sent. I will email you with a link to some online questionnaires. The online tick-box questionnaires will ask you:

1. About your recent experiences of stress, anxiety, and/or low mood
2. About your compassion towards others
3. How mindful you are in everyday life
4. About your self-compassion
5. About your well-being
6. About your levels of work-related burnout

You will also be asked some questions about your age, gender, ethnicity, and job title.

These questionnaires should take around 20 minutes to complete.

What will happen when I have completed the questionnaires?

When you have completed these questionnaires, a statistician independent to the research team will randomly allocate you to either receive the self-help MBCT course immediately or to receive the book and CD 21 weeks later.

What will happen if I have been allocated to start the course immediately?

If you have been allocated to start the self-help course immediately, you will be sent the book and CD when you have completed the initial questionnaire. You will be asked to read the introductory chapters but not to start the course until you receive an email from me approximately one week after you have completed the baseline questions. Participants who receive the book immediately will be encouraged to complete the MBCT course in 8 weeks. You will be sent an email at the end of each week during the intervention providing some

additional information about mindfulness and encouraging you to complete the exercises and practices recommended by the book for that week.

The weekly emails will also ask you to answer six tick-box questions regarding your engagement with the course during the previous week. These should take no more than two minutes to complete each week. It is important for the purposes of this study that you answer these questions as accurately as possible as the information you provide will be useful in evaluating whether the course is feasible for NHS staff.

Eight weeks after starting the course, you will be asked to complete the same set of questionnaires that you completed before starting the course. You will also be asked some brief questions about your engagement with and experience of the intervention. You will be asked to complete a final set of questionnaires 20 weeks after starting the course.

What will happen if I have been allocated to receive the book at a later date?

If you have been allocated to receive the book at a later date you will be sent an email from me when you have completed the online questionnaires telling you that I will be in touch in 9 weeks to ask you to complete the same set of questionnaires that you completed at the beginning of the study. I will then get back in touch 12 weeks later to ask you to complete a final set of questionnaires. When you have completed this final set of questionnaires, you will be sent the MBCT book and CD, and an email from me encouraging you to read the book and complete the 8-week course by using the book as a guide.

How much time is involved in taking part in the study?

The total time involved in the study will be about 8-16 hours, depending on the amount of time you choose to spend engaging with the intervention.

What does the mindfulness-based self-help intervention involve?

The MBCT book is a self-help guide that teaches mindfulness principles and practices through the text and an accompanying CD. The structure of the book is faithful to the eight-week face-to-face MBCT course, and comprises an introduction to the course followed by eight chapters. Each chapter is based on the equivalent weekly session in the group MBCT course. Readers are advised to follow one chapter and per week. You will have 8 weeks to complete the intervention, and the course will take about 1-2 hours of your time each week, including time for reading the self-help book, completing exercises and audio-guided mindfulness meditation practices, and answering the brief weekly questions.

Where will I have to go?

The course is designed to be completed at times and locations that are convenient for you. The book comes with a CD of guided mindfulness practices which can be undertaken anywhere that feels right for you.

What are the advantages and disadvantages of taking part?

Mindfulness-based interventions have been shown to increase self-acceptance, self-compassion, and foster a non-judgmental attitude. Mindfulness training may also increase attention to the present moment, reducing focus on past worries and future concerns and helping people to let go of unpleasant experiences. It may also decrease symptoms of stress, anxiety and depression.

The mindfulness-based self-help course is a type of self-help that is not routinely provided in the NHS because it has not been researched in a high quality study. For this reason, it is not known whether or not it will be helpful. By taking part in the study you will be helping to find out if mindfulness-based self-help courses are helpful in improving NHS staff wellbeing and this will help NHS trusts when they are planning what support to offer staff.

Reflecting on thoughts, feelings and experiences can be helpful, although it can also sometimes feel difficult. During mindfulness practice it is possible to become aware of some unpleasant thoughts, feelings and/or experiences: this is completely normal. The self-help guides provide advice on ways of coping when such feelings arise. However, if you are feeling distressed and that you need additional advice or support, contact details of organisations that you may find useful are provided on the last page of this information sheet. You may also wish to contact your GP for further guidance.

Please note that the intervention used in this study is unguided self-help and I am not able to offer individual support.

This study has received approval from the Salomons centre of applied psychology ethics panel, as well as Health Research Authority which have indicated that there are no substantial risks relating to participation and also no major disadvantages associated with taking part.

Confidentiality

All information collected will be kept strictly confidential and stored securely. Anonymity will be ensured in the publication of findings. Only other members of the research team (named above) and regulatory authorities will have access to information gathered through the study. This information will be coded and your name and contact details will be removed so that you cannot be recognised from it. The study complies with data protection laws.

In the event that I become significantly concerned about your wellbeing to the extent that I am concerned about your safety or about the safety of others I will talk with you about my concerns. If my concerns remain, I will be obliged to inform your manager and you would be withdrawn from the study. If your manager becomes significantly concerned about your wellbeing during the study they will be asked to inform me. In this event I will talk to you and discuss your continued participation in the study.

Who has reviewed the study?

The study has been reviewed and approved by the Heath Regulation Authority [and give ref number here].

Next Steps

If you are interested in taking part in the study please allow yourself as much time as you need to consider your decision before completing the consent questions on the next page. This is to ensure that you have had time to consider your decision.

Please note that this study is only funded for 90 participants, and I will only be able to enrol the first 90 staff members who fill in a consent form. If you would like to take part, please fill in the consent form at your earliest convenience to avoid disappointment.

If you would like any further information about this study please contact Emily Ironmonger email at xxx

Emily Ironmonger
Research & Development
Sussex Education Centre
Mill View Hospital Site
Nevill Avenue
Hove
BN3 7HZ

The research lead for the study is:

Emily Ironmonger
Trainee clinical psychologist
Salomons Centre for Applied Psychology
Canterbury Christ Church University
1 Meadow Road
Tunbridge Wells
Kent
TN1 2YG

Should you have concerns in relation to your psychological wellbeing during this study you may wish to let me know. If you do have concerns about your psychological wellbeing, I would encourage you to contact your GP for advice and/or support. You may also wish to discuss your concerns with your manager. In addition, you can self-refer or your manager can refer you to Sussex Partnership NHS Foundation Trust Occupational Health Services (provided by West Sussex Health):

SPFT Occupational Health Department:
Occupational Health Department
Southlands Hospital,
Upper Shoreham Road,
Shoreham-by-Sea,
BN43 6TQ
01273 446056
occupationalhealth.admin@westsussexpct.nhs.uk

Oxleas Occupational Health Department: 0208 302 2678 Ext:4816

Alternatively, Mind (08457 90 90 90; http://www.mind.org.uk/) provides information, advice, and support for people experiencing psychological distress.

If you have any complaints about the research, please contact the research team in the first instance. Alternatively contact Professor Paul Camic Research Director - Salomons Centre
Tel: 03330117114

Address:
Salomons Centre for Applied Psychology
Canterbury Christ Church University
1 Meadow Road
Tunbridge Wells

Kent
TN1 2YG

Appendix F – Consent form

Sussex Partnership NHS
NHS Foundation Trust
A teaching trust of Brighton and Sussex Medical School

Canterbury Christ Church University

CONSENT FORM

Title A Randomised Control Trial of mindfulness-based self-help for NHS employees.
Name of Researcher leading the study: Emily Ironmonger

		Please initial box
1	I confirm that I have read and understand the Participant Information Sheet for the above study and have had the opportunity to ask questions.	☐
2	I confirm that I have had sufficient time to consider whether or not I want to be included in this study.	☐
3	I understand that my participation is voluntary and that I am free to withhold personal information or to withdraw at any time, without giving any reason, and without my rights being affected.	☐
4	I understand that if I choose to withdraw that any questionnaires I have already completed will be kept by the research team.	☐
5	I understand that data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	☐
6	I give permission for findings from the study to be written up for publication. Any publication would not identify me	☐
7	I give permission for non-identifiable data to be shared with other research teams for research purposes.	☐
8	I understand that, as part of this study and with my consent, the study research team will ask Human Resources to release my sickness absence records for the three months preceding the study intervention period and for the three months following the study intervention period. I give permission for HR to release my sickness absence records to the study research team. I understand that these records will be anonymised for the purposes of the study.	☐
9	I agree to take part in the above study	☐

Name of participant: Date:

Participant email address:

Appendix G - Advert

A randomised controlled trial of a Mindfulness-based Self-Help Intervention for NHS Employees

Are you interested in learning mindfulness?

A research team based at Canterbury Christchurch University is recruiting NHS staff working in Oxleas or Sussex Partnership NHS Foundation Trust to a study investigating mindfulness-based self-help.

Mindfulness training aims to help people relate to their experiences in a different way that can improve decision making and increase the ability to manage difficult situations. A large body of evidence now supports the positive effects of mindfulness training in improving wellbeing and reducing psychological distress and emerging evidence suggests that self-help mindfulness-based courses may also be beneficial.

This study aims to investigate a self-help mindfulness-based intervention for NHS staff that uses a book and CD as a guide. Participants will be randomly allocated either to receive the 8-week course immediately, or to receive the self-help course materials 21 weeks later. Participants will also be asked to complete questionnaires during the study.

If you are employed by Oxleas or Sussex Partnership NHS Foundation Trust in a role that involves the direct delivery of healthcare to patients and have not previously completed 50% or more of a mindfulness intervention, you may be eligible to take part.

This study is only funded for 90 participants and recruitment will stop when 90 staff members have agreed to take part. If you are interested in taking part please get in touch with the principal investigator early to avoid disappointment.

If you are interested in taking part or would like to know more, please get in touch with Emily Ironmonger, the principal investigator, at: **xxxx** or on xxxxx.

I look forward to hearing from you!

Appendix H - Advert

A randomised controlled trial of a Mindfulness-based Self-Help Intervention for NHS Employees

Mindfulness-based interventions have been found to improve wellbeing and reduce stress. A research team based at Canterbury Christchurch University is investigating whether self-help mindfulness-based interventions could be helpful for NHS staff. Staff participants will have the opportunity to learn mindfulness using a self-help book and a CD of audio-guided mindfulness practices.

If you are a Sussex Partnership employee and are interested in taking part or would like to know more, please contact Emily Ironmonger, principal investigator:

xxxx or by calling **xxxx**

Appendix I – Weekly emails

Week 1 (Course Introduction) email:

Subject: Welcome to the mindfulness-based self-help course!

Hi XXX

Welcome to the first week of your mindfulness course! We hope you are well, and have had some time to familiarise yourself with your book (*Mindfulness: A practical guide to finding peace in a frantic world*).

We would like to invite you to start the course by reading chapter 5 (Mindfulness Week One) and starting your exercises for the first week. If you haven't yet read chapters 1-4, don't worry! You might find it helpful to flick through chapter 4, then go straight to chapter 5. If you get a chance, you can read chapters 1-4 as you go along. If you have any questions, or are unsure about anything, do get in touch.

Week one is about becoming aware of when we are on 'automatic pilot' and exploring what happens when we 'wake up'. This week, you will learn a mindfulness practice and two exercises designed to guide you along this journey. The course is all about experience: the time you spend practicing mindfulness really does make a difference.

Here is a link to the mindfulness tracks you need for the course in-case you have trouble accessing a CD player.

https://www.dropbox.com/sh/imzcp8gyjtv7u17/AACVO3hg7siJHrDdbFbdPGWxa?dl=0

Try to be gentle with yourself as you engage with the course this week – it can take time to learn the mindfulness approach. So whatever your experience of practising mindfulness, see if you can stay with it – this is, in itself, a way of being mindful!

We'll be back in touch at the end of the week.

Best wishes,

Emily

Appendix J - The Depression, Anxiety and Stress Scale

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Appendix K **- Compassion Scale**

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Total = …….

Adapted from Pommier (2011)

Appendix L- **The Maslach Burnout Inventory**

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Appendix M - **The Short Warwick Edinburgh Mental Well-Being Scale**

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Appendix N - **Five Facet Mindfulness Questionnaire (FFMQ): Short form**

Appendix O - **Self-Compassion Scale (SCS): Short Form**

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Appendix P - **Participant Engagement Questions – Weekly questionnaire**

Over the past week:

1. How much time in total have you spent reading the book (not including time spent engaging in mindfulness practices)?

   ☐ hours and ☐ minutes

2. On how many days have you spent time reading the book (not including time spent engaging in mindfulness practices)?

   0 1 2 3 4 5 6 7

3. How much time in total have you spent listening to the CD of mindfulness audio recordings and engaging in the mindfulness meditation practices?

   ☐ hours and ☐ minutes

4. On how many days have you spent time listening to the CD of mindfulness audio recordings and engaging in mindfulness practices?

   0 1 2 3 4 5 6 7

5. On how many occasions over the past week have you brought mindfulness to a daily activity (e.g. mindful eating, mindful walking)?

   On ☐ occasions

6. On how many days have you brought mindfulness to a daily activity?

   0 1 2 3 4 5 6 7

7. How much do you really feel this intervention is helping your wellbeing? Where 1 = not at all and 9 = very much.

   1 2 3 4 5 6 7 8 9

Participant Engagement Questions – End of Course Questionnaire

1. On average, how much time did you spend reading the book per week over the eight week intervention period (not including time spent engaging in mindfulness practices)?

☐ hours and ☐ minutes per week

Appendix Q – End of study letter to ethics panel

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CC: supervisors Dr Fergal Jones, Dr Clara Strauss and Dr Kate Cavanagh (by email)

Appendix R: Note regarding feedback to participants

At the time of consent participants were asked when they enrolled whether they would like to be sent a short report of the study results. At the time of submission of this MRP in April 2018 the study had not yet completed because some participants had not completed the final set of questionnaires. Once all data has been collected, a short, single-page document will be sent to participants via email, that summarises results in a succinct and accessible way and agreed with supervisors.