Improving influenza vaccine uptake in Hong Kong pregnant women: a randomised controlled trial
INFORMED CONSENT FORM

Purposes

We would like to tell you about a project studying a vaccine that is available in Hong Kong but that has not yet been added to the routine Antenatal Care. This is a project by the Department of Paediatrics of The Chinese University of Hong Kong. This study plans to test whether providing key messages about influenza disease and influenza vaccine to mothers can increase the uptake of influenza vaccine in pregnant women.

Study Procedures

This study will compare different information given to participants. There will be three possible study groups and you will be randomly allocated to one. This means that it is like a "roll of the dice" and that you cannot select which group you prefer to be part of. You will NOT be informed about which group you are in and what type of information you will receive. Participants in each of the three groups will receive similar information on influenza disease and influenza vaccine but at different levels of detail and with different ways of sharing the information.

Your involvement in the study will be for less than 2 years. During this time, you may receive information by post, e-mail, telephone or text message. You will also complete short questionnaires through face-to-face interview, telephone follow-ups, on web or by post.

<u>At recruitment (the first survey)</u>

You will complete a self-administered questionnaire (around 8 minutes). We will collect details of your family characteristics, health and vaccination information, information of your knowledge and attitudes in relation to influenza vaccine, and contact details.

<u>During pregnancy</u>

You may receive information on influenza disease and influenza vaccine by post, e-mail, telephone or text message.

<u>At around 3 – 4 weeks after your expected date of delivery (the second survey)</u>

You will receive a text message to confirm your delivery and then complete an online questionnaire (around 5 minutes) followed by a further telephone follow-up if necessary. We will collect information of you and your child's health, and your knowledge, attitudes and practices in relation to influenza vaccine.

<u>[OPTIONAL] At your child's age of approximately 1 year old (the third survey)</u>

You will complete a short online questionnaire (around 1-2 minutes) followed by a further telephone follow-up if necessary. We will collect information of you and your child's health and vaccination status.

Foreseeable Risks or Discomforts

There is no risk to you or your child in answering questions in this study.

Expected Benefits

You will be provided with information of influenza disease and influenza vaccine. All participants who successfully complete the second survey will be given supermarket coupons with equivalent value of HKD200 (USD26). This study will provide insights into strategies that could enhance delivery of health messages and thus benefit our community in future.

Confidentiality

We will keep all personal and study information in secure files under lock and key, and only research staff under authorisation will have access to them. The record will be electronically stored in coded form with a study number. Data will be analysed within the Department of Paediatrics of The Chinese University of Hong Kong anonymously. No report from the study will include information that could identify you. The data collected will be kept for at most 15 years.

Under the laws of Hong Kong (in particular the Personal Data (Privacy) Ordinance, Cap 486), you enjoy or may enjoy rights for the protection of the confidentiality of your personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of Hong Kong, non-disclosure, erasure and/or in any way dealing with or disposing of any of your personal data in or for this study. For any query, you should consult the Privacy Commissioner for Privacy Data or his officer (Tel no.: 2827 2827) as to the proper monitoring or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured.

Cost of the Study

There is no cost to you for taking part of the study.

Voluntary participation/ Withdrawal

Your participation in the study is completely voluntary and you may withdraw from the study at any time and for any reason without penalty, loss of benefits or impact on you or your child’s present or future health care.

Ethics approval

The research ethical aspects of this study have been reviewed and approved by the Joint Chinese University of Hong Kong - New Territories East Cluster Clinical Research Ethics Committee (+852 3505 3935) and Hong Kong East Cluster Research Ethics Committee (+852 2595 6111). The Committees can be contacted at their contact numbers during office hours.

Enquiry

If you or your family have any further additional questions at a later time, please contact the Principal Investigator, Prof Albert Li, at (+852) 3505 2850 or the project coordinator, Ms Christy Yeung, at (+852) 9140 6004 (Department of Paediatrics, Prince of Wales Hospital, Shatin, Hong Kong).

Study no.: _____

INFORMED CONSENT FORM OF "IMPROVING INFLUENZA VACCINE UPTAKE IN HONG KONG PREGNANT WOMEN: A RANDOMISED CONTROLLED TRIAL"

1. I agree to take part in this study.
2. The titled study has been clearly explained to me by the research team. I have read and understood the information provided and had the opportunity to ask questions.
3. I understand that my child's and my identities will be treated securely.
4. I understand that I have the right to decline to participate in the study and that I have the right to withdraw from the study at any time for any reasons, without affecting my child's and my present or future health care.
5. I ☐ agree
   ☐ do not agree
   to by followed up at my child's age of 1 year.
6. If I withdraw from the study, I ☐ agree
   ☐ do not agree
   the data collected up to my withdrawal can be continued to be used for research purposes.
7. The research team in the Department of Paediatrics, The Chinese University of Hong Kong wishes to contact me for further research concerning child health. I have the right to withdraw the consents at any time. I ☐ agree
   ☐ do not agree
   to be contacted for further research.
8. By signing a written informed consent form, I am authorizing the Research Ethics Committee and the regulatory authority(ies) will be granted direct access to my child's and my study data for data verification.

Name:

Signature: _____ Date: _____

After signing this Informed Consent Form, I will receive a copy of this form for my future reference.

Person administering the consent:

Signature of person administering the consent: _____ Date: _____

Chinese version of the informed consent form

「提升香港孕婦流感疫苗使用率的隨機對照試驗」

知情同意書

研究目的

我們將為你講解一個由香港中文大學兒科學系舉辦，有關一種香港可用，但沒有加入常規產前護理的疫苗之研究。本研究將測試母親獲得有關流行性感冒（流感）和流感疫苗的重點資訊，能否提升孕婦流感疫苗的使用率。

研究程序

本研究將比較參加者獲得的不同資訊。參加者將會分成三個研究組，就像擲骰子般，你將會隨機分配到其中一個。你將不能選擇你所屬的研究組，你亦不會知道你給隨機地分配到哪一個研究組，及獲得哪類型的資訊。每組的參加者將收到有關流感和流感疫苗的資訊，內容類似但以不同程度及方式傳遞。

你將會參與本研究約 2 年，在此期間你可能會從郵寄、電郵、電話或簡訊形式獲得資訊，你亦需要透過面訪、電話跟進、網上或郵寄方式完成簡短的問卷調查。

<u>招募時（第一份問卷）</u>

你將會花約八分鐘時間完成一份簡短問卷。你會提供你的家庭背景資料、健康和疫苗接種資料，對流感疫苗的知識和態度的資料，以及你的聯絡方法。

<u>懷孕期間</u>

你可能會從郵寄、電郵、電話或簡訊形式獲得有關流感和流感疫苗的資訊。

<u>在你預產期後的大概 3 – 4 週（第二份問卷）</u>

你將會收到簡訊確認孩子是否已出生，然後花約五分鐘時間完成一份簡短的網上問卷，如有需要，我們可能會以電話作簡單的跟進。你將會進一步提供你和孩子的健康資料，以及對流感疫苗的知識、態度和行為的資料。

<u>[可選擇]在你孩子大約一歲時（第三份問卷）</u>

你將會完成一份簡短的網上問卷（大約 1-2 分鐘），以收集你和你孩子的健康資料和疫苗接種記錄。如有需要，我們可能會以電話作簡單的跟進。

潛在的風險

你參與這項研究所提供的資料不會對你或你的孩子構成危險。

參與研究的好處

你將會獲得有關流感和流感疫苗的資訊。所有完成第二份問卷的參加者，將會獲得價值港幣 200 元正（約 26 美元）的超級市場禮券。本研究可讓我們更了解有效地傳遞健康訊息的策略，這對社區將來有很大益處。

個人資料保密

我們將把所有個人資料和完成的問卷上鎖，並以一個研究編號代替你的姓名及相關的個人資料，儲存至電腦作匿名的數據分析。而匿名的數據分析將在香港中文大學兒科學系進行，只有研究人員可以獲得研究數據。研究的報告將不會涉及能夠區分你身份的個人資料。所有數據將保存最多 15 年。

依香港法律規定（特別是第 486 章《個人資料（私隱）條例》），你享有或可享有確保你的個人資料保密的權利，例如在或為本研究中有關收集、監管、保留、管理、控制、使用（包括分析或比較）、轉進或轉出香港、不披露、清除和／或以任何方式處理或棄置的權利。如有任何問題，請你咨詢個人資料私隱專員或其職員（電話號碼：2827 2827），以瞭解妥善監控或監管你的個人資料保護之事宜，以確保你完整掌握和瞭解遵守規管個人資料私隱的法律之重要性。

參與研究收費

你不需要為研究中的任何一項操作付費。

自願參與／中途退出

你的參與全屬自願，你可選擇不參與或隨時退出此次研究，而你的退出將不會影響你及你的孩子現在和日後的醫療服務。

倫理委員會的批准

本研究所涉及的研究倫理問題已經過香港中文大學－新界東醫院聯網臨床研究倫理聯席委員會（+852 3505 3935）及港島東聯網研究倫理委員會（+852 2595 6111）的審查並通過。你可以在辦公時間致電委員會電話以咨詢你作為研究參與者的權益。

聯絡方法

如果你或你的家人對此研究有任何問題，請致電聯絡本研究的首席研究員李民瞻教授（+852 3505 2850）或負責人楊靜媛女士（+852 9140 6004）（香港沙田威爾斯親王醫院兒科學系）。

研究編號：_____

知情同意書－「提升香港孕婦流感疫苗使用率的隨機對照試驗」

1. 本人茲同意參與這項研究。
2. 研究人員已經詳細解釋此研究的相關情況，同時本人也認真閱讀和理解所提供的相關資料，並有充分機會提問。
3. 本人明白本人及本人孩子的身份將獲得保密處理。
4. 本人知道我有權拒絕加入此研究，同時本人也有權在任何時間無需任何理由退出此研究，而不會對本人和本人的孩子現在和日後的醫療服務有任何影響。
5. 本人 ☐ 同意
   ☐ 不同意
   於本人孩子大概一歲時接受跟進。
6. 若本人要求退出本研究，本人 ☐ 同意
   ☐ 不同意
   研究人員可以繼續使用本人退出本研究前所提供的研究數據。
7. 香港中文大學兒科學系研究團隊希望就其他兒童健康的研究可以日後再聯絡本人，我可以隨時聯絡研究人員以撤回同意、拒絕和退出研究。本人 ☐ 同意
   ☐ 不同意
   日後收取相關研究的訊息。
8. 通過簽訂書面同意書，本人授權臨床研究倫理委員會和監管機構直接核查本人和本人的孩子的研究數據。

姓名：

簽署：_____ 日期：_____

簽署知情同意書後，本人將獲得一份已簽署的複印本作為今後的參照。

獲取知情同意人員姓名：

獲取知情同意人員簽署：_____ 日期：_____