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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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Study website
http://www.melatools.org

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Other

Participant information sheet
Not available in web format; please use the contact details to request an participant information sheet.

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/04/2016

Completion date
31/03/2018

Eligibility

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

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
200

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
England

United Kingdom

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
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United Kingdom
MK40 2TX

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

Study participating centre
Sheringham Medical Centre
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NR26 8RT

Study participating centre
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18 Bridewell Street
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Sponsor information

Organisation
University of Cambridge

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CB2 0SP

Sponsor type
University/education

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

Publication and dissemination plan

1. The trial findings will be disseminated at national and international meetings such as Society for Academic Primary Care, and Cancer Primary Care Research International meeting
2. Findings will be published in high-impact peer-reviewed journals with the intention to publish within 12 months of the trial completion (December 2018)

Intention to publish date
31/12/2018

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
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