Official title: Mindfulness-Based Intervention for Caregivers of Frail older adults: Towards a model of intergenerational caregiving for Chinese families

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The research questions of the proposed study are:
1) investigate the effects of a brief mindfulness-based intervention for caregivers of frail elders in reducing caregiver burden and depression;
2) compare the effects of mindfulness-based intervention with an evidence-based caregiver programme; and
3) explore the factors that contribute to the positive improvements of both caregiver programmes, and develop a preliminary model for understanding and reducing caregiver burden and depression.

RESEARCH PLAN AND METHODOLOGY

Study design

In view of the research objectives about efficacy of the MBI and in the interest of developing a model of mediators in the MBI and intergenerational caregiving, a multi-site, three-arm, randomized controlled trial will be implemented (Baron et al., 2013). The effects of the MBI for caregivers for frail elderly will be tested by comparing the MBI (Arm 1), with psychoeducation (Arm 2), and treatment-as-usual (Arm 3). Assessments will be scheduled pre-intervention (T0), post-intervention (T1), and at 6-month follow-up (T2). The program effects will be tested using both pairwise between-subject comparisons (Arm 1 vs Arm 2, Arm 2 vs Arm 3, and Arm 1 vs Arm 3) and within-subject comparisons (measures at T0, T1, and T2). The between-group analyses will be adjusted for baseline scores and for factors related to outcomes, including the age and sex of the caregivers, the severity of depression, anxiety, caregiver burden, and the level of frailty of elderly. Refinement of design from a pilot study. A pilot study has been conducted in August to September 2019.

Sample size estimation. We calculated the sample size needed for the first two hypotheses and choose the larger one for the estimation of overall sample size. For the first hypothesis, the calculation is based on a previous study of an MBI for caregivers (Hou et al., 2014), in which an effect size of 0.64 in depression, with an estimation of an effect size of 0.14 for Arm 3. For a two-tailed α error of 5%, an 80% power, and a test of three independent groups, the required sample size will be 64 per arm (Cohen, 1988). For the second hypothesis, the calculation is based on a non-inferiority comparison was conducted. A non-inferiority margin of 50%, as common practice in non-inferiority trials (Althunian et al., 2017), is selected and the required sample size will be 51 per arm. We further adjust the sample size based on an estimation of drop-out rate and intra-class correlation. An estimation of a drop-out rate of 15% is based on two local studies of mindfulness-based intervention (Hou et al., 2014; Lo et al.,

2015). Besides, an estimation of intra-class correlations of 0.07 is based on PI's two recent mindfulness multi-site studies ranged from 0 to 0.07 (Lo et al., 2017; Lo et al., in press), and 240 caregivers will be recruited for this study. Based on such estimation, it should also be necessary to conduct mediational studies with .8 statistical power (Fritz & MacKinnon, 2007).

Recruitment of participants. The inclusion criteria for participation in this study are: 1) Caregivers of frail elderly based on a professional's assessment of Clinical Frailty Scale with a score of 6, indicating a moderate level of frailty or above (Rockwood et al., 2005). 2) Caregivers being adult children or children in-law of the elder care receiver. 3) Caregivers who are experiencing caregiver burden at the time of study, with scores of 8 or above in ZBI-4 (Bedard et al., 2001). The exclusion criteria include: 1) Caregivers who have diagnoses of psychosis, developmental disabilities, or cognitive impairment, which may present difficulties in comprehending the content of the program. 2) Spouses, siblings, or friends will be excluded as their burden or depressive symptoms may be attributed to different reasons. 3) Caregivers of elders with moderate to severe dementia will be excluded and the Clinical Dementia Rating Scale will be administered (Huges et al., 1982), and 4) Caregivers who had participated in a MBSR or equivalent.

The research project will be announced and promoted among collaborating NGOs and through advertisement in social media, promotional emails, and project leaflets. Four NGOs have indicated their intentions to contribute to this study by assisting in promotion, recruitment, program implementation and data collection. Support letters of these NGO collaborators have been provided in the appendix.

We will organize briefing sessions for explaining the rationale and procedures of the study half yearly. All interested caregivers will be screened using Clinical Frailty Scale, Clinical Dementia Rating Scale, and caregiver stress. Written consent will be collected for eligible participants. All NGO collaborators will provide standard care to the participants, including participants in Arm 3 who will not receive MBI nor psychoeducation before T2. The Research Assistant who is blinded to the personal data of the participants, will administer the random assignment using computer generated programming. Participants will be randomly assigned to MBI (Arm 1), psychoeducation (Arm 2), or treatment-as-usual (Arm 3). During the recruitment and implementation, both arm 1 and 2 are called "Family Psychoeducation Program", and the term "mindfulness" will not be used for Arm 1 to minimize the potential placebo effect. Cash remuneration coupons will be provided to caregivers who can complete the study at T1 and T2. A recruitment flowchart is attached in Appendix 1.

Procedures

Program planning and training. The themes and content of arms 1 and 2 are summarized in Appendix 2.

MBI (Arm 1). Based on the protocols of PI's previous clinical trials, brief mindfulness exercises will be integrated with psychoeducation of caregiving for frail elderly. The protocol for Arm 1 has been developed on mid-Sept, 2019 for the first pilot study.

Psychoeducation.

(Arm 2). The research team will modify START (STrAtegies for RelaTives) program for

caregivers of dementia (Livingstone et al., 2014) into a 10-hour group program. Major changes include the content originally related to the caregiving needs of dementia will changed to frail elderly. Two hours will be added to allow for more discussion of individual caregiver's concerns. The protocol for Arm 2 will be developed and a pilot study will be conducted shortly in early 2020. Arm 1 and 2 are parallel in program design. Both will be 4-session programs to be organized bi-weekly, and last for 10 hours in total. Both programs include 15-minute daily home practice assignments, with Arm 1 being guided with mindfulness exercises, and Arm 2 with coping and problem-solving skills. Both arms will be delivered in group format, with 10 to 15 caregivers in each group. Programs will be conducted in the service units of four NGO collaborators and PI's university. All instructors for Arm 1 require basic professional training in MBI, plus at least two-year experience in conducting MBI. Instructors for Arm 2 will be recruited from NGO with experience in working with caregivers of frail elderly for more than two years. Implementation and assessment.

After the pre-intervention assessment (T0), caregivers who meet inclusion criteria will be randomized into a MBI (Arm 1), psychoeducation (PSY, Arm 2), or treatment-as-usual (TAU, Arm 3). After the intervention programs, participants in three arms will complete the post-intervention assessment (T1). A 6-month follow up (T2) is offered as a booster and final assessment for arms 1 and 2. This study will be single-blinded and outcome assessors will be blinded to randomization status.

To ensure intervention fidelity, all program sessions will be audio-recorded and an independent rater will listen to 20% of the selected clips on random basis, and assess whether each element in the intervention protocol has been implemented with consistency. Higher concordance rates will signify greater fidelity to the intervention protocol, which will be carefully monitored throughout the study. The treatment fidelity of Arm 1 will be further assessed by Mindfulness-based Interventions-Teaching Assessment Criteria Scale (Crane et al., 2013). Those of Arm 2 will be assessed by a checklist for implementing START program.

Table 1. Outcome variables and measures

Study variables and measures	Validation in HK samples
Primary outcome variables	
Caregiver burden - Measured by 22-item Zarit Burden Interview (ZBI) (Zarit et al., 1980)	α = .88 (Tang et al., 2017)
Secondary outcome variables	
Depressive symptoms - measured by 10-item The Center for Epidemiologic Studies Depression Scale (CES-D) (Radloff, 1977)	α = 0.78 (Boey, 1999)
Anxiety symptoms - measured by 7-item Hospital Anxiety and Depression Scale – Anxiety subscale (HAD-A) (Zigmond & Snaith, 1983)	α = 0.77 to 0.82 (Leung et al., 1999)
Positive caregiving experiences - Measured by 9-item Positive Aspects of Caregiving Scale (PAC) (Tarlow et al., 2004)	α = 0.89 (Lou et al., 2015)
Spiritual well-being - measured by 12-item Functional Assessment of Chronic Illness Therapy–Spiritual Well-Being Scale (FACIT-Sp-12) (Peterman et al., 2002), with two subscales in meaning/peace and faith	α = 0.80 (Wang, 2016)
Family conflicts - measured by 10-item Revised Conflict Tactics Scale (CTS2) (Beach et al., 2005), with subscales in psychological mistreatment (5 items) and physical abuse (5-items)	α = .81 to .82 (Yan & Tang, 2001)
Biomarker: Heart rate variability - measured by the CorSense Heart Rate Variability monitor	N.A.
Mediators of outcome	
Cognitive factor: Coping styles - measured by 28-item brief COPE (Carver, 1997), with 11 subscales (problem-solving, accommodation, support-seeking, behavioral disengagement, denial, self-distraction, self-blame, humour, venting, substance use, and religion)	α = 0.76 for whole scale, and α = .49 to .87 for subscales (Tang et al., 2016)
Cognitive factor (psychoeducation-specific): Self efficacy - Measured by 5-item subscale of controlling upsetting thoughts (5 items) in the Revised Scale for Caregiving Self-Efficacy (RSCSE) (Steffen et al., 2002)	α = .86 (Au et al., 2009)
Cognitive factor (mindfulness-specific): Experiential avoidance - measured by 15-item The Brief Experiential Avoidance (BEAQ) Questionnaire (Gamez et al., 2011)	α = 0.81 (Lo *et al.*, in review)

3. Data Analyses

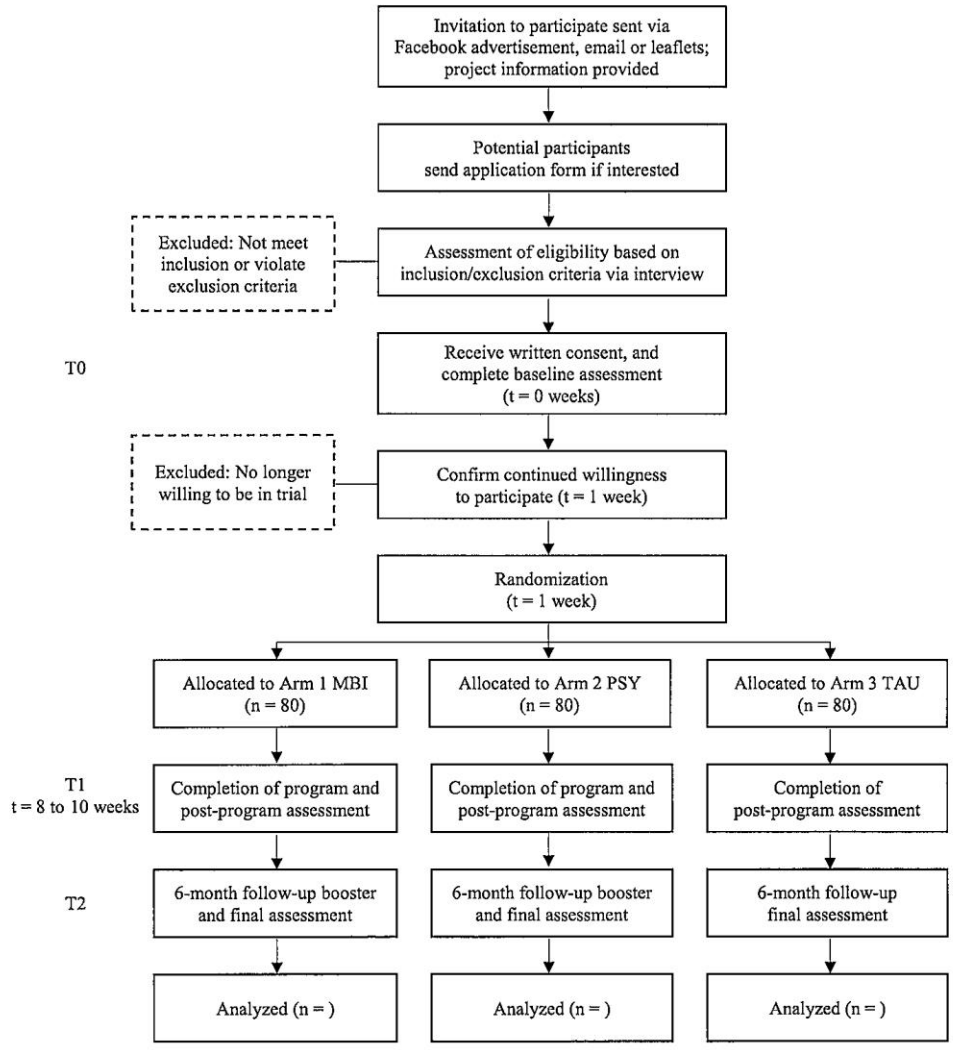
All analyses will be carried out according to the intention-to-treat approach and all participants who receive randomization and allocation to one of three treatment arms will be included for analyses (Moher et al., 2010). Repeated measure ANOVA will be used to evaluate the effects of the MBI (Arm 1), relative to PSY (Arm 2) and TAU (Arm 3), and the analyses of the primary and secondary outcome measures will be analyzed. In addition to the immediate programme effects, outcomes measured at T1 and T2 will be compared, to assess whether maintenance effects will be sustained at 6-months.

The mediation effects on the relationships between group (MBI or PSY vs. TAU)

variables and caregiver outcome variables (ZBI, CES-D, HAD-A), controlling the baseline variables (sex and age of caregivers, frailty score), will be evaluated using the PROCESS macro in SPSS (Hayes, 2012), in order to compute the effect of the independent variable on the mediator (a), the effect of the mediator on the dependent variable (b),_total effect (c), direct effect (c'), and bootstrapped (i.e., 10,000 random samples) bias-corrected 95% confidence intervals of the indirect effect (ab). According to Hayes (2009), with significant paths a and b, even without a significant path c, confidence intervals that do not include zero indicate a significant indirect (i.e., mediation) effect.

Appendix 1

Recruitment Flowchart



Appendix 2 Procedures

MBI (Arm 1)
Session 1: Stress of caregivers

- aware of automatic reactions of caregiving stress
- raisin exercise and body scan

Session 2: Respond to old adults

- mindful stretching
- fight-or-flight reactions
- avoidance and aggression in caregiving

Session 3: Working with challenges and difficulties in caregiving

- mindful sitting
- working with difficulties using mindfulness
- mindful communication exercise
- pleasant and unpleasant events in caregiving

Session 4: Self-care of caregivers

- brfriending exercise
- review of learning
- planing for future

Psychoeducation (Arm 2)
Session 1: Stress of caregivers

- overview of frailty
- behaviour and emotions of caregivers
- managing stress
- trigger-behaviour-reaction chain

Session 2: Making a behaviour plan for old adults

- setting behavioural goals
- changing behaviours by changing reactions
- changing unhelpful thoughts

Session 3: Communicating with old adults

- assertiveness skills
- communicating with old frail adults
- care plan and managing health of old frail adults

Session 4: Caregiver Self-care

- Identify and plan pleasant events
- monitoring mood of caregivers
- review of course learning; making future plan