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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

Daphne Sze Ki Cheung, PhD., Assistant Professor, Patrick Pui Kin Kor, PhD., Clinical Instructor, Cindy Jones, PhD., Associate Professor, Nathan Davies, PhD., Senior Research Fellow, Wendy Moyle, PhD., Professor, Wai Tong Chien, PhD., Professor, Annie Lai King Yip, MSc., Senior Clinical Associate, Suzanne Chambers, PhD., Professor, Clare Tsz Kiu Yu, Research Assistant, Claudia Lai, PhD., Honorary Professor

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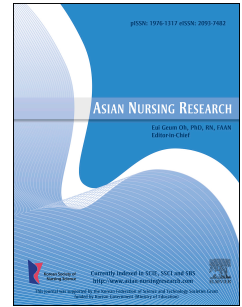
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Title: The use of modified Mindfulness-based Stress Reduction and Mindfulness-based Cognitive Therapy programme for family caregivers of people living with dementia: a feasibility study

Running head: Mindfulness-Based Interventions for Dementia Caregiver

D. S. K. Cheung¹, P. P. K. Kor², C. Jones³, N. Davies⁴, W. Moyle⁵, W.T. Chien⁶, A. L. K. Yip⁷, S. Chambers⁸, C. T. K. Yu⁹, C. K. Y. Lai¹⁰

¹Cheung Daphne Sze Ki, PhD. Assistant Professor, School of Nursing, The Hong Kong Polytechnic University, Hong Kong SAR;

¹Kor, Patrick Pui Kin, PhD. Clinical Instructor, School of Nursing, The Hong Kong Polytechnic University, Hong Kong SAR;

²Jones Cindy, PhD. Associate Professor, Faculty of Health Sciences & Medicine, Bond University, Gold Coast, Australia;

³Davies, Nathan, PhD. Senior Research Fellow, Primary Care and Population Health, UCI Medical School, University College London, London, United Kingdom;

⁴Moyle, Wendy, PhD. Professor, School of Nursing and Midwifery, Griffith University, Brisbane, Australia;

⁵Chien, Wai Tong, PhD. Professor, The Nethersole School of Nursing, The Chinese University of Hong Kong, Hong Kong SAR;

¹Yip, Annie Lai King, MSc. Senior Clinical Associate, School of Nursing, The Hong Kong Polytechnic University, Hong Kong SAR;

⁴Chambers, Suzanne, PhD. Professor, Menzies Health Institute QLD, Griffith University, Australia;

¹Yu, Clare Tsz Kiu. Research Assistant, School of Nursing, The Hong Kong Polytechnic University, Hong Kong SAR;

¹Lai, Claudia, PhD. Honorary Professor, School of Nursing, The Hong Kong Polytechnic University, Hong Kong SAR.

Correspondence: Prof. Claudia Lai Kam Yuk,
School of Nursing, The Hong Kong Polytechnic University,
Hung Hom, Kowloon, Hong Kong
Tel: +852 27664290
Fax: +852 23649633
Email: claudia.lai@polyu.edu.hk

Declaration of interests

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1 **Abstract**

2 **Purpose**

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

7 **Methods**

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

13 **Results**

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

20 **Conclusions**

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

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

27

28

29 **Introduction**

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

41 Researchers are keen to develop interventions to reduce the perceived stress of
42 caregivers of PWD and improve their well-being. Such interventions have included case
43 management, cognitive stimulation, cognitive and behavioural interventions, education,
44 physical activity interventions, psychosocial support, relaxation, respite, and skill-building
45 [6]. Although most psychosocial interventions appear to be effective at reducing caregiver
46 stress and psychological morbidity [7-9], the treatment effect sizes have been relatively
47 small and inconsistent [10].

48 Mindfulness-Based Interventions (MBIs) have been broadly used to reduce stress
49 and emotional problems in both healthy individuals and caregivers of people with chronic
50 conditions, as well as to improve mental health and well-being in general, with consistent

51 and promising results [11-12]. MBIs help participants to focus on the experience of the
52 present moment and adopt an orientation of openness and acceptance towards their
53 experience [13]. Through practising the meditation exercises in the MBI, improvements
54 were observed in trait mindfulness (a keen awareness and attention to our thoughts and
55 feelings in the present moment), cognitive reactivity, and emotional reactivity, leading to
56 insight and a non-reactive acceptance of one's experience, which in turn eventually led to
57 positive psychological outcomes [11]. In recent years, MBIs are increasingly being used to
58 reduce stress in caregivers of PWD. However, a Cochrane Review reported that the existing
59 evidence found in the majority of prior trials is of low to very low quality and that the risk
60 of bias is high (e.g., performance bias, detection bias) [14], which may hinder the use of
61 MBIs in clinical practice. Also, different forms of MBIs were adopted in previous studies.
62 It is therefore important to find an appropriate modality of MBIs for caregivers of PWD
63 before conducting a more rigorous clinical trial to test its effectiveness.

64 The most popular types of MBIs are Mindfulness-Based Stress Reduction (MBSR)
65 and Mindfulness-Based Cognitive Therapy (MBCT). MBSR was used as early as 1979 as a
66 training vehicle to relieve pain and distress in the general population with chronic health
67 problems [11]. Later, it was integrated with Cognitive Theory and Cognitive Behavioural
68 Therapy to create MBCT, and used for preventing the relapse or reoccurrence of depression
69 in people who had been diagnosed with that ailment [11]. Both types of interventions have
70 been preliminarily tested with caregivers in separate studies and found to be effective at
71 reducing stress and promoting well-being [15-17]. In the MBSR, caregivers learn about
72 how to adopt mindfulness to respond to the stressors of caregiving. In the MBCT,

73 caregivers learn more about how to disengage with their negative thinking patterns through
74 mindfulness and CBT techniques. Although the programmes appear to be very similar in
75 structure and content, it is not known which intervention is more suitable. Since family
76 caregivers are a non-clinical population, MBSR would be an appropriate approach [18].
77 However, several studies have indicated that the majority of family caregivers of PWD
78 experience depressive symptoms resulting from repeatedly thinking about the unpredictable
79 progress of the disease and the symptoms of the PWD [19]. Family caregivers of PWD
80 always report higher levels of stress than the family caregivers of people with other chronic
81 diseases [20]. The MBCT, which targets ruminative thoughts, may be more suitable for
82 family caregivers of PWD.

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

91 **Purpose of this study**

92 The aim of this study was to (1) investigate the feasibility of implementing the
93 modified MBSR and modified MBCT protocols on family caregivers of PWD; and (2)
94 explore and compare the preliminary efficacy of the two interventions in improving the

95 psychological symptoms of the caregivers, namely, perceived stress, depressive symptoms,
96 and subjective caregiver burden.

97

98 **Methods**

99 *Design*

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

103 *Participants*

104 The participants were family caregivers of PWD. Convenience sampling was
105 adopted to recruit family caregivers from two elderly centres in Hong Kong that provide
106 dementia services. The inclusion and exclusion criteria were drawn from the standard
107 practice guideline of the Mindfulness-Based Stress Reduction Programme (MBSR)
108 published by the Centre of Mindfulness, University of Massachusetts Medical School [21].
109 The criteria for participation included: (a) being 18 years or older; (b) being the primary
110 family caregiver of an individual with a confirmed medical diagnosis of dementia who is
111 residing in the community; and (c) having provided care for at least three months prior to
112 recruitment. In this study, a primary caregiver is defined as an unpaid individual who has a
113 significant personal relationship with the person with whom he/she is living and who assists
114 that person with the activities of daily living. Excluded were those with (a) acute mental
115 disorders; (b) serious or chronic pain and/or a physical disease such as cancer and

116 cardiovascular disease in an acute phase; and/or (c) those who had participated in any MBI,
117 cognitive therapy, or structured psychosocial intervention in the six months prior to
118 recruitment. Verification of eligibility was conducted individually before the signing of the
119 consent to participate form.

120 ***Sample size***

121 For feasibility studies, it may not be possible to produce a formal calculation of
122 sample size. However, minimum sample sizes of between 24 and 50 have been recommended
123 [22-23]. Therefore, in this study, a minimum sample size of 50 was required, although 53
124 caregivers were ultimately recruited.

125 ***Interventions (Modified MBSR and Modified MBCT)***

126 To improve the adherence of family caregivers to the MBSR and MBCT
127 programmes, we made the following changes to the MBSR and MBCT protocols by 1)
128 integrating the content of some sessions to shorten the face-to-face training, 2) providing
129 telephone follow-ups to monitor their progress and adherence to the practice of mindfulness
130 and; 3) extending the last three sessions from weekly to bi-weekly to help the participants
131 develop a habit of practising mindfulness on a daily basis. The modifications to the
132 protocols were based on recommendations from previous studies [24-29]. The protocols
133 were then reviewed by a panel of experts consisting of mindfulness interventionists,
134 registered nurses experienced in dementia care, and a clinical psychologist. Details of the
135 modifications and the rationales for them can be found in our recent publications [24].

136 Both intervention programmes lasted for 16 weeks and consisted of seven 2.5-hour
137 face-to-face group-based training sessions. In the first month, the participants took part in
138 four weekly sessions, followed by three monthly sessions. In between the three monthly
139 sessions, three trained research assistants with nursing backgrounds provided bi-weekly 15-
140 minute telephone follow-ups (a total of three times) to encourage and advise the
141 participants, and to ensure fidelity to the intervention. A certified cognitive therapist, who
142 was also a mental health nurse as well as a mindfulness teacher with more than 10 years of
143 experience, delivered both interventions. An audio CD of recordings of mindfulness
144 exercises was also provided to all participants.

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

154 *Measurements*

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

158 ***Feasibility assessment***

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

164 ***Efficacy***

165 To explore the efficacy of the two interventions, psychological outcomes were
166 measured at baseline before randomization (T0), immediately post-intervention (T1), and
167 three months after the intervention (T2). The primary psychological outcome was the
168 participants' perceived stress. Secondary psychological outcomes were depressive
169 symptoms and subjective caregiver burden, which have been found to be related to MBIs
170 [15, 32]. We also examined trait mindfulness as a process indicator, as it had been
171 identified in previous studies as an indicator of the participants' mastery of mindfulness
172 skills [11]. Trait mindfulness refers to a state of keen awareness and attention to our
173 thoughts and feelings in the present moment [33].

174 (1) The primary psychological outcome

175 Perceived stress was assessed using the Chinese version of the Perceived Stress
176 Scale (PSS) [35]. This is a 14-item, self-reported scale that is employed to evaluate
177 the degree to which individuals appraise situations in their lives as stressful in the
178 previous month, using a 5-point Likert Scale (0 = never to 4 = very often). The total

179 score ranges from zero to 56, with higher scores indicating greater perceived stress.
180 The Chinese version of the PSS (C-PSS) was tested in the community, with 500
181 adults receiving mindfulness interventions. A factor analysis revealed that the scale
182 contains two factors (namely, positive and negative factors), with a factor loading
183 ranging from 0.26 to 0.78 and a Cronbach's alpha of between 0.76 and 0.83. The
184 test-retest reliability coefficient was 0.85 (Chu & Kao, 2005). These results support
185 the view that the scale is a reliable and valid instrument [34].

186 (2) Secondary psychological outcomes

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

200 Subjective caregiver burden was assessed using the Chinese version of the Zarit
201 Burden Interview (ZBI) [37]. For each of the 22 items, the participants were asked

202 to indicate their level of caregiving distress on a 5-point Likert Scale (0 = never to 4
203 = nearly always). Higher total scores indicate a greater caregiver burden. This
204 instrument demonstrated a high intraclass correlation coefficient of 0.99 and a split-
205 half correlation coefficient of 0.81 [37]. The correlation between the ZBI and the
206 General Health Questionnaire was 0.59, and between the ZBI and the Activity
207 Survey was 0.57. This supports the view that the scale is a reliable and valid
208 instrument [37].

209 (3) Process indicator

210 Trait Mindfulness was assessed using the Chinese version of the Five-Facet
211 Mindfulness Questionnaire – Short Form (FFMQ-SF) [38]. The FFMQ-SF consists
212 of 20 items in five domains, namely: observing (4 items), describing (4 items), non-
213 judging of experience (4 items), acting with awareness (4 items), and non-reactivity
214 to inner experience (4 items). The participants were asked to rate these items on a 5-
215 point Likert Scale (1 = never to 5 = very often). A higher total score (ranging from
216 20 – 100) reflects a higher level of trait mindfulness, which could support their
217 mastery of the mindfulness skills, resulting in an increase in trait mindfulness. The
218 Chinese version of the FFMQ was tested among Chinese adults in the community (n
219 = 230), and among adult and clinical patients with significant psychological distress
220 (n = 156) (Hou et al., 2014a). Internal consistency was high in five subscales: non-
221 reactivity = 0.75, observing = 0.83, acting with awareness = 0.87, nonjudging =
222 0.87, and describing = 0.91. The results showed good test-retest reliability (0.88)
223 and a high level of internal consistency of 0.83 in the community sample and 0.80

224 in the clinical sample). This supports the view that the scale is a reliable and valid
225 instrument [38].

226 *Randomization and blinding*

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

234 *Ethical considerations*

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

239

240 *Data analysis*

241 Quantitative data were entered, managed, and analysed using IBM SPSS Statistics
242 Version 23.0 (IBM Corp, 2015). To determine the feasibility of the interventions (objective
243 1), the recruitment, attendance, and completion rates of the two programmes were
244 descriptively reported in percentage and mean (standard deviation) terms where appropriate.

245 To explore and compare the efficacy of the two interventions (objective 2), mixed ANOVA
246 was conducted to examine the change in psychological outcomes and trait mindfulness
247 across time-points in the two groups. All of the participants were included in the final
248 analysis based on an intention-to-treat principle. Missing data were replaced using the last
249 observation carried forward method. To assess homogeneity between the two groups, an
250 independent t-test (as the data were found to be normally distributed) and a Chi-square test
251 were used for continuous and categorical baseline data, respectively. Preliminary statistical
252 assumptions were tested, and no violations were noted on normality, linearity, univariate
253 and multivariate outliers, the homogeneity of the variance-covariance matrices, and multi-
254 collinearity. Since there were three-time points of measurement in this study, a Helmert
255 contrast test was performed to examine which pairs of time-points (i.e., T0-T1, T0-T2, T1-
256 T2) showed differences if there was a significant Group x Time interaction effect. To
257 further investigate changes in the outcomes of two individual groups between time-points, a
258 pairwise comparison with a Bonferroni adjustment was conducted. All of the participants
259 were included in the final analysis based on the intention-to-treat principle involving 27
260 caregivers in the MBSR group and 26 caregivers in the MBCT group.

261 **Results**

262 *Participant characteristics*

263 Ninety-seven family caregivers showed an interest in joining this study. Of these,
264 80 met the sample selection criteria and 53 agreed to take part in the study (please refer to
265 the CONSORT flow chart in Figure 1). The participants were randomly allocated into
266 either the modified MBSR group (n = 27) or the modified MBCT (n = 26) group Their

267 demographic and clinical characteristics are summarized in Table 2. All of the participants
268 were Chinese (100%) and the majority were female (86.8%). Their mean age was 56 (SD =
269 9.26) years. Most of the participants were the adult children of people with dementia for
270 whom they were the caregivers (71.7%). The average duration of cognitive impairment in
271 the people with dementia was 71.1 (SD = 59.96) months, while the average duration of
272 caregiving was 8.72 (SD = 10.56) years. No significant differences were found between the
273 two groups in any of the demographic and clinical characteristics at baseline.

274 *Feasibility of the interventions*

275 *Recruitment*

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

282 *Attendance*

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

286 *Completion*

287 The overall dropout rate was 3.8%. The completion rate (defined as having attended
288 80% or more of the sessions) was 63.0% ($n = 17$) for the modified MBSR group and 69.2%

289 (n = 18) for the modified MBCT group. There was no significant difference between the
290 two groups in completion rate ($p = .610$).

291 *Adverse reactions*

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

294 *Preliminary efficacy*

295 Mixed ANOVA were conducted for all outcomes, and the results are given in Table
296 3. Significant time effects were found in all of the outcomes, including perceived stress (p
297 = .030, Cohen's $d = .54$), depressive symptoms ($p = .002$, Cohen's $d = .77$), and subjective
298 caregiver burden ($p < .001$, Cohen's $d = 1.12$) at the three-month follow-up (T2). A
299 significant interaction effect (Group x time) was found only for stress ($p = .019$, Cohen's d
300 = .63).

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

307 In the pairwise comparison of the outcomes of the two groups between time-points,
308 the results showed that the Modified MBSR group showed significant improvement from
309 T0 to T1 in burden (mean difference = 5.41, SE = 1.73, $p = .013$), while the Modified
310 MBCT group showed significant improvement from T0 to T1 in stress (mean difference =
311 3.19, SE = 1.14, $p = .030$), and significant improvement from T1 to T2 in burden (mean

312 difference = 5.19, SE = 1.68, $p = .014$). There were no significant differences in other
313 outcomes in other time-point comparisons. The results are tabulated in Table 4.

314 *Trait Mindfulness*

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

321

322 **Discussion**

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

333 found to be more effective at reducing stress, with a similar improvement being observed in
334 other outcomes including burden and depression.

335 This study reported a low dropout rate of 3.8%. Compared with a recent systematic
336 review of the implementation of MBIs on family caregivers of PWD [39], which included
337 four RCTs ($n = 168$) with attrition rates ranging from 10.3% to 17.2%, our study
338 demonstrated the lowest attrition rate. We believe that the low attrition rate may be
339 attributed to our modified protocol, in which we provided bi-weekly telephone follow-ups,
340 reduced the number of face-to-face sessions from eight to seven, and abridged the whole-
341 day retreat. Despite reducing the number of sessions, a significant increase in trait
342 mindfulness was also identified immediately after the MBI. A study with a similar number
343 of sessions also demonstrated a moderate to large effect size on psychological outcomes
344 [25]. These outcomes support the argument that our modified interventions are sufficient to
345 reduce the stress of caregivers of PWD.

346 Our findings showed that both modified protocols were effective at reducing the
347 level of perceived stress, depressive symptoms, and subjective caregiver burden, and that
348 the effects lasted for at least three months post-intervention. MBSR is widely used in non-
349 clinical populations (e.g., health professionals and family caregivers), while MBCT is
350 usually used in clinical settings (e.g., among people with recurrent depression or other
351 mental illnesses). There are no standard guidelines for recommending either protocol to
352 family caregivers of PWD [40]. In MBCT, techniques from cognitive behavioural therapy
353 are used to promote greater awareness of depressive thought patterns. In the programme,
354 mindfulness practices are used to help participants to disengage from negative thinking. In

355 fact, the prevalence of depression and psychological distress is high in family caregivers of
356 PWD (ranging from 45.0% to 85.0%) resulting from recurrent negative thoughts about
357 caregiving [41, 42]. Compared with MBSR, which uses psychoeducation to help
358 participants recognize habitual, unhelpful reactions to difficulties, MBCT may be more
359 helpful to family caregivers.

360 A significant interaction effect (Group x time) was found in the caregivers' stress,
361 indicating that the modified MBCT has a larger effect on reducing stress than the modified
362 MBSR programme. Similar findings were also shown in a study in which 33 patients with
363 comorbid depression and cardiovascular disease were randomized into three groups
364 receiving adapted MBCT, MBSR, or the usual care [43]. Greater improvements in
365 psychological outcomes, and higher acceptability and engagement were found in the
366 adapted MBCT group than in the MBSR group and the usual care control group. The
367 adapted MBCT focused more on depression-specific mechanisms, including rumination
368 about the causes of disease, and the meanings and consequences of low mood, which would
369 be more suitable for people with ruminative thoughts. Rumination refers to the focusing of
370 attention on and the repetition of the same thoughts about various aspects of situations that
371 are upsetting. It is a common symptom in family caregivers of PWD, who are highly
372 stressed as a result of their negative thoughts about the progression of their relative's
373 disease and their own caregiving tasks [44]. This rumination aggravates the chronic stress
374 that caregivers feel through a prolonged pattern of negative thinking [45]. This may explain
375 why MBCT could have a larger effect on reducing stress than MBSR. Caregivers with
376 more of a tendency to ruminate have higher levels of depression and anxiety, and lower

377 levels of satisfaction with life [44, 45]. Compared with MBSR, MBCT focuses more on
378 negative thoughts and thus may be a better modality for improving the psychological health
379 of caregivers of PWD. Given the small sample in this feasibility study, it is suggested that
380 future randomized controlled trials with appropriate sample sizes be conducted to compare
381 the effect between MBSR and MBCT in improving various psychological outcomes of
382 caregivers.

383 Both MBSR and MBCT require the practise at home of mindfulness skills, the
384 duration of which has been associated with beneficial effects [18]. However, some
385 participants reported having difficulty finding the time to practise the 45-minute body
386 scanning exercise. The 45-minute body scan is regarded as a major component of the
387 original MBSR and MBCT protocols [11,13]. A body scan directs a caregiver's attention to
388 the present moment through observations of one's breath and bodily sensations, while
389 becoming aware of, and accepting without judgement, any thoughts and feelings that arise
390 [13]. In the past few decades, several brief versions of the scan have been developed,
391 ranging in duration from 10 to 30 minutes [46, 47]. The UCLA Mindful Awareness
392 Research Center has also developed a 13-minute version of the body scanning technique
393 [48]. Caregivers are busy people and may find it difficult to comply with the intervention. It
394 is important to design interventions that consume less time but are effective. Since there are
395 different brief versions of the mindfulness-based body scan, to increase compliance it is
396 suggested that further research be conducted to compare the effects of the 45-minute body
397 scan technique and the brief versions. Apart from the scan, both modified protocols
398 involved other mindfulness activities, such as mindful eating, mindful walking, and sitting

399 meditation, to help the participants develop a mindful attitude. We evaluated the caregivers'
400 trait mindfulness. The statistical analysis revealed that the improvement in trait mindfulness
401 was statistically significant.

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

410

411 **Limitations and suggestions**

412 This study is not without limitations. First, the cognitive status or behavioural symptoms
413 of the people with dementia who were being cared for by the caregiver participants were
414 not measured. These are major stressors for caregivers [50], which might have affected the
415 results. Similarly, the positive effects of the interventions on psychological symptoms (i.e.,
416 perceived stress, depressive symptoms, and subjective caregiver burden) might have been
417 mediated by other factors. Examples of such factors are repetitive negative thinking, self-
418 compassion, cognitive and emotional reactivity, and psychological flexibility [11]. Second,
419 we did not precisely monitor the number of hours in which the participants were engaged in

420 the daily practise of mindfulness during and after the programme. During the telephone
421 follow-ups, we asked the participants about their home practise, but did not quantify the
422 data so that it could be used for analysis. This information would be useful in
423 understanding the participants' adherence to the mindfulness-based intervention protocol
424 and in examining the relationship among adherence, the level of mastery of mindfulness,
425 and the outcomes of the study. Lastly, this study did not have a no-treatment control group,
426 which potentially weakens its internal validity.

427 **Implications for future study**

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

442 caregivers experienced a significant increase in their trait mindfulness after attending the
443 MBSR or MBCT programme. However, whether the improvement in their psychological
444 outcomes was related to the increase in their trait mindfulness is unknown, and should be
445 addressed in a future study.

446 **Conclusion**

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

452

453 **Number of words:** 4973

454

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TABLE 1: Modified MBSR and Modified MBCT Protocols

Modified MBSR Programme			Modified MBCT Programme		
Session	Theme	Description & Activities	Session	Theme	Description & Activities
S1	Awakening to automatic pilot	Mindful awareness by paying attention, on purpose, in the present moment, non-judgementally. <u>Activities: Raisin-eating meditation; abdominal breathing; body scan.</u>	S1	Waking up from automatic pilot	Emphasis on our minds being taken over by the doing mode – the automatic pilot, then to the driven-doing mode – the rumination. <u>Activities: Raisin-eating meditation; body scan.</u>
S2	Body-mind connectedness	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. <u>Activities: Guided body scan; mindful yoga; guided sitting meditation with awareness of breathing.</u>	S2	Knowing in the awareness	Experiencing the doing mode so that we know about our experience through thought, and the knowing in the awareness through direct experience. <u>Activities: Thoughts & feelings exercises; body scan; brief mindfulness of breathing.</u>
S3	Pleasantness/ Unpleasantness & body-mind in the present moment	Emphasis on gentleness, non-judgement, curiosity, respect for current physical limits and non-striving. Noticing the tendency to label events as pleasant or unpleasant. <u>Activities: Walking meditation; mindful yoga.</u>	S3	Living in the present	Learning to disengage from unhelpful and unintended mental time travel and to gather and settle scattered minds. <u>Activities: Focus on unpleasant experiences exercises; practise seeing/hearing; sitting with breath and body and responding to painful sensations; 3-minute breathing space; combining stretching and breath meditation; mindful movement.</u>
S4	Stress & body-mind reactions	Emphasis on the development of concentration, openness to the full range of experiences, and a more flexible capacity	S4	Recognizing aversion & allowing	Emphasis on turning to face, investigate, and recognize unpleasant feelings and reactions to them so that

		<p>for attention. Learning new ways to reduce the negative effects of stress reactivity and developing effective ways of responding positively to stressful situations. Highlighting the conditioned patterns of stress reaction – fight and flight reactivity.</p> <p><u>Activities: Mindful yoga; sitting meditation with a focus on breathing, body sensations, and the whole body; choiceless awareness/open presence.</u></p>			<p>they can be held in awareness and met with a conscious response rather than an automatic reaction. Allowing difficult feelings, thoughts, sensations, and inner experiences to be held in awareness and to be just as they already are.</p> <p><u>Activities: Defining the territory of depression exercise; sitting with breath, body, sounds, thoughts, open awareness; 3-minute breathing space (regular); mindful walking; expanded breathing space.</u></p>
S5	Dancing with difficulties	<p>Emphasis on the attentiveness to perception and appraisal in difficult moments. Exploring the effect of emotional reactivity in health and illness.</p> <p><u>Activities: Mindful yoga; sitting meditation with choiceless awareness; speaking and listening exercise.</u></p>	S5	Thoughts are not facts	<p>Highlighting how moods and feelings shape the frame of mind, which is constantly making meaning out of what is actually there in the world.</p> <p><u>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).</u></p>
S6	Living moment to moment	<p>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.</p> <p><u>Activities: Changing seat exercise; sitting meditation with choiceless awareness; speaking and listening exercise.</u></p>	S6	Kindness – the healing power	<p>Engaging in mastery or pleasurable activities as an act of kindness to oneself – changing what to do can change how to feel.</p> <p><u>Activities: Activity and mood exercise; identifying habitual emotional reactions to difficulties; sitting with breath, body, sounds, thoughts, choiceless awareness; 3-minute breathing space (responsive).</u></p>

S7	Formal & informal mindfulness in life	<p>Integrating the practise of mindfulness into daily life and identifying adaptive and self-limiting lifestyle choices.</p> <p>Maintaining momentum in the practise of mindfulness and reviewing related support to help integrate the learning over time.</p> <p><u>Activities: Body scan; mindful yoga; sitting meditation; life nourishment.</u></p>	S7	Mindfulness in the caregiver's life	<p>Reflecting on what one has experienced, learned, and values most and how to integrate all this into the caregiver's life.</p> <p>Consolidating the aims of MBCT in terms of recognizing habitual patterns of mind and cultivating a new way of being.</p> <p><u>Activities: Looking forward exercise; Preparing for the future exercise; body scan; 3-minute breathing space (responsive).</u></p>
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MBSR = Mindfulness-based stress reduction, MBCT = Mindfulness-based cognitive therapy

TABLE 2: Demographic and clinical characteristics of the participants at baseline

	Total (n = 53)	Modified MBSR (n = 27)	Modified MBCT (n = 26)	Test value [†]	<i>p</i> valu e
	n (%)	n (%)	n (%)	χ^2	
Gender				.21	.649
Female	46 (86.8)	24 (88.9)	22 (84.6)		
Male	7 (13.2)	3 (11.1)	4 (15.4)		
Educational level				1.49	.475
Primary	7 (13.2)	5 (18.5)	2 (7.7)		
Secondary	18 (34.0)	8 (29.6)	10 (38.5)		
Tertiary or university	28 (52.8)	14 (51.9)	14 (53.8)		
Income per month (HKD\$) [‡]				9.35	.229
Less than \$2000	16 (30.2)	7 (25.9)	9 (34.6)		
\$2000 - \$9999	12 (22.7)	7 (25.9)	5 (19.2)		
\$10000 - \$19999	8 (15.1)	3 (11.1)	5 (19.2)		
More than \$20000	17 (32.1)	10 (37)	7 (26.9)		
Relationship with the PWD				3.65	.724
Spouse	4 (7.5)	3 (11.1)	1 (3.8)		
Parent	38 (71.7)	19 (70.3)	19 (73.1)		
Grandparent	3 (5.7)	2 (7.7)	1 (3.8)		
Parent-in-law	5 (9.4)	2 (7.7)	3 (11.4)		
Other (e.g., sibling)	2 (3.8)	0 (0.0)	2 (7.6)		
Number of participants attending \geq 80% of sessions	35 (66.0)	17 (63.0)	18 (69.2)	.23	.630
	Mean (SD)	Mean (SD)	Mean (SD)	t score	<i>p</i> valu e
Age	56.00 (9.26)	56.74 (9.49)	55.20 (9.12)	.60	.554
Mean duration of cognitive impairment (month)	71.09 (59.96)	84.63 (65.61)	55.4 (52.97)	1.71	.094
Mean duration of providing care to PWD (year)	8.71 (10.56)	9.43 (10.11)	9.57 (11.16)	.50	.623
Attendance rate (%)	77.90 (24.99)	73.55 (28.45)	82.42 (20.32)	-1.30	.197
PSS total score	26.00 (6.24)	24.63 (5.94)	27.42 (6.34)	-.84	.403
CESD total score	17.87 (9.50)	17.15 (10.25)	18.62 (8.79)	-.12	.912
ZBI total score	40.02 (13.95)	38.48 (13.04)	41.62 (14.92)	-.43	.672
FFMQ-SF total score	62.96 (10.35)	63.33 (10.94)	60.26 (9.90)	.90	.371

[†]Test value: Chi-square or Independent sample t test (2-tailed) was used.

[‡]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

Instrument	Modified MBSR (n = 27)						Modified MBCT (n = 26)						Time effect	Group effect	Group × Time
	T0		T1		T2		T0		T1		T2				
	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD	p value (Cohen's d)		
PSS	24.63	5.94	24.85	5.68	24.70	4.79	27.42	6.34	23.73	4.50	23.38	6.17	.030* (.54)	.927 (<.001)	.019* (.63)
CESD	17.15	10.25	14.81	8.95	14.59	8.55	18.62	8.79	13.73	7.61	13.08	7.36	.002* (.77)	.852 (.06)	.345 (.29)
ZBI	38.48	13.04	33.07	11.93	33.37	15.31	41.62	14.92	35.73	10.67	31.92	11.62	<.001*** (1.12)	.656 (.13)	.186 (.35)
FFMQ-SF	63.33	10.94	64.88	8.63	65.48	8.97	60.26	9.90	65.88	8.03	65.42	9.03	.041* (.53)	.979 (<.001)	.646 (.20)

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

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

	Time-points	Mean difference	SE	<i>p</i> value [†]	95% CI
PSS total score					
Modified MBSR	T0 – T1	-.41	.73	1.000	-2.27–1.46
	T1 – T2	.33	.82	1.000	-1.76–2.43
	T0 – T2	-.07	.93	1.000	-2.44–2.30
Modified MBCT	T0 – T1	3.19	1.14	.030*	0.26–6.13
	T1 – T2	.73	1.01	1.000	-1.87–3.33
	T0 – T2	3.92	1.59	.061	-.015–7.99
CESD total score					
Modified MBSR	T0 – T1	2.33	1.83	.637	-2.34–7.00
	T1 – T2	.22	.82	1.000	-1.87–2.31
	T0 – T2	2.56	1.73	.452	-1.86–6.97
Modified MBCT	T0 – T1	3.73	2.13	.276	-1.74–9.20
	T1 – T2	.42	.99	1.000	-2.10–2.95
	T0 – T2	4.15	2.31	.253	-1.78–10.08
ZBI total score					
Modified MBSR	T0 – T1	5.41	1.73	.013*	.99–9.82
	T1 – T2	-.30	1.44	1.000	-3.98–3.38
	T0 – T2	5.11	2.11	.068	-.28–10.51
Modified MBCT	T0 – T1	4.46	2.84	.385	-2.82–11.74
	T1 – T2	5.19	1.68	.014*	.89–9.49
	T0 – T2	9.65	2.28	.001	3.80–15.51
FFMQ-SF total score					
Modified MBSR	T0 – T1	-1.56	1.37	.797	-5.06–1.94
	T1 – T2	-.59	1.09	1.000	-3.39–2.20
	T0 – T2	-2.15	1.43	.435	-5.81–1.51
Modified MBCT	T0 – T1	-5.81	2.82	.149	-13.03–1.42
	T1 – T2	1.00	1.08	1.000	-1.78–3.78
	T0 – T2	-4.81	2.44	.179	-11.06–1.45

[†]*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.

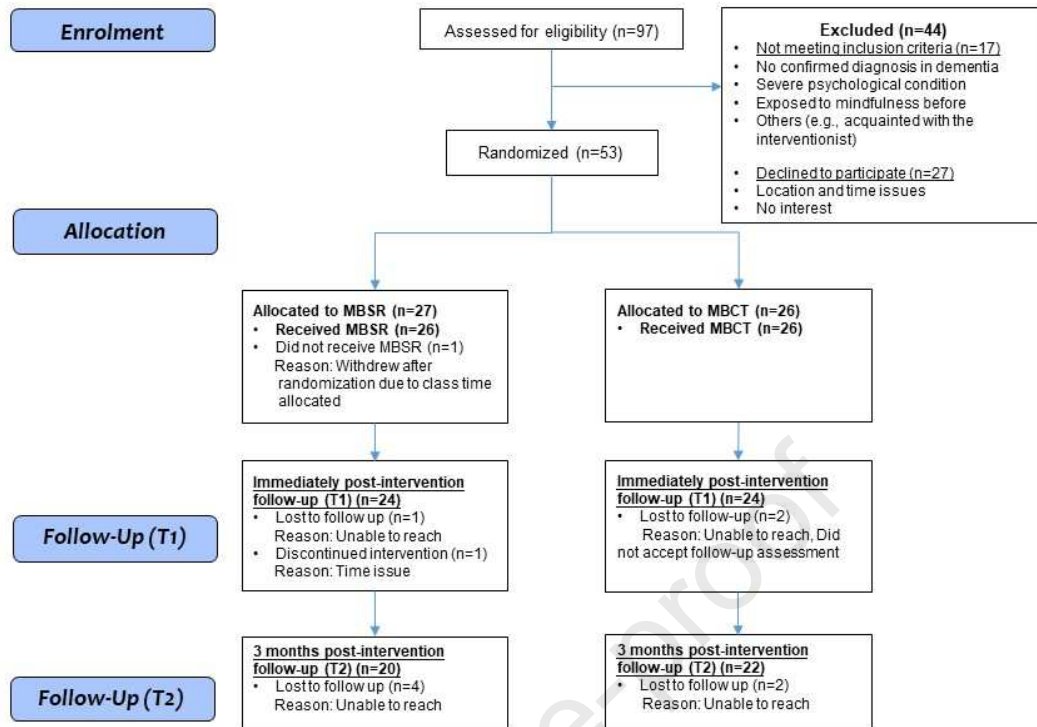


Figure1 Consolidated Standards of Reporting Trials (CONSORT) flow diagram