Cover page

Official Title of the study: Family-based Mindfulness Training for Promoting Child Development and Stress Management in Economically Disadvantaged Families

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Application of mindfulness training in a family-based intervention for improving development and stress management for children in economically disadvantaged families

Study Objectives

1. To investigate the effectiveness of a FBMI in reducing parental stress and promoting child development
2. To develop an evidence-based practice approach for reducing stress of EDF in Hong Kong Chinese context.
3. To add to theory and develop a better understanding of factors related to EDF and child development to aid policy makers and practitioners working with them

Research plan and methodology

Hypotheses of the study

In responding to the objectives proposed in last section, we hypothesize that the children in the intervention will have lower physiological stress, less behavioral problems, better attention, behavioural and emotional regulation than participants in the control group at the end of intervention, and parents in the intervention will have lower physiological stress and self-reported parental stress, less anxiety and depressive symptoms, better mindfulness in parenting and perceived family functioning than participants in the control group at the end of intervention.

Research plan

The effects of this family-based intervention will be tested using a two-arm randomized controlled trial, comparing the family-based mindfulness intervention (arm 1) to a wait-list control (arm 2). After the completion of the programme and a three month follow-up, participants in arm 2 will be given the same intervention. Assessments will be made before (T1) and after intervention (T2) and at the three month follow-up (T3). Programme effects can be tested using both between-subject (comparison of two arms) and within-subject (comparison of measures at T1, T2, and T3).

Sample size estimation. There are two primary outcomes in this study. Outcomes of two mindfulness training by Bogels and colleagues (2013), with an effect size of 0.4 in parental stress, and the one by Black and Fernando (2010), with an effect size of 0.4 in paying attention and selfcontrol, are chosen for sample size calculation. For a two-tailed α error of 5%, an 80% power, and a test of two independent groups, the required sample size will be 100 families per arm (Cohen, 1988). With references to two local mindfulness training studies which reported 30% drop-out rate (Hou et al., 2013; Lo et al., 2013), we aimed to recruit 130 families per group, and 260 families for two arms in total.

Recruitment of participants. Considering the feasibility of recruiting a large number of economic disadvantaged families and the arrangement of intervention programme within their living district, three districts (Kwai Ching, Kwun Tong, and Sham Shui Po), which ranked the first, third, and the fourth among 18 districts in Hong Kong, in terms of percentage of the children aged 0 to 15 from low income families (Census and Statistical Department, 2013). All kindergartens joining the education voucher scheme which are affordable to low income families in above three districts will be assigned a random number. Kindergartens will be randomly selected, and all K2 and K3

parents from the kindergarten will receive an invitation to participate in this study. Interested participants will be assigned to two arms randomly. The randomization allocation is administered by an independent research assistant who is blind to the identity of participants and will not be involved in contacts with families and programme implementation. With the estimation of an average response rate of 40%, and a 33% of families in these districts are families in economic disadvantaged, 1500 invitations are required to meet the expected sample size. Quota will be divided by three districts according to their number of student populations proportionally. At the beginning of the study, parents of the participating schools will be asked to complete the parenting stress inventory and demographic information. Inclusion criteria of this study include: (1) monthly household income below one half of the median of those in Hong Kong; (2) moderate to high parental stress: to be assessed by a self-reported inventory Parenting Stress Index Short Form (PSI-SF) (Abidin, 1990). A cut-off point of 100 is selected, as reported by Lam as the mean in her sample, and only parents with a PSI score of 101 or above will be included in this study. The only exclusion criteria will be children or parents with disability. Families are formed into groups of 20 to 25 for programme implementation.

Procedures

Programme planning and training. The programmes for parents and children were developed by following the first three steps in intervention research, which was proposed to be completed a large scale of clinical trial was conducted (Feaser & Galinsky, 2010). First, develop programme theories: FMBI adopted themes and approaches about stress responses, with reference to the chronic situation of poverty, and promote the use of acceptance and approach coping in the programmes. Two evidence-based mindfulness training programmes were selected for further adaptation for the present project. The parent mindfulness training is a brief version of the Mindful Parenting course developed by Bogels and Restifo (2014). The evidence-based programme was originally developed for reducing the stress of parents of adolescents with ADHD or aggression (Bogels et al., 2013). The protocol for the child programme was developed by Eline Snel (2013), which was suitable for children at ages from 5 to 8. Concerning the suitability of a programme for coping with poverty-related stress, Wadsworth (2012) highlighted three major principles for promoting effective responses to stress: addressing the involuntary stress responses, appraising the controllability of the situation using approaching-oriented coping, and selecting coping method that matches the specific stressor. Both parent and children programmes follow the mechanisms of mindfulness training, assisting participants to address, acknowledge and accept difficult experiences, and develop self-care strategies or plan for mental health. For children programme, seeking help from adults including parents, caregivers, or other significant others in view of their own limitation of resources (Wadsworth, 2012). This component will be added to the 8 week mindfulness programme for children.

Second, programme structure and processes in the intervention design. In the first draft of the parent programme contents were developed by the principal researcher. Five experienced mindfulness training instructors formed a practice team and gathered for providing comments to the session contents for three times before the pilot studies. Two overseas reviewers were further invited to comment the programme content and responded to the proposed areas of modification for finalizing the intervention protocol. Third, refinement of the protocol in pilot study. Pilot tests have been conducted in 2013/14. Minor modification was made in each of the three major components of a mindfulness-based intervention, namely, in-class mindfulness exercises,

discussion of relevance to context, and home exercises, after the second round of practice team meeting and consultation with overseas reviewers.
Four instructors will be recruited to conduct the programmes. They should have a bachelor degree in social work, psychology, education, or nursing, and complete a basic eight week mindfulness training programme. They are required to complete instructor's training, either a two day training for parent programme, or a six day training for child programme. Please refer to table 1 and table 2 for the sessions outline for programmes for children and parents.
The applicant has conducted two pilot studies to explore the feasibility of FBMI from May to October 2014. Pilot study 1 implemented to six children at 5 and found that they had improved in anxiety-depression symptoms ($t=2.61$, $p=.05$) and attention accuracy ($t=2.63$, $p=.02$). Pilot study 2 was implemented to 10 parents and their children. (to be completed in two weeks).

Implementation and assessment. After the first assessment (T1), the participating families in arm 1 receive eight session mindfulness training. After the intervention, students in both arms will complete the second assessment of the study (T2). Participants in the wait-list (arm 2) will not receive any intervention during this phase. Each session lasts 60 minutes for children and 90 minutes for adults and a 10 minute daily home practice is required. In view of the age factor, a smaller group size of 6 to 8 was adjusted for the children after the pilot study, and a size of 16 to 18 remained for parent group. The class sizes are identical to the recommendation of mindfulness training programme as proposed by overseas training bodies and was confirmed by the overseas reviewers (Kabat-Zinn, 1990: Snel, 2013). Session plans of two programmes are attached in Appendix 1. Three Non-government organizations have committed to participate in the study. They are Hong Kong Family Welfare Society, Christian Family Service Centre, and Yang Memorial Methodist Social Service. Programmes will be conducted in their family service centres at Kwai Chung, Kwun Tong, and Mongkok. Each centre will be responsible for conducting intervention programmes for the families recruited within or in a nearby district. Participants in the wait-list (arm 2) will receive the same intervention after three month follow up (T3).
Intervention fidelity. The intervention will be assessed for fidelity of implementation by videotaping all group sessions. Two independent experts in mindfulness training will be recruited to view six randomly selected clips and rate the level of compliance to the intervention protocol. High concordance rate between two experts signifies great fidelity to intervention.
Additional qualitative studies to offset the threats of internal validity. 1. Parent's weekly diary: The use of weekly diary for recording the use and reflection of homework exercises is a regular practice in MBCT (Segal, Williams & Teasdale, 2013). Weekly diary is also a common evaluation strategy to examine programme effect and it has also been used in local intervention study (Shek, 2010). For each parent group, two parents will be randomly assigned to write up their experiences, feelings and thoughts about stress and their coping in daily life. Since the participants are from economic disadvantaged families, research assistants will confirm with selected participants if they are literate and feel competent to submit their diary. 2. Focus group interviews: All parents will be invited to participate in the 8th week and attend a focus group interview. They will be gathered face-to-face to reflect and share their perception about the programme and the changes their family experience after joining the programme. The procedure of the interview will be structured, addressing topics about participant' overall conditions about their family stress, their reports of changes after joining the intervention programmes, their attributions about changes, and the helpful and unhelpful components of the programmes. The interview protocol is adapted from Client Change Interview (CCI) developed by Elliott, Slatick and Urman (2001).

Measures

Figure 1 list out all variables and measures to be used in this study.

Demographics. Questions about age and gender of parent and child, place of birth, number of family members and children, parent's marital status, household income will be asked.

Child functioning

1. physiological stress. Salivary cortisol and HRV are useful biomarkers that have been selected as outcome measures for mindfulness-based intervention (Matousek, Dobkin & Pruessner, 2010; Nijjar et al., 2014). They are also useful stress indicators for young children (Blair et al., 2011a; Michels et al., 2013).

Salivary cortisol: Salivary cortisol of both parents and children will be collected by Salivette tubes. Two saliva samples (wake up and 2100 h) at two time-points (T1, T2) on two consecutive days are used. The participants were reminded not to brush their teeth or eat within thirty minutes before sample collection to avoid contamination and were advised to follow their normal daily routines otherwise. Collected tubes were kept frozen until they underwent laboratory analysis of the salivary cortisol using an enzyme-linked immunoassay kit (Salimetrics, PA, USA). *Heart Rate Variability* (HRV): HRV is a measure of cardiac autonomic function by counting the cyclic variations of RR intervals in electrocardiogram. It is also an early marker of cardiovascular risk (Taylor, 2010). HRV will be measured by using ambulatory electrocardiogram to reflect on mother's cardiovascular risk and autonomous nervous system functioning. Polar heart-rate monitors (Polar Vantage NV, Polar Electro Oy, Finland) will be used to continuously collect heart-rate data (in the form of R to R peak intervals) from the mothers for 30 mins. During the HRV assessments, the participants will be asked to do a stressful computer game to create an acute stressful environment. The participants' spectral HRV data including (1) normalised low frequency (LF) power (0.04-0.15 Hz), (2) normalised high frequency (HF) power (0.15-0.4 Hz) and (3) the low frequency/high frequency (LF/HF) power ratio will be recorded by using Kubios HRV version 2.1 software package (Biosignal Analysis and Medical Imaging Group, University of Eastern Finland, Finland).

2. behavior problem. The Chinese-Cantonese version of Child Behavior Checklist (CBCL) will be used to assess child behaviour problems through collection of parent's ratings (Achenbach & Rescorla, 2000). The test-retest reliability and criteria validity of the school children version of CBCL have been established for Hong Kong (Leung et al., 2006). However, a preschool version CBCL/1.5-5 which applies to children aged 1.5 to 5 was developed in 2000 forming a similar factor structure in Mainland and overseas studies (Liu, Cheng, Leung, 2011). It has 67 items involving seven subscales (emotionally reactive, anxious/depressed, somatic complaints, withdrawn, aggressive behavior, attention problem, sleep problems). The first four was classified as internalizing problems and the following two was classified as externalizing problems, and such factor structure were confirmed in Mainland's study. Correlations between seven subscales ranged from 0.38 to 0.71 and those between internalizing and externalizing problems was 0.75 (Liu, Cheng & Leung, 2010).

3. attention. The Child Attention Network Test (ANT) was developed by Posner and Petersen (1990). It presents five fish in a horizontal row that appear above or below the fixation point. Children were instructed to press a key indicating in which direction the central fish was pointing

and to ignore the flanker fishes. Completion of the task allows calculation of three scores related to the efficiency of attention networks. Alerting is measured by the additional time required to respond with no cue, compared to a cue that inform the child that a target will occur shortly. Orienting is measured by the time taken to respond to a cue at the target location minus reaction time to a central cue. Executive attention is measured as interference by the flanker fish on the child's score. The ANT was used in one of the Co-Investigator's pilot study for mindfulness training for ADHD children (Wong, Kwok & Lam, 2012).

4. *emotion and behaviour regulation*. A two dimensional assessment will be used and scores from both tests will be combined to form the child's assessment of emotion and behaviour regulation. The Snack Delay and the Toy Wrap tests are used to assess the child's emotional and behavioral regulation. In the Snack Delay test, children are instructed to put their hands flat on the table and watch a snack being placed under a cup. They can wait until the assessor tells them that "time is up" that they can have the snack. The assessor administers four trials, which last 10, 20, 30, and 60 seconds respectively. The assessor scores each trial using a four point rating (1=eats snack, 2=touches snack, 3=touches cup or timer, 4=waits for time and does not touch cup or timer). The mean score across four trials will be the score of child's emotional and behavioral regulation. In the Toy Wrap test children are asked not to peek while assessor wraps a toy in tissue and bag for one minute. The latency in seconds to first touch of toy will be measured. In the selection of test, a rule of not having more than 50 percent of participants got highest scores will be observed (Bassett, Denham, Wyatt, & Warren-Khot, 2012). Construct validity of this measure was evaluated in the applicant's pilot study in 2014. In a study with 8 samples, the Snack Delay was significantly negatively correlated with emotionally reactive syndromes (r = -.82, $p < .05$), aggressive behaviors syndromes (r = -.79, $p < .05$), externalizing problems (r = -.80, $p < .05$) and total problems (r = -.73, $p < .05$) in parent-reported Child Behavior Checklist. In a study with 7 samples, the Toy Wrap was significantly negatively correlated with attention problems (r = -.80, $p < .05$), internalizing problems (r = -.86, $p < .05$), externalizing problem (r = -.77, $p < .05$) and total problems (r = -.84, $p < .05$).

5. cognitive and language development. The Hong Kong Early Child Development Scale has been developed for assessing the children from three to six for their overall development conditions (Rao et al., 2013). Within the eight domains, language development (13 items), pre-academic learning (27 items), and cognitive development (10 items) will be selected for the present study. Cronbach's alphas of the above three subscales are .80, .95, and .70 respectively. Normative data for K3 students in Hong Kong is available for comparison (Rao et al., 2013).

Parent functioning

1. physiological stress. Salivary cortisol and HRV of parents and data collection follows same procedure as child salivary cortisol and HRV.

2. parental stress Parenting Stress Index Short Form (PSI-SF) The Parenting Stress Index Short Form has 36 items and was developed by Abidin (1990) for tapping the sources of difficulties and level of parenting stress experienced by parents. The scale was divided into three subscales,

parental distress, parental-child dysfunctional interaction, and difficult child. The Chinese version was validated by Lam (1999). The reliability estimates for the total score and three subscales were 0.92, 0.86, 0.82, and 0.86 respectively.

3. mental health. Anxiety and depression symptoms are assessed by The Chinese-Cantonese version of Hospital Anxiety and Depression Scale (HADS), originally developed by Zigmond and Snaith (1983). It consists of two sub-scales with seven items related to the level of depression and anxiety respectively (Leung et al., 1993). The Chinese-Cantonese version of HADS shows good convergent validity with close correlation with both the Hamilton rating Scale of Depression (HRSD) and the Hamilton Rating Scale of Anxiety (HRSA) (Leung et al., 1999). The Cronbach's alpha coefficients are .80 and .71 for the anxiety and depression subscales respectively and its split-half *r* is 0.86.

4. *interpersonal mindfulness.* The Interpersonal Mindfulness in Parenting (IM-P) has 31 items that assess the parent's quality of mindfulness in specific to their family context (Duncan, Coatsworth, & Greenberg, 2009). The original subscales include listening with full attention, emotional awareness of self and child, self-regulation in parenting relationship, non-judgmental acceptance of self and child, and compassion for self and child. The inter-item coefficient ranged from 0.45 to 0.72. IM-P was found to mediate the effects of family-based mindfulness intervention (Coatsworth et al., 2010). A validation study of IM-P on Hong Kong parents with preschool children will be conducted by the P-I on late 2013.

Analysis

Quantative data: Baseline equivalence. The values of the primary outcome measures (i.e., parental stress and child behavior problem) at T1 will be compared among participants in the two trial arms. The outcomes at T1 and the treatment-condition variable will be used as the dependent variables, after controlling for age and sex of child.

Intervention effects. All analyses were carried out according to the intention-to-treat approach. Missing values of participants were imputed using the last-observation-carried-forward method. With the between-subject design, the effectiveness of the programmes will be tested and compared using multilevel regression models. The trial-arm memberships will be dummy-coded, so that the family-based intervention group (arm 1) will serve as the reference group. The outcomes measured at T2 and the dummy variables will be used as the dependent and independent variables, respectively, controlling for the outcomes measured at T1 and other demographic covariates. For the within-subject design, four-level regression models (changes within parents, changes within children) will be used to examine the effects of the intervention programme. The time points will be dummy-coded, so that the outcome measures at T2 will serve as reference. The dependent variables are outcome measures, whereas the independent variables are dummy variables identifying the measurement time points. Demographic covariates are controlled. The T1-T2 difference and the T2-T3 difference will be compared by testing the size of coefficients of the dummy-coded variables in the models using Wald tests. Reduction in the values of the outcome measures between T1 and T2 will indicate significant programme effects. The outcomes measured at T2 and T3 will be compared among arms 1 and 2 to see whether maintenance effects will be found around 3 months after the end of the programme. Using the same analytical techniques for the within-subject design, the models for testing maintenance effects will be conducted separately for participants in arm 1 and arm 2.

Qualitative data: Weekly dairies: Two research assistants will be assigned to rate the participant's uses of mindful approaches in coping with stress in weekly diaries. Participant's reports of benefits of mindfulness training in terms of frequency and areas of benefits (self, children, physical health, mental health, attention, learning and other cognitive functioning) will be counted in categories. Focus group interview: Contents of the interview will be transcribed and analyzed in a coding process. The text will be divided into small units (phrases, sentences and paragraphs) and labels will be assigned in each unit, and then codes will be grouped into themes (Creswell & Clark, 2011). Intra-rater and inter-rater reliabilities will be calculated

Project funding (in Hong Kong dollars)

Research assistant $16 000 x 24 months X 0.6 x 1.05 (MPF) =$241 920

Instructors fee $600 per session x 18 children groups + $1200 per session x 9 parent groups

=$21 600

Salivary cortisol analysis $120 per sample x 520 participants x 2 samples x 2 time points

$124 800

Cash coupon for program completers $200 per families x 200 =$40 000

Miscellaneous $20 000

Amount requested **$448 320**

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Appendix 1

Mindfulness training for children (developed by Eline Snel, 2013)

Session	Theme	Goal
1	A for attention	• establish motivation of be attentive and mindful • use breathing as a beginning of exploration of attention
2	Exploring our body	• introduce mindful movement exercises • expand awareness of body sensation
3	Tasting, Smelling, Hearing, Seeing and Feeling	• introduce the use of multiple senses in understanding our inner and outside world
4	Feel our feelings	• learn to be aware and describe our feelings
5	Accepting feelings	• acknowledge feelings of self and others • experience the importance of accepting feelings
6	Conscious movement	• bring attention and awareness to self and others
7	The power of awareness and thoughts	• experience the application of mindful attention and thoughts in daily life
8	Being nice is good	• consolidate learning • celebrate

Mindfulness training for parents

Session	Theme	Goal
1	orientation	• introduce mindfulness • Collection of baseline
2	Automatic reactions	• introduce body scan (lying exercise) • understand the symptoms and stress reactivity notice physiological, emotional and cognitive reaction in stressful moments of parenting • use of mindful breathing and nonjudgmental attitude in managing the reaction
3	Understand our children	• introduce mindful movement • Enhance attention and sensitivity to child's developmental and emotional needs • develop nonjudgmental attitude to child's behaviors
4	Respond to children mindfully	• notice reactive patterns in parenting and communication • introduce three minute breathing as coping

		• practice deep listening in mindfulness
5	Goals and expectations in parenting	• notice different needs and wants of children and adults • identify healthy qualities for parents and children
6	Communicate with mindfulness	• communicate needs and wants in parenting and family relationship
7	Self-care of parents	• promote self-care for supporting children and family in adversity • consolidate learning
8	focus group interview	• embedded for research purpose • investigate the mechanism of change

Figure 1

Variables and measures of the proposed study