Participant Information Sheet

Achieving Self-directed Integrated Cancer Aftercare (ASICA) for melanoma survivors: Developing a prototype with trial participants

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IRAS 223906

Invitation

You have previously participated in the ASICA study and used the ASICA intervention. This is a further invitation to take part in a short study to develop a prototype of an improved version of the ASICA intervention.

Before you decide we would like you to understand why this research is being done and what it would involve for you and answer any questions you have. Talk to others about the study if you wish and please ask us if there is anything that is not clear.

WHAT IS THE STUDY ALL ABOUT?

The purpose of the study is to use your feedback to develop a prototype of an improved version of the ASICA intervention. We will ask you to use and review the prototype, which will be similar to the ASICA app you have already used. With your permission we will send an SMS text message to you to enable you to use the new ASICA prototype. Instruction on using the prototype will be integrated within the system. We will also ask you to attend a half day online (using Microsoft Teams or equivalent virtual meeting software) or face to face focus group with other participants, programmers and the researchers to feedback your experiences and potential suggestions for further improvement. We will record these meetings and transcribe them following the meeting. This is so we can use this feedback to refine the prototype and will ask you to review and provide further feedback on the refined prototype. We are looking to speak to about 30 ASICA participants to get their point-of-view.

Why have I been invited?

You have been invited because you participated in the ASICA study and used the ASICA intervention. In this additional study, we aim to answer questions about:

1. The design and usability of the refined ASICA prototype on personal devices,
2. Whether the prototype designed for personal devices addresses the technical suggestions for improvements made by ASICA participants,
3. Further improvements that could be made to meet the needs of melanoma survivors in supporting monthly total skin self-examination.

Do I have to take part?

No. It is your decision about whether or not you wish to take part. If you do agree to take part and then change your mind, you can withdraw at any time without giving a reason. Your decision will not affect your current treatment or any future medical treatment. Data collected up until the point of withdrawal may still be used in analysis.

OK, so what happens next?

If you have any questions before you make a decision about whether or not to take part in this study, you can contact the researchers, details below, if you need any further information.

If you would like to take part, please read, initial and sign the consent form and return it in the reply-paid envelope. The researchers will then contact you to discuss what happens next.

If you have any questions before you make a decision about whether or not to take part, you can contact the researcher (*[Insert researcher name]* – details overleaf).

What are the benefits/disadvantages of taking part?

There will be no extra benefit to you if you do take part in the study but by doing so you will be helping us with our research. Our research will help further develop the ASICA app and help us determine how it may be improved to meet the needs of future users.

What will happen to the results of the study?

We will use the results of this study to help make decisions about a future larger ASICA study as well as any suggested upgrades and improvements to the ASICA app technology. The researchers may also report the findings in a scientific journal and at a scientific research meeting. The information that we report would be completely anonymous and would not identify you in any way. We may be in touch again in the future to ask if you would be willing to participate in a further discussion about ASICA.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the researchers (contact details overleaf) who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints (contact details can be obtained from your local hospital) or the University of Aberdeen complaints mechanisms (*insert contact details*).

Will my information be kept confidential?

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

This information will include your name and contact details. 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 [email]
- by ringing us on [phone number].

What ethical and data permissions are in place?

This study has been approved by the North of Scotland Research Ethics Committee 2.

We are working with a software development company called Pinnacle who are helping in the development of the prototype. Pinnacle will be hosting the information entered in the app, this will include your phone number and your email address. We can ensure you that all appropriate safeguards have been put in place for handling the data.

Please take time to read this information leaflet. Discuss it with your family, friends or your GP if you wish. You can also contact us at any time if there is anything you do not understand or if you would like more information

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