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# MelaTools skin self-monitoring study for primary care patients at higher risk of melanoma

**Submission date**
09/08/2016

**Recruitment status**
No longer recruiting

**Registration date**
17/08/2016

**Overall study status**
Completed

**Last Edited**
18/09/2023

**Condition category**
Cancer

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Melanoma is a common skin cancer that can spread to other organs in the body. It Is the leading cause of skin cancer deaths in the UK. If the disease is not diagnosed early enough the cancer will spread and may result in death. Early, timely detection and prompt treatment can therefore make the difference as to whether someone recovers from melanoma or not. The use of a smartphone application for detecting skin changes could potentially assist in earlier diagnosis of melanoma, in prompting users to monitor their skin over time, and in suggesting professional, timely review of any suspicious moles detected. The purpose of this study is to test a novel skin self-monitoring (SSM) intervention (a smartphone app) in general practice aimed at promoting timely consulting by people that are considered to be at particular risk of developing melanoma.

Who can participate?
Patients aged 18-75 years old considered to be at higher than average risk of melanoma (roughly 25% of the UK population) will be recruited from GP practices in the East of England.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (intervention group) have a standard consultation about prevention of skin cancer with the research nurse. They are then asked to use the SSM app for 12 months. Those in group 2 (control group) also have the consultation but are not given the SSM app. All participants in both groups are asked to complete a questionnaire about their health with the nurse and after 6 and 12 months. If participants go to see their GP or practice nurse about a skin change or mole during the study, they are also be asked to complete a questionnaire about why they decided to go.

What are the possible benefits and risks of participating?
Although there are no direct benefits for people taking part in this study, it is possible that they may find a skin change or mole that concerns them. If this happens, they are advised to make an appointment with their GP to have this checked. By taking part, participants will be contributing to research that could help patients and doctors in the future.

Where is the study run from?
The study is being organised by the Primary Care Unit, University of Cambridge and run in GP practices in the East of England.

When is study starting and how long is it expected to run for?
April 2016 to March 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Katie Mills
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# Contact information

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Public

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Scientific

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# Additional identifiers

### Protocol serial number
2

# Study information

### Scientific Title
Skin self-monitoring for primary care patients at higher risk of melanoma: a phase II randomised controlled trial

### Acronym
MelaTools-SSM Trial

### Study objectives
1. The MelaTools SSM Trial intervention (use of a skin self-monitoring smartphone application) will increase the number of consultations for pigmented skin lesions in people at above-population risk of melanoma
2. The MelaTools SSM Trial intervention will be acceptable and will reduce the patient interval (including symptom appraisal and help-seeking intervals) in people at above-population risk of melanoma
3. The MelaTools SSM Trial intervention will not cause significant distress or worry in people at above population risk of melanoma

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
East of England - Cambridgeshire and Hertfordshire Research Ethics Committee, 11/07/2016, ref: 16/EE/0248

### Study design
Phase II multi-site randomised controlled feasibility trial

### Primary study design
Interventional

### Study type(s)
Other

### Health condition(s) or problem(s) studied
Melanoma

### Interventions
All participants will attend a consultation with a research nurse. With all participants, the nurse will follow a scripted explanation of the standardised information on skin cancer detection, based on Cancer Research UK's publications 'Skin Cancer: How to spot the signs and symptoms', and 'Be sun-smart: cut your cancer risk'. All participants will be given these leaflets.

Participants will then be randomised 1:1 to either the control arm (standard information) or to the intervention arm (standard information and SSM App). A block randomisation method, using computer-generated, randomly permuted blocks of size 2, 4, and 6, established by a professional

independent randomisation service, will be applied. Research nurses will log into an online system during the trial consultation at the point of randomisation.

With the help of the research nurse the intervention participants will then install the SSM App onto their smartphone during this consultation, and be given instructions how to use it. They will be asked to use the App for 12 months.

All participants will be sent follow up questionnaires at 6 and 12 months following randomisation.

More info about the SSM App:
The SSM App used in the trial is an existing App that is available on both the Android and Apple App stores. It encourages skin self-monitoring by photography of moles and provides reminder prompts to repeat this at intervals defined by the user. Photographs taken can be mapped to a body part and notes can be written to describe features of the mole for future reference. Photographs taken prior to usage of the App can also be imported for comparison. There is also the facility to complete a full body scan of all moles. In addition, the ABCDE-signs of melanoma guidance is available for reference.

### Intervention Type
Behavioural

### Primary outcome(s)
1. Consultation rates for any skin changes/pigmented skin lesions presented to their GP/practice nurse during the 12 months following the trial consultation compared with the 12 months prior to the trial and; identified by auditing the general practice electronic medical records. All actions taken during the consultation will be recorded including: diagnosis, referral, excision in the GP surgery, advice to monitor.
2. The patient interval (time from first noticing a skin change to presentation) for all skin changes /pigmented skin lesions presented to their GP/practice nurse during the 12 months following the trial consultation. This will be measured by the completion of a skin questionnaire sent to the participant after presentation to their GP/practice nurse.

### Key secondary outcome(s))
1. Patient-Reported Outcomes, including: sun protection habits, skin self-examination, melanoma worry and perceived melanoma risk, self-efficacy for consulting without delay; anxiety, depression and quality of life. This will be measured by the completion of a baseline questionnaire, 6 month and 12 month follow up questionnaires
2. Trial feasibility and acceptability, including: data on patient recruitment, attrition, and response rates to outcome measures to inform decisions about a future phase III trial
3. Melanoma incidence across participating practices, to contextualise trial findings and after 5 years identified by data collected from primary care records

### Completion date
31/03/2018

## Eligibility

### Key inclusion criteria
1. Age between 18-75 years
2. Own a smartphone

### Participant type(s)
Healthy volunteer

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Upper age limit
75 years

### Sex
All

### Total final enrolment
238

### Key exclusion criteria
1. Severe psychiatric or cognitive disorder
2. Inability to read English to a reasonable standard
3. Physical disorder severe enough to inhibit the use of a smartphone

### Date of first enrolment
15/08/2016

### Date of final enrolment
15/01/2017

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Linton Health Centre**
Coles Lane
Linton
Cambridgeshire
United Kingdom
CB21 4JS

**Study participating centre**
**Sawston Medical Centre**
London Road
Sawston
Cambridgeshire
United Kingdom
CB22 3HU

**Study participating centre**
**New Queen Street Surgery**
Syers Lane
Whittlesey
Peterborough
United Kingdom
PE7 1AT

**Study participating centre**
**Royston Health Centre**
Melbourn Street
Royston
United Kingdom
SG8 7BS

**Study participating centre**
**Flitwick Health Clinic**
Highlands
Flitwick
Bedfordshire
United Kingdom
MK45 1DZ

**Study participating centre**
**De Parys Medical Centre**
23 De Parys Avenue
Bedford
Bedfordshire
United Kingdom
MK40 2TX

**Study participating centre**

**Beccles Medical Centre**
St Mary's Road
Beccles
Norfolk
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NR34 9NX

**Study participating centre**
**Sheringham Medical Centre**
Cromer Road
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NR26 8RT

**Study participating centre**
**Wymondham Medical Centre**
18 Bridewell Street
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NR18 OAR

# Sponsor information

**Organisation**
University of Cambridge

**ROR**
https://ror.org/013meh722

# Funder(s)

**Funder type**
Government

**Funder Name**
National Institute for Health Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

# Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Data sharing statement to be made available at a later date

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 05/02/2020 | 27/02/2020 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Protocol file | version 1.0 | 11/05/2016 | 18/09/2023 | No | No |
| Statistical Analysis Plan | version 1.2 | 01/02/2019 | 18/09/2023 | No | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |