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The miskin trial for holidaymakers sun protection

Submission date
09/10/2012

Recruitment status
Stopped

Registration date
13/02/2013

Overall study status
Completed

Last Edited
25/05/2016

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Excessive sun exposure during sunny holidays increases the risk for skin cancer. The British population receives about 30% of their annual UV exposure during their 2-weeks holidays abroad. Strategies to promote sun protection have been unsuccessful in changing holidaymakers sun-protection practices. In this study, we want to see whether receiving a newly developed mobile-phone application would encourage holidaymakers to protect themselves from excessive sun exposure and, subsequently, prevent skin damage. We also want to see if using sun protection factor (SPF) 30 reduces skin damage compared to SPF 15.

Who can participate?
The mISkin study aims to recruit about 200 holidaymakers going for up to 2-weeks holidays, age > 18 years and that own an Android™ smartphone.

What does the study involve?
Participants will be randomly (by chance) allocated to one of four groups: a) those who receive sunscreen with SPF30 and the mobile phone application; b) those who receive sunscreen with SPF15 the and mobile phone-application; c) those who receive sunscreen with SPF30 but not the mobile phone intervention and d) those who receive sunscreen with SPF15 but not the mobile phone intervention.
Before participants go on holidays and after their return, we will assess the degree of damage on the outer layers of the skin related to recent sun exposure.
We will also measure a range of specific sun protective behaviours. By comparing the groups to which participants were randomly allocated to, we can understand if the mobile phone application has been successful in reducing skin damage and increasing sun protection practices. We will be able to also see if using SPF30 rather than SPF15 would be more beneficial in preventing skin damage.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part. But there should be benefits to future holidaymakers. Participants will contribute to the development of a mobile phone app that can, if proven successful, help to prevent skin cancer.
Successful interventions to promote sun protection are needed to support skin cancer

prevention. Participants might find that participating in this study might help them make some behaviour changes and improve their own sun protection practices.

Where is the study run from?
This study has been set up within Newcastle University, involving the collaboration of researchers from three different departments: Health Psychology, Dermatological Sciences and Computing Science.

When is study starting and how long is it expected to run for?
It is anticipated that recruitment will start in late 2012. Participants will be enrolled until October 2013.

Who is funding the study?
The Newcastle Institute for Research on Sustainability (NIReS), UK

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A factorial randomised controlled trial of the mISkin Smartphone intervention and sunscreen with SPF 15 vs. SPF 30 to prevent epidermal DNA skin damage amongst holidaymakers

Acronym
mISkin

Study objectives
We hypothesise that participants allocated to the newly developed Smartphone intervention aimed at promoting safe sun exposure, the mISkin application (app), will
1. Show less epidermal DNA skin damage (primary outcome)
2. Use more sunscreen (measured as amount [residual sunscreen in provided bottles]
3. Increase frequency of sunscreen use [using tri-axial accelerometers attached to sunscreen bottles]) and
4. Self-report more sun protective behaviours (seeking shade, using protective clothing) following their holiday at a high UV destination (UV Index ¡Ã 6) than waiting list controls.

The mISkin intervention was developed at Newcastle University based on a previous systematic review and user centred design.
We also hypothesise that those participants allocated to SPF30 will show less epidermal DNA skin damage but show no difference in terms of sunscreen use and self-reported protective behaviours (seeking shade, using protective clothing) during their holiday at a high UV destination compared with participants allocated to SPF15. In the UK, the National Institute for Clinical Excellence (NICE) recommends using sunscreen SPF15, whereas the British Association of Dermatologists, Cancer Research UK and the British Skin Foundation recommend SPF30.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Newcastle University Faculty of Medical Science Ethics Committee, 07/03/2012, ref: 00427_1 /2012

Study design
Single centre assessor-blinded factorial randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Sun protection behaviours amongst holidaymakers

Interventions
Participants will be randomised to a 2 (mISkin intervention vs. waiting list control [no mISkin intervention]) x 2 (Sunscreen provision: SPF 15 vs. SPF 30) factorial design.

1. Behavioural Intervention
mISkin Intervention Group
Participants randomised to the intervention group will receive a behavioural intervention (¡®mISkin¡¯) delivered through their mobile-phones (Android Smartphones) during their holiday.

The behaviour change strategies utilised in this app are based on a systematic review and the interventions have been developed using user-centred design principles. The application will also include an initial skin assessment upon which the intervention delivery will be tailored. Participants will be asked to interact daily (1 to 3 times per day) with the application. Each day participants will also be asked to respond, through the application, to brief questions about their sun-protection practices.

Waiting list Control
Participants randomised to the control condition will not receive an intervention targeting sun-protective behaviours and will be offered the intervention/app next time they go on holiday if the intervention is found to be efficacious in this trial (waiting list control).

2. Sun Protection Factor
All participants will be provided with two bottles of sunscreen (Ambre Solaire, 200ml), with either SPF15 or SPF30.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Skin sun damage will be assessed objectively using a reliable epithelial skin swab to test for mitochondrial DNA (mDNA) damage caused by UV exposure (Harbottle et al. 2010) before and after their holiday.

Key secondary outcome(s))
1. Sunscreen use(amount) measured by weighting provided sunscreen bottles at baseline and post-test
2. Sunscreen use (frequency and time-stamped patterns) measured using tri-axial accelerometers attached to the sunscreen bottles providing time and date stamped data of bottle movement sufficient to identify instances of use
3. Self-reported sun protection behaviours using the questionnaire developed by Glanz et al. (2008) (at baseline and post-test)
4. Skin damage using a UV photo taken before and after the study displaying sun damage in the form of mottled pigmentation
5. Psychological measures of knowledge, intention, attitudes, self-efficacy, social influences towards sun protection behaviours and consideration of immediate and future consequences based on standard procedures (at baseline and post-test)

Internal Pilot (Feasibility) Study
To ensure the feasibility of the trial procedures, we will define the period until the first 30 participants have completed the study as internal pilot study. For this internal pilot, the main outcomes are: a) acceptability (measured by completion rates and post study interviews); b) feasibility, measured by attrition rates and user activity in interacting with the mobile-phone intervention.
Stop rules:
If we find that more than 10 out of the first 30 participants do not accept their group allocation, measurement procedures or other aspects of the trial procedures or if the post holiday interviews identify any significant problems with the acceptability of the trial protocol we will

either modify the protocol to enhance acceptability and feasibility based on the insights gained , or we will consider discontinuing the trial. If during this period no significant problems with acceptability and feasibility are detected the data from the internal pilot will become part of the main dataset and analyses as part of the trial. If any major modifications to the protocol need to be implemented, the data from the internal pilot will not be analysed alongside the main trial.

Completion date
30/09/2013

Eligibility

Key inclusion criteria
1. Holidaymakers from the North East of England travelling for up to two weeks
2. Age >=18 years old
3. Individuals owning an Android Smartphone, as the mISkin app is available for Android platforms only

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. People with known dermatological conditions
2. People with known allergic reactions to sunlight and/or sunscreen
3. People under photosensitive drugs for whom UV exposure is undesirable
4. People experiencing ill health
5. Pregnant women
6. Non-English speakers

Date of first enrolment
15/10/2012

Date of final enrolment
30/09/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Institute of Health and Society
Newcastle upon Tyne
United Kingdom
NE2 4AX

Sponsor information

Organisation
Newcastle University (UK)

ROR
https://ror.org/01kj2bm70

Funder(s)

Funder type
University/education

Funder Name
Newcastle University (UK) - Institute of Health and Society

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes