

MelaTools Apps Study: Skin-Self Monitoring App Assessment by Smartphone Users

Participant Information Sheet

Thank you for your interest in this study. Please take time to read about this study and discuss it with others if you wish.

What is the purpose of the study?

We are researching acceptability of smartphone applications ('apps') for monitoring moles in people at above-population risk of melanoma, a serious type of skin cancer. The study will take around three months to complete and will focus on the use of apps rather than trying to detect skin changes over the study period. This study is part of a large programme of research that aims to help doctors to diagnose skin cancer earlier (MelaTools Programme; study website <http://www.melatools.org>).

Why have I been invited to take part?

We are asking people aged 18 to 75 years old who own an iPhone 4 or above to take part in our study. After completing a short survey, people with above the 'normal' population risk of melanoma ('above population risk' – roughly 25% of the UK population) will be invited to take part in the main part of the study. We are aiming to recruit about 50 patients to the main study.

Do I have to take part?

It is entirely up to you whether or not to take part. If you decide not to, your healthcare will not be affected in any way. If you decide to take part, you are still free to withdraw from the study at any time and without giving a reason. You will not then receive any further contact from the study team.

What do I have to do to take part?

The study will involve one workshop held in a local general practice. This workshop will be recorded and will be transcribed in a written form, all quotes will be anonymised. You will be given an iTunes voucher, and helped to download five skin self-monitoring apps onto your iPhone. We will ask you to use these apps to monitor three or more pigmented skin lesions over three months. We will send you a text message reminder at monthly intervals. You will be asked to complete a short diary about using the apps after one and two months. After the third month you will be interviewed to share your experiences. This will take place where you chose- we are happy to come to your home. It will take no longer than 45 minutes. The interviews will be transcribed in a written form, all quotes will be anonymised.

What are the potential benefits and disadvantages of taking part?

Although there are no direct benefits to taking part in this study, it is possible that you may find a mole that concerns you. If this happens, please book to see your GP to have this mole checked. Recognising that taking part means giving up your time we will offer you a £40 gift voucher. By taking part, you will be contributing to research that could help patients and doctors in the future.

What will happen if I decide not to take part in the main study, but the questionnaire finds me to be at above 'normal' population risk of melanoma?

If you are found to be at above the 'normal' population risk of melanoma but do not wish to take part, we have included information about skin cancer at the end of this sheet, or you could speak to your GP.

What if there is a problem?

If you have any concerns about the study at any time, please contact Dr Katie Mills who will do her best to answer your questions (01223 746867; ko298@medschl.cam.ac.uk).

If you remain unhappy and wish to complain formally, please contact the manager at your GP practice. This person will be independent of the study and will direct your concern appropriately.

Will my taking part in the study be kept confidential?

Any photos or additions you make to your iPhone will be held and owned by you – we will not ask to see any of your personal photographs or information. All information collected from your participation in the questionnaire, workshop, diaries and interview will be held at the University of Cambridge. Only members of the study team will have access to this data. It will be processed, stored and destroyed after 5 years in compliance with the NHS Code of Confidentiality and the Data Protection Act 1998. The audio recording of the workshop and interview will be destroyed at the end of the project. Your information will have your name and address removed so that you cannot be identified from it.

What will happen if I don't want to carry on with the study?

If you withdraw from the study, you will receive no further contact from the study team. Information collected prior to your withdrawal will be included in the study.

What will happen to the results of the research study?

The results of the research study will be published in medical journals, but you will not be identified. We will announce these publications on our study website where we will also summarise our findings in an easy to understand way.

Who is organising and funding the research?

The study is being organised by the Primary Care Unit, University of Cambridge and funded by the NHS National Institute for Health Research.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and approved by the North West - Haydock Research Ethics Committee.

What should I do next?

Please follow the link to start the questionnaire. You will be asked to give consent before you begin. This questionnaire will ask you some questions about yourself, including physical characteristics, lifestyle and family history of melanoma.

At this stage, all the information you give will be anonymous, we will not ask for any other information from which you could be identified.

If you are found to be at above 'normal' population risk of melanoma, you will then be invited to leave your contact details so we can contact you and invite you on to the main study.

Study website

This study is part of the MelaTools Programme of research (study website: <http://www.melatools.org>).

Information about Melanoma

If you are interested in finding out more about risk factors for melanoma you might find the following websites useful:

Cancer Research UK: <http://www.cancerresearchuk.org/cancer-help/type/melanoma/>

Melanoma Focus: <http://melanomafocus.com/>