

Patient Volunteer Participant Information Sheet

Work stream 2 (WS2)

Achieving Self-directed Integrated Cancer Aftercare (ASICA) in melanoma: Optimising the intervention using pilot evidence, assisted intelligence and behavioural science: The ASICA Optimization Project.

Chief Investigator: Professor Peter Murchie

Introduction

You are being invited to take part in a research study. Before you decide 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 and discuss it with others, such as your family, friends and GP if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part. Thank you for reading this.

What is the purpose of the study?

WHAT IS THE BACKGROUND TO ASICA?

ASICA is a new technology which helps melanoma survivors to look after their own skin with their smartphone. We know that if melanoma survivors check their total skin once per month, they are more likely to spot if melanoma has come back or a new one has appeared. They can then get medical attention at the earliest stage. ASICA reminds people that it's time to check their skin and reminds them how to do it with animated videos. When they find something concerning on their skin, they can send a photograph and a text describing it to a specialist who will check it over and get back to them. We carefully developed ASICA over several years before conducting a trial funded by Cancer Research UK. We asked 120 melanoma survivors to use ASICA for 1 year and collected information about their experience using questionnaires and interviews. Overall, people seemed to like ASICA and did not find it worrying. However, we found two problems. First, people who were depressed at the outset, who felt too busy, or who had not planned / were not confident about when to check their skin seemed less able to keep to the monthly schedule. Second, we found that when concerns arose (about 5% of checks overall) some ASICA users struggled to provide clear photographs and enough information for the specialist to be able to review immediately.

Important: ASICA does not provide medical advice, diagnosis or real-time review by a clinician or the research team. It is a research tool designed for self-monitoring only.

WHAT DO WE WANT TO DO IN THIS PROJECT?

We want to find out how to solve both of these problems:

1. We will work with melanoma survivors to optimise the app for different individuals. For example, building in extra content to support users and amending the timing of reminders so that they work better for people who are busy.
2. We will develop a “Chat-bot”, a computer programme behaving as though someone is texting you back, that helps to ensure that ASICA always collects all the information needed by the specialist and that the images captured are as clear as possible.

Why have I been chosen?

You have been chosen either because you were diagnosed with melanoma in the last five years, or because you responded to an advert indicating that you have been treated for melanoma within the last five years.

Do I have to take part?

No. It is up to you to decide whether to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?

If you agree to take part in this research, we ask you to return the completed consent form via email or post. You will then be invited to take part in a short pilot study where you will use a new prototype version of the ASICA app for 6 months.

We will invite a group of people to use the new version of ASICA on their own smartphones for six months. You will be invited by a text message to interact with the app at least once per month, although will be free to use the functions at all other times. The app will record how you are using it. At the end of the six-month period, we will offer options about how you can feedback to us about your experiences. If you choose, we will talk to you over the telephone or the internet (using MS Teams or Near Me) to discover how you have experienced ASICA and any changes that you might have to suggest. Alternatively, we will hold a further workshop at which users can share their experiences.

You will be included in the study for 6 months. Taking part in this study will not involve any changes to your medical care and no additional visits to hospital or to visit your GP. The telephone call or meeting you attend for us to receive your feedback of using the app will be audio-recorded using a secure encrypted recording device so that accurate notes can be taken by the research team. During the 6-month piloting period we may ask you to take some photographs of your skin and, with your consent, we will store these anonymously to use in our future research. We will seek your consent to contact you again in the future to take part in follow-up studies or future research as appropriate. You will be free to withdraw from the study at any time and if you do, we will, with your consent, retain the data collected up until the point you withdraw and may use the information in analysis.

Important information about ASICA

ASICA does not replace medical care and should not be used to diagnose any condition. No clinician will review your submissions in real time, and the research team will not monitor or act on individual health data. If you notice anything that worries you about your skin or general health, please contact your GP, dermatologist or usual health care team. The research team cannot provide medical advice or investigate individual concerns.

What is the procedure that is being tested?

This study is seeking to test and further develop ASICA which is a new technology which helps melanoma survivors to look after their own skin with their smartphone.

Are there any likely side effects of taking part?

We do not foresee any side-effects of taking part in this study or using the ASICA app.

What are the possible disadvantages and risks of taking part?

Taking part in this study will involve you spending time that you are able to give to work with us. We do not anticipate any disadvantages, inconveniences or risks of taking part. It is possible that taking part could lead to issues of concern about your skin coming to light. In this instance we will advise you to make appropriate contact with your GP and the clinical team looking after your skin.

What are the possible benefits of taking part?

We do not anticipate any direct benefit to you of taking part. The information we get from this study may help us to treat future participants treated for melanoma better.

What happens when the research study ends?

It is important to note that this project is about developing the ASICA app and it will not be available for you to use once the study ends. Your usual care will continue throughout your involvement with the study and once the study ends.

What if something goes wrong?

If you have a concern about any aspect of this study, you should speak to the principal investigator, Prof Peter Murchie (email: asica@abdn.ac.uk) who will do their best to answer your questions.

If you remain unhappy and wish to complain formally, you can do this by contacting NHS feedback service, postal address Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE. Tel: 0345 337 6338

E-mail gram.nhsgrampianfeedback@nhs.scot

Or you can contact the sponsor for the research by emailing researchgovernance@abdn.ac.uk.

How will we use information about you?

We will need to use information from you for this research project.

This information will include name and contact details, which will be securely held by both the University of Aberdeen and the University of Stirling. With your consent, your contact details will be used to make contact with you to invite you to participate in study activities. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to dpa@abdn.ac.uk, or
- by ringing us on 01224 272596.
- at www.abdn.ac.uk/about/privacy/

What will happen to the results of the research study?

The results of the research will be used to further develop the ASICA app to make it more effective and acceptable to patients. We will also publish the results of the study in academic journals and present them at academic conference. You will not be identified in any report or publication. You will be given the option of receiving a copy of the published results from the research team.

Who is organising and funding this research study?

The study is being run by the University of Aberdeen with funding received from Cancer Research UK.

Who has reviewed the study?

The study has been reviewed by Cancer Research UK, Research Governance at the University of Aberdeen and the [Insert ethics committee details] Ethics Committee.

What do I do now?

If you are interested in participating in the study and have any concerns or queries about the study, contact Professor Peter Murchie by email (asica@abdn.ac.uk).

If you are happy to participate in the study please **initial** each box on the enclosed consent form and sign it. Then return the completed consent form either to this email address: [Study email address]. Alternatively, if you would prefer to complete a paper copy and return by post, please let the research team know by emailing the study email address above. The research team will post you a consent form with a reply-paid envelope for you to return the form in. Once complete please return to this address:

ASICA OPTIMISATION STUDY, Polwarth Building, Foresterhill, University of Aberdeen, AB25 2ZD

Thank you for considering taking part in this study.