The ASICA Study

PATIENT INFORMATION LEAFLET

Achieving Self-directed Integrated Cancer Aftercare (ASICA) in melanoma

INVITATION TO TAKE PART

We would like to invite you to participate in a research study to help understand how technology can be used to support people who have had skin cancer. The ASICA study is looking at how the NHS might use technology in the future to more effectively support people who have been treated for melanoma.

Before you decide if you would like to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information.

BACKGROUND TO THE CONDITION

Melanoma is common disease and has increased in incidence by 360% since the late 1970s. Approximately 20% of patients treated for a melanoma experience a recurrence and 4-8% may develop a new melanoma. The risk of having a recurrence or developing a new melanoma is highest in the first five years after initial treatment. For this reason, current UK melanoma treatment guidelines recommend that all people treated for melanoma attend regular hospital follow-up appointments to help detect any recurrences or new melanomas that may have developed as soon as possible.

WHAT IS THE PURPOSE OF THE STUDY?

As you have been treated for melanoma, you are advised to regularly examine your own skin (total-skin-self-examinations). We are investigating whether a digital app we have developed (ASICA) can help you to use a hand-held tablet computer to do more regular and effective total-skin-self-examinations, and whether this would lead to earlier detection of recurrent and new melanomas. The ASICA app also uses the internet to enable you to electronically communicate the findings of your total-skin-self-examinations to a specialist nurse.

We aim to recruit and collect data from 240 participants from two UK centres, Aberdeen Royal Infirmary (covering the NHS Grampian area) and Addenbrooke's Hospital, Cambridge. 120 people will be randomised to use ASICA in addition to their existing melanoma follow-ups, and 120 will be randomised to continue with their existing melanoma follow-ups without ASICA.

DO I HAVE TO TAKE PART?

No. It is entirely up to you whether or not you take part. Please take as much time as you need to make this decision. You can also contact the research team and ask as many questions as you like. The teams contact details are at the end of this leaflet.

If you do decide to take part you will be asked to sign a form giving your consent to be included in the study. You are free to withdraw from the study at any time without giving a reason. Your decision will not affect the standard of care you receive now or in the future.

WHAT WOULD TAKING PART INVOLVE?

If you agree to take part, please initial the boxes where appropriate and sign the enclosed consent form. We would also be grateful if you could complete the confidential baseline questionnaire enclosed. Please return the consent form and the questionnaire to the local clinical team in the enclosed envelope. No stamp is required.

Randomisation:

A computer programme randomly allocates participants into one of the two study groups. If you decide to take part in this study, neither you nor your doctors can decide which group you will be in. There is an equal chance you will be placed into either group.

What will I have to do?

If you decide to take part in the study, you will be randomly allocated into one of two groups:

- One group will attend their routine melanoma follow-ups;
- The other group will use the ASICA app in addition to their routine follow-ups.

Whichever group you are allocated to we will ask you to:

- tell us about your skin and melanoma
- complete a questionnaire at approximately three, six and twelve months from the start of the study. These questionnaires will ask you similar questions to those asked when you joined the study. In addition we will ask you about any recurrences or new melanomas. The questionnaires will take approximately 30 minutes to complete. We will send you up to two reminders if we don't hear back from you and will contact you by post, email and/or telephone, taking into account which communication method is best for yourself.

If you are randomised to receive ASICA, you will be invited to attend the hospital to have photographs of your skin taken. These will be used to develop an individual skin map which will be uploaded to your tablet computer and only visible to you. You will receive training locally on how to undertake the total skin assessment. You will also be issued with your personalised hand-held ASICA computer tablet and trained how to use it to record your skin assessment results and send them on to the study specialist nurse for checking. In addition, you will receive an email or text message prompt to undertake monthly skin assessments for one year in addition to your usual melanoma follow-ups. At the end of the

year you will be asked to return the hand-held computer to the research team.

The study nurses and/or or doctors will also collect information regarding recurrence or new melanomas from your NHS records. Data for all participants in the study will be kept securely for a minimum of 5 years.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?
You will receive the same health care from your doctors whether or not you choose to participate in the study. You may not benefit personally from taking part but you will be directly helping us to plan the care of future patients with melanoma. The results of the study will help plan effective services offered by the NHS in the future.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?
We do not think that there are any possible disadvantages or risks to you in taking part in this study. Whichever group you are allocated to the follow-up care you are receiving for your melanoma will continue as standard of care at your local hospital.

WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?
You will be told if the study is stopped earlier than expected for any reason. When the study concludes or if you leave the study, the research team will collect the hand-held tablet computer so that it can be used in future research. All of your personal data will be removed from the device.

WHAT IF THERE IS A PROBLEM?
We do not expect any harm to come to you by taking part in this study. You will continue to receive your routine melanoma follow-up care.

However, if you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (contact details of your local study nurse and the Study Office can be found at the end of this information sheet). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. They can be contacted using the details below:

NHS Grampian Feedback Service

Summerfield House
2 Eday Road
Aberdeen
AB15 6RE

Tel: 0345 337 6338

E-mail nhsgrampian.feedback@nhs.net

Or

PALS and complaints department, Box 53
Cambridge University Hospitals NHS Foundation Trust
Hills Road, Cambridge, CB2 0QQ
Email: pals@addenbrookes.nhs.uk
Telephone: 01223 216756

In the event that something does go wrong and you are harmed during the research then you may have grounds for a legal action for compensation through the research sponsor of this study, the University of Aberdeen. Contact details for the research sponsor is available through the research team. The normal National Health Service complaints mechanisms will still be available to you.

If you become unable or unwilling to continue in this study we would withdraw you from the study. If this happens we will keep the relevant information already collected about you (with your permission) for the study results. This information will remain confidential and will not be used for any other purpose.

WHO WILL KNOW I AM TAKING PART IN THE STUDY?

Only certain members of the research team will have access to your information in order, for example, to send you the questionnaires.

We will tell your GP you are taking part, but only with your permission.

It is a requirement that your records in this study, together with any relevant medical records, are made available if requested by monitors from the Sponsor(s), the NHS Research & Development Department of your local hospital, and the Regulatory Authorities whose roles it is to

check this research is properly conducted and the interests of those taking part in this study are protected.

WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?
Yes. All information which is collected about you during the course of the research will be strictly confidential, and will be held securely in accordance with the Data Protection Act 1998. Your information will be stored using a unique study number for confidentiality and will be kept secure using passwords.

Other researchers may wish to access data from this study in the future. However, all data will be anonymous so you cannot be identified. The consultant leading the study will ensure that the other researchers comply with legal, data protection and ethical guidelines.

WHAT IF RELEVANT NEW INFORMATION BECOMES AVAILABLE?
Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the ASICA Study Office staff will contact you to let you know about the choices available to you. However, we are not aware that any new, relevant information is likely to become available before the end of this study.

WHAT WILL HAPPEN IF I DON'T WANT TO CARRY ON WITH THE STUDY?
You can decide at any time not to carry on with this study, but you should continue attending your usual melanoma follow-up appointments with your hospital doctor and/or GP as part of your standard care.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?
The results of the study will be used to make future recommendations on the best way to provide follow-up care to people treated for melanoma. We shall publish the results of this study in scientific journals and present the information at appropriate scientific meetings. You will not be identified in any publication of results of the study. We will let you know the results of the study when it is finished unless you tell us that you do not wish to know. We anticipate that anonymised data may be shared with other researchers to enable further relevant research to be undertaken.

WHO IS ORGANISING AND FUNDING THE STUDY?

The University of Aberdeen is sponsoring this study. The study is funded by Cancer Research UK. The research is being carried out by a group of experienced doctors and researchers and is managed by the Centre for Healthcare Randomised Trials (CHaRT), a UK Clinical Research Collaboration registered Clinical Trials Unit at the University of Aberdeen.

WHO HAS REVIEWED THE STUDY?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC) to protect your interests. This study has been reviewed and approved by North of Scotland Research Ethics Committee (2).

Thank you for taking the time to read this information leaflet. We hope that it has been helpful in enabling you to decide if you would like to participate in the ASICA Study. Please ask us if you have questions or would like more information about the study.

FURTHER INFORMATION AND CONTACT DETAILS

If you have any questions or would like any more information, please contact:

ASICA Study Office:	**Local contact details:**
Centre for Healthcare Randomised Trials (CHaRT), **Health Services Research Unit** **University of Aberdeen** **Health Sciences Building** **Foresterhill** **Aberdeen AB25 2ZD** **Tel: 01224 438199** **Fax: 01224 438165** **Email: asica@abdn.ac.uk** **Web:** **https://w3.abdn.ac.uk/hsru/ASICA/**	