

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。在場的註冊社會工作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。

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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

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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

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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

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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.

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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

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Consent form for parents

- | | <u>Please tick</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| 1. I will give permission for my child to participate in the research. | <input type="checkbox"/> |
| 2. I agree to the video recording of my child during the procedure*. | <input type="checkbox"/> |
| 3. I agree to take part in the above study. | <input type="checkbox"/> |
| 4. I agree to the video recording of myself during the procedure*. | <input type="checkbox"/> |
| 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. | <input type="checkbox"/> |

(*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 |