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[Intervention Protocol]

Educational programmes for primary prevention of skin cancer

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To assess the effects of education programmes for skin cancer prevention in the general population.

BACKGROUND

Description of the condition

Skin cancer is a term that includes both melanoma and keratinocyte cancer. Keratinocyte cancer (also known as non-melanoma skin cancer) generally refers to basal cell carcinoma (BCC) and squamous cell carcinoma (SCC), although it also includes other rare cutaneous neoplasms (Madan 2010). Skin cancer is the most common cancer in populations of predominantly fair-skinned people (Donaldson 2011; Lomas 2012; Stern 2010), with incidence increasing (Garbe 2009; Leiter 2012). There are variations in annual incidence rates between these populations, with Australia reporting the highest rate of skin cancer in the world (Lomas 2012). In 2012, the estimated age-standardised incidence rate for melanoma was almost 63 per 100,000 people for Australian men, and 40 per 100,000 people for Australian women (AIHW 2012). In Europe, incidence rates range from 10 to 15 per 100,000 people (Garbe 2009; Lasithiotakis 2006), with rates highest amongst men (Stang 2006). In the United States, incidence rates are approximately 18 per 100,000 people (Garbe 2009), with the highest rates reported for women (Bradford 2010). Keratinocyte cancer is much more common than melanoma. In 2012, the estimated Australian age-standardised rates for BCC and SCC were 884 and 387 per 100,000 people, respectively (Staples 2006). The cumulative three-year risk of developing a subsequent keratinocyte cancer is 18% for SCC and 44% for BCC (Marcil 2000).

Melanoma is the most fatal form of skin cancer. In 2007, the melanoma mortality rate was 8.9 and 3.5 per 100,000 people for

Australian men and women, respectively (AIHW 2012). In 2003, Finland reported mortality rates of 0.8 per 100,000 people for both men and women (Stang 2006). Amongst non-Hispanic whites in the United States, mortality was 1.7 per 100,000 people for those aged under 65 years (Linos 2009). Generally, mortality rates of skin cancer have been stabilising or declining (Cohn-Cedermark 2000; Giles 1996; Jemal 2008), although this trend appears to be happening for women but not for men (Giles 1996; Jemal 2008; Stang 2006; Thompson 2005) or older people (Linos 2009). Survival rates from melanoma have been improving (Thompson 2005), with five-year survival in the United States and 10-year survival in Germany both approximately 80% (Leiter 2012; Singh 2003), and over 90% for young American adults (Reed 2012). High survival rates and improvements in melanoma mortality rates are likely to be due to improvements in early detection and treatment (Chapman 2011; Garbe 2009; Giles 1996). Keratinocyte cancer, by contrast with melanoma, is less fatal yet can cause disfigurement, often on visible areas of the body (English 1997). It is the most common cause of hospitalisations for cancer, accounting for 11% of all inpatient cancer hospitalisations in Australia (AIHW 2012). For individuals, keratinocyte cancer can cause impairment, financial strain, and distress (Burdon-Jones 2010; Leiter 2008). For the healthcare system, skin cancer is one of the most costly cancer groups (Housman 2003), with keratinocyte cancer the driving force behind high costs. While melanoma cost the Australian health system 30 million Australian$ between 2000 and 2001, keratinocyte cancer cost 264 million Australian$ (AIHW 2005). In the United States, keratinocyte cancer is estimated to cost over 450 million US$ per year (Chen 2001).

Risk factors for skin cancer include genotype (an individual's genetic makeup); phenotype (the body's expression of that genotype), both of which determine an individual's predisposition to skin cancer; and environmental factors. The primary environmental risk factor is exposure to ultraviolet (UV) radiation from the sun (IARC 1992; Kricker 2007; Madan 2010; Ramos 2004). Melanoma and BCC appear to be associated with intermittent and childhood sun exposure, whereas SCC appears to be related to constant, cumulative sun exposure (Gallagher 2010). While genotype, phenotype, and ambient UV exposure cannot be altered, individuals have considerable control over their sun protection behaviours.

Cancer authorities recommend five adjunctive methods of sun protection, in addition to avoiding peak UV sun wherever possible:

1. seek shade;
2. wear sun-protective clothing;
3. wear sun-safe hats;
4. apply broad-spectrum, water-resistant, SPF 30+ sunscreen to sun-exposed skin; and
5. wear sun-protective sunglasses (Cancer Council Australia 2013).

These methods have been shown to be effective. In the case of sunscreen, correct usage during childhood is thought to reduce lifetime skin cancer risk by 78% (Stern 1986); daily usage can prevent development of melanoma and SCC; and in the long-term, it may also protect against BCC (Green 1999; Green 2011; Van der Pols 2006). Recent in vivo studies have shown that correct application of SPF 30+ sunscreen can prevent all three cancer types (Hacker 2013). However, each of the adjunctive methods of sun protection encompass several elements, which can make the behaviour, and measuring the behaviour, complex.

Despite these challenges, evidence suggests that interventions aimed at improving people's sun protection behaviours can work. The sustainability of such programmes, however, is less clear. In Australia, despite years of sun protection programmes, improvements in these behaviours appear to have stabilised or worsened (Green 2013; Livingston 2007; Markin 2013). This decrease may be due in part to concerns about potential negative consequences from low serum 25(OH)-vitamin D concentrations. Ultraviolet radiation exposure is required for vitamin D synthesis, and low serum concentrations, which have been associated with growth retardation and skeletal deformation in children, and osteoporosis, cancers, autoimmune diseases, infectious diseases, and cardiovascular disease in adults (Holick 2007), may result from sun protection behaviours (Matsuoka 1987). Unclear or unbalanced messages regarding the vitamin D benefits and the skin cancer risks of sun exposure may also lead to confusion regarding the required level of sun protection (Hiom 2006; Langbecker 2011).

Description of the intervention

As described by Welsh 2011, education involves more than simply providing information, aiming to integrate knowledge, improve self-management, and produce behaviour change. Health education can include 'training', and consequently it is necessary to distinguish between education, which focuses on imparting knowledge and developing understanding, and training, which focuses on the development of skills (Michie 2011).

Interventions to reduce UV exposure are diverse and difficult to classify (Saraiya 2004). Interventions may use various media (e.g. posters, television and radio, and internet) and target multiple audiences (e.g. parents, children, high-risk groups, and healthcare providers) using multiple strategies (e.g. individuals, communities, and populations) in multiple contexts and settings (e.g. schools, healthcare settings, and recreational areas).

For the purposes of this review, we defined education as an intervention to provide information on (a) skin cancer, (b) its causes, (c) its consequences, or (d) how it can be prevented. Based on the definition by Wolf 2002, such interventions may use any instructional strategy or combination of strategies (e.g. problem solving, role-playing, videotapes, computer-assisted instruction, or booklets). These interventions may be delivered to the individual, via group sessions or through general media, including online and social media. Interventions can be targeted at the general population or specific high-risk groups (e.g. outdoor workers).

Education interventions can address different levels of prevention, although this review will only consider primary prevention programmes.

Primary prevention

The aim of the intervention is to reduce the risk of skin cancer by informing people how to minimise UV radiation exposure.
Secondary prevention, which is not the subject of this review, is an intervention that aims to increase appropriate healthcare service use in response to signs of skin cancer (e.g. recognise skin changes and seek early diagnosis and treatment) and reduce the risk of reoccurrence or further development of skin cancer (Spratt 1981).

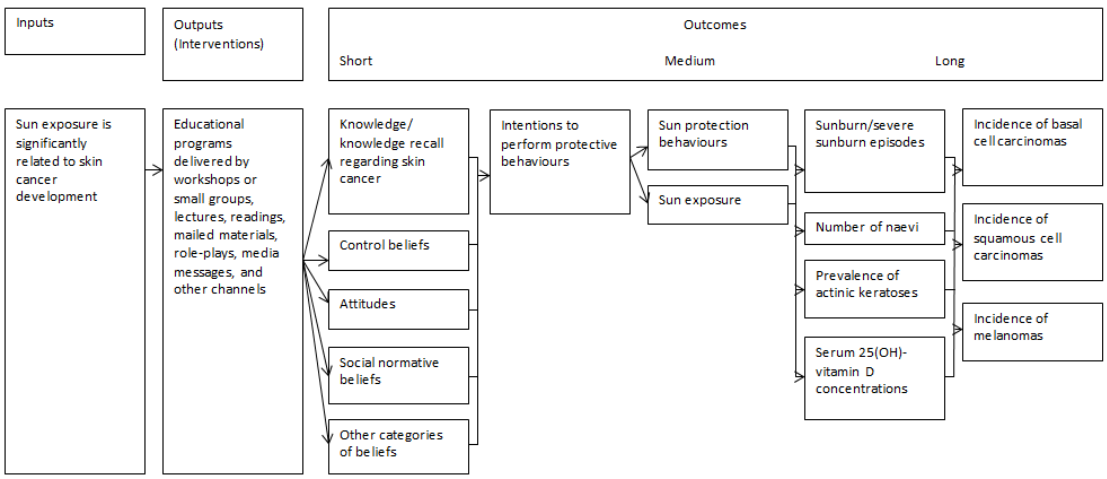
How the intervention might work

Educational interventions aim to change sun-protective behaviour by informing people of the severity and consequences of skin cancer (e.g. death), the risk factors associated with skin cancer (e.g. exposure to direct sunlight during the peak sun hours and use of solaria), and which protective behaviours to perform (e.g. wearing sunscreen that contains UVA and UVB protection and wearing hats and other protective clothing while in the sun). Thus, in addition to providing sufficient knowledge of potential dangers to warrant action, education programmes also offer guidance on efficacious actions to reduce the health threat if they are to successfully change health behaviours.
Specific components of primary education interventions (WHO 2012) may affect behaviour change by:

- reinforcing basic information about skin cancer to embed understanding;
- emphasising adherence to UV-protective behaviours; and
- emphasising the importance of avoiding environmental triggers.

The logic model developed by the review authors (Figure 1) shows how educational programmes may influence skin cancer prevention outcomes.

Figure 1. Logic model of how educational programmes may influence skin cancer



Why it is important to do this review

Despite strategies and efforts to prevent skin cancer, a recent review highlighted the need for further research to improve skin cancer prevention (Lomas 2012). The incidence of both melanoma and keratinocyte cancer has increased dramatically over previous decades (Garbe 2009; Leiter 2012). Although melanoma is less common than keratinocyte cancer, it is more serious than other types of skin cancer and causes a large majority of skin cancer deaths (AIHW 2012). Both melanoma and keratinocyte cancer contribute to the high cancer-related health system costs (AIHW 2005; Chen 2001; Housman 2003).
There is an existing Cochrane review examining non-education interventions (e.g. use of topical therapies, retinoids, antioxidants, dietary modifications, and complementary therapies) for preventing keratinocyte cancer in people at high risk of developing these cancers (Bath-Hextall 2007). Elsewhere, there are reviews of the

use of education programmes for primary-care physicians (Goulart 2011) and interventions to prevent skin cancer by reducing exposure to ultraviolet radiation (Saraiya 2004), which found evidence that education and policy interventions increase sun-protective behaviours in primary school and in tourism or recreational settings. Research findings in other settings provided insufficient evidence to warrant recommending specific interventions. Despite these limitations, educational programmes are commonly used in an effort to prevent skin cancer.

This proposed review will attempt to evaluate the effectiveness of educational programmes to prevent skin cancer, providing much needed evidence to guide governmental and community organisations acting in this field.

OBJECTIVES

To assess the effects of education programmes for skin cancer prevention in the general population.

METHODS

Criteria for considering studies for this review

Types of studies

We will include all randomised controlled trials (RCTs) and cluster RCTs providing a comparison between an eligible intervention and no intervention, or between two or more eligible interventions.

Types of participants

The participants we will include are children and adults.

In this review, we will not include high-risk groups for the development of skin cancer (e.g. transplant patients) or participants selected for a history of skin cancer.

Types of interventions

We will include studies that compare an educational programme with the aim of preventing skin cancer with a placebo (e.g. an educational programme about other health issues) or no intervention. Given that this review is concerned with the effectiveness of interventions for skin cancer prevention, we will exclude any programmes that do not specifically include information or educational opportunities with regard to how to prevent skin cancer (even if we include other elements of skin cancer education). For the purposes of this review, an educational programme will be defined using the World Health Organization definition of health education as "consciously constructed opportunities for learning involving some form of communication designed to improve health literacy, including improving knowledge, and developing life skills which are conducive to individual and community health" (WHO 1988, page 4).

A variety of media may deliver these interventions for a variety of audiences, using a variety of methods, and in a variety of settings. For example, some types of interventions may include workshops or small groups, lectures, readings, mailed materials, role-plays, media messages, and other educational programmes.

We will exclude interventions that include a policy or environmental component (unless a comparison is made of the educational component alone), so that we can ascertain the effectiveness of the educational programme, rather than a broader health promotion intervention.

Types of outcome measures

Primary outcomes

The most important outcome measure would be to measure the incidence of skin cancer following an educational programme. Our included trials may not have a suitably long follow-up period to analyse incidence rates, but later follow-up studies may report these outcomes.

1. Basal cell carcinoma (BCC) incidence - ascertained by clinical or histopathological examination, medical records, or as reported by participants.
2. Squamous cell carcinoma (SCC) incidence - ascertained by clinical or histopathological examination, medical records, or as reported by participants.
3. Melanoma incidence - ascertained by clinical or histopathological examination, medical records, or as reported by participants.

Secondary outcomes

Secondary outcomes are predominantly proxy outcome measures for the development of skin cancer, and sun exposure and protection knowledge, attitudes and behaviours, which are likely to be targeted by education programmes. For each of these outcomes, we will group available data by time point. We will categorise data as short-term (within one month of the end of the education programme), medium-term (within six months of the end of the education programme), or long-term (beyond six months after the end of the education programme). If multiple outcomes within one of these time intervals are reported for a secondary outcome, we will use the outcome with the longest follow-up period within the interval.

1. Number of naevi: Naevi are a marker of cumulative UV exposure and subsequent melanoma risk, and may be particularly useful for measurement of these factors among children, as childhood is a critical time for the evolution of naevi (Harrison

2000; LaVigne 2005) and as children are unlikely to demonstrate skin cancers within a trial follow-up.

2. Prevalence of actinic keratoses (AKs) - ascertained by clinical examination, medical records, or as reported by participants; although non-malignant per se, AKs may progress to SCCs (Cohen 2010).

3. Number of sunburn episodes or number of severe sunburn episodes since the educational programme - questionnaire results. Although subject to recall errors or social desirability biases, the number of recent sunburns is commonly used as a measure of the efficacy of skin cancer prevention interventions (Buller 2011). Questionnaires commonly define sunburns as referring to skin reddening or pain, lasting at least 12 hours or one day; severe sunburns are commonly defined as sunburn with blisters (Buller 2011).

4. Sun exposure since the educational programme - self-reported (e.g. via a diary) or measured via dosimetry badges.

5. Usual sun protection and tanning behaviours (hat-wearing, sunscreen application, staying in shade, umbrella use, use of sunglasses, wearing long sleeves, and solarium use) - observational or questionnaire results.

6. Attitudes, beliefs, and intentions regarding sun exposure and sun protection behaviours - questionnaire results.

7. Awareness or knowledge, or knowledge recall regarding skin cancer - questionnaire results.

8. Serum 25(OH)-vitamin D concentrations: We have included vitamin D concentrations as a secondary (adverse) outcome.

9. Costs associated with the intervention, including direct and indirect costs to the intervention provider (labour and educational materials, etc).

Search methods for identification of studies

We aim to identify all relevant RCTs regardless of language or publication status (published, unpublished, in press, or in progress).

Electronic searches

We will search the following databases to identify reports of relevant RCTs and cluster RCTs:

- the Cochrane Skin Group Specialised Register;
- the Cochrane Central Register of Controlled Trials (CENTRAL) in *The Cochrane Library*;
- MEDLINE via OVID (from 1946);
- EMBASE via OVID (from 1974);
- PsycINFO via OVID (from 1806);
- LILACS (Latin American and Caribbean Health Science Information database, from 1982);
- CINAHL via EBSCO (Cumulative Index to Nursing and Allied Health Literature, from 1981); and
- Web of Science.

We have devised a draft search strategy for RCTs for MEDLINE (OVID), which is displayed in Appendix 1. This search strategy will be used as the basis for search strategies for the other databases listed.

Trials registers

We will search the following trials registers:

- The metaRegister of Controlled Trials (www.controlled-trials.com).
- The US National Institutes of Health Ongoing Trials Register (www.clinicaltrials.gov).
- The Australian New Zealand Clinical Trials Registry (www.anzctr.org.au).
- The World Health Organization International Clinical Trials Registry platform (www.who/int/trialsearch).
- The EU Clinical Trials Register (www.clinicaltrialsregister.eu/).

Searching other resources

References from included studies

We will check the bibliographies of included studies for further references to relevant trials.

Unpublished literature

We will search the ProQuest Dissertations and Theses database (http://www.proquest.com/en-US/catalogs/databases/detail/pqdt.shtml) for grey literature.

Adverse effects

We will not perform a separate search for adverse effects of the target intervention. However, we will examine data on adverse effects from the included studies we identify.

Data collection and analysis

We plan to include at least one 'Summary of findings' table in our review. In this table, we will summarise the primary outcomes for the most important comparison. If we feel there are several major comparisons or that our findings need to be summarised for different populations, we will include further 'Summary of findings' tables.

Selection of studies

We will download references obtained from all sources and into a reference management software package and remove duplicates. Two authors (DL and AD) will independently pre-screen all search results (titles and abstracts) for possible inclusion based on specific inclusion criteria. We will obtain the full text of selected articles and group multiple publications about the same study together. The same two authors will independently assess the full text of selected articles against the inclusion criteria, with any discrepancies resolved by consensus, with a third author (RC) acting as arbiter and making the final decision for inclusion in the review if disagreements persist.

Data extraction and management

We modified the data extraction template developed by the Cochrane Skin Group as necessary for this review (Table 1), and we will pilot the modified form with the first three eligible studies to identify any further modifications required and amend as needed. Two authors (DL and AD) will independently extract data using this form. A third review author (RC) will clarify any inconsistencies between authors. Two authors (DL and AD) will enter the data into RevMan independently and clarify any inconsistencies with a third author (LM).

Assessment of risk of bias in included studies

Two authors (DL and AD) will independently assess risk of bias in included studies in seven domains (random allocation sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other sources of bias) using The Cochrane Collaboration's tool for assessing risk of bias in the *Cochrane Handbook for Systematic Reviews of Interventions*, Chapter 8 (Higgins 2011). We will contact study authors for additional information about study methods as necessary to assess risk of bias. We will complete a 'Risk of bias' table for each eligible study, characterising each study as at 'low', 'unclear', or 'high' risk of bias for each domain. We will categorise and report the overall risk of bias of included studies according to the following criteria: low risk of bias (low risk of bias for all key domains); unclear risk of bias (unclear risk of bias for one or more key domains); and high risk of bias (high risk of bias for one or more key domains) (Higgins 2011). A third author (RC) will resolve any disagreement related to assessment of risk of bias.

Measures of treatment effect

We will summarise continuous outcomes using the difference of the mean outcomes of the treatment groups with 95% confidence intervals (CIs) or where continuous outcomes are measured using different measures or scales, using standardised mean difference and 95% confidence intervals. We will summarise dichotomous outcomes using risk ratios with 95% CIs. If time-to-event data are provided (e.g. time from randomisation to diagnosis with a skin cancer) and if sufficient data are available, we will summarise these data using hazard ratios or convert to dichotomous data (i.e. we will count the number of people who were diagnosed with a skin cancer in a particular time point). We will only dichotomise when all participants were followed up to the particular time point. We will determine the time point to use for dichotomisation based on the follow-up periods of the individual studies included. If hazard ratios cannot be obtained and dichotomisation is not possible, we will exclude this outcome from meta-analyses, although we will present results in narrative form.

We will analyse data using The Cochrane Collaboration's Review Manager 5 software.

Unit of analysis issues

This review will include studies implemented at the individual, school, work, or community level. As such, study outcomes may be reported at the individual or group level. We will determine whether studies that randomise or allocate clusters have taken the effect of clustering into account (for example, using multi-level models, variance components analysis, or generalised estimating equations). Where clustering has not been taken into account, and if sufficient data are available (i.e. the number of clusters randomised to each intervention group, outcome data ignoring the cluster design for the total number of individuals, and an estimate of the intraclass correlation coefficient), we will employ statistical methods that allow analysis at the level of the individual whilst accounting for the clustering in the data. We will use the generic inverse variance method with effect estimates and their standard errors from correct analyses of cluster randomised trials. We will identify re-analysed data as such in the review.

We may combine the results of individually randomised and (correctly analysed or re-analysed) cluster randomised trials in meta-analyses, depending on the heterogeneity of the trials. If we perform such meta-analyses, we will identify cluster randomised trials as such and conduct sensitivity analyses to investigate the robustness of the conclusions.

As recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* (section 16.5), where more than two relevant intervention groups are included in the intervention, we will, if possible, combine groups to create a single pair-wise comparison.

Dealing with missing data

Analyses will follow intention-to-treat principles, where we will analyse participants according to their allocated treatment groups irrespective of levels of compliance. We will attempt to contact lead study authors where there are missing or unclear data to obtain additional data. Where it is not possible to obtain additional data,

we will record this in the data extraction form and report in the 'Risk of bias' table for the study, and we will analyse available cases, based on the number of participants for whom outcome data are available. We will not perform imputation from other studies as it is assumed the data are missing at random. We may perform sensitivity analyses to assess the sensitivity of the results to this assumption, and we will address the potential impact of missing data in the discussion section. If standard deviations (SD) are missing, where appropriate, we will compute the SD from the standard error or confidence intervals as recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* (section 7.7.3).

Assessment of heterogeneity

We anticipate that the studies identified in this review will be heterogeneous with respect to settings, participants, interventions, and outcomes analysed. We will make the decision whether to undertake a meta-analysis after we have extracted data. We will assess heterogeneity by examining forest plots and quantify it using the I^2 statistic for statistical heterogeneity, together with the P value from the Chi^2 test for statistical heterogeneity. We will consider results heterogeneous if we obtain an I^2 statistic value greater than 50% and the P value from the Chi^2 test is less than 0.10 (Higgins 2011). In this case, we will not pool studies for meta-analysis, and if the appropriate data are available, we will explore the potential causes of heterogeneity by subgroup analysis.

Assessment of reporting biases

We will report each outcome separately. As recommended in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions*, if we identify sufficient studies (at least 10 for each outcome), we will use funnel plots to plot study effect size against sample size to assess publication bias.

Data synthesis

We will report all outcomes, whether or not statistically significant. After we have extracted data, we will examine heterogeneity and decide whether to complete a meta-analysis. If the data are sufficiently homogeneous in design, methodology, and outcomes to conduct a meta-analysis, we will use a random-effects model to calculate a weighted intervention effect across trials. We have chosen a random-effects analysis as we anticipate considerable variation across studies, and this analysis allows more variation than only sample variation within studies. We will report the results from the meta-analysis as pooled mean differences (continuous variables using the same scale), pooled standardised mean differences (continuous variables using different scales), risk ratios (dichotomous variables), or hazard ratios (time-to-event data) and corresponding 95% CIs. Where sufficient data are available, where we estimate results for individual studies with low numbers of outcomes (< 10 in total), or where the total sample size is less than 30 participants, we will report the proportion of outcomes in each treatment group together with a P value from a Fisher's Exact test.

Subgroup analysis and investigation of heterogeneity

If there is evidence of substantial heterogeneity (I^2 statistic > 50%) amongst included studies, we will explore reasons for this heterogeneity. We will perform subgroup analyses where sufficient data are available, grouping the trials by the following:

- age group at start of intervention (for example, children versus adults);
- content of intervention;
- type of intervention (channel of delivery of message, such as written information, didactic small group sessions); and
- low- to middle-income or high-income country.

Sensitivity analysis

We will perform a sensitivity analysis for studies with low risk of bias, as reported in the 'Risk of bias' tables, to establish how they impact on the results.

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* *Indicates the major publication for the study*

ADDITIONAL TABLES

Table 1. Draft data extraction form

Ref no.:	First author:		
Year:	Journal:		
Reviewer's name:			
Eligibility of Study for Review (All must be checked for inclusion in study)			
Study design:	☐ Randomised controlled trial ***or*** ☐ Cluster randomised trial		
Participants:	☐ Relevant according to the PICO inclusion criteria? (Children and adults, excluding high-risk groups for the development of skin cancer or participants selected for a history of skin cancer)		
Intervention:	☐ Relevant according to the PICO inclusion criteria? (Compare educational programmes with other educational programmes, placebo or no intervention; excluding interventions with policy or environmental component)		
Do not proceed with data extraction if answers to any of the above questions are not checked. If study to be included in the 'Excluded studies' section of the review, record the reason for exclusion below **Reason for exclusion:**			
Setting: (where was this study conducted?)			
Start and end date (including follow-up times)			
Funding source (including role of funders if known)			
Conflict of interest			
Participants: - population, setting - inclusion/exclusion criteria - demographics, comorbidities, socioeconomic status - subgroups measured/reported			
Ethics approval			
Consent			
Co-interventions			
Were validated outcome measures used? (yes/no, for which measures)			
	Group A (Intervention)	**Group B (Control)**	
Mean Age (SD) (range)			

Table 1. Draft data extraction form (*Continued*)

Sex (F/M)		
Clusters (if applicable): no., type, no. people per cluster		
Losses to follow up		
Reason 1		
Reason 2		
Reason 3		
Number lost to follow up (with %)		
Final number of participants		
Participants *excluded from the study*	**Number:**	**Number:**
	Reason:	**Reason:**
	No exclusion reported (please circle)	No exclusion reported (please circle)
	Number excluded before randomisation:	Number excluded before randomisation
	Number excluded after randomisation:	Number excluded after randomisation
	Not clear (please circle)	Not clear (please circle)
INTERVENTIONS:		
	Group A (Intervention)	**Group B (Control)**
Describe the interventions each group received - Specify theoretical basis of intervention - Duration, timing, delivery, providers of intervention - Were instructions given to participants adequate? Give details or integrity of delivery and compliance		
Describe any co-interventions		
TYPES OF OUTCOME MEASURES:		
Outcome name:	**Outcome definition (scale used or how it was measured)**	

Table 1. Draft data extraction form (*Continued*)

Primary outcome 1: Basal cell carcinoma (BCC) incidence	Basal cell carcinoma (BCC) incidence ascertained by clinical or histopathological examination, medical records or as reported by participants
Primary outcome 2: Squamous cell carcinoma (SCC) incidence	Squamous cell carcinoma (SCC) incidence - ascertained by clinical examination or histopathological, medical records or as reported by participants
Primary outcome 3: Melanoma incidence	Melanoma incidence ascertained by clinical examination or histopathological, medical records or as reported by participants
Secondary outcome 1: Number of naevi	Number of naevi
Secondary outcome 2: Prevalence of actinic keratoses (AKs)	Prevalence of actinic keratoses (AKs) ascertained by clinical examination, medical records or as reported by participants
Secondary outcome 3: Number of sunburn or severe sunburn episodes	Number of sunburn episodes or number of severe sunburn episodes since the educational programme - questionnaire results
Secondary outcome 4: Sun exposure	Sun exposure since the educational programme - self-reported (e.g. via a diary) or measured via dosimetry badges
Secondary outcome 5: Usual sun protection and tanning behaviours	Usual sun protection and tanning behaviours (hat wearing; sunscreen application; staying in shade; umbrella use; use of sunglasses; wearing long sleeves; solarium use) - observational or questionnaire results
Secondary outcome 6: Attitudes, beliefs and intentions regarding sun exposure and sun protection behaviours	Attitudes, beliefs and intentions regarding sun exposure and sun protection behaviours - questionnaire results
Secondary outcome 7: Awareness, knowledge, or knowledge recall regarding skin cancer	Awareness or knowledge, or knowledge recall regarding skin cancer - questionnaire results
Secondary outcome 8: Vitamin D concentration	Serum 25(OH)-vitamin D concentrations (adverse outcome)
Secondary outcome 9: Intervention costs	Costs associated with the intervention, including direct and indirect costs to the intervention provider (labour, educational materials, etc)
OUTCOMES REPORTED IN THIS PAPER RELEVANT TO REVIEW:	
Outcome:	**Reported in this paper? (scale used or how the outcomes were measured and timing of data collection) (please circle)**
Primary outcome 1: Basal cell carcinoma (BCC) incidence	YES/NO
Primary outcome 2: Squamous cell carcinoma (SCC) incidence	YES/NO

Table 1. Draft data extraction form (*Continued*)

Primary outcome 3: Melanoma incidence	YES/NO
Secondary outcome 1: Number of naevi	YES/NO
Secondary outcome 2: Prevalence of actinic keratoses (AKs)	YES/NO
Secondary outcome 3: Number of sunburn or severe sunburn episodes	YES/NO
Secondary outcome 4: Sun exposure	YES/NO
Secondary outcome 5: Usual sun protection and tanning behaviours	YES/NO
Secondary outcome 6: Attitudes, beliefs and intentions regarding sun exposure and sun protection behaviours	YES/NO
Secondary outcome 7: Awareness or knowledge, or knowledge recall regarding skin cancer	YES/NO
Secondary outcome 8: Vitamin D concentration	YES/NO
Secondary outcome 9: Intervention costs	YES/NO

RESULTS:

Dichotomous (categorical) data table:

Outcome (use 1 row for each time point)	**Group A (Intervention)** Number/Total number (%)	**Group B (Control)** Number/Total number (%)

Table 1. Draft data extraction form (*Continued*)

Continuous data (scale) table		
Outcome (use 1 row for each time point)	**Group A (Intervention)** Mean (SD)	**Group B (Control)** Mean (SD)
Other information that you feel is relevant to results		
Indicate below if results were estimated from graphs, etc, or calculated using a formula (this should be stated in the review and the formula given). (In general, if results were not reported in the paper, but were obtained from another source, this should be made clear in the review)		
'Risk of bias' assessment:		

Domain	Risk of bias			Support for judgement *(include direct quotes where available with explanatory comments)*		Support for judgement *(include direct quotes where available with explanatory comments)*		Support for judgement *(include direct quotes where available with explanatory comments)*
	Low	High	Unclear					
Random sequence generation *(selection bias)*								
Allocation concealment *(selection bias)*								

Table 1. Draft data extraction form (*Continued*)

Blinding of participants and personnel *(performance bias)*				Outcome group: All/
(If separate judgement by outcome(s) required)				Outcome group:
Blinding of outcome assessment *(detection bias)*				Outcome group: All/
(If separate judgement by outcome(s) required)				Outcome group:
Incomplete outcome data *(attrition bias)*				Outcome group: All/
(If separate judgement by outcome(s) required)				Outcome group:
Selective outcome reporting? *(reporting bias)*				
Other bias				
Notes:				
Questions to ask authors/responses				
Date:__/__/2014 Reviewer Signature:_____				

APPENDICES

Appendix 1. MEDLINE (OVID) draft search strategy

1. exp Skin Neoplasms/
2. skin neoplas$.ti,ab.
3. skin cancer$.ti,ab.
4. exp Carcinoma, Basal Cell/
5. basal cell carcinoma$.ti,ab.
6. basal cell epithelioma$.ti,ab.
7. basalioma$.ti,ab.
8. exp Melanoma/
9. (melanoma or nonmelanoma or non-melanoma or melanocyt$ or non-melanocyt$ or nonmelanocyt$ or keratinocyte$).ti,ab.
10. nmsc.ti,ab.
11. non melanoma skin cancer$.ti,ab.
12. or/1-11
13. exp Carcinoma, Squamous Cell/
14. squamous cell carcinoma$.ti,ab.
15. 13 or 14
16. exp Skin/
17. (skin or epiderm$ or cutaneous).ti,ab.
18. 16 or 17
19. 15 and 18
20. 12 or 19
21. exp Education/
22. Health Education/
23. health promotion.ti,ab.
24. Patient Education as Topic/
25. Health Behavior/
26. consumer health information/ or health literacy/
27. workshop$.ti,ab.
28. lecture$.ti,ab.
29. leaflet$.ti,ab.
30. Teaching/
31. Role Playing/
32. (role play$ or role-play$).ti,ab.
33. group work.ti,ab.
34. newsletter$.ti,ab.
35. curriculum.ti,ab.
36. role model$.ti,ab.
37. coaching.ti,ab.
38. modelling.ti,ab.
39. video.ti,ab.
40. instruction.ti,ab.
41. Learning/
42. Counseling/
43. training.ti,ab.
44. Health Knowledge, Attitudes, Practice/
45. or/21-44
46. randomized controlled trial.pt.
47. controlled clinical trial.pt.
48. randomized.ab.

49. placebo.ab.
50. clinical trials as topic.sh.
51. randomly.ab.
52. trial.ti.
53. 46 or 47 or 48 or 49 or 50 or 51 or 52
54. exp animals/ not humans.sh.
55. 53 not 54
56. 20 and 45 and 55

CONTRIBUTIONS OF AUTHORS

DL was the contact person with the editorial base.

DL co-ordinated the contributions from the co-authors and wrote the final draft of the protocol.

DL, AD, LM, and RC worked on the methods sections.

AD drafted the clinical sections of the background and responded to the clinical comments of the referees.

LM responded to the methodology and statistics comments of the referees.

DL, AD, RC, LM, and DH contributed to writing the protocol.

JH was the consumer co-author and checked the protocol for readability and clarity. She also ensured that the outcomes are relevant to consumers.

DL is the guarantor of the final review.

Disclaimer

The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the NIHR, NHS or the Department of Health, UK.

DECLARATIONS OF INTEREST

No known potential conflicts of interest.

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Internal sources

- Royal Brisbane and Women's Hospital (RBWH), Australia.

RBWH provides salary and facilities for RC to conduct this systematic review.

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QUT provides salary and facilities for DL to conduct this systematic review.

- Trinity College Dublin (TCD), Ireland.

TCD provides salary and facilities for DH to conduct this systematic review.

- Menzies School of Health Research (MSHR), Australia.

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