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

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Abstract

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

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

**Results:** Compared to the participants in the control group, participants in the MBSR group had a significantly greater decrease in depressive symptoms at post-intervention and at 3-month post-intervention (p<0.01). The improvement in state anxiety symptoms among participants in the MBSR group was significantly greater than those of the control group at post-intervention (p=0.007), although this difference was not statistically significant at 3-month post-intervention (p=0.084). There was also statistically significant larger increase in self efficacy (controlling negative thoughts) (p=0.041) and mindfulness (p=0.001) among participants in the MBSR group at 3-month post-intervention when compared to the participants in the control group. No statistically significant group effects (MBSR vs. control) were found in perceived stress, quality of life or self-compassion.
Conclusions: MBSR appears to be a feasible and acceptable intervention to improve mental health among family caregivers with significant care burden, although further studies that include an active control group are needed to make the findings more conclusive.

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

Recently, MBSR was further applied to assist family caregivers to cope better with the demands of their roles by improving their self-efficacy and reducing mood disturbance and care burden [12-13] However, these studies had a small sample size and there was limited information on follow-up. Moreover, they were conducted only in Western countries. Furthermore, providing care for people with disabling condition requires significant commitment of time from the caregivers and may deter them from joining a group intervention such as the MBSR that lasts for 8 weeks. Therefore, the current study was conducted to evaluate the acceptability and feasibility, as well as the effectiveness of using the MBSR program to improve mental health among Chinese caregivers of people with disabling chronic condition. Since previous studies have shown that caregivers of someone with a disabling chronic conditions had a higher prevalence of clinically relevant depressive symptoms when compared to non-caregivers[4, 14], the change of clinically relevant depressive symptoms was used as our primary outcome measure in this study. Changes in caregivers’ anxiety symptoms and perceived stress
were also examined as secondary outcomes since these are commonly associated with depressive symptoms. Other secondary outcomes included the change in self-efficacy (how confident the caregivers feel to handle the difficulties in their daily care-giving activities) and quality of life, as these have been shown to be important constructs for evaluating the practical value of a novel intervention for family caregivers. [15] Since previous studies have shown that caregivers tended to use more healthcare services than non-caregivers due to their low perceived health [4, 16], changes in medical service utilization was also examined. The changes in mindfulness level and self-compassion were also investigated as these are potential mediating factors that have been suggested to account for the effectiveness of MBSR on improving mental health of participants. [17]

Methods

Participants

Multiple strategies were used to recruit participants from community centers, outpatient clinics and non-government organizations. The inclusion criteria were as follows: adults aged 18 or above; a Cantonese speaker; having long-term care-giving responsibility for first-degree relatives with chronic illness or chronic condition; scoring 7 or above in the Caregiver Strain Index (CSI);[18] and having no self-reported doctor’s diagnosis of psychiatric illnesses and impaired cognitive status. Participants were excluded if they: had serious chronic diseases that could potentially affect their participation; were under treatment for serious mental disorders or with uncontrolled mood disorders; had thoughts of self-harming or suicide in the preceding six months; had care recipients who had passed away before the study; had previous experience of participating in a mindfulness-based program or regularly practiced meditation, yoga or
tai chi within the preceding year. All participants were blinded to our study hypothesis. Randomization was conducted independently by a research assistant using the random numbers generated in Microsoft Excel 2003, and was not disclosed until the eligible participants completed baseline assessment and signed the informed consent form. Attrition in this study was referred to both dropouts (participants no longer participated in any research related activities after randomization) and loss-of-follow-up.

**Procedure**

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

**Intervention**

The MBSR intervention consisted of eight weekly two-hour sessions led by trained instructors, and the participants were instructed to have CD-guided home practice for 30 to 45 minutes per day. No one-day retreat was included in this study. The main skills taught in MBSR included body scan, sitting meditation, Hatha yoga stretches, and mindfulness in daily activities (mindful eating, walking, listening, etc.). There were three instructors in our study, and all of them had completed the professional training program
in MBSR provided by the originator of this program and had more than three years’
teaching experience in MBSR. They independently led five classes with each class
consisting of 12 to 15 persons. To ensure the homogeneity of program delivery, the same
course protocol and teaching materials were used in the different classes and was
modeled after the original MBSR by Kabat-Zinn [19]. All sessions were audio-taped and
reviewed by a study coordinator to ensure fidelity of the program content.

Control

A self-help booklet with eight chapters of supportive information and health
education was used as health education materials in the control group. All materials in
the health education booklet were prepared by a registered nurse who used information
from a health education website developed by the Department of Health of the
Government of Hong Kong Special Administrative Region

http://www.info.gov.hk/elderly/. The content included stress acknowledgment and
management, common diseases in the elderly and management, skillful communication
and practical home nursing advice, and advice on mental health and a healthy life style.

Measures

All questionnaires used in our study have been validated in Chinese. After
completion of baseline assessments, participants were asked to self-administer
questionnaire immediately at the end of the intervention and at 3-month post-intervention.
Social support [20], physical activity [21] and daily care-giving activities were measured
at baseline by the Multidimensional Scale of Perceived Social Support (MSPSS) [22-23],
the Godin Leisure-Time Exercise Questionnaire (GLTEQ) [24-25] and the scale of
activities of daily living (ADLs) [26] and instrumental activities of daily living
respectively as they were potential confounders of the relationship between intervention assignment and mental health. The frequency and duration of home practice of MBSR (including mindfulness in daily activities) was recorded on a weekly practice log that was collected each week during the course.

Clinically relevant depressive symptoms were measured by the Chinese Center for Epidemiologic Studies Depression Scale (CESD) [28-29]. A cut-off score of 16 [30-31] was used to indicate the presence of clinically relevant depressive symptoms. Clinically significant improvement was defined as having a CESD score that changed from ≥ 16 to < 16 or a 50% reduction in the score using the baseline score as comparison. [32]

Validated Chinese versions of the State Trait Anxiety Inventory (STAI) [33-34], the Perceived Stress Scale (PSS) [35] [36], the short form of Health Survey (SF-12) [37] and the Five Facets Mindfulness Questionnaire (FFMQ) [38] were used to measure anxiety, perceived stress, quality of life and levels of mindfulness respectively. The Self-Compassion Scale – Short Form (SCS-SF) [39-40] was used to measure the self-compassionate attitude towards oneself when encountering difficulties and suffering. The revised care-giving self-efficacy scale (CRSE) [41] was used to assess how confident caregivers were to obtain respite (CRSE-OR) and to control upsetting thoughts (CRSE-UT), with a score ranging from 0 to 100. [42] The monthly medical service use (MSU) was self-reported according to the following six types of health service: over-the-counter use of medications (OTC); private clinic visits; general outpatient clinic visits (GOPC); specialist outpatient clinic (SOPC) visits; traditional Chinese medicine (TCM) clinic visits; and accident and emergency (A&E) visits. One single question was used to assess the self-rating effectiveness of the intervention in both groups with a 5-point Likert scale.
(from 1 “not at all” to 5 “very much”): “Do you think MBSR/health education booklet is helpful?”

Statistical analysis

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

Sample size calculation

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

Results

One hundred forty-one participants were randomly assigned to the MBSR group (n=70) and self-help control group (n = 71). A total of 113 participants completed the follow-up at 3-month post-intervention. (Figure 1). Our sample had an average age of
57.49 years (SD = 8.83). Eighty-three percent of participants were female. No statistically significant differences were found in all reported baseline measures (Table 1). The total attrition rate of this study was 19.9%, and the MBSR group had a significantly lower attrition rate than that of the control group (12.9% vs 26.8%, $\chi^2 = 4.28$, $df = 1$, $p = 0.039$). The attritions were significantly younger ($t = 2.60$, $df = 139$, $p = 0.01$), and had a lower level of physical activity ($t = 2.83$, $df = 139$, $p = 0.005$).

**Effects on primary outcome measure**

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

**Effects on secondary outcome measures**

The participants of the MBSR group showed greater improvement in state and trait anxiety levels as reported by the STAI than the participants of the control group immediately post-intervention, but this difference was not statistically significant at 3-month post-intervention. Increase in self-efficacy (controlling negative thoughts) and mindfulness, as measured by CRSE-UT and FFMQ, respectively were significantly greater in MBSR group than those of the control group at 3-month post-intervention. (Table 2). The differences of changes in monthly MSU between the two groups were
statistically significant only in TCM service utilization immediately post-intervention ($Z = -2.7, p = 0.007$) with a total of 53% decrease of TCM service utilization in the MBSR group as compared to the 15% increase in TCM service utilization in the control group.

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

**Adherence**

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

However, the number of sessions attended and the weekly home practice time were not associated with changes in any of the outcome measures.

**Correlations between mindfulness and other outcome measures**

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

**Self-rated effectiveness**

At the end of the intervention, the average score of self-rated effectiveness in MBSR group was $4.3 \pm 1.17$ with 42 participants (62.7%) rating MBSR as “helpful” or
“very helpful”. At 3-month post-intervention, there were still 36 participants (53.7%) who rated MBSR as “helpful” and “very helpful”, whereas 14 (20.1%) participants thought that MBSR had no effect on them.

Adverse effects of MBSR

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

Per protocol analyses

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

Discussions

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

The positive effects of MBSR on depressive symptoms reduction persisted for at least three months after intervention. This finding is consistent with the results of meta-analyses on the effects of MBSR both on clinical and non-clinical samples, [48-49] and it suggests that MBSR may have at least comparable effects to other established psychotherapies used for caregivers.[5]
The vast majority of caregivers were able to attend more than six sessions of MBSR, even though they usually had considerable time constraints and commitment to look after their first degree relatives who suffered from chronic conditions. The adherence rate and the average number of sessions attended were comparable to those reported in previous studies conducted in other populations who experienced significant psychological stress. [43, 50-51] Of importance, over half of the participants in the MBSR group continued to practice at 3-month follow-up and stated that they experienced ongoing benefits from MBSR although the dose–response relationship was not demonstrated in our study. There are several potential explanations for this finding. Firstly, only half of the participants submitted their home practice logs during the eight-week course. For the missing logs, values of zero were entered. This might have resulted in an underestimation of the practice time. Secondly, it might have been very difficult for caregivers to complete the daily practice without interruption or to record the exact amount of time spent in practice. [12, 52] Finally, caregivers tended to take informal practice such as being mindful during their daily activities (e.g., mindful walking, driving, and eating). [12] which might not be correlated with the changes in levels of mindfulness being measured by the mindfulness scale or other psychological instruments. [53]

Our study replicated the effects of MBSR on increasing participants’ general level of mindfulness, [17, 51, 54] and the correlation between increased mindfulness and improved mental health. [17, 55] Although the exact mechanism of the relationship between levels of mindfulness and improvement in mental health is unknown, recent neurobiological studies may shed some light on the potential reasons for this relationship. Holzel et al. [56] revealed that the reduced perceived stress among participants of an 8-
week MBSR was associated with decreased gray matter density in the right basolateral amygdale. Farb et al.[57] also reported that increased activities in ventrolateral prefrontal cortices were observed among participants who have completed an 8-week MBSR programme which the authors attributed this change to be associated with augmented inhibitory control.

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

Although this study shows some promising results, there are still a number of limitations. The first and most important limitation is that we did not employ an active control group. The effects of MBSR can be overestimated because of the potential beneficial effects of social interaction and extra attention given to them by the intervention. Future studies are thus required to more conclusively demonstrate the effectiveness of MBSR in improving mental health in this group using a design with an active control that can account for the group and attention effects of simply participating in an intervention group. Second, participants in our study were recruited from elderly centers, clinics and NGOs. The study findings might not be generalizable to caregivers with different characteristics and illness behavior[59]. Third, we followed our
participants for only three months after the eight-week intervention, and thus we were unable to demonstrate the long-term effects of MBSR or were able to address any potential barriers associated with long-term practice. Fourth, only self-reported daily practice time and medical services utilization were collected in this study and potential recall bias could not be prevented. Finally, the use of self-rating psychological scales prohibited us from assessing the change of clinician rated clinical assessment which might have been more relevant to clinical practice. [60]

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