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Skin cancer prevention in primary care

Submission date
23/04/2019

Recruitment status
No longer recruiting

Registration date
26/04/2019

Overall study status
Completed

Last Edited
12/06/2023

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
In light of increasing skin cancer incidences worldwide, preventive measures to promote sun protection in individuals with risky sun habits have continued relevance and importance. The efficacy of tailored sun protection advice has been studied in different settings, with varying results, of which primary care is one important provider previously identified. However, evidence on long-term sustainability of the effect of such advice given is lacking.
Aim: To report the long-term effect of individualised sun protection advice given in primary healthcare (PHC), on sun habits/sun protection behaviour, and attitudes towards sunbathing.

Who can participate?
Patients > 18 years of age visiting the study primary health care centre during the recruitment period.

What does the study involve?
All participant completed a questionnaire mapping sun habits and attitudes towards sunbathing, and were then randomised to three possible interventions: 1) Individualised, written sun protection advice, 2) Individualised sun protection advice mediated orally by a GP, and 3) Individualised sun protection advice mediated orally by a GP and performance of a skin phototest for assessment of individual ultraviolet skin sensitivity.

What are the possible benefits and risks of participating?
All participants were given individualised sun protection advice based on their personal risk profile with regard to skin cancer, advice that in case followed, would be likely to be beneficial in terms of reducing ultraviolet exposure risks, or at least lead to increased awareness. Since the intervention did not include any kind of invasive, sensitive or integrity intruding elements, there was no obvious risk for the participants for taking part in the study. The phototest performed in one of the intervention groups comprised the illumination of ultraviolet radiation on very small, well-defined skin areas, insufficient to cause any harm or increased skin cancer risk.

Where is the study run from?
Kärna Primary Healthcare centre, Linköping, Sweden

When is the study starting and how long is it expected to run for?
February 2005 for 3 weeks

Who is funding the study?
Region Östergötland, Sweden

Who is the main contact?
Dr Magnus Falk (scientific contact), magnus.falk@liu.se

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
LIO-14711

Study information

Scientific Title
Skin cancer prevention in primary care - a randomised study

Study objectives
1. Sun protection advice given in a primary care setting is more effective in reducing individual ultraviolet exposure if mediated orally by a general practitioner in comparison with solely

written information.
2. Addition of an ultraviolet photo test to the oral information contributes to reinforce the sun protection advice given.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/12/2004, The Regional Ethical Review Board in Linköping (Etikprövningsmyndigheten, Box 2110, 750 02 Uppsala, Sweden; registrator@etikprovning.se; +4610-475 08 00) ref: Dnr. M187-04.

Study design
Single center Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
See additional file

Health condition(s) or problem(s) studied
Sun exposure habits with regard to skin cancer

Interventions
The participants were consecutively computer-randomised to the three intervention groups, at registration in the reception of the healthcare centre. All participants completed a questionnaire mapping sun exposure habits, attitudes towards sunbathing and propensity to increase sun protection.
Interventions given:
All groups: A brief written, general sun protection advice information sheet.
Group 1: Written, individualised sun protection advice based on the questionnaire responses, mediated in letter-form.
Group 2: Individualised sun protection advice based on the questionnaire responses, mediated orally in the form of a personal GP’s consultation, taking approximately 20 minutes, including a nevi check.
Group 3: The corresponding intervention as in Group 2 but also including a skin phototest for estimation of individual ultraviolet sensitivity with feedback of the test outcome.

Intervention Type
Behavioural

Primary outcome measure
Sun exposure habits, measured by a questionnaire based of a number of 5-grade Likert scored question, reflecting frequency and degree of sun exposure and protection, and five questions measuring propensity to increase sun protection based on the transtheoretical model of behaviour change. Measurement time points: Baseline (at study start, prior to intervention), after 6 months, 3 years and 10 years.

Secondary outcome measures
Secondary outcome variable: Attitudes towards sunbathing, measured by a number of 5-grade Likert scored questions. Measurement time points: Baseline (at study start, prior to intervention), after 6 months, 3 years and 10 years.

Overall study start date
01/09/2004

Completion date
30/10/2015

Eligibility

Key inclusion criteria
1. Patients > 18 years of age visiting the study primary health care centre during the recruitment period.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Total final enrolment
316

Key exclusion criteria
1. Abnormal UV-sensitivity
2. Intake of UV-sensitising medication
3. Cognitive impairment

Date of first enrolment
01/02/2005

Date of final enrolment
25/02/2005

Locations

Countries of recruitment
Sweden

Study participating centre
Kärna Primary Healthcare centre
Kärnabrunnsgatan 10
Linköping
Sweden
58662

Sponsor information

Organisation
County Council of Östergötland

Sponsor details
Region Östergötland
Linköping
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58185
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Sponsor type
Hospital/treatment centre

Website
www.regionostergotland.se

ROR
https://ror.org/0326gsy75

Funder(s)

Funder type
Government

Funder Name
Länsstyrelsen Östergötland

Results and Publications

Publication and dissemination plan
Half-year results were published in 2008, 3-year results in 2011. 10-year results are intended to be published in 2019.

Intention to publish date
01/06/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2008		Yes	No
Results article	results	01/09/2011		Yes	No
Participant information sheet	10 year follow up	24/04/2019	23/05/2019	No	Yes
Results article		01/10/2019	12/06/2023	Yes	No