The use of modified Mindfulness-based Stress Reduction and Mindfulness-based Cognitive Therapy programme for family caregivers of people living with dementia: a feasibility study

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Running head: Mindfulness-Based Interventions for Dementia Caregiver


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Declaration of interests
The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Abstract

Purpose

The aim of this study was to investigate the feasibility and preliminary efficacy of a modified Mindfulness-Based Stress Reduction (MBSR) programme and Mindfulness-Based Cognitive Therapy (MBCT) programme for reducing the stress, depressive symptoms, and subjective burden of family caregivers of people with dementia (PWD).

Methods

A prospective, parallel-group, randomized controlled trial design was adopted. Fifty-seven participants were recruited from the community and randomized into either the modified MBSR group (n = 27) or modified MBCT group (n = 26), receiving seven face-to-face intervention sessions over 16 weeks. Various psychological outcomes were measured at baseline (T0), immediately post-intervention (T1), and at the 3-month follow-up (T2).

Results

Both interventions were found to be feasible in view of the high attendance (over 70.0%) and low attrition (3.77%) rates. The mixed ANOVA results showed positive within-group effects on perceived stress ($p = .030$, Cohen’s $d = .54$), depressive symptoms ($p = .002$, Cohen’s $d = .77$), and subjective caregiver burden ($p < .001$, Cohen’s $d = 1.12$) in both interventions across the time points, while the modified MBCT had a larger effect on stress reduction, compared with the modified MBSR ($p = .019$).

Conclusions
Both the modified MBSR and MBCT are acceptable to family caregivers of PWD. Their preliminary effects were improvements in stress, depressive symptoms, and subjective burden. The modified MBCT may be more suitable for caregivers of PWD than the MBSR. A future clinical trial is needed to confirm their effectiveness in improving the psychological well-being of caregivers of PWD.

**Keywords:** mindfulness, stress, caregivers, dementia, depression
Introduction

Dementia is a neurocognitive degenerative disease with no known cure. As the disease progresses, the cognitive function and self-care ability of people with dementia (PWD) gradually declines. Family caregivers are usually the backbone of informal care. The demanding caregiving tasks that are involved always create a high level of stress and burden on family caregivers, which negatively affects their physical and psychological health [1]. Compared with other caregivers, caregivers of people with dementia have higher rates of depression and anxiety [2], and poorer physical morbidity [3]. Around 70.0% of caregivers of PWD have reported various degrees of psychological distress [1] and a higher rate of healthcare utilization [4]. Providing support for family caregivers is important to maintain their continued ability to care for their relative with dementia and prevent the latter’s premature institutionalization [5].

Researchers are keen to develop interventions to reduce the perceived stress of caregivers of PWD and improve their well-being. Such interventions have included case management, cognitive stimulation, cognitive and behavioural interventions, education, physical activity interventions, psychosocial support, relaxation, respite, and skill-building [6]. Although most psychosocial interventions appear to be effective at reducing caregiver stress and psychological morbidity [7-9], the treatment effect sizes have been relatively small and inconsistent [10].

Mindfulness-Based Interventions (MBIs) have been broadly used to reduce stress and emotional problems in both healthy individuals and caregivers of people with chronic conditions, as well as to improve mental health and well-being in general, with consistent
and promising results [11-12]. MBIs help participants to focus on the experience of the present moment and adopt an orientation of openness and acceptance towards their experience [13]. Through practising the meditation exercises in the MBI, improvements were observed in trait mindfulness (a keen awareness and attention to our thoughts and feelings in the present moment), cognitive reactivity, and emotional reactivity, leading to insight and a non-reactive acceptance of one’s experience, which in turn eventually led to positive psychological outcomes [11]. In recent years, MBIs are increasingly being used to reduce stress in caregivers of PWD. However, a Cochrane Review reported that the existing evidence found in the majority of prior trials is of low to very low quality and that the risk of bias is high (e.g., performance bias, detection bias) [14], which may hinder the use of MBIs in clinical practice. Also, different forms of MBIs were adopted in previous studies. It is therefore important to find an appropriate modality of MBIs for caregivers of PWD before conducting a more rigorous clinical trial to test its effectiveness.

The most popular types of MBIs are Mindfulness-Based Stress Reduction (MBSR) and Mindfulness-Based Cognitive Therapy (MBCT). MBSR was used as early as 1979 as a training vehicle to relieve pain and distress in the general population with chronic health problems [11]. Later, it was integrated with Cognitive Theory and Cognitive Behavioural Therapy to create MBCT, and used for preventing the relapse or reoccurrence of depression in people who had been diagnosed with that ailment [11]. Both types of interventions have been preliminarily tested with caregivers in separate studies and found to be effective at reducing stress and promoting well-being [15-17]. In the MBSR, caregivers learn about how to adopt mindfulness to respond to the stressors of caregiving. In the MBCT,
 caregivers learn more about how to disengage with their negative thinking patterns through mindfulness and CBT techniques. Although the programmes appear to be very similar in structure and content, it is not known which intervention is more suitable. Since family caregivers are a non-clinical population, MBSR would be an appropriate approach [18]. However, several studies have indicated that the majority of family caregivers of PWD experience depressive symptoms resulting from repeatedly thinking about the unpredictable progress of the disease and the symptoms of the PWD [19]. Family caregivers of PWD always report higher levels of stress than the family caregivers of people with other chronic diseases [20]. The MBCT, which targets ruminative thoughts, may be more suitable for family caregivers of PWD.

In a meta-analysis of five studies, the stress levels of caregivers of PWD were found to have dropped significantly after either MBSR or MBCT, which had a moderate effect size [14]. The review also showed that the long duration and highly intensive training involved in MBCT and MBSR often results in a high attrition rate, which justifies the need for modifications to be made to the protocols to meet the needs of caregivers. Moreover, using MBIs to support caregivers of PWD is a relatively novel approach, especially among Asian populations. Therefore, this study adopted the modified version of the MBSR and MBCT protocols and tested them on family caregivers of PWD in the local context.

**Purpose of this study**

The aim of this study was to (1) investigate the feasibility of implementing the modified MBSR and modified MBCT protocols on family caregivers of PWD; and (2) explore and compare the preliminary efficacy of the two interventions in improving the
psychological symptoms of the caregivers, namely, perceived stress, depressive symptoms, and subjective caregiver burden.

Methods

Design

This study is a two-arm randomized controlled trial with an allocation ratio of 1:1. It was undertaken between February 2016 and May 2017 in the Hong Kong SAR, China [ClinicalTrials.gov Identifier: NCT02667782].

Participants

The participants were family caregivers of PWD. Convenience sampling was adopted to recruit family caregivers from two elderly centres in Hong Kong that provide dementia services. The inclusion and exclusion criteria were drawn from the standard practice guideline of the Mindfulness-Based Stress Reduction Programme (MBSR) published by the Centre of Mindfulness, University of Massachusetts Medical School [21]. The criteria for participation included: (a) being 18 years or older; (b) being the primary family caregiver of an individual with a confirmed medical diagnosis of dementia who is residing in the community; and (c) having provided care for at least three months prior to recruitment. In this study, a primary caregiver is defined as an unpaid individual who has a significant personal relationship with the person with whom he/she is living and who assists that person with the activities of daily living. Excluded were those with (a) acute mental disorders; (b) serious or chronic pain and/or a physical disease such as cancer and
cardiovascular disease in an acute phase; and/or (c) those who had participated in any MBI, cognitive therapy, or structured psychosocial intervention in the six months prior to recruitment. Verification of eligibility was conducted individually before the signing of the consent to participate form.

Sample size

For feasibility studies, it may not be possible to produce a formal calculation of sample size. However, minimum sample sizes of between 24 and 50 have been recommended [22-23]. Therefore, in this study, a minimum sample size of 50 was required, although 53 caregivers were ultimately recruited.

Interventions (Modified MBSR and Modified MBCT)

To improve the adherence of family caregivers to the MBSR and MBCT programmes, we made the following changes to the MBSR and MBCT protocols by 1) integrating the content of some sessions to shorten the face-to-face training, 2) providing telephone follow-ups to monitor their progress and adherence to the practice of mindfulness and; 3) extending the last three sessions from weekly to bi-weekly to help the participants develop a habit of practising mindfulness on a daily basis. The modifications to the protocols were based on recommendations from previous studies [24-29]. The protocols were then reviewed by a panel of experts consisting of mindfulness interventionists, registered nurses experienced in dementia care, and a clinical psychologist. Details of the modifications and the rationales for them can be found in our recent publications [24].
Both intervention programmes lasted for 16 weeks and consisted of seven 2.5-hour face-to-face group-based training sessions. In the first month, the participants took part in four weekly sessions, followed by three monthly sessions. In between the three monthly sessions, three trained research assistants with nursing backgrounds provided bi-weekly 15-minute telephone follow-ups (a total of three times) to encourage and advise the participants, and to ensure fidelity to the intervention. A certified cognitive therapist, who was also a mental health nurse as well as a mindfulness teacher with more than 10 years of experience, delivered both interventions. An audio CD of recordings of mindfulness exercises was also provided to all participants.

Although the class structure and mode of delivery were similar in both groups, the two protocols differed slightly in content within each session. In the modified MBCT a greater focus was placed on addressing low moods and negative thoughts to help the participants gain experience in recognizing emotional symptoms and become confident in responding skillfully early in the programme [30]. By contrast, in the MBSR, minus the CBT component, psychoeducation was adopted to help the participants understand their habitual reactions to stress and teach them how to adopt the skill of mindfulness to respond non-judgementally to stressors [11]. Details about the contents of the programmes and the differences between them are listed in Table 1 (the modified MBSR and MBCT protocols).

**Measurements**

Demographic data were collected at baseline before randomization, including data on age, gender, level of education, marital status, household income, relationship with the person living with dementia, and the number of hours spent in providing care.

8
Feasibility assessment

To assess the feasibility of the interventions, we collected information about recruitment, attendance, and completion rates in the face-to-face intervention sessions, and asked the therapist to report any adverse reactions during those sessions. Some potential adverse effects reported in previous studies include transient negative emotions reported by the caregivers, and muscle or joint pain after practising mindful yoga [31].

Efficacy

To explore the efficacy of the two interventions, psychological outcomes were measured at baseline before randomization (T0), immediately post-intervention (T1), and three months after the intervention (T2). The primary psychological outcome was the participants’ perceived stress. Secondary psychological outcomes were depressive symptoms and subjective caregiver burden, which have been found to be related to MBIs [15, 32]. We also examined trait mindfulness as a process indicator, as it had been identified in previous studies as an indicator of the participants’ mastery of mindfulness skills [11]. Trait mindfulness refers to a state of keen awareness and attention to our thoughts and feelings in the present moment [33].

(1) The primary psychological outcome

Perceived stress was assessed using the Chinese version of the Perceived Stress Scale (PSS) [35]. This is a 14-item, self-reported scale that is employed to evaluate the degree to which individuals appraise situations in their lives as stressful in the previous month, using a 5-point Likert Scale (0 = never to 4 = very often). The total
score ranges from zero to 56, with higher scores indicating greater perceived stress. The Chinese version of the PSS (C-PSS) was tested in the community, with 500 adults receiving mindfulness interventions. A factor analysis revealed that the scale contains two factors (namely, positive and negative factors), with a factor loading ranging from 0.26 to 0.78 and a Cronbach’s alpha of between 0.76 and 0.83. The test-retest reliability coefficient was 0.85 (Chu & Kao, 2005). These results support the view that the scale is a reliable and valid instrument [34].

(2) Secondary psychological outcomes

The depressive symptoms of the participants were measured using the Chinese version of the Centre of Epidemiological Studies – Depression Scale (CES-D) [35]. The scale has 20 items, which measure an individual’s depressive symptoms over the past week on a 4-point Likert Scale (0 = rarely to 3 = almost all the time). The total score ranges from zero to 60, with higher scores indicating higher levels of depression. The Chinese version of the CESD (C-CESD) was tested in the community with 3,686 Chinese adults attending primary care services (Chin, Choi, Chan, & Wong, 2015). A factor analysis revealed that the instrument contains four factors (namely, depressed affect, positive affect, somatic and retarded activity, and interpersonal problems) with a factor loading ranging from 0.12 to 0.88. The results showed acceptable levels of psychometric properties, which include an intraclass correlation coefficient of 0.91 and an internal consistency for general depression figure of 0.855 [36].

Subjective caregiver burden was assessed using the Chinese version of the Zarit Burden Interview (ZBI) [37]. For each of the 22 items, the participants were asked
to indicate their level of caregiving distress on a 5-point Likert Scale (0 = never to 4 = nearly always). Higher total scores indicate a greater caregiver burden. This instrument demonstrated a high intraclass correlation coefficient of 0.99 and a split-half correlation coefficient of 0.81 [37]. The correlation between the ZBI and the General Health Questionnaire was 0.59, and between the ZBI and the Activity Survey was 0.57. This supports the view that the scale is a reliable and valid instrument [37].

(3) Process indicator

Trait Mindfulness was assessed using the Chinese version of the Five-Facet Mindfulness Questionnaire – Short Form (FFMQ-SF) [38]. The FFMQ-SF consists of 20 items in five domains, namely: observing (4 items), describing (4 items), non-judging of experience (4 items), acting with awareness (4 items), and non-reactivity to inner experience (4 items). The participants were asked to rate these items on a 5-point Likert Scale (1 = never to 5 = very often). A higher total score (ranging from 20 – 100) reflects a higher level of trait mindfulness, which could support their mastery of the mindfulness skills, resulting in an increase in trait mindfulness. The Chinese version of the FFMQ was tested among Chinese adults in the community (n = 230), and among adult and clinical patients with significant psychological distress (n = 156) (Hou et al., 2014a). Internal consistency was high in five subscales: non-reactivity = 0.75, observing = 0.83, acting with awareness = 0.87, nonjudging = 0.87, and describing = 0.91. The results showed good test-retest reliability (0.88) and a high level of internal consistency of 0.83 in the community sample and 0.80
in the clinical sample). This supports the view that the scale is a reliable and valid instrument [38].

Randomization and blinding

Those who met the criteria for eligibility and provided informed consent were randomly allocated into either the modified MBSR group or the modified MBCT group by block randomization (with a block size of six) and computer-generated random numbers. An independent researcher who was not involved in collecting or entering the data or delivering the interventions conducted the randomization. The group assignments were concealed from the other researchers and staff members of the centre (with the exception of the therapist) until the data collection process was complete.

Ethical considerations

Ethical approval for the study was received from the University (Ref: HSEARS20151213002-01). The research team explained to the potential participants the nature of a randomized controlled trial and their rights as research participants, before asking them to voluntarily sign the informed consent forms.

Data analysis

Quantitative data were entered, managed, and analysed using IBM SPSS Statistics Version 23.0 (IBM Corp, 2015). To determine the feasibility of the interventions (objective 1), the recruitment, attendance, and completion rates of the two programmes were descriptively reported in percentage and mean (standard deviation) terms where appropriate.
To explore and compare the efficacy of the two interventions (objective 2), mixed ANOVA was conducted to examine the change in psychological outcomes and trait mindfulness across time-points in the two groups. All of the participants were included in the final analysis based on an intention-to-treat principle. Missing data were replaced using the last observation carried forward method. To assess homogeneity between the two groups, an independent t-test (as the data were found to be normally distributed) and a Chi-square test were used for continuous and categorical baseline data, respectively. Preliminary statistical assumptions were tested, and no violations were noted on normality, linearity, univariate and multivariate outliers, the homogeneity of the variance-covariance matrices, and multicollinearity. Since there were three-time points of measurement in this study, a Helmert contrast test was performed to examine which pairs of time-points (i.e., T0-T1, T0-T2, T1-T2) showed differences if there was a significant Group x Time interaction effect. To further investigate changes in the outcomes of two individual groups between time-points, a pairwise comparison with a Bonferroni adjustment was conducted. All of the participants were included in the final analysis based on the intention-to-treat principle involving 27 caregivers in the MBSR group and 26 caregivers in the MBCT group.

**Results**

**Participant characteristics**

Ninety-seven family caregivers showed an interest in joining this study. Of these, 80 met the sample selection criteria and 53 agreed to take part in the study (please refer to the CONSORT flow chart in Figure 1). The participants were randomly allocated into either the modified MBSR group (n = 27) or the modified MBCT (n = 26) group.
demographic and clinical characteristics are summarized in Table 2. All of the participants were Chinese (100%) and the majority were female (86.8%). Their mean age was 56 (SD = 9.26) years. Most of the participants were the adult children of people with dementia for whom they were the caregivers (71.7%). The average duration of cognitive impairment in the people with dementia was 71.1 (SD = 59.96) months, while the average duration of caregiving was 8.72 (SD = 10.56) years. No significant differences were found between the two groups in any of the demographic and clinical characteristics at baseline.

**Feasibility of the interventions**

**Recruitment**

Two day-care centres for the elderly that were known to the research team were invited to participate in this project. A public seminar and seven briefing sessions were organized at the University and at the day-care centres for the elderly to introduce the MBI, and to attract potential participants to this project. A total of 253 people attended the public seminar and briefing sessions. Ninety-seven caregivers were eligible to participate in this study, and 53 agreed to do so. The recruitment rate was 54.6%.

**Attendance**

The mean attendance rate of the 10-week training sessions was 73.5% (S.D. = 28.48) for the modified MBSR group and 82.4% (S.D. = 20.32) for modified MBCT group. There was no significant difference in attendance rate between the two groups ($p = .197$).

**Completion**

The overall dropout rate was 3.8%. The completion rate (defined as having attended 80% or more of the sessions) was 63.0% ($n = 17$) for the modified MBSR group and 69.2%
(n = 18) for the modified MBCT group. There was no significant difference between the two groups in completion rate (p = .610).

Adverse reactions

No adverse events were reported in any of the mindfulness sessions, indicating that both modified interventions are safe.

Preliminary efficacy

Mixed ANOVA were conducted for all outcomes, and the results are given in Table 3. Significant time effects were found in all of the outcomes, including perceived stress (p = .030, Cohen’s d = .54), depressive symptoms (p = .002, Cohen’s d = .77), and subjective caregiver burden (p < .001, Cohen’s d = 1.12) at the three-month follow-up (T2). A significant interaction effect (Group x time) was found only for stress (p = .019, Cohen’s d = .63).

A Helmert’s contrasts test found significant improvements in: (1) stress at both T0-T1 and T0-T2 (mean difference = 1.74 and 1.98, standard error [SE] = .78 and .91, respectively); (2) depression at both T0-T1 and T0-T2 (mean difference = 3.61 and 4.05, standard error [SE] = 1.27 and 1.27, respectively); and (3) burden at both T0-T1 and T0-T2 (mean difference = 5.65 and 7.40, standard error [SE] = 1.47 and 1.55, respectively). There was no significant change between T1 and T2 in any of the psychological outcomes.

In the pairwise comparison of the outcomes of the two groups between time-points, the results showed that the Modified MBSR group showed significant improvement from T0 to T1 in burden (mean difference = 5.41, SE = 1.73, p = .013), while the Modified MBCT group showed significant improvement from T0 to T1 in stress (mean difference = 3.19, SE = 1.14, p = .030), and significant improvement from T1 to T2 in burden (mean
difference = 5.19, SE = 1.68, \( p = .014 \)). There were no significant differences in other outcomes in other time-point comparisons. The results are tabulated in Table 4.

**Trait Mindfulness**

The mixed ANOVA results showed that there was a significant time effect on mindfulness from T0 to T2 [\( F(2, 135) = 3.70, p = .040, \text{ partial } \eta^2 = .07 \)]. The results of the Helmert’s contrasts test indicated that the trait mindfulness of the participants improved significantly at both T0-T1 and T0-T2 (mean difference = 2.43 and 2.50, standard error [SE] = 1.16 and 1.22, respectively), but that there were no significant changes from T1 to T2.

**Discussion**

To the best of our knowledge, this is the first study to investigate the feasibility of two types of MBI, namely modified MBSR and modified MBCT, for improving the perceived stress and other psychological outcomes of caregivers of PWD; and to provide preliminary evidence of which intervention appears to be more effective. Our findings suggest that, given the good attendance rates, the modified MBSR and modified MBCT interventions are both feasible for use among family caregivers of PWD. In addition, a statistically significant increase in trait mindfulness in both the MBSR and MBCT groups demonstrated that our modified MBSR and MBCT protocols are effective at developing a mindful attitude in family caregivers. There were no reported adverse events during the mindfulness sessions. Comparing the effect between the two interventions, MBCT was
found to be more effective at reducing stress, with a similar improvement being observed in other outcomes including burden and depression.

This study reported a low dropout rate of 3.8%. Compared with a recent systematic review of the implementation of MBIs on family caregivers of PWD [39], which included four RCTs (n = 168) with attrition rates ranging from 10.3% to 17.2%, our study demonstrated the lowest attrition rate. We believe that the low attrition rate may be attributed to our modified protocol, in which we provided bi-weekly telephone follow-ups, reduced the number of face-to-face sessions from eight to seven, and abridged the whole-day retreat. Despite reducing the number of sessions, a significant increase in trait mindfulness was also identified immediately after the MBI. A study with a similar number of sessions also demonstrated a moderate to large effect size on psychological outcomes [25]. These outcomes support the argument that our modified interventions are sufficient to reduce the stress of caregivers of PWD.

Our findings showed that both modified protocols were effective at reducing the level of perceived stress, depressive symptoms, and subjective caregiver burden, and that the effects lasted for at least three months post-intervention. MBSR is widely used in non-clinical populations (e.g., health professionals and family caregivers), while MBCT is usually used in clinical settings (e.g., among people with recurrent depression or other mental illnesses). There are no standard guidelines for recommending either protocol to family caregivers of PWD [40]. In MBCT, techniques from cognitive behavioural therapy are used to promote greater awareness of depressive thought patterns. In the programme, mindfulness practices are used to help participants to disengage from negative thinking. In
fact, the prevalence of depression and psychological distress is high in family caregivers of PWD (ranging from 45.0% to 85.0%) resulting from recurrent negative thoughts about caregiving [41, 42]. Compared with MBSR, which uses psychoeducation to help participants recognize habitual, unhelpful reactions to difficulties, MBCT may be more helpful to family caregivers.

A significant interaction effect (Group x time) was found in the caregivers’ stress, indicating that the modified MBCT has a larger effect on reducing stress than the modified MBSR programme. Similar findings were also shown in a study in which 33 patients with comorbid depression and cardiovascular disease were randomized into three groups receiving adapted MBCT, MBSR, or the usual care [43]. Greater improvements in psychological outcomes, and higher acceptability and engagement were found in the adapted MBCT group than in the MBSR group and the usual care control group. The adapted MBCT focused more on depression-specific mechanisms, including rumination about the causes of disease, and the meanings and consequences of low mood, which would be more suitable for people with ruminative thoughts. Rumination refers to the focusing of attention on and the repetition of the same thoughts about various aspects of situations that are upsetting. It is a common symptom in family caregivers of PWD, who are highly stressed as a result of their negative thoughts about the progression of their relative’s disease and their own caregiving tasks [44]. This rumination aggravates the chronic stress that caregivers feel through a prolonged pattern of negative thinking [45]. This may explain why MBCT could have a larger effect on reducing stress than MBSR. Caregivers with more of a tendency to ruminate have higher levels of depression and anxiety, and lower
levels of satisfaction with life [44, 45]. Compared with MBSR, MBCT focuses more on negative thoughts and thus may be a better modality for improving the psychological health of caregivers of PWD. Given the small sample in this feasibility study, it is suggested that future randomized controlled trials with appropriate sample sizes be conducted to compare the effect between MBSR and MBCT in improving various psychological outcomes of caregivers.

Both MBSR and MBCT require the practise at home of mindfulness skills, the duration of which has been associated with beneficial effects [18]. However, some participants reported having difficulty finding the time to practise the 45-minute body scanning exercise. The 45-minute body scan is regarded as a major component of the original MBSR and MBCT protocols [11,13]. A body scan directs a caregiver’s attention to the present moment through observations of one’s breath and bodily sensations, while becoming aware of, and accepting without judgement, any thoughts and feelings that arise [13]. In the past few decades, several brief versions of the scan have been developed, ranging in duration from 10 to 30 minutes [46, 47]. The UCLA Mindful Awareness Research Center has also developed a 13-minute version of the body scanning technique [48]. Caregivers are busy people and may find it difficult to comply with the intervention. It is important to design interventions that consume less time but are effective. Since there are different brief versions of the mindfulness-based body scan, to increase compliance it is suggested that further research be conducted to compare the effects of the 45-minute body scan technique and the brief versions. Apart from the scan, both modified protocols involved other mindfulness activities, such as mindful eating, mindful walking, and sitting.
meditation, to help the participants develop a mindful attitude. We evaluated the caregivers’
trait mindfulness. The statistical analysis revealed that the improvement in trait mindfulness
was statistically significant.

Although our findings suggest that the modified MBCT is more effective at
reducing stress than the MBSR, the qualifications of the interventionist have to be
considered when advising caregivers of PWD. A UK survey of 103 MBCT interventionists
providing MBCT under the National Health Service found that over 67.0% of them
indicated that they had received insufficient training in delivering MBCT, and 54.0% had
not undertaken formal postgraduate training in MBCT. Keeping in good practice in the
coaching of mindfulness through formal training, continuing education, and supervision is
important in controlling and maximizing the effects of the intervention [49].

Limitations and suggestions

This study is not without limitations. First, the cognitive status or behavioural symptoms
of the people with dementia who were being cared for by the caregiver participants were
not measured. These are major stressors for caregivers [50], which might have affected the
results. Similarly, the positive effects of the interventions on psychological symptoms (i.e.,
perceived stress, depressive symptoms, and subjective caregiver burden) might have been
mediated by other factors. Examples of such factors are repetitive negative thinking, self-
compassion, cognitive and emotional reactivity, and psychological flexibility [11]. Second,
we did not precisely monitor the number of hours in which the participants were engaged in
the daily practise of mindfulness during and after the programme. During the telephone
follow-ups, we asked the participants about their home practise, but did not quantify the
data so that it could be used for analysis. This information would be useful in
understanding the participants’ adherence to the mindfulness-based intervention protocol
and in examining the relationship among adherence, the level of mastery of mindfulness,
and the outcomes of the study. Lastly, this study did not have a no-treatment control group,
which potentially weakens its internal validity.

Implications for future study

Based on the results of this feasibility study, several recommendations can be made
for the main study. First, the results of the feasibility suggested that the MBCT would be a
better modality of MBI for the family caregivers of PWD, compared with the MBSR. The
MBCT should be adopted in a future study and its effectiveness on reducing stress in family
caregivers of PWD investigated using larger samples and a control group. Second, the
pattern and duration of the MBCT protocol could be further revised in the later study to
further raise the completion rate in order to yield positive health outcomes. In addition, the
majority of family caregivers commented that the interval between the last three sessions
(one month) was too long. They could not immediately ask the therapist questions when
they encountered problems while practising the protocol, but needed to wait for the next
monthly session. Consideration should be given in a future study to adding several more
telephone follow-up sessions to monitor their progress and address their concerns. Lastly,
the relationship between the trait mindfulness and the psychological outcomes of the family
caregivers should be investigated in a future study. In this feasibility study, the family
caregivers experienced a significant increase in their trait mindfulness after attending the MBSR or MBCT programme. However, whether the improvement in their psychological outcomes was related to the increase in their trait mindfulness is unknown, and should be addressed in a future study.

Conclusion

Despite the abovementioned limitations, the findings of this study suggest that both the modified MBSR and modified MBCT are feasible for use among family caregivers of PWD, and that the modified MBCT may be more suitable for caregivers of PWD than the MBSR. These protocols can be further tested and compared with treatment as usual to confirm their effectiveness in this population.

Number of words: 4973
References


<table>
<thead>
<tr>
<th>Session</th>
<th>Theme</th>
<th>Modified MBSR Programme</th>
<th>Modified MBCT Programme</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1</td>
<td>Awakening to automatic pilot</td>
<td>Mindful awareness by paying attention, on purpose, in the present moment, non-judgementally. Activities: Raisin-eating meditation; abdominal breathing; body scan.</td>
<td>Waking up from automatic pilot</td>
</tr>
<tr>
<td>S2</td>
<td>Body-mind connectedness</td>
<td>Perception and creative responding by experiencing how to perceive pain, illness, and the stresses and pressures in life. Emphasizing the principle that it is not the stressors themselves but how they are to be handled and the level of commitment. Activities: Guided body scan; mindful yoga; guided sitting meditation with awareness of breathing.</td>
<td>Knowing in the awareness</td>
</tr>
<tr>
<td>S3</td>
<td>Pleasantness/Unpleasantness &amp; body-mind in the present moment</td>
<td>Emphasis on gentleness, non-judgement, curiosity, respect for current physical limits and non-striving. Noticing the tendency to label events as pleasant or unpleasant. Activities: Walking meditation; mindful yoga.</td>
<td>Living in the present</td>
</tr>
<tr>
<td>S4</td>
<td>Stress &amp; body-mind reactions</td>
<td>Emphasis on the development of concentration, openness to the full range of experiences, and a more flexible capacity</td>
<td>Recognizing aversion &amp; allowing</td>
</tr>
<tr>
<td>Section</td>
<td>Theme</td>
<td>Activities</td>
<td></td>
</tr>
<tr>
<td>---------</td>
<td>----------------------------</td>
<td>----------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>S5</td>
<td>Dancing with difficulties</td>
<td>Emphasis on the attentiveness to perception and appraisal in difficult moments. Exploring the effect of emotional reactivity in health and illness. Activities: Mindful yoga; sitting meditation with choiceless awareness; speaking and listening exercise.</td>
<td></td>
</tr>
<tr>
<td>S5</td>
<td>Thoughts are not facts</td>
<td>Highlighting how moods and feelings shape the frame of mind, which is constantly making meaning out of what is actually there in the world. Activities: Moods, thoughts, and alternative viewpoints exercise relating to distress in taking care of demented people; sitting with breath, body, and difficulty; 3-minute breathing space (responsive).</td>
<td></td>
</tr>
<tr>
<td>S6</td>
<td>Living moment to moment</td>
<td>Developing a greater awareness of interpersonal communication patterns particularly under situations of acute and chronic stress in order to cultivate the capacity for rapid recovery. Activities: Changing seat exercise; sitting meditation with choiceless awareness; speaking and listening exercise.</td>
<td></td>
</tr>
<tr>
<td>S6</td>
<td>Kindness – the healing power</td>
<td>Engaging in mastery or pleasurable activities as an act of kindness to oneself – changing what to do can change how to feel. Activities: Activity and mood exercise; identifying habitual emotional reactions to difficulties; sitting with breath, body, sounds, thoughts, choiceless awareness; 3-minute breathing space (responsive).</td>
<td></td>
</tr>
<tr>
<td>S7</td>
<td>Formal &amp; informal mindfulness in life</td>
<td></td>
<td></td>
</tr>
<tr>
<td>----</td>
<td>-------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Integrating the practise of mindfulness into daily life and identifying adaptive and self-limiting lifestyle choices. Maintaining momentum in the practise of mindfulness and reviewing related support to help integrate the learning over time.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Activities: Body scan; mindful yoga; sitting meditation; life nourishment.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>S7</th>
<th>Mindfulness in the caregiver’s life</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reflecting on what one has experienced, learned, and values most and how to integrate all this into the caregiver’s life. Consolidating the aims of MBCT in terms of recognizing habitual patterns of mind and cultivating a new way of being.</td>
</tr>
<tr>
<td></td>
<td>Activities: Looking forward exercise; Preparing for the future exercise; body scan; 3-minute breathing space (responsive).</td>
</tr>
</tbody>
</table>

MBSR = Mindfulness-based stress reduction, MBCT = Mindfulness-based cognitive therapy
## Table 2: Demographic and clinical characteristics of the participants at baseline

<table>
<thead>
<tr>
<th></th>
<th>Total (n = 53)</th>
<th>Modified MBSR (n = 27)</th>
<th>Modified MBCT (n = 26)</th>
<th>Test value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>( \chi^2 ) p value</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>46 (86.8)</td>
<td>24 (88.9)</td>
<td>22 (84.6)</td>
<td>.21</td>
</tr>
<tr>
<td>Male</td>
<td>7 (13.2)</td>
<td>3 (11.1)</td>
<td>4 (15.4)</td>
<td>.649</td>
</tr>
<tr>
<td>Educational level</td>
<td></td>
<td></td>
<td></td>
<td>1.49</td>
</tr>
<tr>
<td>Primary</td>
<td>7 (13.2)</td>
<td>5 (18.5)</td>
<td>2 (7.7)</td>
<td>.475</td>
</tr>
<tr>
<td>Secondary</td>
<td>18 (34.0)</td>
<td>8 (29.6)</td>
<td>10 (38.5)</td>
<td></td>
</tr>
<tr>
<td>Tertiary or university</td>
<td>28 (52.8)</td>
<td>14 (51.9)</td>
<td>14 (53.8)</td>
<td></td>
</tr>
<tr>
<td>Income per month (HKDS$)(^\d)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than $2000</td>
<td>16 (30.2)</td>
<td>7 (25.9)</td>
<td>9 (34.6)</td>
<td>9.35</td>
</tr>
<tr>
<td>$2000 - $9999</td>
<td>12 (22.7)</td>
<td>7 (25.9)</td>
<td>5 (19.2)</td>
<td>.229</td>
</tr>
<tr>
<td>$10000 - $19999</td>
<td>8 (15.1)</td>
<td>3 (11.1)</td>
<td>5 (19.2)</td>
<td></td>
</tr>
<tr>
<td>More than $200000</td>
<td>17 (32.1)</td>
<td>10 (37)</td>
<td>7 (26.9)</td>
<td></td>
</tr>
<tr>
<td>Relationship with the PWD</td>
<td></td>
<td></td>
<td></td>
<td>3.65</td>
</tr>
<tr>
<td>Spouse</td>
<td>4 (7.5)</td>
<td>3 (11.1)</td>
<td>1 (3.8)</td>
<td>.724</td>
</tr>
<tr>
<td>Parent</td>
<td>38 (71.7)</td>
<td>19 (70.3)</td>
<td>19 (73.1)</td>
<td></td>
</tr>
<tr>
<td>Grandparent</td>
<td>3 (5.7)</td>
<td>2 (7.7)</td>
<td>1 (3.8)</td>
<td></td>
</tr>
<tr>
<td>Parent-in-law</td>
<td>5 (9.4)</td>
<td>2 (7.7)</td>
<td>3 (11.4)</td>
<td></td>
</tr>
<tr>
<td>Other (e.g., sibling)</td>
<td>2 (3.8)</td>
<td>0 (0.0)</td>
<td>2 (7.6)</td>
<td></td>
</tr>
<tr>
<td>Number of participants attending ≥ 80% of sessions</td>
<td>35 (66.0)</td>
<td>17 (63.0)</td>
<td>18 (69.2)</td>
<td>.23 .630</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>t score</td>
<td>p value</td>
</tr>
<tr>
<td>Age</td>
<td>56.00 (9.26)</td>
<td>56.74 (9.49)</td>
<td>55.20 (9.12)</td>
<td>.60 .554</td>
</tr>
<tr>
<td>Mean duration of cognitive impairment (month)</td>
<td>71.09 (59.96)</td>
<td>84.63 (65.61)</td>
<td>55.4 (52.97)</td>
<td>1.71 .094</td>
</tr>
<tr>
<td>Mean duration of providing care to PWD (year)</td>
<td>8.71 (10.56)</td>
<td>9.43 (10.11)</td>
<td>\textbf{9.57} (11.16)</td>
<td>.50 .623</td>
</tr>
<tr>
<td>Attendance rate (%)</td>
<td>77.90 (24.99)</td>
<td>73.55 (28.45)</td>
<td>82.42 (20.32)</td>
<td>-1.30 .197</td>
</tr>
<tr>
<td>PSS total score</td>
<td>26.00 (6.24)</td>
<td>24.63 (5.94)</td>
<td>27.42 (6.34)</td>
<td>-.84 .403</td>
</tr>
<tr>
<td>CESD total score</td>
<td>17.87 (9.50)</td>
<td>17.15 (10.25)</td>
<td>18.62 (8.79)</td>
<td>-.12 .912</td>
</tr>
<tr>
<td>ZBI total score</td>
<td>40.02 (13.95)</td>
<td>38.48 (13.04)</td>
<td>41.62 (14.92)</td>
<td>-.43 .672</td>
</tr>
<tr>
<td>FFMQ-SF total score</td>
<td>62.96 (10.35)</td>
<td>63.33 (10.94)</td>
<td>60.26 (9.90)</td>
<td>.90 .371</td>
</tr>
</tbody>
</table>

\(^\d\)Test value: Chi-square or Independent sample t test (2-tailed) was used.

\(^\dd\)Income per month: USD$1 = HKD$7.8.

PSS = Perceived Stress Scale; CES-D = Centre of Epidemiological Studies – Depression; ZBI = Zarit Burden Interview; FFMQ = Five-Facet Mindfulness Questionnaire Short Form.
### TABLE 3: Outcome measure at three time-points and results of mixed ANOVA

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Modified MBSR (n = 27)</th>
<th>Modified MBCT (n = 26)</th>
<th>Time effect</th>
<th>Group effect</th>
<th>Group × Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T0</td>
<td>T1</td>
<td>T2</td>
<td>M</td>
<td>SD</td>
</tr>
<tr>
<td>PSS</td>
<td>24.63</td>
<td>5.94</td>
<td>24.85</td>
<td>5.68</td>
<td>24.70</td>
</tr>
<tr>
<td>CESD</td>
<td>17.15</td>
<td>10.25</td>
<td>14.81</td>
<td>8.95</td>
<td>14.59</td>
</tr>
<tr>
<td>ZBI</td>
<td>38.48</td>
<td>13.04</td>
<td>33.07</td>
<td>11.93</td>
<td>33.37</td>
</tr>
<tr>
<td>FFMQ-SF</td>
<td>63.33</td>
<td>10.94</td>
<td>64.88</td>
<td>8.63</td>
<td>65.48</td>
</tr>
</tbody>
</table>

*p < .05, **p < .01, ***p < .001.

T0: baseline; T1: immediate post-intervention; T2: 3 months follow-up; PSS: Perceived Stress Scale; CESD, Center for Epidemiological Studies Depression Scale; ZBI: Zarit Burden Interview; FFMQ-SF: Five Facet Mindfulness Questionnaire-Short form.
### TABLE 4: Pairwise comparison of the outcomes between time-points of the two groups with a Bonferroni adjustment

<table>
<thead>
<tr>
<th>Time-points</th>
<th>Mean difference</th>
<th>SE</th>
<th>p value†</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PSS total score</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Modified MBSR</td>
<td>T0 – T1</td>
<td>-.41</td>
<td>.73</td>
<td>1.000</td>
</tr>
<tr>
<td></td>
<td>T1 – T2</td>
<td>.33</td>
<td>.82</td>
<td>1.000</td>
</tr>
<tr>
<td></td>
<td>T0 – T2</td>
<td>-.07</td>
<td>.93</td>
<td>1.000</td>
</tr>
<tr>
<td>Modified MBCT</td>
<td>T0 – T1</td>
<td>3.19</td>
<td>1.14</td>
<td>.030*</td>
</tr>
<tr>
<td></td>
<td>T1 – T2</td>
<td>.73</td>
<td>1.01</td>
<td>1.000</td>
</tr>
<tr>
<td></td>
<td>T0 – T2</td>
<td>3.92</td>
<td>1.59</td>
<td>.061</td>
</tr>
<tr>
<td><strong>CESD total score</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Modified MBSR</td>
<td>T0 – T1</td>
<td>2.33</td>
<td>1.83</td>
<td>.637</td>
</tr>
<tr>
<td></td>
<td>T1 – T2</td>
<td>.22</td>
<td>.82</td>
<td>1.000</td>
</tr>
<tr>
<td></td>
<td>T0 – T2</td>
<td>2.56</td>
<td>1.73</td>
<td>.452</td>
</tr>
<tr>
<td>Modified MBCT</td>
<td>T0 – T1</td>
<td>3.73</td>
<td>2.13</td>
<td>.276</td>
</tr>
<tr>
<td></td>
<td>T1 – T2</td>
<td>.42</td>
<td>.99</td>
<td>1.000</td>
</tr>
<tr>
<td></td>
<td>T0 – T2</td>
<td>4.15</td>
<td>2.31</td>
<td>.253</td>
</tr>
<tr>
<td><strong>ZBI total score</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Modified MBSR</td>
<td>T0 – T1</td>
<td>5.41</td>
<td>1.73</td>
<td>.013*</td>
</tr>
<tr>
<td></td>
<td>T1 – T2</td>
<td>.30</td>
<td>1.44</td>
<td>1.000</td>
</tr>
<tr>
<td></td>
<td>T0 – T2</td>
<td>5.11</td>
<td>2.11</td>
<td>.068</td>
</tr>
<tr>
<td>Modified MBCT</td>
<td>T0 – T1</td>
<td>4.46</td>
<td>2.84</td>
<td>.385</td>
</tr>
<tr>
<td></td>
<td>T1 – T2</td>
<td>5.19</td>
<td>1.68</td>
<td>.014*</td>
</tr>
<tr>
<td></td>
<td>T0 – T2</td>
<td>9.65</td>
<td>2.28</td>
<td>.001</td>
</tr>
<tr>
<td><strong>FFMQ-SF total score</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Modified MBSR</td>
<td>T0 – T1</td>
<td>-1.56</td>
<td>1.37</td>
<td>.797</td>
</tr>
<tr>
<td></td>
<td>T1 – T2</td>
<td>-.59</td>
<td>1.09</td>
<td>1.000</td>
</tr>
<tr>
<td></td>
<td>T0 – T2</td>
<td>-2.15</td>
<td>1.43</td>
<td>.435</td>
</tr>
<tr>
<td>Modified MBCT</td>
<td>T0 – T1</td>
<td>-5.81</td>
<td>2.82</td>
<td>.149</td>
</tr>
<tr>
<td></td>
<td>T1 – T2</td>
<td>1.00</td>
<td>1.08</td>
<td>1.000</td>
</tr>
<tr>
<td></td>
<td>T0 – T2</td>
<td>-4.81</td>
<td>2.44</td>
<td>.179</td>
</tr>
</tbody>
</table>

† p value: Bonferroni adjustment for multiple comparisons.
* p < .05, ** p < .01, *** p < .001.

T0: baseline; T1: immediate post-intervention; T2: 3 months follow-up; PSS: Perceived Stress Scale; CESD: Center for Epidemiological Studies Depression Scale; ZBI: Zarit Burden Interview; FFMQ-SF: Five Facet Mindfulness Questionnaire-Short form.
Figure 1 Consolidated Standards of Reporting Trials (CONSORT) flow diagram