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1 **The Effects of Mindfulness-based Stress Reduction Program on the Mental Health**
2 **of Family Caregivers: A Randomized Controlled Trial**

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2 **Running head:** The effects of MBSR on family caregivers

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1 **Abstract**

2 **Background:** Caregivers of people with chronic conditions are more likely than non-
3 caregivers to have depression and emotional problems. Few studies have examined the
4 effectiveness of mindfulness-based stress reduction (MBSR) on improving their mental
5 well-being.

6 **Methods:** Caregivers of persons with chronic conditions who scored 7 or above in the
7 Caregiver Strain Index were randomly assigned to the 8-week MBSR group (n=70) or the
8 self-help control group (n=71). Validated instruments were used to assess the changes in
9 depressive and anxiety symptoms, quality of life, self-efficacy, self-compassion and
10 mindfulness. Assessments were conducted at baseline, post-intervention and at 3-month
11 follow-up.

12 **Results:** Compared to the participants in the control group, participants in the MBSR
13 group had a significantly greater decrease in depressive symptoms at post-intervention
14 and at 3-month post-intervention ($p<0.01$). The improvement in state anxiety symptoms
15 among participants in the MBSR group was significantly greater than those of the control
16 group at post-intervention ($p=0.007$), although this difference was not statistically
17 significant at 3-month post-intervention ($p=0.084$). There was also statistically
18 significant larger increase in self efficacy (controlling negative thoughts) ($p=0.041$) and
19 mindfulness ($p=0.001$) among participants in the MBSR group at 3-month post-
20 intervention when compared to the participants in the control group. No statistically
21 significant group effects (MBSR vs. control) were found in perceived stress, quality of
22 life or self-compassion.

1 **Conclusions:** MBSR appears to be a feasible and acceptable intervention to improve
2 mental health among family caregivers with significant care burden, although further
3 studies that include an active control group are needed to make the findings more
4 conclusive.

5 **Key words:** Mindfulness, depressive symptoms, psychology, randomized controlled trial,
6 caregiver

1 It is well established that family caregivers of people with chronic conditions
2 experience high levels of psychological and physical distress.[1-4] Various types of
3 psychological and social interventions have been developed to reduce the caregivers’
4 depressive symptoms and improve their general well-being with an overall small to
5 moderate effect size. [5-7] Among the psychosocial interventions to improve
6 psychological health among caregivers with chronic stress, the eight-week mindfulness-
7 based stress reduction (MBSR) program [8] has showed its positive effects on decreasing
8 nurses’ and medical students’ stress, anxiety, burnout,[8-9] as well as enhancing their
9 self-efficacy. [8, 10-11]

10 Recently, MBSR was further applied to assist family caregivers to cope better
11 with the demands of their roles by improving their self-efficacy and reducing mood
12 disturbance and care burden [12-13] However, these studies had a small sample size and
13 there was limited information on follow-up. Moreover, they were conducted only in
14 Western countries. Furthermore, providing care for people with disabling condition
15 requires significant commitment of time from the caregivers and may deter them from
16 joining a group intervention such as the MBSR that lasts for 8 weeks. Therefore, the
17 current study was conducted to evaluate the acceptability and feasibility, as well as the
18 effectiveness of using the MBSR program to improve mental health among Chinese
19 caregivers of people with disabling chronic condition. Since previous studies have shown
20 that caregivers of someone with a disabling chronic conditions had a higher prevalence of
21 clinically relevant depressive symptoms when compared to non-caregivers[4, 14], the
22 change of clinically relevant depressive symptoms was used as our primary outcome
23 measure in this study. Changes in caregivers’ anxiety symptoms and perceived stress

1 were also examined as secondary outcomes since these are commonly associated with
2 depressive symptoms. Other secondary outcomes included the change in self-efficacy
3 (how confident the caregivers feel to handle the difficulties in their daily care-giving
4 activities) and quality of life, as these have been shown to be important constructs for
5 evaluating the practical value of a novel intervention for family caregivers. [15] Since
6 previous studies have shown that caregivers tended to use more healthcare services than
7 non-caregivers due to their low perceived health [4, 16], changes in medical service
8 utilization was also examined. The changes in mindfulness level and self-compassion
9 were also investigated as these are potential mediating factors that have been suggested to
10 account for the effectiveness of MBSR on improving mental health of participants. [17]

11 **Methods**

12 *Participants*

13 Multiple strategies were used to recruit participants from community centers,
14 outpatient clinics and non-government organizations. The inclusion criteria were as
15 follows: adults aged 18 or above; a Cantonese speaker; having long-term care-giving
16 responsibility for first-degree relatives with chronic illness or chronic condition; scoring
17 7 or above in the Caregiver Strain Index (CSI);[18] and having no self-reported doctor's
18 diagnosis of psychiatric illnesses and impaired cognitive status. Participants were
19 excluded if they: had serious chronic diseases that could potentially affect their
20 participation; were under treatment for serious mental disorders or with uncontrolled
21 mood disorders; had thoughts of self-harming or suicide in the preceding six months; had
22 care recipients who had passed away before the study; had previous experience of
23 participating in a mindfulness-based program or regularly practiced meditation, yoga or

1 tai chi within the preceding year. All participants were blinded to our study hypothesis.
2 Randomization was conducted independently by a research assistant using the random
3 numbers generated in Microsoft Excel 2003, and was not disclosed until the eligible
4 participants completed baseline assessment and signed the informed consent form.
5 Attrition in this study was referred to both dropouts (participants no longer participated in
6 any research related activities after randomization) and loss-of-follow-up.

7 *Procedure*

8 The present study was conducted between October 2010 and March 2012 and was
9 approved by the Clinical Research Ethics Committee of Joint the Chinese University of
10 Hong Kong – New Territories East Cluster. The intervention group received MBSR,
11 while the control group received self-help health education booklets. At the end of the
12 study, participants in the intervention group had their round-trip transportation fee
13 reimbursed to cover the eight-session interventions, while participants in the control
14 group were given the incentives of HK\$200 (US\$20) per person to reimburse for their
15 participation and time. All data were entered by a research assistant who was blinded to
16 the randomization and allocation results.

17 *Intervention*

18 The MBSR intervention consisted of eight weekly two-hour sessions led by
19 trained instructors, and the participants were instructed to have CD-guided home practice
20 for 30 to 45 minutes per day. No one-day retreat was included in this study. The main
21 skills taught in MBSR included body scan, sitting meditation, Hatha yoga stretches, and
22 mindfulness in daily activities (mindful eating, walking, listening, etc.). There were three
23 instructors in our study, and all of them had completed the professional training program

1 in MBSR provided by the originator of this program and had more than three years'
2 teaching experience in MBSR. They independently led five classes with each class
3 consisting of 12 to 15 persons. To ensure the homogeneity of program delivery, the same
4 course protocol and teaching materials were used in the different classes and was
5 modeled after the original MBSR by Kabat-Zinn [19]. All sessions were audio-taped and
6 reviewed by a study coordinator to ensure fidelity of the program content.

7 *Control*

8 A self-help booklet with eight chapters of supportive information and health
9 education was used as health education materials in the control group. All materials in
10 the health education booklet were prepared by a registered nurse who used information
11 from a health education website developed by the Department of Health of the
12 Government of Hong Kong Special Administrative Region
13 <http://www.info.gov.hk/elderly/>. The content included stress acknowledgment and
14 management, common diseases in the elderly and management, skillful communication
15 and practical home nursing advice, and advice on mental health and a healthy life style.

16 *Measures*

17 All questionnaires used in our study have been validated in Chinese. After
18 completion of baseline assessments, participants were asked to self-administer
19 questionnaire immediately at the end of the intervention and at 3-month post-intervention.
20 Social support [20] , physical activity [21] and daily care-giving activities were measured
21 at baseline by the Multidimensional Scale of Perceived Social Support (MSPSS) [22-23],
22 the Godin Leisure-Time Exercise Questionnaire (GLTEQ) [24-25] and the scale of
23 activities of daily living (ADLs) [26] and instrumental activities of daily living

1 (IADLs)[27] respectively as they were potential confounders of the relationship between
2 intervention assignment and mental health. The frequency and duration of home practice
3 of MBSR (including mindfulness in daily activities) was recorded on a weekly practice
4 log that was collected each week during the course.

5 Clinically relevant depressive symptoms were measured by the Chinese Center for
6 Epidemiologic Studies Depression Scale (CESD) [28-29]. A cut-off score of 16 [30-31]
7 was used to indicate the presence of clinically relevant depressive symptoms. Clinically
8 significant improvement was defined as having a CESD score that changed from ≥ 16 to
9 < 16 or a 50% reduction in the score using the baseline score as comparison. [32]
10 Validated Chinese versions of the State Trait Anxiety Inventory (STAI) [33-34], the
11 Perceived Stress Scale (PSS) [35] [36], the short form of Health Survey (SF-12) [37] and
12 the Five Facets Mindfulness Questionnaire (FFMQ) [38] were used to measure anxiety,
13 perceived stress, quality of life and levels of mindfulness respectively. The Self-
14 Compassion Scale – Short Form (SCS-SF) [39-40] was used to measure the self-
15 compassionate attitude towards oneself when encountering difficulties and suffering. The
16 revised care-giving self-efficacy scale (CRSE) [41] was used to assess how confident
17 caregivers were to obtain respite (CRSE-OR) and to control upsetting thoughts (CRSE-
18 UT), with a score ranging from 0 to 100. [42] The monthly medical service use (MSU)
19 was self-reported according to the following six types of health service: over-the-counter
20 use of medications (OTC); private clinic visits; general outpatient clinic visits (GOPC);
21 specialist outpatient clinic (SOPC) visits; traditional Chinese medicine (TCM) clinic
22 visits; and accident and emergency (A&E) visits. One single question was used to assess
23 the self-rating effectiveness of the intervention in both groups with a 5-point Likert scale

1 (from 1 “not at all” to 5 “very much”): “Do you think MBSR/health education booklet is
2 helpful?”

3 *Statistical analysis*

4 To compare potential differences on baseline variables between the two groups,
5 independent t-tests were used for continuous variables and Chi-square tests were used for
6 categorical variables. The Analysis of Covariance (ANCOVA) was performed to evaluate
7 the group effects of MBSR vs. control at post-intervention and 3-month post-intervention
8 with treating the baseline measures as covariance. The percentage changes of monthly
9 MSU relative to baseline were compared between MBSR and the control group by using
10 the Mann-Whitney test. All analyses were conducted on an intention-to-treat (ITT) basis
11 in SPSS 16.0 for Windows. Per protocol analyses were also conducted in completers,
12 who were defined as participants who have attended at least six sessions and completed
13 the questionnaire at baseline and at 3 months post-intervention.

14 *Sample size calculation*

15 According to the study of Lengacher *et al.*, [43] the mean score of CESD adjusted
16 by the baseline measure was 6.3 ± 6.45 in the MBSR group, and 9.6 ± 6.61 in the usual
17 care group after MBSR training. A sample size of 70 participants per group was required
18 for 80% statistical power at a two-sided 5% significance level and assuming a 20%
19 attrition rate.

20 **Results**

21 One hundred forty-one participants were randomly assigned to the MBSR group
22 (n=70) and self-help control group (n = 71). A total of 113 participants completed the
23 follow-up at 3-month post-intervention. (Figure 1). Our sample had an average age of

1 57.49 years (SD = 8.83). Eighty-three percent of participants were female. No statistically
2 significant differences were found in all reported baseline measures (Table1).The total
3 attrition rate of this study was 19.9%, and the MBSR group had a significantly lower
4 attrition rate than that of the control group (12.9% vs 26.8%, $\chi^2 = 4.28$, $df=1$, $p = 0.039$).
5 The attritions were significantly younger ($t = 2.60$, $df=139$, $p = 0.010$), and had a lower
6 level of physical activity ($t = 2.83$, $df = 139$, $p=0.005$).

7 *Effects on primary outcome measure*

8 As shown in Figure 2, the participants in the MBSR group had a significantly
9 greater decrease in depressive symptoms, as measured by CESD, immediately post-
10 intervention and at 3-month post-intervention. A total of 77 participants (34 in MBSR
11 and 43 in control group) had clinically significant depressive symptoms at baseline. At
12 the end of intervention, there was a significantly larger proportion of participants with
13 clinical improvement in the MBSR group as compared to that of the control group
14 (41.2% vs 11.6%, $\chi^2 = 8.92$, $df=1$, $p = 0.003$) although only a non-significant trend was
15 seen at 3-month post-intervention (29.4% vs 14.0%, $\chi^2 = 2.76$, $df=1$, $p = 0.097$).

16 *Effects on secondary outcome measures*

17 The participants of the MBSR group showed greater improvement in state and
18 trait anxiety levels as reported by the STAI than the participants of the control group
19 immediately post-intervention, but this difference was not statistically significant at 3-
20 month post-intervention. Increase in self-efficacy (controlling negative thoughts) and
21 mindfulness, as measured by CRSE-UT and FFMQ, respectively were significantly
22 greater in MBSR group than those of the control group at 3-month post-intervention.
23 (Table 2). The differences of changes in monthly MSU between the two groups were

1 statistically significant only in TCM service utilization immediately post-intervention (Z
2 $= -2.7, p = 0.007$) with a total of 53% decrease of TCM service utilization in the MBSR
3 group as compared to the 15% increase in TCM service utilization in the control group.

4 No significant between-group differences were found in PSS, the physical and
5 mental component of SF12 and SCS at the end of intervention and at 3-month post-
6 intervention.

7 *Adherence*

8 The attendance of the MBSR was 6.76 ± 1.72 sessions. Fifty-eight (83%)
9 participants attended at least six sessions in MBSR and 30 participants (43%) attended all
10 eight sessions. No statistically significant demographic difference was found between
11 participants who attended at least six sessions and those who did not. The average weekly
12 home practice time was 34.4 ± 49.4 minutes, with a range of 0 to 225 minutes. At 3-
13 month post-intervention, 37 (53%) participants stated that they were still practicing
14 meditation exercises once or twice per week and for about 15 minutes each time.
15 However, the number of sessions attended and the weekly home practice time were not
16 associated with changes in any of the outcome measures.

17 *Correlations between mindfulness and other outcome measures*

18 At the end of the intervention, increased mindfulness was associated with
19 decreased depression, anxiety and perceived stress, and mental health component
20 measured by the SF-12. Similar correlations were also found at the 3-month follow-up.

21 *Self-rated effectiveness*

22 At the end of the intervention, the average score of self-rated effectiveness in
23 MBSR group was 4.3 ± 1.17 with 42 participants (62.7%) rating MBSR as “helpful” or

1 “very helpful”. At 3-month post-intervention, there were still 36 participants (53.7%)
2 who rated MBSR as “helpful” and “very helpful”, whereas 14 (20.1%) participants
3 thought that MBSR had no effect on them.

4 *Adverse effects of MBSR*

5 Only one male aged 80 strained his neck when practicing yoga at home, which
6 did not inhibit him from participating in the weekly MBSR course. No other adverse
7 effects were reported by the other participants.

8 *Per protocol analyses*

9 A total of 109 completers were included in per protocol analyses. The results were
10 very similar to those of the ITT analyses.

11 **Discussions**

12 This is the first RCT study to examine the effects of MBSR on improving
13 psychological health of family caregivers with a large sample size. Also, this is one of the
14 few trials that have studied the effects of MBSR on mental health in the Chinese
15 population. Several studies have shown that caregivers in Hong Kong endure levels of
16 stress and burden comparable to their counterparts in Western countries.[44-45] The
17 characteristics of participants in our study were similar to those of the previous studies:
18 mainly females; with a secondary or lower education level; and a low income. [45-47]

19 The positive effects of MBSR on depressive symptoms reduction persisted for at
20 least three months after intervention. This finding is consistent with the results of meta-
21 analyses on the effects of MBSR both on clinical and non-clinical samples, [48-49] and it
22 suggests that MBSR may have at least comparable effects to other established
23 psychotherapies used for caregivers.[5]

1 The vast majority of caregivers were able to attend more than six sessions of
2 MBSR, even though they usually had considerable time constraints and commitment to
3 look after their first degree relatives who suffered from chronic conditions. The
4 adherence rate and the average number of sessions attended were comparable to those
5 reported in previous studies conducted in other populations who experienced significant
6 psychological stress. [43, 50-51] Of importance, over half of the participants in the
7 MBSR group continued to practice at 3-month follow-up and stated that they experienced
8 ongoing benefits from MBSR although the dose–response relationship was not
9 demonstrated in our study. There are several potential explanations for this finding.
10 Firstly, only half of the participants submitted their home practice logs during the eight-
11 week course. For the missing logs, values of zero were entered. This might have resulted
12 in an underestimation of the practice time. Secondly, it might have been very difficult for
13 caregivers to complete the daily practice without interruption or to record the exact
14 amount of time spent in practice.[12, 52] Finally, caregivers tended to take informal
15 practice such as being mindful during their daily activities (*e.g.*, mindful walking, driving,
16 and eating),[12] which might not be correlated with the changes in levels of mindfulness
17 being measured by the mindfulness scale or other psychological instruments.[53]

18 Our study replicated the effects of MBSR on increasing participants’ general level
19 of mindfulness, [17, 51, 54] and the correlation between increased mindfulness and
20 improved mental health.[17, 55] Although the exact mechanism of the relationship
21 between levels of mindfulness and improvement in mental health is unknown, recent
22 neurobiological studies may shed some light on the potential reasons for this relationship.
23 Holzel et al. [56] revealed that the reduced perceived stress among participants of an 8-

1 week MBSR was associated with decreased gray matter density in the right basolateral
2 amygdale. Farb et al.[57] also reported that increased activities in ventrolateral prefrontal
3 cortices were observed among participants who have completed an 8-week MBSR
4 programme which the authors attributed this change to be associated with augmented
5 inhibitory control.

6 Our current study did not demonstrate the effects of MBSR on caregivers' health
7 related quality of life and perceived stress. There are several potential explanations. First,
8 the reduced sample size resulting from drop-out decreased the power to test for
9 significant difference between the two groups and thus there may have been a type I error.
10 Second, the instruments used in our study might not have been sensitive enough to
11 measure the changes in quality of life or perceived stress. Finally, MBSR may have
12 changed participants' reactions to chronic perceived stress, rather than perceived stress
13 itself, resulting in no change of perceived stress among caregivers. [58].

14 Although this study shows some promising results, there are still a number of
15 limitations. The first and most important limitation is that we did not employ an active
16 control group. The effects of MBSR can be overestimated because of the potential
17 beneficial effects of social interaction and extra attention given to them by the
18 intervention. Future studies are thus required to more conclusively demonstrate the
19 effectiveness of MBSR in improving mental health in this group using a design with an
20 active control that can account for the group and attention effects of simply participating
21 in an intervention group. Second, participants in our study were recruited from elderly
22 centers, clinics and NGOs. The study findings might not be generalizable to caregivers
23 with different characteristics and illness behavior[59]. Third, we followed our

1 participants for only three months after the eight-week intervention, and thus we were
2 unable to demonstrate the long-term effects of MBSR or were able to address any
3 potential barriers associated with long-term practice. Fourth, only self-reported daily
4 practice time and medical services utilization were collected in this study and potential
5 recall bias could not be prevented. Finally, the use of self-rating psychological scales
6 prohibited us from assessing the change of clinician rated clinical assessment which
7 might have been more relevant to clinical practice. [60]

8 MBSR appears to be a feasible and acceptable intervention for Chinese family
9 caregivers with significant care burden. The effects of MBSR on reducing depressive
10 symptoms and improving self-efficacy and mindfulness, as shown in this study, need to
11 be further examined using a study with an active control arm and more objective
12 assessments.

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