

PARTICIPANT NEWSLETTER - MARCH 2017

A chance to have your say

Over the coming months we will be starting a study that involves talking with some of you about your involvement in the HI-Light trial. We are particularly interested to hear about how you got on in the study and how you found it using the vitiligo treatments. We hope to talk to around 45 participants of all ages (including parents whose children took part in the trial), gender and ethnic group, and will be interested in your views whether the treatments worked for you or not.

If you have a visit with your nurse coming up and would like to find out more, then do ask about the conversation study, and your nurse will be able to tell you more. If the treatments being used in the HI-Light trial are shown to be effective, we hope that the results of the conversation study will help us to understand how best to implement the trial findings into normal clinical practice.

More participants needed

The trial's original target of 440 participants has been increased to 516: we will now continue recruiting into summer 2017. One of the reasons that we are looking for more people to take part in the study is that fewer participants than expected have attended their follow-up clinic visits. This means we don't have as much data as we need to answer the clinical question the study poses. Read more about what you can do to help in a message from the Chief Investigator over the page.

Thank you so much for your continued support in the HI-Light Vitiligo Trial. Your participation is helping us answer very important questions about the treatment of vitiligo. Remember, if you are unsure about anything at all, please contact a member of your local research team who will be happy to assist!

Trial by numbers

- **457** people have joined the study to date
- **516** people required in total to take part
- **202** participants have reached the end of the treatment phase
- **15** NHS Trusts in England, Wales & Scotland are involved in the study



An important message from the Chief Investigator

Hello all,

Thank you for participating in the HI-light Vitiligo Trial - your help means we can conduct this crucial research into potential treatments for vitiligo.

It is important to remember that vitiligo tends to respond very slowly to any treatment. This means that *any response to treatment may only become obvious after a long time* (potentially several months). Therefore, it is **important not to be discouraged** if there does not seem to be a response to treatment initially, and to continue with treatment as planned.



The other important thing to remember is that the **treatments can take some time to administer** (especially using the light unit), so you should *try and set aside enough time to do this*. However, there may be times when you are simply too busy to use one or both of the treatments.

If this is the case, it doesn't mean that you should withdraw from the trial altogether; on the contrary **data collected from participants no longer able to treat is just important as those still treating**. If necessary it is OK to stop using one or both of the treatments for a period, and then start using them again at a later stage, *so long as this is recorded in your treatment diary*. The overall aim is simply to use the treatments as much as possible.

You may also decide, due to time constraints or other reasons, that you wish to stop using one or both of the treatments altogether. If this is the case, we would ask that you **consider remaining in the trial** so that you can still be followed-up. This will still provide valuable data for the study. However, if you would prefer not to be followed-up, you are of course entitled to withdraw from the study altogether if you wish to do so.

Remember your local study nurse is available to answer any questions you may have.

Many thanks for your continued support and participation

Dr Jonathan Batchelor

The HI-light Vitiligo Trial - As seen on TV



The HI-light vitiligo Trial was featured on **BBC Inside Out East Midlands** on Monday 6 February 2017. The report by Lukwesa Burak (pictured left) explored what it's like living with vitiligo, and featured an interview with Maxine Whitton (MBE), a patient researcher who is taking part in the trial, as well as Dr Jonathan Batchelor.

Things to remember about the trial treatments

- If you have finished treatment but still have the light device or any unused ointment either take these to your nurse at your 9 month visit or call the study coordinating centre on 0115 823 1586.

We will send you a pre-paid label to send your device back to us free of charge. It is important for your safety and the results of the trial that you return your device to your nurse at your 9 month visit, as you are no longer being monitored by the team.

- If you are going on holiday you can take your light device and ointment with you. If you are travelling abroad don't forget to take a plug adapter. If however you are going away and do not wish to take your study treatments with you, please ensure that this is noted in your diary and contact your study nurse on your return before restarting treatment.
- If you miss 4 or more treatment sessions please contact your local research team who will advise you on what to do next.



A reminder: Before your 9 month visit

Here are a few things to remember about your last visit with the nurse at 9 months:

- **Before your visit - please stop using trial treatments for 2 days** before your appointment.

This will allow for any redness you may have to settle down before the nurse sees you.

- Remember to take your light device with you to clinic.
- Remember to take any unused ointment with you to clinic.





Follow up questionnaires

We will be sending questionnaires every 3 months for a year after your final clinic appointment. If you are happy to receive questionnaires via email to complete online, but have not yet provided your research nurse with an email address, then please do so.



Please also be aware that the link we send you will expire so please complete the questionnaire at your earliest convenience.

Emails will be sent from ctu@nottingham.ac.uk

Please add this to your contacts to avoid this email being sent to your junk folder

Keep in touch



Please be sure to get in touch with either your local research team or the study coordinating centre if your address or contact details have changed recently.

For any general queries please get in touch with the study coordinating team at Nottingham Clinical Trials Unit:

Email: hlight@nottingham.ac.uk

Telephone: 0115 823 1586



Ask to speak to Garry Meakin (HI-light Trial Manager) or Jen White (HI-light Trial Coordinator)

Please keep this newsletter alongside your HI-Light trial treatment package as it contains important information that you may need to refer to in the future.