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Efficacy of the integrative Body–Mind–Spirit group intervention for improving quality of life in parent–child dyads adjusting to atopic dermatitis: protocol for a randomised controlled trial

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ABSTRACT

Introduction Atopic dermatitis (AD) is the most common childhood inflammatory skin problem affecting 15%–30% of children. Although AD adversely impacts the psychosocial well-being of children and their parent caregivers, parents' psychosocial well-being is seldom mentioned in most non-pharmacological education programmes. A family-based psychosocial intervention, Integrative Body–Mind–Spirit (I-BMS) intervention, is examined. This study compares the efficacy of two versions of the I-BMS intervention (one delivered to both parents and children; one delivered to parents only) with a health education active control (delivered to parents only) in promoting adaptive emotional regulation and quality of life of children with AD and their parent caregivers.

Methods and analysis This is a three-arm, with equal randomisation, parallel randomised controlled trial. 192 parent–child dyads will be recruited through hospitals and non-governmental organisations in Hong Kong. Each dyad will complete an individual pre-group screening interview. Eligible dyads will be randomised in a ratio of 1:1:1 into one of the three arms. Each arm consists of six weekly sessions. A computer-generated list of random numbers will be used to perform randomisation. The primary outcomes are quality of life and emotional regulation. Assessments are administered at baseline, post-intervention and 6-week follow-up. Mixed factorial Analysis of Covariance (ANCOVAs) based on intention-to-treat principle will be conducted to examine the efficacy of the two I-BMS interventions. Structural equation modelling will be conducted to examine the parent–child interdependent effects of intervention.

Ethics and dissemination Ethics approval was obtained from the Human Research Ethics Committee of the University of Hong Kong (EA2001001) and the Institutional Review Board of the Hospital Authority of Hong Kong (UW 21-400, KC/KE-20-0360/FR-2, NTEC-2021-0408). Consent will be sought from participating parents and children. Parental consent for child participants will also be obtained. Findings will be presented in peer-reviewed journals and at conferences in medical dermatology, paediatrics and social work.

Strengths and limitations of this study

- Our pioneer Integrative Body–Mind–Spirit intervention for families with children living from atopic dermatitis has been empirically tested and effectively enhanced parents' psychosocial well-being, an area which is seldom mentioned by most non-pharmacological training programmes.
- This study supports the design of a more parsimonious atopic dermatitis intervention targeting at parent caregivers (without involving children) to transfer post-intervention parental improvements to their children.
- This study also supports the incorporation of a psychosocial component into childhood atopic dermatitis health education to address parental distress and needs.
- The generalisability of the findings is limited by the sample characteristics in terms of the age group, as well as by the self-reported intervention fidelity measure.

Trial registration number ClinicalTrials.gov Registry (NCT04617977).

INTRODUCTION

Childhood atopic dermatitis is a chronic skin disease with increasing prevalence

Atopic dermatitis (AD) is a recurrent inflammatory skin disease. Incidence of AD has increased twofold to threefold in industrialised countries, impacting approximately 15%–30% of children.[1 2] In Hong Kong, AD is the most common skin problem,[3] and 60% of primary school children ranked AD as the highest in the list of skin problems.[4] Although 60% of children will grow out of their AD when they reach their teens, about half of these children may continue to suffer from AD in adulthood.[1] As such, childhood

AD raises public health concerns in terms of medical and financial costs to patients, caregivers and healthcare systems.[5 6]

Interdependence between family members calls for a systemic family-based intervention

Childhood AD not only engenders adverse physical–psychosocial impacts on children,[7–9] but also creates tremendous burden for parents who provide primary care for them.[3] Several studies found that parents suffered from poor physical health, emotional disturbance, social isolation and disruption of daily lives.[10–12]

According to a review study on the familial impact of AD, the quality of life (QoL) of children and their family members was highly correlated, regardless of climate, living location and the socioeconomic background of the families.[13] Likewise, Fung and colleagues[14] found that parents were emotionally attached to their children, and they would feel depressed and anxious when their children expressed physical and emotional distress arising from AD.

Moreover, parents' emotional well-being was found to have a spillover effect on children's emotional regulation, acquisition of regulation strategies and relationship with their parents.[15] Such new insight calls for a systemic family-based intervention on AD management by involving both the patients and their family caregivers.[16]

Moving beyond non-pharmacological childhood AD management programmes

Childhood AD is a multifaceted health condition that requires both medical and psychosocial interventions. Yet, most of the non-pharmacological training programmes are recovery based and focus on treatment compliance and symptom management.[17] Nurse-led parental education predominantly focuses on knowledge and skills in AD management, as shown by a systematic review on the psychological and educational interventions for childhood AD.[18] These findings show that parents' psychosocial well-being has received little attention in the illness trajectory of childhood AD.

The Integrative Body–Mind–Spirit (I-BMS) intervention is a non-pharmacological intervention approach that is effective in improving one's physical and psychosocial well-being for various clientele, including those diagnosed with psoriasis.[19–22] Recently, our research team developed and empirically tested a family-based I-BMS group intervention for families with children suffering from AD by conducting a randomised waitlist-controlled trial,[14 23] in which parents and children attended group sessions simultaneously. Results are promising. Relative to a waitlist control group, parents in the I-BMS group reported significantly more improvements in perceived stress, depression and holistic well-being.[14] Relative to a waitlist control group, children in the I-BMS group reported significantly more improvements in somatic AD severity, generalised anxiety, social phobia and emotional regulation.[24] With encouraging findings on the efficacy of our family-based I-BMS intervention, it is worth examining the mechanism underlying the intervention effect, an area that is poorly reported in past studies.[25] The associations between parents' and children's post-intervention outcome improvements serve as a potential mechanism of change that underpins the family-based I-BMS intervention effect.

However, interventions that involve both children and their family caregivers can be costly, because several social workers and other supporting staff are employed to deliver parallel sessions in separate rooms in the long run. Extra human resources are also required to retain participants. Hence, designing a more cost-effective family-based group intervention and investigating its efficacy are of great value.

Objectives

This study aims to examine if the I-BMS intervention delivered only to the parents would be: (1) as efficacious as the I-BMS intervention delivered to both the parents and children, and (2) more efficacious than the health education active control delivered only to the parents, in improving children and their parent caregivers' emotional regulation and QoL. The rationale for choosing health education as the active comparison group is to control for the amount of group effect on the intervention outcomes across the three arms. It also examines whether children's baseline primary outcomes and post-intervention primary outcome improvements are associated with those of their parents. This paper outlines the study protocol, in accordance with the Standard Protocol Items: Recommendations for Interventional Trials[26] guidelines.

METHODS AND ANALYSIS

Trial design

This is a three-arm, with equal randomisation, parallel randomised controlled trial (RCT).

Hypotheses

H1: after the intervention, parents and children in the two I-BMS intervention groups will report significantly more improvements in emotional regulation and QoL than those in the health education active control group. *H2*: there is no significant difference between the two I-BMS intervention groups in terms of post-intervention improvements in emotional regulation and QoL. *H3*: the post-intervention improvements in emotional regulation and QoL will be maintained at 6-week follow-up for the two I-BMS intervention groups, but not for the health education active control group. *H4*: children's baseline QoL is predicted by their own baseline emotional regulation and by their parents' baseline QoL. *H5*: parents' baseline QoL is predicted by their own baseline emotional regulation and by their children's baseline QoL. *H6*: children's post-intervention improvements in QoL are predicted by their own post-intervention improvements in emotional regulation and their parents' post-intervention improvements

in QoL. *H7*: parents' post-intervention improvements in QoL are predicted by their own post-intervention improvements in emotional regulation and their children's post-intervention improvements in QoL.

Recruitment

One hundred and ninety-two parent–child dyads will be recruited through hospitals and non-governmental organisations (NGOs) in various districts in Hong Kong. Our interdisciplinary research team and collaborating partners have an extensive network in recruiting participants through medical consultations by doctors, social service by NGOs, patient support networks, as well as publicity through social media. The project start date is 23 August 2021 and the expected project completion date is 31 December 2023. The participant recruitment started on 23 August 2021, and is expected to finish by 30 September 2023.

Sample size calculation

The sample size calculation for each parent's primary outcome (ie, QoL and emotional regulation) is conducted using G*Power V.3.1.9.4 'ANOVA: Repeated measures, between factors'. The alpha value is set to 0.05. Correlation among repeated measures is set at 0.5. A minimum of 108 parents will be required to detect a small effect of 0.25 among the three arms across three assessment points with 80% power. Considering 25% attrition at each assessment point, a total sample of 192 parents is needed.

Sample size calculation for each child's primary outcome (ie, QoL and emotional regulation) is the same as that of the parents. A minimum of 108 children will be required to detect a small effect of 0.25 among the three arms across three assessment points with 80% power. Considering 25% attrition at each assessment point, a total sample of 192 children is needed. Taken together, the final target sample consists of 192 parent–child dyads (64 dyads per arm).

Eligibility

Inclusion criteria

Children will be recruited if they: (1) age between 6 and 12 years; (2) are diagnosed with AD as assessed by the doctors (International Classification of Diseases, Tenth Revision, codes L20–L30); (3) are able to communicate in Cantonese; (4) consent to participate; and (5) obtain parental consent to participate in this RCT. Their parents will be recruited if they: (1) are the primary caregivers; (2) are able to communicate in Cantonese; and (3) consent to participate.

Exclusion criteria

Children will be excluded if they are diagnosed with autism spectrum disorder or attention deficit hyperactivity disorder. Parent caregivers will be excluded if they exhibit a history of family abuse and present with clinically significant psychiatric morbidity such as psychosis.

Participant timeline

Each prospective parent–child dyad will attend: (1) a pre-group medical screening performed by a doctor to assess the clinical condition of childhood AD so as to confirm the diagnosis of AD, and (2) a semistructured pre-group individual interview performed by a research assistant and a registered social worker to assess their eligibility, explain the purpose and process of the intervention, as well as obtain informed consent. Ineligible participants will be referred for follow-up if necessary. After eligible participants give their consent and complete the baseline assessment (T0), they will be randomly assigned in a 1:1:1 ratio into one of the three arms. A research team member who is not involved in the trial will perform the randomisation using a computer-generated list of random numbers. The allocation information will be saved in a password-protected Excel file, and will remain concealed until trial completion. Eligible participants will be contacted within 2 weeks after completing the baseline assessment to inform them of their intervention schedule. Clinical treatment of AD will continue as usual throughout the trial, regardless of the group assignment. Immediately after the intervention, participants will complete the post-intervention assessment (T1). Six weeks after finishing the intervention, participants will complete the follow-up assessment (T2). Participants will receive email or text reminders when their assessments are due and/or not completed. Participant flow chart is displayed in figure 1.

Non-pharmacological interventions: I-BMS versus health education intervention groups

Each arm consists of six 3-hour weekly sessions (see table 1).

Arm 1 (I-BMS intervention delivered to both children and parents)

Both children with AD and their parent caregivers will attend the six I-BMS sessions in a parallel group format. The I-BMS intervention is an evidence-based model that adopts a strength-based and empowerment perspective.[21 22] It focuses on the connection between physical and emotional well-being, and the spiritual transformation of adverse life experiences through fostering forgiveness and letting go. It integrates Eastern philosophies and Western therapeutic techniques to transcend adverse life experiences under a meaning-oriented framework. Parent caregivers will attend the parents group led by a social worker in the first 2.5 hours; while their children will attend the children group led by two social workers in a separate room in the first 2.5 hours. Both parents and children will later reunite in the joint group led by the three social workers in the final 0.5 hours. All three social workers are well trained with the I-BMS intervention.

Arm 2 (I-BMS intervention delivered to parents only)

Only parent caregivers will attend the six I-BMS sessions led by one social worker. The content of the 2.5-hour session will be the same as the one in arm 1, with an additional 0.5 hour of reflective group discussion among the

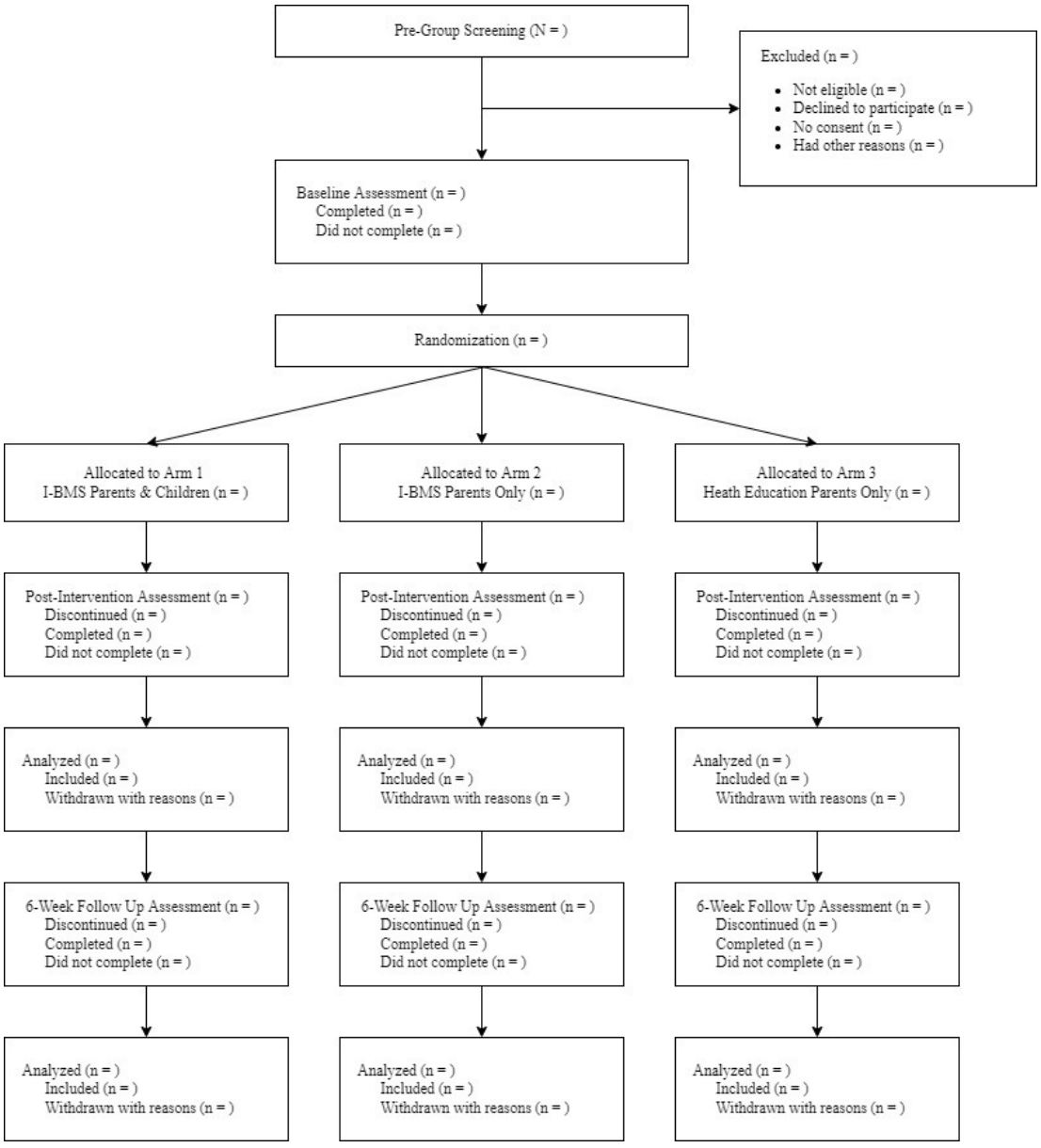

Figure 1 Trial profile. I-BMS, Integrative Body–Mind–Spirit.

parents. The children group will simultaneously attend a group activity class in a separate room for 3 hours.

Arm 3 (health education delivered to parents only)

Only parent caregivers will attend the six health education sessions led by a registered nurse specialised in paediatric dermatology, with a focus on AD management. It consists of a didactic approach to teaching different health-related topics (see table 2). Each session consists of 2.5-hour lecture and 0.5-hour question and answer. The children group will simultaneously attend a group activity class in a separate room for 3 hours.

Outcome measures

Primary outcomes

Quality of life

The 10-item Chinese version[27] of the Family Dermatology Life Quality Index[28] will be used to measure how much a child's AD affects the QoL of their parent caregivers. It has been validated in a Hong Kong sample and the Cronbach's alpha was 0.95.[3] The 10-item Chinese version[29] of the Children's Dermatology Life Quality Index[30] will be used to measure the impact of AD on the lives of children. It has been validated in a Hong Kong sample and the Cronbach's alpha was 0.83.[31]

Emotional regulation

The 18-item Cognitive Emotion Regulation Questionnaire-Short Version[32] will be modified and translated into Chinese to measure the specific cognitive emotion regulation strategies parent caregivers have used when caring for the participating child. References to the experience of threatening or stressful events in the original items will be modified to 'taking care of my child with eczema'. Cronbach's alpha ranged from 0.62 to 0.85.[32] Eighteen

Table 1 The standardised I-BMS sessions for children with AD and their parent caregivers (arms 1 and 2)

Session	I-BMS psychosocial intervention group for parents	Session	I-BMS psychosocial intervention group for children
P1	Awareness of body–mind connection ► To acknowledge the interconnectedness between mind and body ► To normalise the parental caregiving experience and its physical and psychosocial impact on health	C1	Awareness of body–mind connection ► To acknowledge the interconnectedness between mind and body ► To normalise the illness experience
P2	Regulation of emotions ► To realise the negative emotions and their impacts on self and others ► To be aware of the condition of emotional interdependence ► To learn different means of emotional expression	C2	Regulation of emotions ► To realise the negative emotions and their impacts on self and others ► To learn different means of emotional expression
P3	Acknowledgement of the gains and losses in the caregiving experience ► To acknowledge that losses and limitations are common humanity experiences ► To facilitate benefit findings in the caregiving experience	C3	Acknowledgement of the gains and losses in the illness experience ► To acknowledge that living with AD is a normal and common experience ► To facilitate benefit findings in the AD experience
P4	Appreciation of self and others ► To identify personal and family strengths ► To appreciate the inner resources and those of the children	C4	Appreciation of self and others ► To identify personal and family strengths ► To appreciate the inner resources and those of the parents
P5	Cultivation of acceptance ► To accept negative thoughts and emotions with openness and clarity, so that they are held in mindful awareness ► To foster acceptance and forgiveness throughout the caregiving experience as parents	C5	Cultivation of acceptance ► To accept negative thoughts and emotions with openness and clarity, so that they are held in mindful awareness ► To cultivate self-kindness by accepting AD as part of their lives
P6	Meaning reconstruction of caregiving experience ► To expand the identity from victim to survivor	C6	Meaning reconstruction of illness experience ► To affirm self-identity, 'I am much more than my eczema' ► To expand the identity from victim to survivor

Arm 1 is I-BMS intervention delivered to both children (sessions C1–C6) and their parent caregivers (sessions P1–P6). Arm 2 is I-BMS intervention delivered to parent caregivers only (sessions P1–P6).
AD, atopic dermatitis; I-BMS, Integrative Body–Mind–Spirit.

items will be extracted and modified from the 36-item Chinese Child Version of the Cognitive Emotion Regulation Questionnaire[33] to measure the specific cognitive emotion regulation strategies children have used to cope with AD. These 18 extracted items correspond to the 18-item Short Version of the Cognitive Emotion Regulation Questionnaire for Spanish Kids.[34] References to the experience of threatening or stressful events in the original items will be modified to 'having eczema'. Cronbach's alpha was 0.88.[34]

Secondary outcomes

Depression and anxiety

The 14-item Chinese version[35] of the Hospital Anxiety and Depression Scale[36] measures parent caregivers' levels of depression and anxiety. It has been validated in a Hong Kong sample and the Cronbach's alpha was 0.82 for the depression subscale and 0.77 for the anxiety subscale.[35] Because there is no Chinese translation for the 25-item Revised Child Anxiety and Depression Scale-Short Version,[37] the corresponding (identical) 25 items will be extracted and modified from the 47-item Chinese version of the Revised Child Anxiety and Depression Scale[38] to measure children's levels of depression and anxiety. Grammar of several Chinese simplified translated items will be modified, without changing the original English items, to make the scale applicable to Hong Kong Chinese participants. Cronbach's alpha for the depression subscale ranged from 0.79 to 0.80.[37] Cronbach's alpha for the anxiety scale ranged from 0.71 to 0.74.[37]

Stress

The 14-item Chinese version[39] of the Perceived Stress Scale[40] will be used to measure parent caregivers' perceived level of stress. It has been validated in a Hong Kong sample and the Cronbach's alpha was 0.85.[39] The 14-item Perceived Stress Scale for Children[41] will be translated into Chinese to measure children's perceived level

Table 2 The standardised health education sessions for parent caregivers of children with AD (arm 3)

Session	Health education active control group for parents
H1	Information about the physiology of AD and its health impact
H2	Recognition and avoidance of trigger factors, and daily skin care
H3	Dealing with itching and scratching
H4	Stage-related treatment of symptoms, and unconventional therapies
H5	General child nutrition, food allergies in AD, different forms of diets
H6	Self-management plan, and problems in integrating it into daily routine

Arm 3 is health education delivered to parent caregivers only (sessions H1–H6).
AD, atopic dermatitis.

of stress. One item is for illustration purposes and is not scored.

Parent–child relationship

The 10-item Personal Relationship Subscale of the Parent–Child Relationship Questionnaire (Parent Form[42]) will be translated into Chinese to measure parents' perception of their relationship with the participating child. Cronbach's alpha ranged from 0.71 to 0.83.[43] The 10-item Personal Relationship Subscale of the Parent–Child Relationship Questionnaire (Child Form[42]) will be translated into Chinese to measure children's perception of their relationship with the participating parent. Cronbach's alpha ranged from 0.63 to 0.88.[43]

Parent-reported AD severity in children

The 7-item Chinese version[44] of the Patient-Oriented Eczema Measure for Child (Parent Form[45]) measures parent caregivers' perception of the participating child's AD severity. Cronbach's alpha was 0.88.[45]

Other measures

Demographics

Single items will be used to measure the demographics of children (age, gender, and education level) and their parent caregivers (age, gender, education level, marital status, employment status, household income, type of housing, and number of children).

Clinical information on childhood AD

Eight self-constructed items will be used to measure the onset age of childhood AD, the types of AD treatments the children are receiving, and the presence of other clinical comorbidities such as allergy.

Intervention evaluation

The 5-item Satisfaction with Treatment Program Scale[46] will be translated into Chinese to measure parent caregivers' satisfaction with the intervention. The Cronbach's alpha was 0.88.[46]

Cross-condition contamination check

Only parent participants in the health education active control group will complete a self-constructed cross-condition contamination checklist to control for the confounding effect of unexpected exposure to I-BMS intervention materials during the trial on primary outcomes. These participants are asked if: (1) they have viewed part or all I-BMS intervention session content, or (2) they have completed part or all of the homework or activities as shown in the I-BMS intervention session materials. The schedule of enrolment, interventions and assessments is displayed in table 3.

Data analysis

Because the participants and our research team are not blinded from group assignment, statistical analyses will be carried out by an independent researcher who is blinded to the study protocol and group assignment. Intention-to-treat analysis will be conducted. Missing data will be handled by multiple imputation.[47] Differences in baseline participants' characteristics across the three arms will be examined by using X^2 tests and between-subject ANOVAs.

A three (arms) × two (assessment points) mixed factorial Analysis of Covariance (ANCOVA) will be conducted to test if the two I-BMS intervention groups are more efficacious than the health education active control group in improving the primary outcomes. Baseline participants' characteristics that are found to differ significantly across the three arms will be the covariates. Planned comparisons with Bonferroni adjustment will be conducted to test: (1) if the post-intervention improvements in the two I-BMS intervention groups are greater than those in the health education active control group, and (2) if there is no significant difference in the post-intervention improvements between the two I-BMS intervention groups. Sensitivity analysis will be conducted to examine whether cross-condition contamination will affect the efficacy of I-BMS intervention in improving the primary outcomes.

Likewise, a three (arms) × two (assessment points) mixed factorial ANCOVA will be conducted to test if the post-intervention primary outcome improvements will be maintained at 6-week follow-up in the two I-BMS intervention groups, but not in the health education active control group. Baseline participants' characteristics that differ significantly across the three arms will be the covariates. Planned comparisons with Bonferroni adjustment will be conducted to test: (1) if there is no significant change in primary outcomes from post-intervention to follow-up in the two I-BMS intervention groups, and (2) if there is significant deterioration in primary outcomes from post-intervention to follow-up in the health education active control group. Sensitivity analysis will be conducted to examine whether cross-condition contamination will affect the efficacy of I-BMS intervention in maintaining the primary outcome improvements.

Table 3 The schedule of enrolment, interventions and assessments

	Pre-group screening	Baseline assessment	Allocation	Post-intervention assessment	6-week follow-up assessment
Time point (week)	0	0	2	8	14
Enrolment					
Eligibility screening	●				
Informed consent	●				
Allocation			●		
Interventions					
I-BMS intervention for parents and children (arm 1)		●	●	●	●
I-BMS intervention for parents only (arm 2)		●	●	●	●
Health education for parents only (arm 3)		●	●	●	●
Assessments					
Primary outcomes					
Quality of life (FDLQI, CDLQI)		●		●	●
Emotional regulation (CERQ-SV, CERQ-SK-SV)		●		●	●
Secondary outcomes					
Depression and anxiety (HADS, RCADS-SV)		●		●	●
Stress (PSS, PSS-C)		●		●	●
Parent–child relationship (PRS-PF, PRS-CF)		●		●	●
Clinical information on childhood AD (including POEM)		○		○	○
Other measures					
Demographics		●			
Intervention evaluation (STP)				○	
Cross-condition contamination check				✪	

●=parents and children; ○=parents only; ✪=parents in arm 3 only.
AD, atopic dermatitis; CDLQI, Children's Dermatology Life Quality Index; CERQ-SK-SV, Cognitive Emotion Regulation Questionnaire for Spanish Kids-Short Version; CERQ-SV, Cognitive Emotion Regulation Questionnaire-Short Version; FDLQI, Family Dermatology Life Quality Index; HADS, Hospital Anxiety and Depression Scale; I-BMS, Integrative Body–Mind–Spirit; POEM, Patient-Oriented Eczema Measure for Child (Parent Form); PRS-CF, Personal Relationship Subscale (Child Form); PRS-PF, Personal Relationship Subscale (Parent Form); PSS, Perceived Stress Scale; PSS-C, Perceived Stress Scale for Children; RCADS-SV, Revised Child Anxiety and Depression Scale-Short Version; STP, Satisfaction with Treatment Program Scale.

Regression analyses and structural equation modelling will be used to examine the interdependent associations between children's and their parent caregivers' primary outcomes at baseline, and between children and their parent caregivers' baseline to post-intervention changes in primary outcomes. Secondary outcomes will be analysed in line with that used for the primary outcomes as described above.

Clinical trial monitoring

Social workers who are leading the I-BMS groups will attend a 3-day training on the I-BMS intervention model, delivered by one coauthor (YLF) and the corresponding author (CHYC), to enhance their clinical competence. Nurses who are leading the health education active control group will attend a training delivered by one team member (Dr Vivian Fei-Wan Ngai) who is a nursing academic. Group leaders of the three arms will complete a treatment fidelity checklist[23] for every session, which measures their competence and adherence to the intervention protocol. The research team will also conduct site visits during the intervention period to monitor treatment fidelity. All group leaders will maintain regular contact with the participants to monitor and encourage treatment adherence, as well as to facilitate participant retention. An independent clinical trial monitoring committee, which comprises of experienced dermatologists, I-BMS researchers and practitioners, will be set up to provide independent assessment regarding the safety, scientific validity, and integrity of the trial.

All adverse events will be recorded and reported to the clinical trial monitoring committee. Referrals for counselling at the collaborating hospitals and NGOs will be made

for participants, if deemed necessary. The sponsor organisation is the University of Hong Kong. The trial may be discontinued due to sponsor, principal investigator, clinical trial monitoring committee, ethics committee, or funder's decision to terminate the trial for safety reasons.

Data management system

Participants will directly enter their data via Qualtrics and data collected will be reviewed immediately by the research team. Any missing data will be rectified, and exceptions, if they exist, will be managed in a timely manner. Data will be collected for research purposes only. Personal information will be handled with strict confidentiality and stored in locked cabinets. Questionnaire data and video recordings will be stored digitally in password-protected files. Unless otherwise agreed, all personal identifiers will be kept separate from the primary data file and will not appear in the analysis reports. Participants reserve the right to review and remove part or the entire of their video recordings at any time, or request that their identity be further anonymised in the video recordings. If participants do not agree to be videotaped, they may be left outside of the camera view or have their images blurred on editing. Data containing personal identifiers and anonymised data will be destroyed 3 years after publication of the first academic paper. The principal investigator and the research team will have access to the full dataset. Participants' research files may be reviewed by the Human Research Ethics Committee of the University of Hong Kong to ensure that the trial is being carried out correctly.

Patient and public involvement

Patients are not formally involved in the trial design, but initial results of our pioneer family-based I-BMS group intervention for families with children suffering from AD[14 24] are promising. Besides, two team members (Professor Ellis Kam-Lun Hon and Dr Patrick Ip) are senior academics and clinicians in paediatrics with an extensive track record in researching children's health and AD; while four team members (Dr David Chi-Kong Luk, Dr James Wesley Ching-Hei Cheng, Dr Ashleigh Ka-Ying Chu, and Dr Sam Ying-Yin Lam) are experienced paediatricians with clinical experience in providing medical care for children with AD. Furthermore, the corresponding author (CHYC) has already established a research and service collaboration with the healthcare and social service agencies from both public (eg, the police, local authorities) and private sectors to maximise the policy impact of this study.

Ethics and dissemination

Ethics approval for the study was obtained from the Human Research Ethics Committee of the University of Hong Kong (EA2001001), the Institutional Review Board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (UW 21-400), the Research Ethics Committee–Kowloon Central/Kowloon East (KC/KE-20-0360/FR-2), and the Joint Chinese University of Hong Kong-New Territories East Cluster Clinical Research Ethics Committee (NTEC-2021-0408). Any amendments to the current protocol (EA2001001, version 2, last updated on 31 August 2021) will be submitted to the Human Research Ethics Committee of the University of Hong Kong for approval. Written and/or electronic consent for parents (see online supplemental file) and children, and parental consent for child participants will be obtained by the research assistant during the pre-group screening interview. A project website will be activated throughout the trial to publicise the research results to the wider Hong Kong and Chinese-speaking communities, as well as to promote ways of accessing support for potential participants. Findings will be presented in peer-reviewed journals and at practitioner conferences in the field of medical dermatology, paediatrics, and social work. Results will also be integrated into undergraduate and postgraduate courses to contribute to public education on the psychosocial impacts and treatments of childhood AD.

DISCUSSION

This is the first study of its kind in the world to examine the interdependence of changes in psychosocial intervention outcomes between children with AD and their parent caregivers. Such findings regarding the association between parents' and children's post-intervention outcome improvements will also serve to generate hypotheses about mechanism of change that underpins family-based psychosocial intervention for paediatric diseases.

Since the intervention targets at children aged between 6 and 12 years, it is difficult to generalise results to older children with AD (age over 12 years) in other geographical locations. Another limitation relates to the self-reported nature of the intervention fidelity check. There is a possibility that the ratings might be subjected to recall bias and social desirability, thereby reducing the reliability of the intervention fidelity check and the study results. Hence, in addition to self-reported treatment fidelity check, the research team will conduct site visits during the intervention period for monitoring treatment fidelity.

Despite these limitations, this study has several strengths. If the I-BMS intervention delivered only to the parents is found to be as efficacious as the I-BMS intervention delivered to both the parents and children, such results will shed light on how non-pharmacological interventions delivered only to parents could break the negative parent–child emotional transmission, as well as enhance the dyads' QoL and emotional regulation. These prospective findings will also inform the future design of systemic family-based psychosocial AD interventions, for example, by employing a more parsimonious design targeting only at parent caregivers (without involving children) to transfer post-intervention parental improvements to their children.

If the two I-BMS interventions are found to be more efficacious than the health education, such findings suggest that incorporating a psychosocial component into childhood AD health education is needed to address parental distress and needs. Such results will also encourage wider dissemination and utilisation of I-BMS intervention as a community-based early intervention for at-risk parent caregivers.

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Contributors CLWC and CHYC innovated the I-BMS intervention. CHYC and YLF conceived and designed this study. VKYH and MSKL prepared the ethics applications. All authors contributed to the management of the study. VKYH drafted the protocol, with critical feedback from YLF and CHYC. All authors read and approved the final manuscript.

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ORCID iD

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香港大學非臨床研究操守委員會參考編號：EA2001001

為濕疹兒童及其父母而設的健康課程 - 隨機對照試驗成效研究

研究簡介（家長）

有鑒於您的孩子患有濕疹，您及您的孩子被邀請參與由香港大學社會工作及社會行政學系副教授陳凱欣博士統籌的一項研究。

研究目的

此研究項目旨在調查患有濕疹的兒童患者及其父母的生活質量和心理健康。此外，我們希望探討健康介入模式是否能有效提升兒童濕疹患者及其父母的心理社交健康。

過程

如您同意參與此項研究，除卻常規醫療覆診外，您及您的孩子將被邀請參與額外的研究介入前檢查，醫生將會為您的孩子診斷他/她的濕疹症狀，研究人員和註冊社工也會與您作簡短訪談，了解父母平日如何處理孩子的濕疹症狀和困擾等，並評估您和孩子是否適合參與此研究。若您和孩子符合參加資格，研究人員會於研究介入前檢查後的兩星期內通知您和孩子確實上課時間地點。您及您的孩子的健康課程時段將由電腦隨機分配 。您和孩子所獲安排的課程，一經分配，將不能更改。整個健康課程合共六節，每周一節，每節三小時，連續六周，以小組形式進行。課程預計於社區的非牟利志願機構或香港大學舉行，父母與孩子將分別在不同課室上課。課程將由受專業訓練的社工、輔導員、心理學家、兒科醫生及護士、皮膚科專家所組成的專業團隊設計及指導。 所有課程將被錄影，並用於本研究的分析。若不同意被錄影，也可以參與課程。工作人員將不會拍攝到您及/或您的孩子。您和您的孩子會於三個不同時間填寫問卷，分別是研究介入前檢查當日，完成課程後，和完成課程後的六星期。問卷內容旨在了解濕疹兒童患者及其父母的生活質量和精神健康，每次填寫問卷大約需時三十分鐘。研究名額有限，先到先得，額滿即止。

潛在風險或不適

本研究不會對參加者構成風險。您可能會在課堂中進行輕度的運動。在罕見的情況下，如您或您的孩子因進行有關運動而感到不適，您或您的孩子可隨時暫停活動，我們建議您或您的孩子下課後盡早聯絡家庭醫生跟進。在場的註冊社工會為您及您的孩子提供所需的協助。如有需要，社工或研究員亦可為您及您的孩子轉介到合適的輔導服務、兒科醫生、或香港大學社會工作及社會行政學系 跟進情況。

參與者的回報

參加者不會獲得金錢回報。除要繳付常規醫療費用外，您及您的孩子無需繳交額外費用及不會收到任何報酬。

香港大學非臨床研究操守委員會參考編號：EA2001001

對參與者的利益

參與此研究計劃，您有機會學習日常濕疹處理的技巧，以改善您及您的孩子的生活質量。更重要的是，本研究將提供寶貴資料，有助將來發展一套適用於華人社區，能有效改善濕疹兒童患者及其父母之身心健康的服務項目。

資料保密

本研究所收集的資料只作研究用途。所有涉及個人私隱的資料將妥善保密並儲存在上鎖的文件櫃中。問卷數據及視頻剪輯將保存在電腦的加密文件夾中。除非您表示同意，否則所有可供身分識別的個人資料（包括您的姓名和樣貌）將與您的原始數據分開存放，並絕不會出現於研究報告中。您有權利檢視您的錄影及要求移除您的部分或全部的錄影，或要求您的身份在錄影中作進一步匿名化。如您不同意被錄影，工作人員不會拍攝到您及/或您的孩子。若涉及集體錄影，您的影像會在鏡頭以外或有關部分錄像會被模糊。

資料保存及處理

所有個人資料及數據會在第一份學術文獻出版的三年內被妥善銷毀。

參與及退出

我們建議您用充足的時間考慮是否參與此研究項目。參與這項調查研究純屬自願性質，無論您決定參加與否，您的決定都會被尊重。此外，您可以隨時終止參與這項調查，亦不會因有關決定而引致任何不良後果 ，亦不會影響您和您的孩子現在或日後所接受的醫療及護理服務。此外在參與研究過程中，若您的孩子情緒或身體上有任何不適現象，您的孩子有可能會被終止繼續參加這項研究。一旦您的孩子要退出研究，如果沒有得到您的同意，退出前所收集的數據將會被銷毀。我們會給予您足夠的時間去考慮是否讓您的孩子參與這項研究。

疑問與查詢

如您對是項研究有任何查詢或意見，請與研究團隊（電郵：ibms_swsa@hku.hk）或陳凱欣博士聯絡（電話號碼: 3917-2089，電郵： chancelia@hku.hk）。如您想知道更多有關研究參與者的權益，請聯絡香港大學研究操守委員會 (電話號碼: 2241-5267)。

多謝您的支持。

香港大學社會工作及社會行政學系副教授

陳凱欣博士

香港大學非臨床研究操守委員會參考編號：EA2001001

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同意書

1. 我同意我的孩子參加上述研究。
   - ❑ 是, 我同意
   - ❑ 不, 我不同意

2. 我同意我的孩子在過程中被錄影。
   - ❑ 是, 我同意
   - ❑ 不, 我不同意

3. 我同意參加上述研究。
   - ❑ 是, 我同意
   - ❑ 不, 我不同意

4. 我同意在過程中被錄影。
   - ❑ 是, 我同意
   - ❑ 不, 我不同意

5. 若我要求我及我的孩子退出上述研究，我同意研究人員可以繼續使用我及我的孩子退出上述研究前所提供的研究數據。
   - ❑ 是, 我同意
   - ❑ 不, 我不同意

孩子參與者名稱	日期	簽署
家長參與者名稱	日期	簽署
研究員名稱	日期	簽署

HREC Reference：EA2001001

A randomized trial assessing efficacy of a health education program for children with eczema and their caregivers
Information sheet for parents

Given that your child is diagnosed with eczema, you and your child are invited to participate in a research study conducted by Dr. Celia Chan, Associate Professor of the Department of Social Work and Social Administration, the University of Hong Kong.

PURPOSE OF THE STUDY

We aim to investigate the quality-of-life and the state of psychological well-being of children diagnosed with eczema and their parent caregivers. We will also test the efficacy of a health intervention in promoting well-being.

PROCEDURES

If you agree to take part in this study, you and your child will be invited to attend a pre-group screening interview in addition to your regular clinical follow-up. The pre-group screening interview, which aims to assess your and your child's eligibility, includes a clinical eczema assessment conducted by a medical doctor and a semi-structured interview conducted by a researcher and a registered social worker to understand your management of and distress for childhood eczema in daily life. Eligible participants will be informed of the time and venue of the program within two weeks of the pre-group screening interview. You and your child will be randomly assigned by the computer into a program, and the assigned program cannot be changed once allocated. The program is designed and coached by an interdisciplinary team of trained social workers, counsellors, psychologists, pediatrics and dermatologists. It consists of six three-hour weekly group sessions spanning across six consecutive weeks. Parents and children will attend the program in separate rooms. The program is expected to be held at the NGO community centre or University of Hong Kong. All programs will be videotaped for analysis and record purposes. If you do not agree to be videotaped, you and your child could still attend the program and the staff will not videotape you and/or your child. You and your child will be invited to complete a set of questionnaires on three occasions, namely, on the day of pre-group screening interview, upon completion of the assigned program, and six weeks after completion of the assigned program. The questionnaire is designed to assess the quality-of-life and psychological well-being of children and parents. Each questionnaire takes approximately 30 minutes to complete. Seats are limited on a first-come first-served basis.

POTENTIAL RISKS / DISCOMFORTS AND THEIR MINIMIZATION

This study involves no more than minimal risk than those incurred in normal daily activities. You may be invited to conduct light exercises during the program. Should you feel any physical or psychological discomfort, you may opt out of any session/activity as you feel necessary and we recommend that you consult your family practitioner afterwards. Support will be provided by on-site registered social workers

or researchers as needed. Where necessary you will be informed about relevant support services for follow-up, for instance, counselling services, paediatrics or the Department of Social Work and Social Administration of the University of Hong Kong.

COMPENSATION FOR PARTICIPATION

Participants will not receive monetary compensation. You and your child are not subjected to additional payment other than your regular medical expenses.

POTENTIAL BENEFITS

By taking part in this study, you will have the opportunity to learn essential techniques for the everyday management of eczema, in order to improve your and your child's quality of life. More importantly, your participation will provide valuable information that will inform the development of more targeted, well-equipped psychosocial intervention for children with eczema and their family members.

CONFIDENTIALITY

Information obtained in this study will be used for research purposes only. Personal information will be handled with strict confidentiality and stored in locked cabinets. Questionnaire data and video recordings will be stored digitally in password-protected files. Unless otherwise agreed, all personal identifiers (including your name and face) will be separated from the primary data file and will not appear in analysis reports. You reserve the right to review and remove part or the entire of your recording at any time, or request that your identity be further anonymized in the recording. If you do not agree to be videotaped, the staff will not videotape you and/or your child. If it involves group video recording, you may be left outside of the camera view or have your image blurred on editing.

DATA RETENTION

Data containing personal identifiers and anonymized data will be retained up to a period of three years after the first academic publication.

PARTICIPATION AND WITHDRAWAL

You may spend as much time as you need to consider your participation. Your participation is entirely voluntary, and your decision will be respected regardless of whether or not you choose to take part. You may choose to withdraw from the study at any point without negative consequences. Your withdrawal will not affect your current and prospective medical services. If your child experiences emotional or physical discomfort during the program, she/he may be requested to withdraw from the program. Once withdrawn, all collected data will be disposed of if your consent for data access and usage is not granted.

HREC Reference：EA2001001

You will be given as much time as you need to decide if you would or would not let your child take part in this study.

QUESTIONS AND CONCERNS

If you have any questions or concerns regarding the research, please feel free to contact our research team (Email: ibms_swsa@hku.hk) or Dr. Celia Chan Hoi-Yan (Tel: 3917 2089, Email: chancelia@hku.hk). If you have questions about your rights as a research participant, you can contact the Human Research Ethics Committee of HKU (Tel: 2241 5267).

Thank you for your support!

Yours sincerely,

Dr. Celia Chan

Department of Social Work and Social Administration

The University of Hong Kong

HREC reference: EA2001001

HREC Reference：EA2001001

Consent form for parents

	Please tick
1. I will give permission for my child to participate in the research.	□
2. I agree to the video recording of my child during the procedure*.	□
3. I agree to take part in the above study.	□
4. I agree to the video recording of myself during the procedure*.	□
5. If I withdraw and request my child to be withdrawn from the above study, I give permission to the research team to access and use all the collected data.	□

(*If no consent to video recording, you could still attend the program, and the staff will not videotape you and/or your child. If it involves group video recording, you may be left outside of the camera view or have your image blurred on editing.)

Name of parent participant	Date	Signature
Name of person taking consent	Date	Signature
Name of researcher	Date	Signature