

Participant Information Sheet

(30 March 2016)

Head Louse Control in Queensland Primary Schools Study

Your child has been invited to take part in a study of the nit-comb-and-conditioner technique and medicated-head-lice-treatment technique of head louse control for children. The purpose of this Information Sheet is to help you decide if you would like your child to be involved. This study is being run by The University of Queensland and will involve children from Australian primary schools. The study will run until the end of 2022. The head louse team of The University of Queensland plans to visit your school on several occasions in 2016 to 2022.

The aim of this particular study is to compare the efficacy of the conditioner-and-nit-comb technique and of head lice treatment lotions, shampoos, mousses and devices. The products to be compared are listed or registered with the Therapeutic Goods Administration (TGA) of the Commonwealth Government.

What will happen during the study?

Your child's involvement in the study would last up to 15 days. First, your child's hair will be checked to see if he/she has live lice. If lice are present, your child's hair will be treated with the conditioner-and-nit-comb technique or a medicated lotion, shampoos, mousse or devices. Then your child's hair will be thoroughly washed with either a non-medicated or a medicated shampoo or rinsed with water. Louse eggs ("nits") may also be removed from your child's hair by combing or by snipping individual hairs, that have eggs attached, with hairdressers scissors.

The head louse team may come back to your child's school one day after the treatment to see if the lice have died. The head louse team may then return to retreat your child's hair 7 and 14 days later. These treatments will kill any lice that have hatched from eggs in your child's hair. Unfortunately, no head lice treatments kill all of the eggs so we must re-treat your child after 7 and 14 days.

What must my child do to qualify for inclusion into the study?

- Have live head lice
- Be available for examination and/or treatment, during the following 2 weeks (maximum 4 X 10-minute examinations in total)
- The parent or guardian must provide written informed consent

Which children do not qualify for inclusion?

- If your child has a history of skin allergies or adverse reactions to head lice products
- If your child was treated with any head lice product in the 4 weeks prior to the planned study entry if your child has a history of any skin disease (eg. eczema or dermatitis)
- If your child has any severe or chronic medical condition which may interfere or complicate the assessment of head lice treatment

Are there any possible inconveniences and risks involved?

Children involved in the study will not be able to use other head lice products or louse / nit combs to treat their head lice for up to 15 days after the first treatment.

Care will be taken in the use of the medicated lotions, shampoos, mousses and devices around children, as there is a chance of mild eye or skin irritation. As with any medicinal product, unknown side effects may also occur.



What are the potential benefits of taking part?

By taking part in this study, it is likely that your child will be louse-free at the end of the study. The results of this study are expected to identify effective treatments for head lice. Proof that treatments actually work is needed because head lice are becoming more resistant to currently available treatments. The study findings will be published as a scientific paper in a medical journal and/or presented at a medical conference. The study findings will also be reported to your school. This will be the first major study to compare the efficacy of the nit-comb-and-conditioner technique and the medicated-head-lice-treatment technique.

There will be no costs involved with your child's involvement in the study. The products are provided free of charge. You will not be paid for your child's involvement.

Does my child have to take part in the study?

Your child's involvement in this study is entirely voluntary. Your child can refuse to take part or you can withdraw your consent for your child's involvement at any time with no penalty to your child. Any new information that might cause you to change your mind about taking part in this study will be given to you as soon as possible. There is also the possibility that your child's involvement could end before the final study visit without your consent. Reasons for stopping the study early may include Professor Barker deciding that your child's continued involvement in the study is not in your child's best interest or Professor Barker may decide to cancel the study.

Will my child's involvement be kept confidential?

Any information from this study that identifies your child will be kept confidential and, to the extent allowed by the law, will not be made publicly available. However, representatives of The University of Queensland, Government Regulatory Authorities and the Ethics Committee will be able to look at study results that identify your child by name for the purpose of checking the accuracy of the study findings. Such checking is routine in studies like this and is required by Australian law. Your child's identity will remain confidential in all study reports and publications. Information collected on your child during this study is mainly for the purposes of this study, although your child's data may be used or re-analysed in the future for other studies.

Who can I contact to ask questions?

If you or your child have any questions about the study, including your child's right as a participant and any privacy issues, please contact Professor Stephen Barker, Parasitology Section, The University of Queensland, phone 07 3365 3303. If you would prefer to talk to another person, please contact Dr James McCarthy, Consultant Infectious Diseases Physician, Royal Brisbane Hospital, phone 07 3845 3796.

If your child has any side effects during the trial, you should contact Dr James McCarthy, Royal Brisbane Hospital, phone 07 3845 3796 or mobile 041 442 4659.

You and your child have the right to see your child's study data. Please contact Professor Stephen Barker, Parasitology Section, The University of Queensland, phone 07 3365 3303.

Informed Consent Form (30 March 2016)
Head Louse Control in Queensland Primary Schools Study

Staff and volunteers at The University of Queensland plan to screen all the children at your school for the presence of head lice on several occasions in 2016 to 2022.

If head lice are found in your child's hair, the head lice can be treated only if you complete and sign this Informed Consent Form. Your child will be examined in 2016 to 2022.

The head lice (if found) can be treated by either:

OPTION 1. A MEDICATED HEAD LICE LOTION, SHAMPOO, MOUSSE OR DEVICE

You can only choose OPTION 1 if the following conditions are met:

- a) You must read carefully the Participant Information Sheet dated 30 March 2016 before you decide to complete and sign this form.
- b) Your child must NOT ever have had an allergic reaction to a head louse product.
- c) You must NOT have treated your child with a head lice shampoo/lotion etc. in the last 4 weeks.
- d) You must AGREE not to further treat your child's head lice with either head lice shampoos/lotions etc. or by combing with a head lice comb for a period of 15 days.

OR

OPTION 2. BY COMBING YOUR CHILD'S HAIR WITH A HEAD LOUSE / NIT FINE TOOTH COMB TO PHYSICALLY REMOVE HEAD LICE AFTER A CONDITIONER HAS BEEN APPLIED. In this case, you do not need to read the Participant Information Sheet.

NOW - IF YOU WANT YOUR CHILD'S HAIR TREATED, CIRCLE THE OPTION (ABOVE) YOU PREFER (remember if you choose OPTION 1 all the conditions a, b, c & d must be met).

I understand that my child's participation in this study is entirely voluntary and that my child can refuse to take part at any stage. I also understand that I can withdraw my consent for my child's involvement at any time with no penalty to my child. I have discussed the study with my child and they have agreed to participate. I also know whom to contact if I have any questions about the study.

I, _____, the legal parent / guardian of
PLEASE PRINT

_____ (child's name) whose date of birth is
PLEASE PRINT

_____ of class _____ consent to their participation in the above
dd/mm/yyyy

study.

Signature of Parent / Guardian:

Date: _____
(please date)

Signature of Child (if capable):
(Optional)

Date: _____
(please date)

Signature of Investigator or
authorized representative:

Date: _____