

# Multicomponent intervention for family caregivers of dementia: a randomised controlled trial using the multiphase optimisation strategy (abridged secondary publication)

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## KEY MESSAGES

1. The multiphase optimisation strategy, combined with fractional factorial design, was used to assess the effects of each intervention component on distressed primary family caregivers of individuals with dementia in Hong Kong.
2. Over 12 months, intervention components of mindfulness-based intervention, support group, behavioural activation, and behavioural problems management led to improvements in dementia management strategies, mindfulness attention awareness, psychological well-being, and functional social support, while reducing anxiety and depression symptoms.

Hong Kong Med J 2025;31(Suppl 3):S17-9

HMRP project number: 18191781

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## Introduction

Dementia places a considerable burden on family members who provide care for individuals affected by the condition.<sup>1</sup> Effective interventions are needed to alleviate the adverse effect of caregiving on family caregivers. This study aimed to identify the effective components of a multicomponent intervention for caregivers of individuals with dementia in Hong Kong using the multiphase optimisation strategy.<sup>2</sup>

## Methods

This prospective, assessor-blinded, randomised controlled trial used the multiphase optimisation strategy to evaluate the effects of five intervention components: self-care skills, behavioural problems management, behavioural activation, mindfulness-based intervention, and support group. Chinese primary family caregivers for individuals with dementia were recruited in Hong Kong. They were aged  $\geq 18$  years, were spouse, adult child, or child-in-law of a care recipient, had no cognitive impairment (based on the Hong Kong version of Montreal Cognitive Assessment 5-Min), provided care for  $\geq 20$  hours per week for  $\geq 1$  year, involved in assisting with activities of daily living and instrumental activities

of daily living, and experienced a certain level of depression or burden (indicated by Patient Health Questionnaire-9 score of  $>9$  or Zarit Burden Interview score of  $>18$ ) to ensure sample homogeneity.<sup>3,4</sup>

Participants were assessed at baseline and received education on dementia and caregiving. They were then randomly assigned using the fractional factorial design to one of the 16 experimental conditions that varied in the delivery of treatment components. Implementation fidelity of all five components was ensured, and adherence to the protocol was monitored. Assessments were conducted at baseline, 6 months, and 12 months. Primary outcome measures included the physical domain of the Short Form-12 Health Survey, the Zarit Burden Interview, the Perceived Stress Scale, Ryff's Psychological Well-Being Scale, the Chinese version of the Anxiety Subscale of the Hospital Anxiety and Depression Scale, the Chinese version of the Patient Health Questionnaire, and the Medical Outcomes Study Social Support Survey. Proximal outcome measures included the self-care subscale in the Risk Appraisal Measure, the criticism, encouragement, and active management domains of the Dementia Management Strategies Scale, the number of meaningful or joyful events over the past

2 weeks, the Five Facet Mindfulness Questionnaire, and satisfaction with the support group.

The intention-to-treat approach was used; all participants were included in the analysis regardless of intervention receipt or study withdrawal. A total of 14 regression models were analysed regarding changes in primary and proximal outcome scores from baseline to 12-month follow-up relative to the five intervention components. Moderation and mediation effects were also examined.

## Results

In total, 171 female and 79 male caregivers (mean age,  $48.9 \pm 13.8$  years) of individuals with dementia (mean age,  $76.7 \pm 8.9$  years) participated in all intervention sessions and were assessed at 6 months ( $n=245$ ) and 12 months ( $n=235$ ). Nearly 90% of the caregivers

were either adult children or children-in-law of the care recipients. They spent approximately 59.5 hours per week on caregiving. The implementation fidelity of all five components was equally high; participants were satisfied with the quality of the intervention.

Over 12 months, participants who received the mindfulness-based intervention component demonstrated a reduction in anxiety symptoms ( $\beta = -1.07$ ,  $P=0.029$ ) and depression symptoms ( $\beta = -2.13$ ,  $P<0.001$ ). They also demonstrated increases in psychological well-being ( $\beta=3.00$ ,  $P=0.029$ ), functional social support ( $\beta=4.76$ ,  $P=0.007$ ), mindfulness attention awareness ( $\beta=4.23$ ,  $P<0.001$ ), dementia management strategies of active management ( $\beta=3.70$ ,  $P<0.001$ ), and satisfaction with the support group ( $\beta=1.97$ ,  $P<0.001$ ) [Table]. Participants who received the support group component reported an increase in functional

TABLE. Adjusted regression analyses for changes in primary and proximal outcomes from baseline to 12-month follow-up in terms of the five intervention components.

| Intervention component          | Model 1 (self-care skills)                       |         | Model 2 (behavioural problems management)      |         | Model 3 (behavioural problems management)          |         | Model 4 (behavioural activation)                       |         | Model 5 (mindfulness-based intervention)                      |         | Model 6 (mindfulness-based intervention)  |         | Model 7 (support group)                      |         |
|---------------------------------|--------------------------------------------------|---------|------------------------------------------------|---------|----------------------------------------------------|---------|--------------------------------------------------------|---------|---------------------------------------------------------------|---------|-------------------------------------------|---------|----------------------------------------------|---------|
|                                 | Primary outcome                                  |         |                                                |         |                                                    |         |                                                        |         |                                                               |         |                                           |         |                                              |         |
|                                 | Physical domain of Short Form-12                 |         | Zarit Burden Interview                         |         | Perceived Stress Scale                             |         | Ryff's Psychological Well-Being Scale                  |         | Anxiety Subscale of the Hospital Anxiety and Depression Scale |         | Patient Health Questionnaire              |         | Medical Outcomes Study Social Support Survey |         |
|                                 | β                                                | P value | β                                              | P value | β                                                  | P value | β                                                      | P value | β                                                             | P value | β                                         | P value | β                                            | P value |
| Self-care skills                | 0.36                                             | 0.640   | 1.07                                           | 0.258   | 0.70                                               | 0.284   | 0.05                                                   | 0.973   | 0.00                                                          | 0.999   | -0.23                                     | 0.519   | -0.03                                        | 0.985   |
| Behavioural problems management | 0.58                                             | 0.439   | -0.21                                          | 0.825   | -0.05                                              | 0.935   | 3.52                                                   | 0.008   | 0.56                                                          | 0.233   | -0.38                                     | 0.292   | 2.89                                         | 0.088   |
| Behavioural activation          | -1.51                                            | 0.048   | -1.56                                          | 0.099   | -1.32                                              | 0.044   | 1.49                                                   | 0.265   | -0.46                                                         | 0.337   | -0.29                                     | 0.426   | 1.22                                         | 0.475   |
| Mindfulness-based intervention  | 1.17                                             | 0.135   | 1.42                                           | 0.145   | 0.66                                               | 0.326   | 3.00                                                   | 0.029   | -1.07                                                         | 0.029   | -2.13                                     | <0.001  | 4.76                                         | 0.007   |
| Support group                   | -0.06                                            | 0.938   | 1.18                                           | 0.200   | -0.53                                              | 0.409   | 0.24                                                   | 0.852   | -0.06                                                         | 0.896   | 0.35                                      | 0.327   | 4.63                                         | 0.006   |
|                                 | Model 8 (self-care skills)                       |         | Model 9 (behavioural problems management)      |         | Model 10 (behavioural problems management)         |         | Model 11 (behavioural problems management)             |         | Model 12 (behavioural activation)                             |         | Model 13 (mindfulness-based intervention) |         | Model 14 (support group)                     |         |
|                                 | Proximal outcome                                 |         |                                                |         |                                                    |         |                                                        |         |                                                               |         |                                           |         |                                              |         |
|                                 | Self-care subscale in the Risk Appraisal Measure |         | Dementia Management Strategies Scale–Criticism |         | Dementia Management Strategies Scale–Encouragement |         | Dementia Management Strategies Scale–Active Management |         | No. of meaningful events                                      |         | Five Facet Mindfulness Questionnaire      |         | Satisfaction                                 |         |
|                                 | β                                                | P value | β                                              | P value | β                                                  | P value | β                                                      | P value | β                                                             | P value | β                                         | P value | β                                            | P value |
| Self-care skills                | 0.57                                             | 0.119   | 0.54                                           | 0.582   | 0.26                                               | 0.770   | -0.21                                                  | 0.828   | 0.14                                                          | 0.390   | -0.49                                     | 0.629   | -0.11                                        | 0.817   |
| Behavioural problems management | -0.60                                            | 0.100   | 0.92                                           | 0.349   | 2.49                                               | 0.005   | 5.99                                                   | <0.001  | 0.29                                                          | 0.072   | 1.98                                      | 0.048   | -0.39                                        | 0.420   |
| Behavioural activation          | 0.75                                             | 0.041   | -0.96                                          | 0.331   | 0.34                                               | 0.708   | -0.13                                                  | 0.889   | -0.31                                                         | 0.056   | -0.11                                     | 0.910   | -0.17                                        | 0.732   |
| Mindfulness-based intervention  | -0.25                                            | 0.504   | -0.29                                          | 0.779   | 1.75                                               | 0.058   | 3.70                                                   | <0.001  | 0.03                                                          | 0.840   | 4.23                                      | <0.001  | 1.97                                         | <0.001  |
| Support group                   | 0.00                                             | 0.990   | 0.29                                           | 0.767   | -1.17                                              | 0.181   | -1.07                                                  | 0.254   | 0.07                                                          | 0.647   | -1.01                                     | 0.303   | -0.39                                        | 0.417   |

social support ( $\beta=4.63$ ,  $P=0.006$ ). Participants who received the behavioural activation component demonstrated a reduction in stress levels ( $\beta= -1.32$ ,  $P=0.044$ ). Participants who received the behavioural problems management component demonstrated an increase in psychological well-being ( $\beta=3.52$ ,  $P=0.008$ ), as well as improvements in dementia management strategies of encouragement ( $\beta=2.49$ ,  $P=0.005$ ) and active management ( $\beta=5.99$ ,  $P<0.001$ ) and in mindfulness attention awareness ( $\beta=1.98$ ,  $P=0.048$ ). Participants who received the self-care skills component did not result in significant improvement in primary or proximal outcome.

For mediational analysis, after controlling for changes in mindfulness attention awareness, the direct effect between the mindfulness-based intervention and changes in depression symptoms remained significant but decreased in magnitude ( $\beta= -1.81$ ,  $P<0.001$ ). These findings support a partial mediation model, indicating that the mindfulness attention awareness acts as a partial mediator.

For moderation analysis, there was no interaction effect among intervention components on primary and proximal outcomes. Similarly, baseline scores of physical health status, stress/burden, psychological well-being, anxiety/depressive symptoms, and social support did not significantly moderate the effects of the five intervention components on changes in scores from baseline to follow-up assessments.

## Discussion

The mindfulness-based intervention component effectively contributed to a reduction in anxiety and depression symptoms, an increase in psychological well-being, and an increase in functional social support, as well as an increase in dementia management strategies of active management, mindfulness attention awareness, and satisfaction with the support group. The behavioural problems management component effectively contributed to an increase in psychological well-being as well as an increase in dementia management strategies of active management and mindfulness attention awareness. The support group component effectively contributed to an increase in functional social support. The behavioural activation component effectively contributed to a reduction in stress. The support group component effectively contributed to increased functional social support. Intervention programmes for distressed family caregivers of individuals with dementia should include

components of mindfulness-based intervention and support group, which are cost-effective and can improve coping mechanisms and foster a supportive environment for their well-being. Inclusion of the components of behavioural problems management and behavioural activation can further enhance caregiver well-being and reduce stress. Future implementation of similar programmes should consider these success factors: organisational support with adequate resources, well-trained staff with ongoing supervision, implementation infrastructure, and comprehensive participant engagement strategies to ensure programme effectiveness and sustainability. Limitations of the present study included variability in intervention dosage, the absence of a comparison group, and limited measurement time points.

## Funding

This study was supported by the Health and Medical Research Fund, Health Bureau, Hong Kong SAR Government (#18191781). The full report is available from the Health and Medical Research Fund website (<https://rfs2.healthbureau.gov.hk>).

## Disclosure

The results of this research have been previously published in:

1. Kwok JYY, Cheung DSK, Zarit S, et al. Multiphase optimization of a multicomponent intervention for informal dementia caregivers: a study protocol. *Trials* 2023;24:791.
2. Kwok JYY, Cheung DSK, Zarit S, et al. Multicomponent intervention for distressed informal caregivers of people with dementia: a randomized clinical trial. *JAMA Netw Open* 2025;8:e250069.

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