Supplementary Document 13: XPAND Trial Participant information sheet and consent form

Patient Information Sheet Version 5 08/01/2018 IRAS 236877

XPAND TRIAL: Enhancing XP Photoprotection Activities – New Directions

We would like to invite you to take part in a research study funded by the National Institute of Health Research (NIHR). Before you decide whether you would like to take part, it is important that you understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the XPAND trial?
The XPAND trial aims to test whether having a limited number of 1:1 sessions with a researcher, to discuss your UVR protection and explore ways to support you to improve or become more consistent with protection, is successful. This means does it improve UVR protection and reduce amount of UVR reaching the skin? We would also like to know whether you find the sessions helpful and enjoyable.

How do you know that people with XP need support with UVR protection?
We conducted a previous research study examining the amount of UVR exposure that people with XP have, and how they protect themselves (you may have taken part in this study in 2016/7). This showed that people vary in the level of protection they use and some patients find it harder than others to avoid UVR. People told us that it can be difficult and not pleasant to have to protect from UVR. As in other physical conditions, people found ways to adapt to living with XP that fitted with their everyday life. Sometimes, this meant that they weren't always protecting at the level needed. We now want to try to help people with XP enhance and be consistent with their UVR protection, in order protect their skin and eyes as much as they can.

Why have I been invited?
You have been asked to help because you are an adult with XP and the clinical team has indicated that your daily photoprotection routines might benefit from the XPAND trial.

If you took part in our previous study, we have access to more detailed information about your photoprotection. We would like to use this information to confirm whether

or not you are eligible. We will ask your permission to access this data as part of the consent process.

What will happen in the sessions?

- During these sessions you will have a guided conversation about XP, UVR protection, and the challenges of living with this condition. We will work with you to explore what things make protecting more difficult for you. These will be different for different people. *It could be could be forgetting, not having a routine that works, not feeling motivated about wanting to fully UVR protect, being worried about what other people think of UVR protection.* The XPAND trial facilitators know about strategies that have been shown to be helpful for people with other physical conditions which also require changes to their everyday life. We will work with you to select strategies that fit with what is getting in the way of protection for you. For example, this could be working together to come up with solutions to your concerns about wearing sunscreen or suggesting things you might try to stop you forgetting to wear your glasses. We'd like to reduce the amount of effort it takes to maintain UVR protection by helping you to develop routines that you can do automatically, without as much thinking.
- As part of these conversations we might use activity sheets, printed materials or video clips.
- If you would find it helpful you could receive text reminder messages.
- If you took part in our previous research, you will also receive a personalized summary of your photoprotection practices and UVR exposure recorded in the summer of 2016.

How many sessions are there?

- You will have 7 sessions over several weeks, either face to face or over the telephone with an XPAND trial facilitator.

Where will they take place?

- There will be 2 face to face sessions in your home, and 5 will be by phone or skype.

How long will they take?

- The length of the sessions will depend on what is best for you. We expect the first session to be the longest but it won't last longer than an hour and a half. The rest will be around 30 to 45 minutes.
- The first 4 sessions will be weekly, moving to fortnightly at a time that is convenient for you. The last session will be between 4 and 6 weeks after the previous one.

Who are the XPAND trial facilitators?
The facilitators are psychologists or clinical nurse specialists trained in evidenced based strategies used to support people with long term conditions that require changes to everyday life. You will work with the same facilitator throughout the trial.

How will the research team know if the sessions work?
The XPAND trial is using a randomised controlled trial design which means that if you agree to take part you would be randomly allocated to either receive the sessions (known as the "intervention") or continue as usual (known as the "control"). Regardless of whether you receive the intervention or not, you would complete the measurement part of the XPAND trial. This would involve completing a daily diary of UVR protection, wearing a dosimeter on the wrist and completing a small number of questionnaires. We will then compare the amount of UVR reaching the face and UVR protection between those receiving the intervention and those who do not. We need 24 people to take part to be able to test the intervention.

If I am in the control group do I receive the intervention?
Yes. To be able to effectively test the impact of the intervention we would like the control group to receive the sessions as well, but this will not be until 2019.

When would the XPAND trial take place?
The XPAND trial will take place between March 2018 – December 2019. If you are randomized to the intervention (Group 1) you will receive the sessions between April and July 2018. If you are randomized to the control (Group 2) you will receive them between April and July in 2019.

What does the measurement in the XPAND trial involve?
If you are in Group 1 or Group 2 you will be asked to do the following in 2018:

- Complete a small number of brief questionnaires on paper which measure a number of things including: your beliefs about UVR protection; concerns you might have about UVR protection; how XP influences your daily life; your emotional wellbeing. This is an example of the type of question we would like you to answer.

  How much do you worry about other people's reactions to the things you have to do to protect against UVR?

0 1 2 3 4 5 6 7 8 9 10
not at all *very much*

These need to be completed in March, June, August and December 2018. They will take approximately 15 minutes to fill out.

- Complete a questionnaire regarding the financial impact of hospital appointments and estimates of what you have to pay because you have XP. This will be on 2 separate occasions – in March and December.

- Wear a dosimeter on the wrist, on top of your clothes, every day between March and September. The dosimeter records how much UVR you are exposed to, in your environment. We will explain how to wear and look after your dosimeter when we visit you at home to complete the consent forms. We will also provide a frequently asked questions sheet for you to keep.

- Complete a daily paper UVR protection diary for three separate periods of 3 weeks in March-April, June-July and August-September. This diary will also include 4 daily questions which measure your mood, how automatic you felt your UVR protection was that day, how important you thought UVR protection was compared to other things you had to do, and how confident you are that you can protect the following day. The diary will take about 5 minutes to complete. This is an example of the type of question on the diary:

  How confident are you that you can protect your face well tomorrow, even if other things get in the way?
  0 1 2 3 4 5 6 7 8 9 10
  not at all *very much so*

- If you are in Group 1, and receive the intervention in 2018, we would also like to find out about your views and opinions of the sessions. This will help us improve what we do, so we can better support other people with XP in the future. For this you will complete a short feedback questionnaire and take part in a recorded (if you give permission) conversation with a trained researcher in September 2018. This would take approximately one hour and take place in your home. The recordings will be transcribed by a professional transcribing company. The company will have agreed to keep the interviews and transcription confidential.

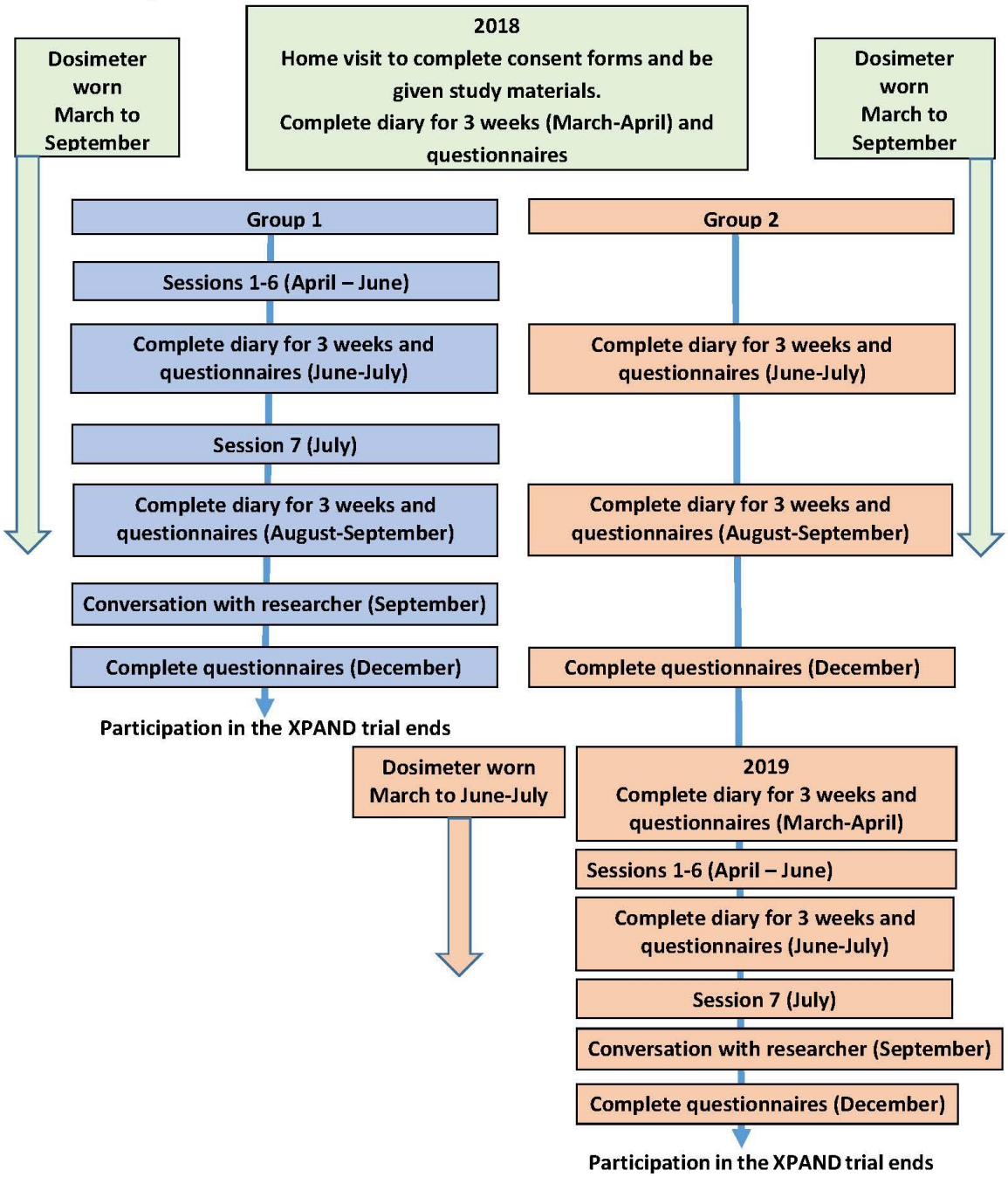
What happens if I am in Group 2 and do not receive the sessions until 2019?

- We will ask you to complete questionnaires in March, June and December 2019.
- Complete the daily UVR protection diary for two separate periods of 3 weeks in March-April and June-July.
- Wear the dosimeter between March and September 2019.
- Take part in the recorded conversation and complete the feedback questionnaire in September 2019.

What happens once I have completed the last set of questionnaires in December 2018 (Group 1) or 2019 (Group 2)?

Your participation in the XPAND trial will be finished and you are not required to do anything else. If you agree, we might contact you if any further information is needed.

This is a summary of what will happen to you if you are randomised to Group 1 or Group 2.



What are the possible benefits of taking part?

We hope that you will find participating in the XPAND trial useful, and that it will help you develop new and useful ways improve your protection from UVR. We anticipate it will help you feel more confident in your day to day management of UVR protection. Also we hope that this work will contribute to improving the long-term care of people with XP in the future.

What are the possible disadvantages and risks of taking part?

It is unlikely that you will experience any harm by taking part in the study. However, some people may find the length of the study inconvenient (if you are allocated to group 2, you will be involved for up to 2 years). If you do find that taking part causes you any concern you are free to stop or withdraw at any time. This decision will not affect the care you receive, now or in the future.

Will my taking part in the study be kept confidential?

The information we obtain from you will be kept confidential.

All the information you provide (including discussion) during the course of the research will be kept confidential. It will be securely stored in locked files or on a secure computer database. Only authorized individuals directly involved with the study will have access to the information obtained.

We will use a unique number on all records, rather than your own name. Your personal details including your name and address will be stored separately in a secure place. Only you and the researchers will know about your involvement in the study.

However, if you disclose any information which suggests a risk to your own safety or the safety of another person we may need to inform the XP clinical team. In this situation we cannot guarantee confidentiality.

What will happen to results of the research study?

Information from the study will be used in presentations or published in scientific reports. These will not identify any individual taking part. If you would like to be sent a full summary of the results at the end of the study please let the research team know.

Do I have to take part?
No, it is completely up to whether you take part. Whether or not you decide to take part will not affect the care you receive, now or in the future from the XP clinical team.

Will the XP clinical team know if I take part?
The clinical team will know if you are eligible to take part and if you decide to take part in the XPAND trial. In the unlikely event that we are concerned about your emotional wellbeing during the XPAND trial we will speak to the XP clinical team and you might be referred to the XP service Clinical Psychologist for further support.

What will happen if I don't want to carry on with the study?
If you do consent to be part of the study you are free to withdraw at any time, without giving a reason. This decision will not affect the care you receive, now or in the future. You are free to refuse to answer any questions which you find too personal or intrusive.

What if I have a question about the research?
It is usual to have comments or questions about research. Contact our research nurse Lesley Foster on 07775111823 or e-mail her at Lesley.Foster@gstt.nhs.uk who will be happy to answer your questions. She can also pass on your query to other members of the team if required.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the researchers, via Lesley Foster, who will do their best to answer your questions. Or you can contact Dr Robert Sarkany, Robert.sarkany@gstt.nhs.uk. If you remain unhappy and wish to complain formally, you can do this through the Guy's and St Thomas' Patients Advice and Liaison Service (PALS) on 020 7188 8801, pals@gstt.nhs.uk. The PALS team are based in the main entrance on the ground floor at St Thomas' Hospital and on the ground floor at Guy's Hospital in the Tower Wing.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against Guys and St Thomas' NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What will happen to the study results?
We aim to publish the results of these studies in scientific journals and give presentations at academic meetings. It will not be possible to identify any individual

patient from the published data. We can provide you with a summary of our findings if you would find this interesting.

Who has reviewed the study?
All the research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable ethical opinion by London – West London & GTAC Research Ethics Committee

What will happen when the research study stops?
After the study has ended, we will keep the information we have collected for at least 5 years. This includes anonymised data and personal information. After this time, it will be disposed of securely. The procedures for handling, processing, storage and destruction of the data are compliant with the Data Protection Act 1998.

What happens now?
If you would like to take part in the XPAND trial please contact Lesley Foster, our Research Nurse on 07775111823 or Lesley.Foster@gstt.nhs.uk.

In the next week you will receive a call from Lesley Foster, our Research Nurse or Jessica Walburn, our researcher to tell you more about the study and to answer any questions you might have. If you decide you want to take part in the XPAND trial, we will organise a home visit, when you will complete the written consent. You can decide not to participate at the home visit.

If you took part in our previous study, we have access to more detailed information about how you photoprotect. When we call you, we will ask your permission to look at that information, to check that XPAND is likely to be helpful. If this shows that it is not going to be useful, we will let you know and you will not be eligible to take part.

If you do not wish us to contact you, please let us know and you will receive no further correspondence about XPAND.

CONTACT DETAILS:

Nurse Lesley Foster, National Xeroderma Pigmentosum Service
Floor 2, Block C, South Wing
St. John's Institute of Dermatology
St Thomas' Hospital
Westminster Bridge Road

Guy's and St Thomas' NHS
NHS Foundation Trust

KING'S College LONDON

XPAND TRIAL: Enhancing **X**P **P**hotoprotection **A**ctivities – **N**ew **D**irections

CONSENT FORM

Please **initial** box

		Yes	**No**
1.	I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐	☐
2.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	☐	☐
3.	I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals at Guy's and St. Thomas' NHS Trust and King's College London where it is relevant to taking part in this research. I give permission for these individuals to have access to my records.	☐	☐
4.	I understand that data collected about me when I participated in the research study *"Interview-based study of psychosocial correlates and ultraviolet protection behaviour in patients with Xeroderma Pigmentosum, 15/LO/1395 17298"* will be accessed and used for this research study. I did not participate in study *15/LO/1395 17298* so this is not applicable ☐	☐	☐
5.	I give permission for the conversation with the researcher to be recorded and understand that the tapes will be deleted once the conversation is written up.	☐	☐
6.	I give permission for the research team to contact me after my participation has ended, if further information is needed.	☐	☐
7.	I agree that the research data obtained can be published in medical/ scientific journals anonymously	☐	☐

8. I hereby consent to take part in the study ☐ ☐

9. I agree that anonymised data may be retained in the study if I lose the capacity to consent, though no further data will be collected ☐ ☐

Name of Patient	*Date*	*Signature*

Name of person taking consent	*Date*	*Signature*

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

London SE1 7EH
Mobile: 07775111823
E-mail: Lesley.Foster@gstt.nhs.uk
Fax: 020 7188 1621