ISRCTN11141528 https://doi.org/10.1186/ISRCTN11141528

"Do you know your skin?": an intervention to increase sunscreen use, skin self-examination and talking about skin cancer

Submission date
13/12/2017

Recruitment status
No longer recruiting

Registration date
02/03/2018

Overall study status
Completed

Last Edited
03/02/2020

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Getting sunburnt is the biggest risk factor for melanoma (the worst type of skin cancer), but using sunscreen can help adolescents protect themselves from the harmful effects of the sun. Skin self-examination can help people detect melanoma and early detection improves the chances of not dying from the disease. Talking about skin cancer with family and friends can help adolescents seek professional help and advice promptly if they are worried about changes to their skin. The aim of this study is to evaluate an intervention called 'Do you know your skin? aimed to increase sunscreen use, skin self-examination and talking about skin cancer.

Who can participate?
Male and female secondary school attenders aged 15-16

What does the study involve?
Participating schools are randomly allocated to the intervention group or the control group. In the intervention group schools the intervention is delivered by a skin cancer specialist nurse. The nurse meets with classes of adolescents for one hour during a school lesson. The lesson includes a short film ('Dear 16 year old me'), factual information about melanoma prevention and early detection, and a short quiz to determine skin type. Sunscreen use and skin self-examination handouts are given to encourage adolescents to plan for using sunscreen and to practice skin self-examination at home. A young adult who was treated for melanoma in the past accompanies the nurse to talk about his experiences of being diagnosed with melanoma. He emphasises the importance of using sunscreen and of skin self-examination. Sunscreen use, skin self-examination and talking about skin cancer are assessed using a survey at 2 weeks before the intervention and 4 weeks after the intervention has been delivered. In Phase II only, in addition to the presentation, text messages are sent to pupils over the summer holidays to encourage sun safe behaviours. In Phases I and II, the schools allocated to the control group receive the presentation after the study has ended.

What are the possible benefits and risks of participating?
The benefits are that students will learn about melanoma from an expert and be able to

examine their skin for signs that might be linked to melanoma. For any student who has personally been affected by cancer the study may make bring up some emotion around this issue, and staff will be on hand to deal with anything that arises of this nature.

Where is the study run from?
University of Stirling, Heriot Watt University, Edinburgh Napier University and University of the Highlands and Islands (UK)

When is the study starting and how long is it expected to run for?
September 2016 to December 2018

Who is funding the study?
Melanoma Focus and Chief Scientist Office

Who is the main contact?
Prof. Gill Hubbard

Contact information

Type(s)
Public

Contact name
Prof Gill Hubbard

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SREC 15/16 – Paper No.66 – Version 2

Study information

Scientific Title
Promoting sunscreen use and skin self-examination to improve early detection and prevent skin cancer: quasi-experimental trial of an adolescent psycho-educational intervention

Study objectives
This feasibility trial, in preparation for a future effectiveness trial, is to test an intervention to increase sunscreen use, and skin self-examination behavior during adolescence.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University of Stirling Research and Ethics Committee, 05/09/2016, ref: SREC 15/16 – Paper No. 66 – Version 2
2. University of the Highlands and Islands ethical committee, 14/05/2018

Study design
Cluster randomised trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Skin cancer

Interventions
The feasibility study uses a quasi-experimental design, with schools allocated by the research team to an intervention group or control group, to find out if the intervention worked as intended and to examine trial procedures.

The intervention "Do you know your skin" was developed by the research team with the support of an expert working group that included two people who had been treated for skin cancer, three experts in health behaviour change, one policy-maker in cancer early detection, one skin cancer specialist nurse and one dermatologist. The intervention has two parts: a presentation delivered to students in school and a home-based assignment.

In Phase I (2017) and Phase II (2018), a practicing skin cancer nurse specialist delivers a 50-minute presentation to students about skin cancer and skin self-examination (SSE). Each

presentation is delivered by the nurse on one occasion during the school day in a classroom. The nurse will deliver the presentation with the aid of Microsoft PowerPoint slides and cover: personal experiences of skin cancer, incidence patterns, risk factors, associations between disease staging and survival, and benefits of SSE. A young adult skin cancer survivor will give a brief 5-minute talk after the nurse-delivered presentation. The talk is about his personal experience of melanoma diagnosis at 16 years old, impacts on his life and his views on sunscreen use and SSE behaviour.

A home-based assignment will compromise a booklet with instructions. Adolescents will be given an exercise to self-examine their skin and be asked to complete an action plan for regular sunscreen use and an action plan for SSE. The SSE component of the booklet has three sections: a) information on the importance of planning; b) instructions of what should be included in the plan; c) formulating 'if-then' action plans (e.g., If I am having a shower then I will check my skin) and coping plans (e.g. To make sure I don't forget, I will add the appointment to my calendar and put a reminder post-it on the fridge).

Added 17/05/2018: In Phase II (2018), in addition to the above, pupils will receive text messages over the summer holidays to encourage sun safe behaviours.

The school allocated to the control group will receive the same intervention after the study has ended.

Intervention Type
Behavioural

Primary outcome measure
All outcomes measured using self-completed survey on pen and paper, administered as a group activity within the allocated schools at 2 weeks before the intervention (baseline), and 4 weeks after the intervention has been delivered:
1. Sunscreen use intention, measured using one item: 'Do you intend to use a high factor sunscreen if you are going out in the sun?' A five-point Likert scale was used to gauge response from 1 (definitely will not) to 5 (definitely will)
2. Sunscreen use planning, measured using five items: 'I have made a detailed plan on… i) What sunscreen I will use; ii) When I will use it; iii) Where I will get it from; iv) How I will remember to carry it'; and, iv) What to do it I am tempted not to use it.' A five-point Likert scale was used to gauge response from 1 (completely disagree) to 5 (completely agree)
3. Skin self-examination (SSE) behaviour, measured using one item: 'In the past month, have you examined your skin for signs of possible skin cancer?' Responses were yes, no or don't know. SSE intention was measured using one item: 'Do you intend to examine your skin for signs of possible skin cancer on a regular basis.' A five-point Likert scale was used to gauge response from 1 (definitely will not) to 5 (definitely will)
4. SSE planning, measured using four items: 'I have made a detailed plan regarding…
4.1. When to examine my skin for signs of possible skin cancer
4.2. Where to examine my skin for signs of possible skin cancer
4.3. How to examine my skin for signs of possible skin cancer'
4.4. 'I have made a plan for dealing with things that could stop me from examining my skin for signs of possible skin cancer'
A five-point Likert scale was used to gauge response from 1 (completely disagree) to 5 (completely agree)
5. Talking about skin cancer, measured using one item: 'Have you spoken to anyone about skin cancer in the last month?' Responses were yes or no

6. Illness perceptions: Five dimensions of the CSM were measured using the following items:
6.1. Identity: 'How much would getting skin cancer affect your life?' An 11-point Likert scale was used to gauge response from 0 (not at all) to 10 (it would severely affect my life)
6.2. Control: 'How much control do you feel you have to prevent yourself from getting skin cancer?' An 11-point Likert scale was used to gauge response from 0 (not at all relevant) to 10 (very relevant)
6.3. Timeline: 'Given your age, how relevant is it to regularly examine your skin for signs of possible skin cancer?' An 11-point Likert scale was used to gauge response from 0 (not at all relevant) to 10 (very relevant)
6.4. Consequence: 'How painful do you think the effects of treatments for skin cancer would be?' An 11-point Likert scale was used to gauge response from 0 (not at all painful) to 10 (extremely painful)
6.5. The following open-ended question was used to measure the CSM dimension cause: 'Please list in rank-order the three most important factors that you believe cause skin cancer'

Secondary outcome measures
1. Intervention adherence and acceptability. Intervention adherence was defined in two ways: proportion of eligible adolescents on a school register receiving the presentation, and number of participating adolescents completing the home-based assignment. The number of adolescents in intervention schools who received the presentation was objectively measured using school attendance records. The number of adolescents doing the home-based assignment was self-reported at follow-up.
2. Adolescents' opinions about relevance, content, format and delivery methods, explored in focus groups conducted in intervention group schools. Focus groups (n=3; 1 intervention group school was unavailable due to exam revision timetabling) to elicit adolescents' views on the intervention's relevance, content, format and delivery methods were conducted approximately 8 weeks after the intervention. Focus groups were audio-recorded and took place during school time, in a classroom, at a time and place selected by the teacher and lasted approximately 50 minutes. Confidentiality was explained and informed consent was obtained in writing.

Added 17/05/2018:
3. In Phase II (2018), an objective measure of melanin will be collected as indicator of sunburn pre- and post-intervention (i.e. before and after the school summer holidays): melanin level measured using a Mexameter

Overall study start date
01/09/2016

Completion date
31/12/2018

Eligibility

Key inclusion criteria
Male and female secondary school attenders aged 15-16 years

Participant type(s)
Other

Age group
Child

Lower age limit
15 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
500

Total final enrolment
487

Key exclusion criteria
Consent not given by parent or guardian

Date of first enrolment
01/04/2017

Date of final enrolment
30/09/2017

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
School of Health Sciences, University of Stirling
United Kingdom
FK9 4LA

Sponsor information

Organisation
University of Stirling

Sponsor details
School of Health Sciences
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Sponsor type
University/education

Organisation
University of the Highlands and Islands

Sponsor details
Research and Contracts
12b Ness Walk
Inverness
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IV3 5SQ

Sponsor type
University/education

Organisation
University of Stirling

Sponsor details

Sponsor type
Not defined

Website
http://www.stir.ac.uk/

ROR
https://ror.org/045wgfr59

Funder(s)

Funder type
Charity

Funder Name
Melanoma Focus

Funder Name
Chief Scientist Office

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The trial chief investigator will make the study protocol available on request. The research team intend to publish the results from this trial in high-impact peer reviewed journals, identifying a publication which the trial will fit in well for their readers, and subscribers. Intention to publish will occur within 12 months of completion of the data analysis from the trial.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication. The data will not be available for data sharing, as this did not form part of the informed consent given by participants.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/05/2018		Yes	No
Results article	results	30/01/2020	03/02/2020	Yes	No