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**PROVIDING PUBLIC HEALTH  
INFORMATION TO PREVENT SKIN  
CANCER**

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*Review of effectiveness and cost-effectiveness*



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# PROVIDING PUBLIC HEALTH INFORMATION TO PREVENT SKIN CANCER

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## Main Body of Report

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## West Midlands Health Technology Assessment Collaboration

The West Midlands Health Technology Assessment Collaboration (WMHTAC) is an organisation involving several universities and academic groups who collaboratively undertake research synthesis to produce health technology assessments. Most of our members are based in the Department of Public Health, Epidemiology & Biostatistics, University of Birmingham, however other members are drawn from a wide field of expertise including economists and mathematical modellers from the Health Economics Facility, University of Birmingham.

WMHTAC produce systematic reviews, health technology assessments and economic evaluations for NHS R&D HTA programme (NCCHTA), the National Institute for Health and Clinical Excellence (NICE), and for the health service in the West Midlands. WMHTAC also undertakes methodological research on research synthesis, and provides training in systematic reviews and health technology assessment.

### Name of other institution(s) involved

WMHTAC work in close collaboration with the Peninsula Technology Appraisal Group (PenTAG) with respect to providing support to the CPHE.

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**Abbreviations and acronyms**

CI confidence interval

IQR interquartile range

OR odds ratio

RCT randomised controlled trial

SD standard deviation

SE standard error

SPF sun protection filter

UV ultraviolet

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## Executive Summary

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The National Institute for Health and Clinical Excellence ('NICE' or 'the Institute') has been asked by the Department of Health (DH) to develop guidance on public health interventions for the NHS and local authorities aimed at preventing skin cancer, specifically: the provision of information, physical changes to the environment and the supply of sun protection resources. This referral is being undertaken in several phases and the current phase focuses on provision of information. Physical changes to the environment and the supply of sun protection resources will be covered in later phases.

This report details two systematic evidence reviews on the effectiveness and cost-effectiveness of the provision of information to prevent skin cancer. A second evidence report focuses on qualitative evidence related to information provision and a third report outlines de novo economic analyses on the cost-effectiveness of methods of information provision.

The objectives of this report are to address the following elements of the referral:

What are the most effective and cost-effective ways of providing information to change people's knowledge, awareness and behaviour and so prevent the first occurrence of skin cancer attributable to UV exposure?

What content do effective and cost-effective primary prevention messages contain? What is the most effective and cost-effective content?

## Methods:

Methods were guided by the Methods for Development of NICE Public Health Guidance 2006. A protocol was developed by the research team in conjunction with the NICE project team, detailing the key elements of the systematic reviews.

### **Identification of Studies:**

A series of separate searches were undertaken for each review. Search were undertaken in bibliographic databases (including Cochrane Library, MEDLINE, EMBASE, CINAHL, NHS EED) and web resources (including EPPI-Centre, Public Health Observatories, Cancer Research UK). The key concepts of the search of bibliographic resources were the combination of search for 'skin cancer' and 'methods of primary prevention' and where possible the use of methodological filters to target specific study designs. The following limits were placed on search strategies: published from 1990 onwards; published in English language. Searches were undertaken up to end August/Beginning September 2008.

In addition to the review of effectiveness and cost-effectiveness primary studies, systematic reviews were identified to facilitate the identification of further primary studies in addition to those found through the targeted searches. References submitted by stakeholders were also used.

### **Study Selection:**

For each review the title and abstract of identified studies were screened for relevance using pre-specified checklists. Full copies were sought for all articles considered relevant and these copies were then assessed for adherence to the full inclusion criteria for the appropriate review.

The inclusion criteria were the same for both the effectiveness and cost-effectiveness reviews except that different studies designs were included. The criteria were:

- Populations:
  - Everyone

- Interventions (universal and targeted) aiming at primary prevention of skin cancer were:
  - One-to-one or group-based verbal advice (with or without use of information resources)
  - Mass-media campaigns
  - Leaflets, other information or teaching resources or printed material including posters
  - New media: the Internet (including social networking sites), emedia and text messaging

These could be delivered in various settings (such as the NHS, schools and workplaces) or by a range of people (such as general practitioners, practice nurses, pharmacists, early childhood services, and teachers).

- Comparator:
  - Current information provision, do nothing or any other intervention listed above
- Locations:
  - Developed/OECD countries
- Time period considered:
  - 1990 onwards

Studies of the following designs were included in the effectiveness review:

- Randomised controlled trials (RCTs)
- Longitudinal intervention studies (i.e. there was at least one follow up measure after baseline) such as controlled before and after, cohort, case control, before and after, and interrupted time series

Studies of the following design were included in the cost-effectiveness review:

- Randomised controlled trials (RCTs) with cost-effectiveness, cost consequences, cost-benefit analysis, cost-utility, cost-minimisation or net monetary (cost) and benefit data – the perspective adopted (employer, societal, governmental) will not affect include/exclude decisions
- Longitudinal intervention studies (i.e. there is at least one follow-up measure after baseline) with cost-effectiveness, cost-consequences, cost-benefit, cost-utility, cost-minimisation or net monetary (cost) benefit data
- Decision analytic models and any other econometric and/or epidemiological models that contain relevant effectiveness and/or economic data or methods of analysis

#### **Quality assessment:**

Quality assessment of studies meeting the inclusion criteria was undertaken using the appropriate assessment tool from the NICE methods manual. Two reviewers independently assessed the quality of each included study. Each study was given a summary quality rating (++ , + or -).

#### **Data Extraction:**

Data extraction was undertaken using formats outlined in the NICE methods manual, adapted to reflect the parameters relevant to the reviews. One reviewer extracted data for each full paper and a second reviewer checked a proportion of the data extraction tables for accuracy.

Data on primary and secondary outcomes relevant to each review were extracted.

For effectiveness studies primary outcomes were:

- Reduction in the incidence of morbidity and mortality from non-melanoma and malignant melanoma skin cancer attributable to natural and artificial UV exposure. This may be measured in terms of a reduction in the incidence of sunburn or cumulative sun exposure etc.

- Increase in knowledge and awareness that can lead to a reduction in the incidence of exposure/over-exposure to natural and artificial UV.
- Changes in behaviours that can lead to a reduction in the incidence of exposure/over-exposure to natural and artificial UV.
- Increase in knowledge and awareness of the ways to prevent non-melanoma and malignant melanoma skin cancer attributable to natural and artificial UV exposure.
- The contents of an intervention that is effective and cost-effective.
- Any adverse or unintended (positive and negative) effects of the intervention

For the cost-effectiveness review primary outcomes were broadly any related to the economic assessment of interventions.

For both reviews, if study a study met the inclusion criteria, then data on any other outcomes considered relevant were extracted. As such, secondary outcomes were decided iteratively on a case by case basis.

### **Reporting Framework:**

Studies were grouped by intervention category (verbal, mass media, new media, printed materials or combinations thereof) and comparator (current provision/do nothing, or one of the intervention categories) combinations. Each of these themes were then subdivided into children or adults. Each of these subcategories was further divided by the interventions setting (e.g. school, university, workplace). In the case of a school setting there were further subdivisions, where possible or evidence allowed, by age bands corresponding approximately to UK school age ranges.



**Volume of evidence:**

For the effectiveness review over 34000 articles were identified and 136 articles met the inclusion criteria. However, 34 of these evaluated an intervention containing elements not relevant to this referral and where relevant data could not be disaggregated.

Forty-nine RCTs, 18 controlled before and after studies and 26 before and after studies were available for analyses.

The before and after studies were not analysed in this report due to the availability of the other study designs and the time available for the review. A brief summary of these studies may be made available at a later date.

Of the controlled before and after studies only 10 were analysed in this report as the remainder covered combinations of population, intervention, comparator and settings for which RCTs were available with similar or longer follow up.

Of the RCTs included a number had one or more arms that were considered to contain interventional components outside of the referral. For these, where possible, those arms relevant to this referral were used.

The heterogeneity between studies with regard to study design, population, intervention, duration of intervention, outcomes measured, duration of follow up etc, in addition to under-reporting of studies in published articles, precluded combining data even at the smallest sub-theme level. As such, a narrative description of each study within a (sub) theme was undertaken and summary statements made where possible.

For the cost-effectiveness review a total of 1288 articles were identified, 48 of them were considered relevant and, of these, three papers satisfied the inclusion criteria but only two contain relevant analysable data.

## Findings: Effectiveness

### **Theme 1: Verbal advice vs. Current provision of information/ do nothing**

#### ***Studies on prevention in children***

##### *School based studies in children aged four to seven years*

Two randomised trials (Buller 2006a, rated - and Loescher, rated +) and one controlled before and after study (Kidskin, rated +) evaluated group-based verbal advice in children aged four to seven years in a school setting. In all studies interventions were cluster allocated. The number of participants in this age group was unclear in Buller 2006a. It was 150 in Loescher and 1221 in Kidskin. Both randomised trials were set in the USA – Buller 2006a in Arizona and there were no details provided for Loescher. Kidskin was conducted in Perth area, Australia. All studies evaluated a school curriculum, but they differed with regard to the time over which it was delivered. Loescher investigated an intervention delivered in three sessions of approximately 45 to 50 minutes. In Buller 2006a a curriculum was taught over six weeks. Kidskin investigated an educational intervention taught over the longest period of time - four years (four to six sessions each spring) and it also had the longest follow-up of six years. In the randomised studies participants were followed-up for seven weeks (Loescher) and from February to April or May the same year (Buller 2006a).

The evidence from randomised studies seems inconsistent. Both assessed changes in knowledge and while in Loescher there was a significant increase in the intervention arm compared to the control group (both at two and seven weeks after baseline), in Buller 2006a there was also a significant difference in changes, but in the opposite direction. Loescher additionally evaluated comprehension (understanding instructions) and application (ability to transfer concepts learned in one situation to another situation or setting). For comprehension there was a significantly higher increase in the intervention group compared to controls at both two and seven weeks. For application there was no significant difference between groups and only at seven weeks did it appear that the application score adjusted for baseline differences was marginally higher in the intervention group. Buller 2006a assessed changes in skin tone using a colorimeter but there was no significant difference between study arms (however for children in the control group there appeared to be less skin darkening and redness).

In the Kidskin study there was no significant difference between groups in sun exposure and suntan (measured by skin reflectance) at two years, however both appeared to be marginally lower in the intervention group compared to controls.

At four years this study evaluated the impact of the curriculum on the number of naevi developed. There was no significant difference between groups, but the number of naevi was lower in the intervention group for each anatomical site examined.

At six years there was some statistically significant evidence of reduced naevus development in the intervention group compared with controls in a pre-specified, sub-group analysis of boys chests. A post-hoc, sub-group analysis of boys backs also revealed significantly lower naevus development in the intervention group compared with controls. A post-hoc, sub-group analysis of boys at the composite anatomical site of the face and arms revealed lower levels of naevus development in the intervention group compared with controls but the results were not statistically significant.

There was no statistically significant evidence of reduced naevus development, at six year follow-up, in the intervention group compared with controls in post-hoc, sub-group analyses of girls at the backs, and the composite of face and arms.

#### School based studies in children aged seven to 11 years

Four RCTs (Buller 1994, rated -, Buller 1997, rated -, Buller 2006a, rated -, and Hornung, rated +) and one controlled before and after study (Hewitt, rated -) investigated the effectiveness of group-based verbal interventions in a school setting in children aged seven to 11 years. All were cluster-allocated. In Buller 2006a the number of participants in this age group was unclear. The numbers in remaining studies were: 130 in Hornung (for this comparison), 139 in Buller 1994, 209 in Buller 1997 and 454 in Hewitt. Different curricula were evaluated in all studies apart from Buller 1997 assessed on an interactive sun safety fair. In this study children were educated both on how to prevent and detect skin cancer. Buller 1994 investigated the effectiveness of “*Sunshine and Skin Health*”, which was an earlier version of “*Sunny Days Healthy Ways*” evaluated in Buller 2006a. All randomised studies were set in Arizona, USA apart from Hornung which was carried out in North Carolina, USA. The only non-randomised study was set in Nottinghamshire, UK. The period during which the intervention was delivered was not clear in two studies (Buller 1997 and Hornung) evaluating curricula and in the remaining was five (Buller 1994) and six (Buller 2006a) weeks. The health fair was held during a single day and classes visited it for 45 to 90 minutes. Follow-up differed across studies and ranged from six weeks (Hewitt) to seven months (Hornung). The remaining studies reported a follow up of: eight weeks (Buller 1994), three months (Buller 1997) and from February to April or May (Buller 2006a).

All randomised studies evaluating curricula (Buller 1994, Buller 2006a and Hornung) reported a statistically significant increase in knowledge in intervention groups compared with controls. In the controlled before and after study there was also a significant positive effect on knowledge compared to the control group, but only in children whose education was based on a workbook and not on a computer program (there was however a non-significant increase). In two randomised trials the change in self-reported behaviours was not significant (there was no obvious direction of effect in Buller 2006a and in Hornung it appeared that the score in the control group was more favourable). In Buller 1994 there was a significant improvement in the curriculum arm in five of 11 evaluated behaviours, this was however not consistent across immediate post-test and the end of the study. Buller 2006a measured changes in skin tone using a colorimeter, there was however no consistent direction of effect.

The sun safety fair (Buller 1997) was reported to increase children's knowledge compared to the control condition. There was no significant difference for self-reported sun protective behaviours. Child-reported parent behaviours adjusted for baseline were significantly more sun protective in the sun fair arm immediately after the intervention, but not three months later.

#### School based studies in children aged 11 – 16 years

Six cluster randomised studies (Buller 2006b, rated +, Girgis, rated -, Hughes, rated -, Kristjánsson, rated +, Mermelstein, rated – and Syson-Nibbs, rated -) were found to evaluate curricula in children aged 11 to 16 in a school setting. Two studies were set in the UK – in Liverpool, Rotherham, Rugby, London, Essex and Kent (Hughes) and in Derbyshire (Syson-Nibbs) and the latter utilised materials evaluated in the first one. Two studies were conducted in the USA – Buller 2006b in Colorado, New Mexico and Arizona and Mermelstein in Chicago. The remaining trials were set in Australia (Girgis) and Stockholm County, Sweden (Kristjánsson). The numbers of participants were: 145 in Syson-Nibbs, 184 in Kristjánsson, probably 543 in Hughes (not entirely clear), 612 in Girgis, 1703 in Mermelstein and 1788 in Buller 2006b. The period over which the intervention was delivered varied from a single-session class (Kristjánsson, Mermelstein) to four (Girgis) and six weeks (Buller 2006b). The shortest follow-up was two weeks (Mermelstein) and the longest eight months (Girgis). In remaining studies follow-up was not always clearly stated, but was approximately three to five months.

An important issue when analysing these studies is that not all of them measured or accounted for baseline data in the analysis (Hughes, Mermelstein). Syson-Nibbs measured outcomes at baseline, however it performed only analyses of within-group changes over time. Girgis only reported a regression analysis to identify predictors of solar protection.

The trials which compared an increase in knowledge between study arms (Buller 2006b and Kristjánsson) reported a significant positive effect of the intervention. Syson-Nibbs provided information of a significant increase in knowledge within the intervention arm (and no significant change in the control arm). Hughes and Mermelstein did not take into account baseline scores and these studies reported significantly higher levels of knowledge in the curriculum condition compared with controls.

Sun protective behaviour was evaluated in various ways in four trials. Girgis found, in a regression analysis, that the intervention was a predictor of solar protection both at five weeks and eight months after baseline. The difference between intervention and control groups in behaviour assessed in self-reports indicated a significant beneficial effect in Buller 2006b and was not significant in Hughes (and authors did not provide further details). Buller 2006b however also assessed participants' sun protective behaviour at school using diary reports and found no significant difference between groups (no direction of effects was observed).

Sunburn in the previous month was assessed only in Buller 2006b and was not found to significantly differ between study arms.

#### Community based studies

Two controlled before and after studies assessed provision of verbal advice in a community setting (Reding and Rodrigue, both rated -). Reding included children aged five to seven years (number of participants was not reported) and Rodrigue 66 mothers of children with mean age of 6.4 years. They were both set in the USA – Reding in Wisconsin and Rodrigue in Florida. The first study investigated an intervention delivered directly to children during summer camps and spring monthly meetings of a children's association. The second one tried to educate Caucasian mothers to better protect their children (90-minute educational sessions) were delivered during evening meetings held at two schools. This study had two intervention groups: a comprehensive prevention programme and information only arm. In both studies the control group received no intervention. Reding assessed outcomes immediately after completion of the intervention and Rodrigue followed-up participants for two and 12 weeks.

In Reding children provided with the intervention had answered seven out of ten questions testing knowledge significantly better compared to the control group. For the remaining questions there was a non-significant difference in favour of the intervention group. In Rodrigue for mothers provided with verbal advice (in both intervention groups) there was a significant increase in knowledge and protection of their children from the sun compared with the control arm.

Studies set in the place of domicile

One American RCT (Turrisi, rated ++) evaluated verbal advice in the place of domicile in 469 parent-child pairs (children were aged nine to 12). In this study parents taught their nine to twelve year old children about skin cancer prevention. Parents were given materials at the start of the study, and were then asked to read them and implement the intervention with their children (for which they were given 30 days). The control group received no materials. Children were post-tested 45 days after distribution of the materials.

This study compared only post-test results between groups. Children in the experimental group were found to report less sunburns and less severe ones than in the control group. There was also a significant difference indicating less sunbathing tendencies in the intervention group.

**Studies on prevention in adults**Studies in a university/ college setting

Three randomised studies were identified to evaluate verbal advice in university or college students. Two studies evaluated a group-based intervention (Jackson, rated ++ and Katz, rated -) and one an individual nurse-led session (Mickler, rated ++). All studies were carried out in the USA – only Jackson provided a more exact location Arizona. Katz analysed 40 participants (age was not reported), Mickler analysed 69 participants (aged 17 to 31 years) in this comparison and Jackson 211 participants (aged 18 to 25 years). Katz and Mickler reported that interventions addressed both prevention and detection of skin cancer. Some participants in Mickler had a history of skin cancer, however exact data was not provided. Jackson included only female students. Katz used a “do nothing” control group and the remaining two trials delivered interventions not relevant to skin cancer (stress management in Jackson and peer leadership in Mickler). In Mickler participants were followed-up for three weeks, while in the remaining two trials they were tested immediately after completing the intervention (in Katz there was a two-week follow-up, but the control group was given the intervention after the first post-test). Only Jackson measured outcomes at baseline.

Jackson provided evidence of a higher adjusted post-test mean level of knowledge in the intervention group compared with controls. The remaining two trials indicated a higher post-test level of knowledge in the intervention arm compared to controls (baseline data was not collected).

Studies in a hospital/ medical practice setting

One controlled before and after study (Jones 2007, rated -) evaluated verbal advice in a hospital setting in 200 patients (mean age 51.2 years). At the time of their review in clinic, patients were given a written education sheet outlining cause, misconceptions, and general information about skin cancer and sun protection. They were also given verbal information from a doctor in the dermatology clinic. The control group received no information.

There was weak evidence that the intervention may increase patient's knowledge at three months follow-up. Against some initially high levels of knowledge statistically significant improvements were seen in only three of seven areas tested for those in the intervention group compared with controls.

There were no statistically significant improvements in sunscreen use, at three months follow-up, amongst the intervention group compared with controls, nor was there any discernable trend.

Studies in a sports venue setting

One American RCT (Parrott, rated -) in 12 soccer coaches aged 33 to 64 years evaluated verbal advice in a sports venue. A seminar about sun protection was conducted and a booklet was distributed to soccer coaches. There was no description of the control group. Follow-up was not reported.

No differences between intervention and control arms were found – the study measured knowledge and sun protective behaviour

**Theme 2: Mass-media vs. Current provision of information/ do nothing****Studies on prevention in children**

There were no studies that evaluated mass-media interventions in children.

### **Studies on prevention in adults**

#### Studies in a university/ college setting

Three randomised studies (Cody, rated -, Mahler 2007, rated + and Mickler, rated ++) evaluated mass-media interventions using videos in students of a university/ college setting. One of them used cluster allocation (Cody). There were 68 participants (aged 18 to 44 years) in Mahler in this comparison, 75 (aged 17 to 31 years) in Mickler and 114 (aged 17 to 48 years) in Cody. Cody was set in Newcastle, Australia and the remaining two in the USA. Intervention times were similar in Cody and Mahler 2007 (11 to 12 minutes) and 15-20 minutes in Mickler. The Australian study used two different types of a video: an emotional and informational one. In two studies the control group received information irrelevant to skin cancer: on dietary recommendations to prevent heart disease (Cody) and on peer leadership (Mickler). Mahler 2007 probably used a “do nothing” control group. Participants were tested immediately upon completion of the intervention (Mahler 2007) or followed up for three (Mickler) to ten weeks (Cody). Some of the participants had a history of skin cancer in Cody (8%) and Mickler (not clearly stated). These two studies addressed both prevention and detection of skin cancer. None of the studies assessed or accounted for baseline outcome measures.

In Mahler 2007 results were not provided for study arms and therefore are not reported. In the remaining two trials there was a significantly higher post-test knowledge level in the intervention compared to the control arm. In Cody this was however only true for participants shown an informational video. Amongst the group receiving the emotional video there was also a higher knowledge level, but it was not statistically significant.

### **Theme 3: Printed materials vs. Current provision of information/ do nothing**

#### **Studies on prevention in children**

##### Studies set in the place of domicile

One German RCT (Bauer, rated +) evaluated printed materials in the place of domicile. Parents of 1210 children (aged two to seven years) in both the intervention and control group were given an initial educational session. Afterwards only parents in the intervention arm received educational



letters three times a year. Participants were tested at baseline. Children were followed-up for three years.

This study provided no evidence of a difference in the number of incident melanocytic naevi after three years. There was also no clear direction of effect. The interview with parents about child protection and sun exposure did not indicate a consistent trend.

#### Studies in a hospital/ medical practice setting

One American controlled before and after study (Bologna, rated -) in 275 mothers evaluated printed materials delivered on the maternity ward to mothers to protect their newborn children.

It provided evidence of statistically significant improvements amongst the intervention group in comparison with controls for some of the behavioural practices examined at seven month follow-up. Compared with the control group, the infants and their mothers spent significantly less time in direct sunlight and less time outdoors. The number of mothers who used sunscreen was similar in both groups. But, when the groups were controlled for sunscreen use, the intervention group spent significantly less 'unprotected' time in the sun. The use of sun protective clothing and equipment for the infants was not significantly different between the groups and there was no discernible trend.

### **Studies on prevention in adults**

#### Studies in a workplace setting

Two randomised trials assessed printed materials in a workplace setting (Hanrahan, rated + and Rasmussen, rated -). Hanrahan was carried out in Newcastle, Australia and covered a wide range of occupations. Rasmussen was set in industrial companies in Scotland, UK. There were 368 participants (aged 45 to 65 years) in Hanrahan and 171 (aged 18 to 73 years) in Rasmussen. Participants in Hanrahan were provided with materials aimed at males over 45 years. Rasmussen evaluated positive and negative messages. Control groups in both studies did not receive any information relevant to skin cancer (not entirely clear in Hanrahan and information describing the characteristics of a common cold). The Australian study followed-up participants for 20 weeks and the British one did not report follow-up. Hanrahan was both on prevention and detection of skin cancer and included some participants with a history of skin cancer (exact numbers were not reported).

None of the studies compared differences between groups, but rather within-arm changes were analysed. Hanrahan reported that participants in the intervention, but not in the control arm significantly increased their level of knowledge. Rasmussen reported that likelihood of using sunscreen significantly increased in participants provided with the intervention (both positive and negative information), but not in the control group.

#### Studies in a university/ college setting

Three randomised trials (Castle, rated +, Mahler 2007, rated + and Mickler, rated ++) and a controlled before and after study (Greene, rated -) evaluated printed materials in university and college students. Castle was set on the south coast of England, UK and the remaining studies in the USA. There were: 69 participants in Mahler (aged 18 to 44 years), 71 (aged 17 to 31 years) in Mickler, 99 (aged 16 to 19 years) in Castle and 141 (aged 19 to 26 years) in Greene. Castle and Mickler evaluated leaflets or brochures containing information on skin cancer and its prevention. Mahler 2007 assessed the influence of UV facial photographs (showing damages to the skin caused by sun exposure, invisible in natural light). Greene evaluated printed materials with messages focusing on problems associated with tanning beds presented either in a statistical or a narrative format. Studies differed on the type of the control group with Mickler providing participants with information on peer leadership and the remaining studies probably using a “do nothing” control group. Castle and Greene included only female participants. Follow-up ranged from an immediate post-test (Mahler 2007) to one week (Castle) and three to four weeks (Mickler, Greene). Only Castle and Greene assessed outcomes at baseline.

Mahler 2007 did not present results for the arms to which participants were randomised and therefore these results are not analysed in this review. The remaining two RCTs indicated a significant increase in knowledge in the intervention group compared to control group (Castle) or a higher post-test knowledge level in the brochures arm (Mickler). Castle assessed sun-protective behaviour, but no results were provided. Other primary outcomes were not assessed.

The controlled before and after study provided evidence of a significant decrease in tanning bed use in participants given statistical information compared to the control group. There was no significant effect of the narrative message compared to the control group.

#### Studies in a hospital/ medical practice setting

One American cluster RCT (Prochaska, rated -) in 3834 patients with mean age of 44.7 years (number only of participants in which the skin cancer prevention intervention was evaluated) from primary care practices investigated the effectiveness of three computer generated reports that were

mailed “at 0, 6, and 12 months”. They included participant’s stage of change and readiness to change and encouraged to change sun protective behaviour. The control group received no intervention. Questionnaires were mailed to participants at 12 and 24 months (the intervention group additionally got a questionnaire at six months to generate the intervention report).

This study indicated that participants in the intervention arm avoided the sun and used sunscreen more.

#### Studies set in the place of domicile

One French RCT (Richard, rated -) evaluated three different leaflets (neutral, worrisome and humoristic) on prevention and detection of skin cancer sent to 900 adults. The control group (300 participants) was sent no leaflet. Age was not reported. Two weeks after mailing the leaflets, a telephone interview was conducted with participants.

This study provided evidence of a higher level of knowledge about melanoma definition, early signs and risk factors in the intervention arms compared to controls. A serious limitation of this study is that in intervention arms only participants who read the leaflet were analysed. No baseline testing was undertaken.

#### Studies on airports and/or flights

Two cluster randomised studies assessed the effectiveness of leaflets distributed to passengers departing for holiday (Dey and Segan, both rated -). In Dey leaflets were distributed in Air UK Leisure flights departing from Manchester. Participants in Segan were departing for the south or north coast of Queensland. The control groups in both studies received no information. In total 12385 passengers (aged 0 to 97 years, median 32 years) were analysed in Dey and 373 (mean age 32.2 years in the intervention and 33.4 in the control group) in Segan. Follow-up was unclear in both studies – in Dey questionnaires were distributed on return flights to a cross-section of participants (no indication of time) and in Segan they were sent for participants to complete after returning home.

Both studies assessed sunburn during holidays and none of them found a statistically significant difference between groups (however in Dey there appeared to be less sunburns in the intervention group). Segan also asked participants about their sun protective behaviours. A composite measure of behaviour did not indicate a significant difference between groups (and no direction of effect) and out of six behaviours assessed, only for number of days outside for at least two hours between

10 am and 2 pm was there a significantly more positive result in the intervention arm. There was no trend observed for the remaining five behaviours.

## **Theme 4: New media vs. Current provision of information/ do nothing**

### **Studies on prevention in children**

#### *School based studies in children aged seven to eleven years*

One American RCT (Hornung, rated +) evaluated a computer program used in the classroom setting via large-screen projection with student volunteers asked to take turns navigating through the program for the class. The control group received no intervention. One hundred and fifty six participants were included in this comparison. Participants were tested at baseline and final scores were adjusted for baseline results. Participants were first post-tested immediately after the intervention and then seven months later.

Adjusted knowledge level was significantly higher in the intervention group both immediately and seven months after baseline. There was no significant difference in self-reported behaviours at both follow-ups, although it appeared that there was a positive trend in the intervention group in the immediate follow-up.

### **Studies on prevention in adults**

#### *Studies in a hospital/ medical practice setting*

One British study (Glazebrook, rated +) in 589 patients (mean age 38.2 years in the intervention and 38.4 in the control group) evaluated in patients a computer program designed to be completed in a single sitting (10-15 minutes) available in a medical practice. It presented messages on both prevention and detection of skin cancer. Outcomes were measured at baseline. Participants were followed-up for six months.

The study provided evidence of an increase in knowledge in the intervention group compared to controls, as the mean difference in knowledge between groups adjusted for baseline scores was significant. There was also evidence on a positive influence on skin protective behaviour in the intervention group compared to controls and the mean difference between groups adjusted for baseline scores was statistically significant.

## **Theme 5: Combination interventions vs. Current provision of information/ do nothing**

### **Verbal advice and printed materials in children**

#### School based studies in children aged seven to eleven years

One Italian RCT (Naldi, rated +) in 11230 children evaluated the effectiveness of “*distribution of educational material to parents and their children, the development of a short curriculum at school, based on a resource developed for health teachers, and the projection of a short video at school.*” The control group was given no intervention. Participants were tested at baseline and followed-up for 14 to 16 weeks.

It provided no evidence of a difference in adjusted OR of any sunburns experienced during the previous year and there was no clear direction of effect. There was no significant difference in sun protective behaviours and it is difficult to indicate any trend in the data, as groups were compared only for “sometimes” or “occasionally/ never” behaving in a certain way (“always” was considered a reference category). The adjusted OR of intense sun exposure in the previous year indicated less sun exposure in the intervention group, but was not statistically significant. The adjusted odds ratio of parents believing that children were adequately protected from the sun during the previous year indicated less sun protection in the intervention group, but was not statistically significant. The ratio of relative change in the number of melanocytic naevi measured in a convenience subsample of the population indicated more naevi in the intervention group.

Studies set in the place of domicile

One American RCT (Benjes, rated +) assessed in 108 mother-child pairs the effectiveness of a telephone call and two newsletters. Before the baseline questionnaire both groups received verbal advice from a maternity nurse. The control group received no information beyond that. Participants were followed-up for 12 months starting with a baseline questionnaire (children aged six months) and finishing with a follow-up questionnaire (children aged 18 months).

This study provided no evidence of more sun protective behaviour in the experimental arm compared to control. Results for individual behaviours did not appear to follow any trend. Mothers in the intervention arm reported a higher post-test level of vigilant protection of their children (no baseline measurements were taken). There was also a smaller increase in child skin damage and sunburn and a higher increase in child tanning in the intervention group, significance levels were however not provided.

Studies set in a recreation site

One American RCT (Mayer, rated +) in 169 children (six to nine years old) evaluated a UV reduction curriculum that was presented at poolside during the first five minutes of aquatic classes by YMCA instructors and home-based activities for children and their parents. The intervention was delivered over six weeks to children aged six to nine years. The control group was not provided with information on sun protection. Participants were tested at baseline and followed-up for six to eight weeks.

This study provided evidence that in the intervention group the adjusted score for frequency of wearing a hat was higher than in the control group. In the intervention group there was a slightly higher adjusted score for frequency of using sunscreen with SPF 15+, but the difference was not statistically significant. The intervention group had a higher adjusted solar protection score than the control group (the difference was not significant). There was a non-significant positive trend in the intervention group compared to controls in the change of skin colour.

**Verbal advice and printed materials in adults**Studies set in workplace

One American RCT (Glanz, rated -) evaluated an intervention in staff (mean age 20.9 years) of recreation sites who were later to deliver education to children. There were 176 participants in the

study which included a mixed-intervention arm (further details were not provided). Participants were given a “60-90 minute staff training, a leader’s guide for staff, on-site activities, and educational materials for children aged six to eight years and their parents”. The control group received no intervention. Participants were tested at baseline. All staff were followed-up for eight weeks and staff who agreed to be mailed a questionnaire – for three months.

It did not provide evidence of any effect of the intervention compared to control on knowledge, sun protection habits and sunscreen use. Only for knowledge there was a consistent pattern with an increase in the intervention group and a decrease in the control group (reported as non-significant) at eight weeks. At three months there was a decrease in knowledge in both groups, but the knowledge level in the intervention arm was still higher than at baseline.

#### Studies set in the place of domicile

One American cluster RCT (Geller 2006, rated -) in 494 siblings (55.7% of the intervention and 60.6% of the control group were aged 50 years or less) of melanoma patients investigated the effectiveness of “computer-generated tailored print materials (...) sent at 1, 3, and 5 months after randomisation” and telephone calls. The information provided covered both prevention and detection of skin cancer. Current practice was the comparator. Participants were tested at baseline. Follow-up tests were carried out six and 12 months after baseline.

At six months there was a significant increase in the intervention compared to control group in the percentage of participants providing correct responses to two questions about melanoma. For two remaining questions there was no significant difference between groups and no consistent trend. The study did not provide evidence of a difference between groups or a visible effect direction at 12 months in change in routine use of SPF 15+ sunscreen. There was a decrease in the percentage of participants who reported being tanned at the end of last summer in the intervention group compared to controls, but there was no statistically significant difference between groups.

### **Verbal advice and new media in children**

#### School based studies in children aged seven to eleven years

One American cluster allocated controlled before and after study (Geller 2003, rated -) evaluated the effectiveness of a cross-curricular classroom based intervention including group based verbal advice and access to a website for 4<sup>th</sup> and 5<sup>th</sup> grade students (mean age ten years). The control

group was not provided with an intervention. The number of participants in this study was not clearly stated. Participants were followed-up for four to five months.

There was evidence indicating knowledge was more likely to increase amongst children receiving the intervention in comparison with controls.

### **Mass-media campaigns and printed materials in adults**

#### Studies set in workplace

One Australian cluster RCT (Borland, rated +) in outdoor employees evaluated a campaign combining materials supplied to depots (four posters and a video “Goodbye sunshine”) with individual folders with printed materials and lapel buttons for employees. The campaign lasted for approximately three months. Standard practice was the control group. Baseline and three months follow-up evaluations were carried out as direct observations of a cross-section of the study population. Numbers of employees in each sample as well as age were not reported.

This study provided evidence, that *“before the campaign the intervention group had a significantly higher protection index than the control group (...); the intervention group significantly increased their superiority in protection after the campaign as compared with the control group.”* The intervention group had a higher hat use before and after the intervention; and there was no change in any of the groups at follow-up. The intervention group increased shirt cover relative to the controls after the campaign; the interaction between group and time of survey was significant. *“There was no significant change in use of shade as a function of experimental condition.* Participants were not followed-up in this study, but two cross-sectional samples were taken.

#### Studies in a university/ college setting

A mass media intervention together with printed materials in a university setting was evaluated in two RCTs (Mahler 2005 and Mahler 2007, both rated +). In Mahler 2005 there were 100 participants (aged 17 to 44 years) and in Mahler 2007 64 (aged 18 to 44 years) in arms relevant to this comparison. Both trials were located in California, USA. In both studies participants were first shown a video on photoaging (11 to 12 minutes) and then a UV facial photograph was taken. Control groups were probably given no intervention. Participants were post-tested immediately after completion of the intervention. 1.4% of participants in Mahler 2005 had a history of skin cancer.



No primary outcomes of this review were assessed in Mahler 2005 and Mahler 2007 did not provide results for study arms.

### **Verbal advice, mass-media and printed materials in adults**

#### Studies in a university/ college setting

One American RCT (McClendon, rated ++) assessed in 61 college students (age was not reported) a combination intervention delivered in two sessions (60-75 minutes) separated by 48 hours. The intervention included participants being asked to read essays, watch a video, work in groups and being given a lecture. Participants in the control group received no intervention before the post-test. Participants were tested at baseline and immediately after the intervention.

None of this review's primary outcomes was reported.

### **Verbal advice, printed materials and new media in adults**

#### Studies based in a recreation site

One cluster RCT (Walkosz, rated ++) set in ski resorts in USA and Canada evaluated a combination intervention aimed at changing the sun protective behaviours of adult guests in ski resorts. Messages were primarily targeted at employees, but some were communicated to guests as well. "*Guest materials included posters and brochures for ski and snowboard schools, signage at the base of chairlifts and on chairlift poles, electronic signs and grooming reports, brochures, and table tents and posters in lodges.*" The control group received no intervention. Participants were not followed-up, but cross-sectional samples were taken in January to April 2001 (2991 participants) and in January to March 2002 (3525 participants).

This study provided no evidence of increased sun protection in guests staying in areas assigned to the intervention, as authors report that the hypothesis that guests in the intervention areas would report more sun protection was not supported.

## **Theme 6: Head to head comparisons between intervention types**

### **Verbal advice vs. Mass-media in adults**

#### *Studies in a university/ college setting*

One American RCT (Mickler, rated ++) compared a nurse-led one-to-one training (on how to perform skin self-examination and recognise skin cancers; participants were also provided with two brochures) with a video in 72 undergraduate students (aged 17 to 31 years). The first post-test was carried out immediately after completion of the intervention and the second three weeks later.

It provided evidence that the knowledge level was higher in the video group compared to the nurse-led group in the immediate post-test. At seven months the score in the video group was still higher, however authors provided no indication if the difference was statistically significant. No baseline measurement of outcomes was carried out.

### **Verbal advice vs. Printed materials in children**

#### *School based studies in children aged seven to eleven years*

Only one Canadian controlled before and after study (Barankin 2001, rated -) compared the effectiveness of group-based verbal advice and literature (intervention) with the provision of literature only (comparator) in 509 children aged 9-10 years.

There was no evidence that the provision of group –based verbal advice along with literature provided statistically significant improvements in the knowledge in comparison with the provision of literature only, although there were improvements in both groups. There was no evidence that the provision of group –based verbal advice along with literature provided statistically significant improvements in behaviours in comparison with the provision of literature only. No differences were observed amongst the groups or time periods. There was no statistically significant evidence of a reduction in the number of sunburns amongst children receiving group-based verbal advice along with literature in comparison with the provision of literature only. However surveys of both children and parents reported the number of children without sunburns improved to a greater extent amongst those receiving the verbal intervention (non-statistically significant trend). At four month

follow-up, data from parental reports indicated there was no significant difference in the number of multiple sunburns ( $\geq 2$ ) amongst the groups, however there was a higher incidence amongst the group receiving the verbal intervention.

### **Verbal advice vs. Printed materials in adults**

#### *Studies in a university/ college setting*

Only one American RCT (Mickler, rated ++) in 68 students (aged 17 to 31) compared a nurse-led one-to-one training (on how to perform skin self-examination and recognise skin cancers) together with two brochures with brochures only. The first post-test was carried out immediately after completion of the intervention and the second three weeks later.

This study found that the mean knowledge level was higher in the brochures group than in the nurse-led group in an immediate post-test. At seven months participants in the brochures group still had a higher mean level of knowledge, significance of the difference was however not provided. No baseline measurement of outcomes was carried out.

### **Verbal advice vs. New media in children**

#### *School based studies in children aged seven to eleven years*

One American cluster RCT (Hornung, rated +) in 132 third and fourth grade children compared sun protection taught by group teachers with a computer program used in the classroom setting via large-screen projection. Participants were first post-tested immediately after the intervention and then seven months later.

Adjusted mean knowledge level was significantly higher in the computer intervention group both directly after the intervention and seven months after baseline. In the first test those receiving the computer intervention had a significantly higher mean score for self-reported behaviours and this difference was still present after seven months it was however not significant.

### **Mass-media campaigns vs. Printed materials in adults**

#### Studies in a university/ college setting

Two randomised studies compared videos with brochures (Mickler, rated ++) or a UV facial photograph (Mahler 2007, rated +) in a university setting. Mahler 2007 evaluated these interventions in 69 participants aged 18 to 44 years and Mickler in 72 participants aged 17 to 31 years. Both were American studies and Mahler 2007 was reported to be carried out in California. Mickler provided participants with information on both prevention and detection and some of the students had a history of skin cancer. Mahler 2007 had an immediate post-test and Mickler followed- up participants for three weeks.

Mahler 2007 did not report results for study arms. Mickler provided no indication if a significantly higher knowledge level was observed in any group.

### **Verbal advice and printed materials vs. Verbal advice in adults**

#### Studies in a hospital/ medical practice setting

One American RCT (Clowers-Webb, rated +) in 202 transplant patients (aged 18 to 76 years), some with history of skin cancer, compared a session with a physician followed by mailing of printed materials with a session with a physician only. Three and ten months after recruitment all patients were sent a questionnaire.

This study did not provide evidence of a significant difference in knowledge between the two groups and mean scores in the two follow-up tests did not follow a uniform pattern. It provided evidence of more sun safe behaviour in the group which was additionally mailed printed materials both at three and ten months.

### **Mass-media campaigns and printed materials vs. Mass-media campaigns in adults**

#### Studies in a university/ college setting

Only one American RCT (Mahler 2007, rated +) compared a videotaped slide show on photoaging together with a facial UV photograph to a video on its own in 64 undergraduate students (aged 18 to 44 years). Participants were tested immediately after the intervention. This study did not provide results for groups that participants were randomised to.

**Mass-media campaigns and printed materials vs. Printed materials in adults***Studies in a university/ college setting*

Only one American RCT (Mahler 2007, rated +) compared a videotaped slide show on photoaging together with a facial UV photograph to a UV photograph on its own in 65 undergraduate students (aged 18 to 44 years). Participants were tested immediately after the intervention.

This study did not provide results for groups that participants were randomised to.

**Theme 7: Head to head comparisons within the same intervention type****Verbal advice in children***School based studies in children aged four to eleven years*

One American controlled before and after study (Buller 2006a, rated -) in 435 children compared curricular based advice delivered in one school year, with provision over two successive years.

There was evidence of a statistically significant improvement in knowledge, at 15 months follow-up, for children in grades 2-5, amongst the group receiving the extended two year curriculum compared with the group receiving the intervention for one year only. There was no evidence of a statistically significant improvement in knowledge, at 15 months follow-up, for children in grades K-1, amongst the group receiving the extended two year curriculum compared with the group receiving the intervention for one year only.

*School based studies in children aged seven to eleven years*

One UK controlled before and after study (Hewitt, rated -) compared the effectiveness of computer-based and workbook based teaching, designed for use in topic work, for children aged 10-11 years at school (number of children in these two arms was unclear).

There was no statistically significant evidence, at six week follow-up, of increased knowledge amongst the group receiving the computer-based intervention in comparison with the group receiving the workbook based intervention. However knowledge increased significantly in both groups with a higher increase evidenced in those receiving the workbook based intervention.

#### School based studies in children aged 11 to 16 years

One British cluster RCT (Hughes, rated -) in children (numbers of participants in relevant arms were unclear) aged 12 to over 16 years evaluated verbal advice together with different types of educational materials: (i) a leaflet; (ii) a workbook; (iii) a video. The first intervention group read through the workbook and took home probably the leaflet, but was not clearly stated. Interventions in the following groups included the same components as in the first group and additional materials or activities: watching the video, being given homework to design posters for public education and having a discussion later in the week about the issues raised. The study commenced in May (there was no baseline survey) and post-tests were carried out in July and September.

Authors reported that there was no difference between groups in knowledge (and no direction of effect indicating superiority of one group was observed) and behaviour (no further details for behaviour were provided). An important limitation of this study is lack of any baseline assessment.

#### Community based studies

One American controlled before and after study (Rodrigue, rated -) evaluated the effectiveness of group-based verbal advice, provided in a community setting to 66 mothers who were targeted as agents of change for their children. Participants were assigned to a comprehensive prevention programme (CPP) intervention, an information only condition (IOC) intervention or a no information control (NIC). Knowledge scores were marginally higher amongst the CPP group in comparison with the IOC group at the two and 12 week follow-ups (and at baseline). The statistical significance of the small difference was not commented on.

There was statistically significant evidence, at the two and 12 week follow-ups, of a greater improvement in sun-safe behaviour amongst the CPP group in comparison with the IOC group.

### **Mass-media campaigns in adults**

#### Studies in a university/ college setting

One Australian RCT (Cody, rated -) in 222 psychology students compared an informational video with an emotional video. Participants were assessed at baseline, immediately after watching the video and ten weeks later.

No significant differences between groups in the mean knowledge score were reported and no obvious direction of effect was present.

### **Printed materials in children**

#### Studies set in the place of domicile

One American RCT (Buller 1998, rated -) assessed in 768 parents the effects of high and low intensity printed materials (they also varied on the logical structure of arguments, but results for this factor were not reported for children) sent in spring and summer in changing sun-protective behaviour relating to children. Mail was sent to participants from March to August. Participants were first post-tested in September and October and then in February 1996 a short post-test was conducted to assess winter sun protection.

No difference between study arms was found for summer protection, although for most behaviours there was more improvement in the high intensity group: frequency of applying sunscreen with SPF 15+, applying sunscreen before school, wearing protective clothing and telling children to play in the shade. For winter protection in five out of seven items there was a significantly higher improvement in the high intensity arm compared to the low intensity arm: frequency of applying sunscreen, applying sunscreen with SPF 15+, applying sunscreen before school, wearing protective clothing and limiting exposure to midday sun. For the remaining two behaviours (wearing a hat and telling children to play in the shade) there was a non-significantly higher increase in frequency in the high intensity group. There was no significant difference in the average time a child spent outside, but it decreased more in the low intensity group.

## Printed materials in adults

### Studies in a workplace setting

One British RCT (Rasmussen, rated -) compared the effects of positive and negative information in 117 employees of industrial companies in Scotland (aged 18 to 73 years). Follow-up was not reported.

This study provided evidence that individuals in the group receiving negative information indicated a lower likelihood of using sunscreen than individuals in the positive group. Later there was a decrease in the likelihood in the negative group.

### Studies in a university/ college setting

Seven randomised studies (Boer, rated ++, Cho, rated -, Jones 1994, rated -, McMath, rated -, Prentice-Dunn, rated -, Rothman, rated + and Stephenson, rated -) and one controlled before and after (Greene, rated -) compared different types of printed materials in university or college students. The numbers of participants in studies and their age varied and they were: 92 participants in Stephenson (median age 21 years), 96 in Greene (aged 19 to 26 years), 136 in Jones 1994 (age 17 to 23), probably 140 in Prentice-Dunn (unclear; age not reported), 146 in Rothman (age not reported), 159 in Boer (aged 17 to 27), 208 in McMath (age not reported) and 274 in Cho (aged 18 to 37). Apart from Boer which was set in the Netherlands, all were American studies. Five studies assessed outcomes in an immediate post-test, one three to four weeks after baseline (Greene) one four weeks after baseline (Cho) and one did not report follow-up (Boer).

Although all used interventions which can be classed as printed materials, they varied both in terms of the format and content. Three studies reported evaluating essays (Jones 1994, McMath and Prentice-Dunn), two reported using "messages" (Cho and Stephenson), one pamphlets (Rothman) and one booklets containing 12 public service announcements (Boer). The issue of content tends to be more complicated, as studies had three or four arms comparing different combinations of investigated factors. For example Prentice-Dunn looked at four essays highlighting either high or low benefits of a tan and high or low efficacy of sun protection.

Five studies did not report or assess primary outcomes of this review or did not report outcomes for arms to which participants were randomised.

Boer (comparing four announcements with or without pictures and with or without textual arguments) did not report significance levels for comparisons of post-test knowledge scores. Only for announcements that did not use picture and textual arguments did the knowledge score appear to be lower.



Cho reported that participants provided with high threat messages were significantly more likely to use sunscreen four weeks after being given the intervention than those who were given low threat messages.

Greene provided evidence that participants who were given information in a statistical format reduced sunbed use significantly more than those who were given information in a narrative format.

#### Studies set in the place of domicile

Four randomised studies compared different content and types of printed materials in the place of domicile (Buller 1998, rated –, Branström, rated +, Gerbert rated – and Richard, rated -). Materials were mailed to 768 participants in Buller 1998, 900 in Richard (age was not reported), 981 in Gerbert (aged 20 to 89 years) and 1743 in Branström (aged 18 to 37). Buller 1998 and Gerbert were set in Arizona and San Francisco Bay Area, USA, Branström in Stockholm County, Sweden and Richard in south of France. Studies differed with respect to the factors the impact of which they tested – it was for example language intensity, source or type of message. Therefore the comparability of their results is seriously limited. Follow-up was clearly stated only in Richard where participants were tested two weeks after being sent leaflets. In Buller 1998 participants were followed-up from January/February to February of the following year and in Branström from May until autumn of the same year. Gerbert did not report follow-up.

Although Branström measured knowledge and frequency of sunbathing, sunburn and sun protection – no information was provided if results were significantly different between groups. Groups received: two brochures and a UV intensity indicator, one brochure and a UV intensity indicator, two brochures and the fourth group – only one brochure. It appears that participants who were given two brochures had the highest level of knowledge and sun protection and the lowest sunbathing frequency. The lowest sunburn frequency was observed in the group which was given one brochure and a UV intensity indicator.

Buller 1998 randomised participants to four groups which received messages with different language intensity (high or low) and argument structure (inductive or deductive). This study indicated that out of six summer protective behaviours participants who received high intensity messages limited their exposure to midday sun compared to participants who received low intensity messages – this did not take into account argument structure. In the remaining behaviours there was a tendency for more sun protection in the high intensity group. For six winter protective behaviours there was no significant difference with respect to language intensity (although the high intensity group tended to report more sun-protective behaviours). Low intensity inductive messages tended to be associated with more sun protective behaviours than high intensity inductive messages (significance not reported). Participants receiving high intensity deductive messages

compared to low intensity deductive messages were reported to have significantly increased the frequency of applying sunscreen, applying sunscreen with SPF 15+ and wearing protective clothing. It was reported that there was no significant difference between groups in the overall change of SPF of sunscreen used (however in the low intensity group the score was marginally higher).

Gerbert measured activation of participants to start sun protective behaviour as dialling a toll-free number (messages varied on the source and content) and found no significant differences between study arms. The highest percentages of activated participants received a message from their own physician (as compared to received from their own Health Maintenance Organisation and a junk mail organisation) and highlighting the risk of skin cancer (compared to ageing and wrinkling with or without a book on the topic).

Richard indicated that participants provided with a humoristic leaflet had a significantly lower knowledge of the definition of melanoma compared to participants who were sent neutral or threatening materials. There was however no significant difference between groups in knowledge of early signs and risk factors of melanoma.

### **New media in adults**

#### *Studies set in workplace*

One Australian RCT (Dixon, rated -) investigated emails containing weather and/or UV forecast and/or behaviour recommendations sent before weekends to employees of consulting firms and a university. Five hundred fifty seven participants (13% aged less than 25 years) were followed-up for 20 weeks (with a two-week break).

There was no evidence of a statistically significant difference between study arms in sunburns and no direction of effect was observed. There was a significant difference between the groups in sun protection in response to forecasts and the group which received weather and UV forecast with recommendations reported the highest sun protection. Of five sun protective behaviours there was a significant difference for lower body cover on Saturdays (however the group which had the most positive results was not obvious) and none on Sundays. There was no obvious trend in results.

Studies in a university/ college setting

One American RCT (Bernhardt, rated +) in 83 undergraduate students (aged 19 to 30 years) compared a webpage tailored for participants with a generic one. Participants were followed-up for four to five weeks.

This study provided no evidence of a difference between participants who accessed tailored or standard websites with regard to sunscreen use behaviours (exact results and significance level were not provided).

## Findings: Cost-effectiveness

An Australian study (cost-minimisation analysis, cost-benefit analysis; rated - ) reported that an educational approach involving provision of material (videos and posters) to outdoor workers accompanied by information provided by nurses is potentially cost saving compared to talks delivered by occupational health nurses, under certain assumptions about unit costs and size of targeted population. The results of the cost benefit analysis show that the cost per outdoor worker exceed the benefits to the company due to reduced compensation, resulting in a net present value of – AUD \$126 (- £93) (Hocking)

There is evidence from one US-based economic evaluation (cost-effectiveness analysis, cost-benefit analysis; rated +) that a classroom lesson results in improved effectiveness and reduced cost compared to no intervention, because of treatment costs saved in terms of cancers averted. (Kyle)

## Conclusions:

The objectives of the evidence reviews in this report were to address questions relating to what are the most effective and cost-effective ways of providing information to change people's knowledge, awareness and behaviour and so prevent the first occurrence of skin cancer attributable to UV exposure. It was also the purpose to identify what is the content of effective and cost-effective primary prevention messages.

It is clear from the studies identified that a large body of research has been undertaken on the effectiveness of the provision of information to prevent the first occurrence of skin cancer. However, this body of evidence is also spread across a breadth of combinations of populations, interventions, comparators and settings. Furthermore there are issues relating to the quality and reporting of the available evidence and potentially about the relevance of some of the outcome measures used. This variety places limits on the conclusions that can be drawn. It is evident however that verbal interventions applied to children might lead to an increase in knowledge about exposure to, and protection from, UV. Whether such knowledge is retained and/or leads to protective behaviours is unclear.

Given the heterogeneity of evidence and that much of it has been undertaken in countries with greater potential for UV exposure than the UK, applicability is also an issue.

The possible harms from UV exposure reduction messages have not been reported and remain unknown.

Very limited evidence is available on the cost-effectiveness of the provision of information to prevent the first occurrence of skin cancer.

Further, and more robust, studies are required which build on the current evidence base.

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# 1 Introduction

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The National Institute for Health and Clinical Excellence ('NICE' or 'the Institute') has been asked by the Department of Health (DH) to develop guidance on public health interventions for the NHS and local authorities aimed at preventing skin cancer, specifically: the provision of information, physical changes to the environment and the supply of sun protection resources. This referral is being undertaken in several phases and the current phase focuses on provision of information. Physical changes to the environment and the supply of sun protection resources will be covered in later phases.

This evidence review covers the effectiveness and cost-effectiveness evidence on the provision of information to prevent skin cancer. A second evidence review focuses on qualitative evidence related to information provision. A third report outlines de novo economic analyses on the cost-effectiveness of methods of information provision.

NICE public health intervention guidance supports implementation of the preventive aspects of national service frameworks (NSFs) where a framework has been published. The statements in each NSF reflect the evidence that was used at the time the framework was prepared. The public health guidance published by the Institute after an NSF has been issued will have the effect of updating the framework. Specifically, in this case, the guidance will support the 'Cancer reform strategy' (DH 2007).

This guidance will support the following policy which specifically refers to skin cancer:

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'The NHS cancer plan: a plan for investment, a plan for reform'<sup>29</sup>.

It will also support the following policy documents:

'Choosing health – making healthy choices easier' (DH 2004)

'Operational plans 2008/09–2010/11'<sup>31</sup>

'PSA delivery agreement 18: promote better health and wellbeing for all'<sup>48</sup>

Tackling health inequalities: a programme for action'<sup>30</sup>

'The new performance framework for local authorities and local authority partnerships: single set of national indicators'<sup>26</sup>.

The guidance will complement NICE guidance on: improving outcomes for people with skin tumours including melanoma; photodynamic therapy for non-melanoma skin tumours; and referral guidelines for suspected cancer.

This guidance will provide recommendations for good practice, based on the best available evidence of effectiveness, including cost effectiveness. It is aimed at professionals, commissioners and managers with public health as part of their remit working within the NHS and local authorities. Examples include: local authority planners, public health practitioners, pharmacists, GPs, school nurses, practice nurses and skin cancer specialists such as clinical nurse specialists (skin cancer), dermatologists and skin cancer surgeons. It will also be of interest to those working in the wider public, private, voluntary and community sectors, as well as members of the public.

## 1.1 Background

Exposure to ultraviolet (UV) radiation is the leading cause of skin cancer. This can occur naturally via sunlight and artificially through the use of sun lamps and tanning beds. The risk of skin cancer can be reduced by, for example, opting to stay in the shade, wearing protective clothing, avoiding the sun during the middle of the day and using high sun protection factor (SPF 30+) products.

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There are two main types of skin cancer: non-melanoma and malignant melanoma:

- Non-melanoma is the most common and is usually the easiest to treat. There are two main sorts: basal cell and the more serious squamous cell (if left untreated, squamous cell can spread to other parts of the body).
- Malignant melanoma is the most serious and causes the majority of skin cancer deaths.

Skin cancer (non melanoma and malignant melanoma) is the most common cancer in the UK and is estimated to account for over a third of all cancers detected. More than 72,000 cases of non-melanoma skin cancer were registered in 2004 (Cancer Research UK 2008a), although estimates suggest that a much higher number are diagnosed each year<sup>78</sup>. Research has shown that non-melanoma is rising in the young, especially within the 30–39 year age group (Bath-Hextall et al. 2007). Over 8900 cases of malignant melanoma are diagnosed each year (Cancer Research UK 2008a) – accounting for 3% of all cancer diagnoses. It causes 1800 deaths a year<sup>19</sup>. Since the 1970s, the incidence of malignant melanoma has more than tripled in the UK: among males it has increased from around 2.5 per 100,000 in 1975 to 11.0 in 2002; the rate among females has increased from 3.9 to 12.7 per 100,000 during the same period<sup>19</sup>. Although morbidity rates are higher among females, more men die from malignant melanoma (Office for National Statistics 2006).

A recent survey highlighted 44% of Britons were unable to recognise key signs of skin cancer (for example, a mole which is getting larger or has an irregular border or colour). Only 34% check their moles at least once a month and 25% never check them. The majority of respondents (85%) thought skin cancer (non melanoma and malignant melanoma) accounted for less than 10% of the incidence of all cancers in the UK (the actual figure is around 33%)<sup>11</sup>. In a 2003 survey, 80% of those questioned mentioned using sunscreen to reduce the risk of skin cancer, but less than half (44%) specifically mentioned using a sunscreen with a 15+ SPF (Office for National Statistics 2003).

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Several factors increase the risk of developing and dying of skin cancer, for example:

- Age and gender – the number of cases of malignant melanoma increases with age and is more common in women <sup>19</sup>. Skin damage (sunburn) that occurs at a young age increases the risk of developing skin cancer later in life (Elwood and Jopson 1997).
- Ethnicity – although incidence rates are lower among those with darker skin, mortality rates are often higher because skin cancer is often diagnosed late.
- Individual risk – skin type, number of moles, hair and eye colour, history of lowered immunity or transplant and family or personal history of skin cancer all affect the risk of melanoma <sup>19</sup>.
- Regional variation – London and the north have the lowest incidence rates, while the highest rates are in the south-west <sup>77</sup>. Sunbed outlets are particularly prevalent in areas of socioeconomic deprivation.
- Social class – currently, malignant melanoma is positively associated with affluence (those from deprived areas show a 60-70% lower incidence rate compared with their more affluent peers) <sup>19</sup>. However, people from more affluent areas are more likely to survive the condition <sup>20</sup>.

In 2005, skin cancer in England was estimated to cost over £190 million. The NHS alone spent approximately £70 million on the condition <sup>74</sup>.

## 1.2 Research Objectives

The objectives of the current phase of this referral addressed fully or in part in this report are:

- What are the most effective and cost-effective ways of providing information to change people's knowledge, awareness and behaviour and so prevent the first occurrence of skin cancer attributable to UV exposure?



- What content do effective and cost-effective primary prevention messages contain? What is the most effective and cost-effective content?

This report addresses these objectives by looking for evidence from existing primary research. In addition, de novo economic analyses of selected interventions are presented in a separate report.

A further report describing the findings of a review of existing qualitative evidence addresses the following questions:

- What factors help to convey information to prevent the first occurrence of skin cancer attributable to UV exposure?
- What factors hinder the communication of primary prevention messages?

### 1.3 Coverage of this referral

The precise nature of the populations and interventions to be covered, and those which are not, are defined below in Table 1:

**Table 1 Populations and interventions covered/not covered**

<b>POPULATION</b>	
<b>COVERED BY GUIDANCE</b>	<b>NOT COVERED BY GUIDANCE</b>
Everyone and, where the evidence permits, specific population groups (such as people within a specific age range or from a particular ethnic group or who are at a higher than average risk of developing skin cancer).	None

<b>ACTIVITIES /INTERVENTIONS</b>	
<b>COVERED BY GUIDANCE</b>	<b>NOT COVERED BY GUIDANCE</b>
<p>The provision of information to prevent the first occurrence of skin cancer (primary prevention of non-melanoma and malignant melanoma) attributable to natural and artificial UV exposure. This includes information that improves knowledge and awareness of the causes of skin cancer, the risks of over-exposure to UV, ways to prevent skin cancer and where to get further information. It will also look at how information can change behaviour to prevent the first occurrence of skin cancer.</p> <p>The guidance will focus on the following types of intervention (universal and targeted). These could be delivered in various settings (such as the NHS, schools and workplaces) or by a range of people (such as general practitioners, practice nurses, pharmacists, early childhood services, teachers).</p> <ul style="list-style-type: none"> <li>• One-to-one or group-based verbal advice (with or without the use of information resources).</li> <li>• Mass-media campaigns.</li> <li>• Leaflets and other printed</li> </ul>	<ul style="list-style-type: none"> <li>• Secondary prevention (activities that aim to prevent a re-occurrence of skin cancer).</li> <li>• Provision of sun protection, for example, protective clothing or sunscreen (for outdoor workers), or structural changes to the environment (to provide areas of shade, for example, in public spaces or school grounds). Please note that these will be covered in guidance produced in response to the other parts of the DH referral (see appendix A).</li> <li>• Policy, legislative or fiscal changes. For example, raising the minimum age of sunbed use to 18 years, removing unsupervised and coin-operated sunbed facilities or reducing VAT on sunscreen products.</li> <li>• Primary prevention combining information provision with another type of intervention (such as changes to the built environment), where the outcomes related to information provision cannot be</li> </ul>

<p>information, including posters, and teaching resources.</p> <ul style="list-style-type: none"> <li>• New media: the Internet (including social networking sites), emedia and text messaging.</li> </ul>	<p>disaggregated from the other intervention/s.</p> <ul style="list-style-type: none"> <li>• Local, regional or national skin cancer screening programmes which solely aim to detect the occurrence of skin cancer or activities to assess its incidence among specific groups.</li> <li>• Assessment of the accuracy of effective information resources.</li> <li>• Clinical diagnosis, treatment and management of skin cancer.</li> </ul>
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## 1.4 Study Designs

The study designs of particular interest for the effectiveness of interventions were: RCT, controlled before and after, cohort, case control, before and after and interrupted time series.

The study designs of particular interest for the cost-effectiveness of interventions were cost-consequences, cost-benefit, cost-minimisation, cost-effectiveness and cost-utility analyses.

## 1.5 Secondary Questions

Apart from the primary questions to be addressed, outlined above, there were a number of secondary research questions reflecting additional areas of interest. These were not to be specifically targeted by the review of effectiveness and cost-effectiveness (i.e. these did not form the basis of literature searches), but any studies that addressed the primary research questions were also assessed for evidence on any of the following:

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- Whether effectiveness and cost-effectiveness vary according to the diversity of the population (for example, in terms of the person's age, gender, ethnicity or individual risk factors such as history of lowered immunity or transplant, skin type or hair and eye colour, literacy levels or any physical and/or mental impairments) and whether the intervention is transferable to other population groups
  - Whether effectiveness and cost-effectiveness vary according to the status, knowledge and influence of the person delivering the intervention
  - Whether effectiveness and cost-effectiveness vary according to the way in which the intervention is delivered (for example, verbal information and advice, or via a leaflet)
  - Whether effectiveness and cost-effectiveness vary according to the relative effectiveness and cost-effectiveness of the content of different interventions the frequency, intensity and duration of the intervention
  - Whether effectiveness and cost-effectiveness vary according to where and when the intervention takes place (for example, a sports event at a school; or information for at those on holiday abroad), what season the message is delivered in and whether it is transferable to other settings (such as the NHS) or seasons
  - The costs of the intervention
  - Which interventions are ineffective and/or not cost-effective
  - Any adverse or unintended effects (positive and negative) of the intervention.

It is important to recognise that any evidence subsequently presented in relation to the secondary research questions was drawn from a limited pool of studies and cannot be considered on the same level as evidence about the primary questions.

## 1.6 Structure of report

The structure of the following sections of the report is:

Chapter 2 - reports the methods employed e.g. literature searches, retrieval and selection of papers, data extraction and quality assessment procedures for both the effectiveness and cost-effectiveness reviews

Chapter 3 – gives an overview of identified evidence for effectiveness and cost-effectiveness.

Chapter 4 - presents the effectiveness findings.

Chapter 5 – presents the cost-effectiveness findings

Chapter 6 - discusses the review findings, highlighting their applicability, limitations and gaps in the evidence.

Appendices present supporting documents such as protocol, example search strategies, inclusion/exclusion checklists and quality assessment tools.

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## 2 Methodology

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The aim of this report was to address part of the objectives of this phase of the referral (see Section 1.2) by reviewing existing evidence relating to the questions:

- What are the most effective and cost-effective ways of providing information to change people's knowledge, awareness and behaviour and so prevent the first occurrence of skin cancer attributable to UV exposure?
- What content do effective and cost-effective primary prevention messages contain? What is the most effective and cost-effective content?

To address the provision of information for primary prevention of skin cancer this report comprises two systematic reviews of existing evidence of:

- Effectiveness and
- Cost-effectiveness

The methods of each systematic review are reported below.

### 2.1 Identifying potentially relevant studies

A series of separate searches were undertaken to identify potentially relevant primary studies. In addition existing systematic reviews were sought to enhance identification of primary studies (see section 2.3). Altogether fourteen databases and 5 websites were searched by WMHTAC. NICE searched the database of documents of the former Health Development Agency (HDA). The details of searches performed for each review are provided below.

### 2.1.1 Effectiveness literature searches

The key concepts of the search question were 'skin cancer' and 'methods of primary prevention'. The following key search terms relating to each concept were defined as follows:

- skin cancer concept: 'skin cancer', 'melanoma', 'carcinoma', 'sunburn', 'ultraviolet exposure' and other synonyms;
- methods of primary prevention concept: 'prevention', 'health education', 'preventive medicine', 'campaigns', 'mass media' and other synonyms.

Methodological filters were also applied to the search, where possible, in order to identify primary studies of randomised control trials (RCTs) and other intervention studies of longitudinal design, as well as systematic reviews. Where this was not possible appropriate terms were combined with the subject terms. The search strategies can be seen in Appendix 1: Search Strategies.

The following limits were placed on the search strategy:

- published from 1990 onwards
- published in English language

The following databases and websites were searched to identify primary studies:

#### Databases

- Cochrane Library (CENTRAL)
- MEDLINE

- MEDLINE In Process
- EMBASE
- CINAHL (Cumulative Index of Nursing and Allied Health Literature)
- PsycINFO
- ASSIA (Applied Social Science Index and Abstracts)
- HMIC (Health Management Information Consortium) database comprising the Kings Fund database and DH-Data database
- The database of the former HDA

#### Websites

- The Evidence for Policy and Practice Information and Co-ordinating Centre (EPPI-Centre) <http://eppi.ioe.ac.uk/cms>
- Websites of Public Health Observatories
- Cancer Research UK <http://www.cancerresearchuk.org>
- SunSmart (Victoria) <http://www.sunsmart.com.au>
- NICE website <http://www.nice.org.uk/>

The following databases and websites were searched to identify systematic reviews:

#### Databases

- Cochrane Library (containing CDSR, DARE and HTA database)



- MEDLINE
- MEDLINE In Process
- EMBASE
- CINAHL (Cumulative Index of Nursing and Allied Health Literature)
- PsycINFO
- ASSIA (Applied Social Science Index and Abstracts)
- HMIC (Health Management Information Consortium) database comprising the Kings Fund database and DH-Data database
- Recent additions to DARE and HTA database via CRD website
- ARIF database of reviews
- Clinical Evidence
- Bandolier
- TRIP database
- The database of the former HDA

#### Websites

- The Evidence for Policy and Practice Information and Co-ordinating Centre (EPPI-Centre) <http://eppi.ioe.ac.uk/cms>
- Websites of Public Health Observatories
- Cancer Research UK <http://www.cancerresearchuk.org>
- SunSmart (Victoria) <http://www.sunsmart.com.au>

- NICE website <http://www.nice.org.uk/>

### 2.1.2 Cost effectiveness literature searches

Searches for economic studies were performed on the following specialist economic databases. These searches used the same limiters as the effectiveness searches. The study design criteria were not applied:

- NHS EED (NHS Economic Evaluation Database)
- Econlit

MEDLINE and EMBASE were also searched using the same limiters as the effectiveness searches and combining a search filter based on the CRD model with the subject component of the search strategy.

The search strategies can be seen in Appendix 1: Search Strategies.

### 2.1.3 Managing search results

The results of the searches were entered into review specific Reference Manager (Thomson ResearchSoft, version 11) databases. In each database automatic duplicate reference removal by Reference Manager was undertaken using the software default matching criteria.

## 2.1.4 Reference screening

The title and abstract (where present) of articles identified in the searches were screened for relevance using checklists. Separate specific screening checklists were used for effectiveness and cost-effectiveness primary studies and for the identification of systematic reviews. Copies of these checklists can be viewed in Appendix 2: Reference screening checklists.

Checklists were applied by one reviewer to titles and abstracts in the appropriate database. An independent assessor undertook a second screening of ten percent of articles in each database. Any discrepancies were discussed.

For the effectiveness review, due to the large number of articles identified as relevant on initial screening, a second stage of screen of titles and abstracts of these studies was performed. Additional criteria based on the list of exclusions identified in the scope were added to the checklist and used to re-screen these articles (see Appendix 2: Reference screening checklists for details of the additional screening criteria). Such a secondary screen was not required for the cost-effectiveness review or the identification of systematic reviews.

Full copies were sought for all articles considered relevant from screening and these copies were then assessed for adherence to the appropriate full article screening criteria (see section 2.2)

## 2.1.5 References from experts

Any additional references submitted by stakeholders, but not previously identified by formal searches, were added to the appropriate Reference Manager database. Such references went through the same selection process as references identified in the literature searches.

## 2.2 Full Article Screening

Full copies of articles deemed relevant from title and abstract screening (section 2.1.4) were subsequently screened to identify studies to be reviewed using checklists (Appendix 3: Full paper screening checklists) based on the inclusion and exclusion criteria for each review. This was undertaken by one reviewer and a second reviewer undertook the process as a check on a planned minimum of ten percent of full papers for each review (actually 25+% for the effectiveness review and the economic review were checked). Disagreements were resolved by discussion.

The inclusion criteria were the same for both the effectiveness and cost-effectiveness reviews except that different study designs were included.

Details about the study designs included for each review can be found in subsequent sections. Below are the common inclusion criteria:

- Populations to be included for all evidence reviews:
  - Everyone
- Interventions (universal and targeted) aiming at primary prevention of skin cancer (for all evidence reviews) are
  - One-to-one or group-based verbal advice (with or without use of information resources)
  - Mass-media campaigns
  - Leaflets, other information or teaching resources or printed material including posters
  - New media: the Internet (including social networking sites), emedia and text messaging

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They could be delivered in various settings (such as the NHS, schools and workplaces) or by a range of people (such as general practitioners, practice nurses, pharmacists, early childhood services, and teachers).

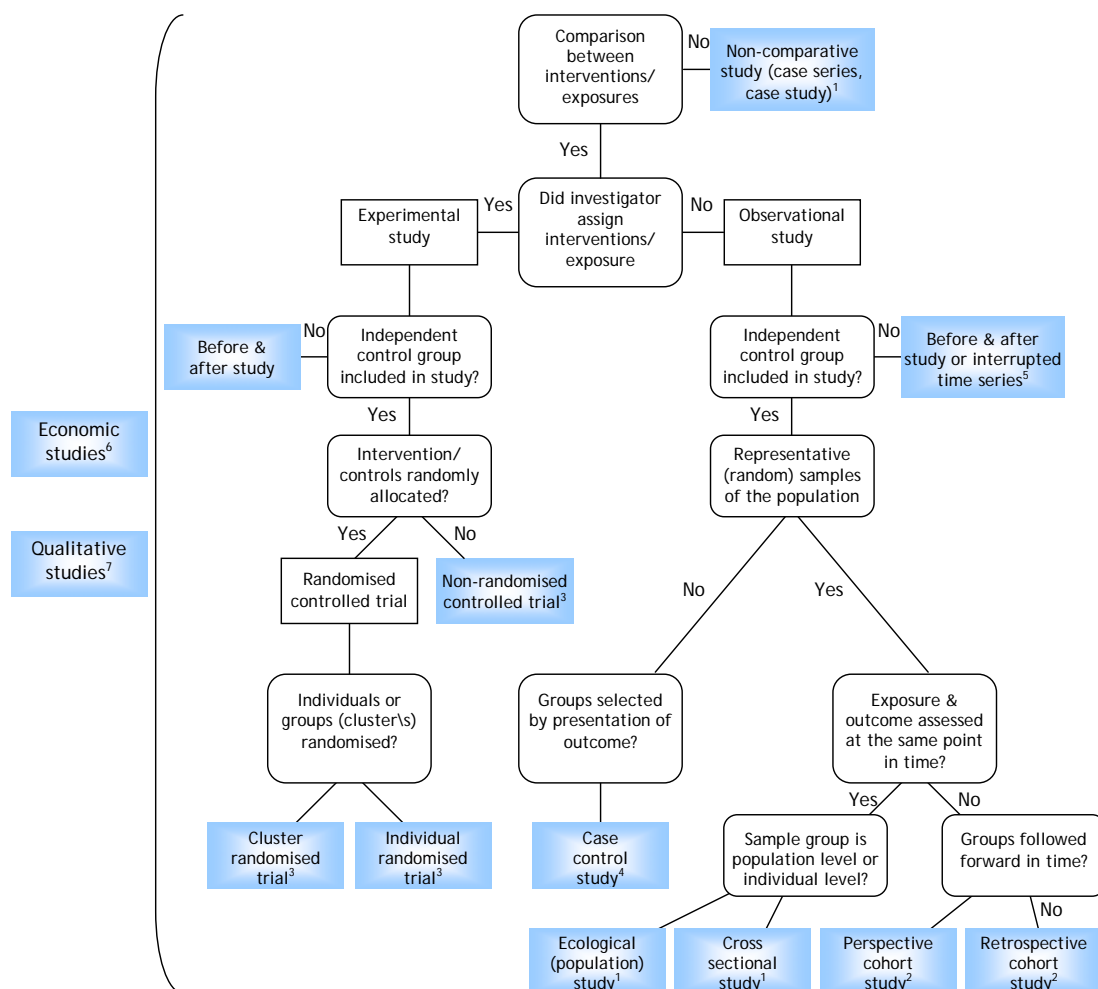
- Comparator (for the effectiveness and cost-effectiveness review)
  - Current information provision, do nothing or any other intervention listed above
- Locations to be included (for all reviews)
  - Developed/OECD countries
- Time period considered (for all evidence reviews)
  - 1990 onwards
- Language
  - Full text in English

### 2.2.1 Selection of relevant studies for effectiveness

Studies of the following designs were included in the effectiveness review:

- Randomised controlled trials (RCTs)
- Longitudinal intervention studies (i.e. there is at least one follow up measure after baseline) such as controlled before and after, cohort, case control, before and after, and interrupted time series

Figure 1 below represents the algorithm for classifying study types from *Methods for development of NICE public health guidance*.



**Figure 1 Algorithm for classifying primary study designs about effectiveness**

## 2.2.2 Selection of relevant studies for cost-effectiveness

Studies of the following design were included in the cost-effectiveness review:

- Randomised controlled trials (RCTs) with cost-effectiveness, cost consequences, cost-benefit analysis, cost-utility, cost-minimisation or net monetary (cost) and benefit data – the perspective adopted (employer, societal, governmental) will not affect include/exclude decisions
- Longitudinal intervention studies (i.e. there is at least one follow-up measure after baseline) with cost-effectiveness, cost-consequences, cost-benefit, cost-utility, cost-minimisation or net monetary (cost) benefit data

- 
- Decision analytic models and any other econometric and/or epidemiological models that contain relevant effectiveness and/or economic data or methods of analysis

### 2.2.3 Tagging articles for relevance to other reviews

Full copy articles identified for one review (effectiveness or cost-effectiveness) but thought also possibly relevant to one of the other reviews (effectiveness, cost-effectiveness or qualitative review) were tagged for easy identification. Such studies were checked against search results for the second review and if not identified were processed for relevancy/inclusion. The full article screening checklists for each review (see Appendix 3: Full paper screening checklists) contain details of the criteria for tagging.

### 2.2.4 Citation Checking

We planned to examine the reference lists of publications reporting primary studies included in the evidence reviews to identify additional relevant studies (see section 2.8.3).

We planned to send a list of the included studies to identified clinical experts for identification of further studies (see section 2.8.3).

## 2.3 References from systematic reviews

Systematic reviews were identified and included in this report to facilitate the identification of primary studies in addition to those found through targeted searches on the effectiveness and cost-effectiveness of interventions. Searches were undertaken as described above in section 2.1.1. From the identified articles, relevant reviews were selected using predefined criteria (Appendix 2: Reference screening checklists and Appendix 3: Full paper screening checklists) the same way as described for the selection of primary studies. The primary studies included

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in included systematic reviews were then checked against those studies identified through the specific searches for primary studies. Any additional studies identified were added to the Reference Manager database and went through the same selection process as references identified in the literature searches. Full details of the identification and selection of systematic review, together with the primary studies identified by this process can be found in Appendix 4 Identification and Utilisation of Systematic Reviews.

Any identified systematic reviews relevant to the cost-effectiveness and qualitative reviews were to be identified. None were directly relevant.

## 2.4 Quality appraisal and data extraction

### 2.4.1 Quality assessment for effectiveness primary studies

Quality assessment was conducted based on the NICE CPHE forms. These forms provide criteria for rating a study based on how robust an example it is of that particular study design. For example, a randomised control trial (RCT) was rated on how well it met the defined standards for a robust RCT. Different criteria exist for each type of study design. Quality ratings for studies of the same design are relative (i.e. an RCT rated ++ should be more robust than an RCT rated +). However, quality ratings for differing study designs cannot be compared.

A uniform system was adapted where if the study met at least 80% of the quality criteria it was rated as “++”, when it met 60 to 79% of the criteria it was rated as “+” and less than 60% it was rated “-”.

For RCTs, NICE raised concern that some criteria may not be met on quality assessment due to the nature of the topic rather than the quality of the study. Particularly of concern was the lack of ability to blind participants to some interventions. It was felt that downgrading the overall quality of a study due to non-adherence to a quality criterion that could never be met was not desirable. Therefore, when rating a study, criteria which were not met because it was not



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possible to meet them did not affect the overall score. The flipside of this is that the more criteria that are not applicable, the more weight there is given to the remaining criteria. Thus, caution is required in comparing quality ratings between RCTs.

Non-randomised studies were quality assessed in a similar way.

Two independent reviewers assessed the quality of each included study. Any differences in quality assessment were resolved by discussion with a third reviewer or, if agreement could not be reached, details were reported in the review. See Appendix 5: Effectiveness studies - Quality Assessment for details of the quality assessment score for each included effectiveness study.

#### 2.4.2 Quality assessment for cost-effectiveness primary studies

Quality assessment was conducted using the NICE CPHE forms based on the Drummond approach. Two independent reviewers assessed the quality of each included study with any differences in quality assessment resolved by discussion or, if agreement could not be reached, details were reported in the review.

The uniform system adopted was:

- ++ All or most of the criteria have been fulfilled. Where they have not been fulfilled the conclusions of the study are thought very unlikely to alter.
- + Some of the criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought unlikely to alter the conclusions.
- Few or no criteria fulfilled. The conclusions of the study are thought likely or very likely to alter.

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See Appendix 6: Economic studies - Quality Assessment for details of the quality assessment score for each included cost-effectiveness study.

### 2.4.3 Data extraction

Data from each included effectiveness and cost-effectiveness study were directly extracted into an evidence table. The format of the evidence tables was adapted to reflect the parameters of each review. The evidence tables for each included study are presented in Appendix 11: Effectiveness evidence tables for the effectiveness review and Appendix 12: Economic evidence tables for the cost-effectiveness review.

One reviewer extracted data for each full paper using these forms. A second reviewer checked 10% of the data extraction tables for accuracy (100% for the cost-effectiveness review) and any differences were resolved by discussion

Only data on primary and secondary outcomes for each review were extracted. These are listed below.

For effectiveness studies primary outcomes were:

- Reduction in the incidence of morbidity and mortality from non-melanoma and malignant melanoma skin cancer attributable to natural and artificial UV exposure. This may be measured in terms of a reduction in the incidence of sunburn or cumulative sun exposure etc.
- Increase in knowledge and awareness that can lead to a reduction in the incidence of exposure/over-exposure to natural and artificial UV.
- Changes in behaviours that can lead to a reduction in the incidence of exposure/over-exposure to natural and artificial UV.

- 
- Increase in knowledge and awareness of the ways to prevent non-melanoma and malignant melanoma skin cancer attributable to natural and artificial UV exposure. (For example, by wearing a hat in the sun, keeping in the shade, avoiding sunlight around the middle of the day, wearing protective clothing and appropriate use of a high protection 30+ sunscreen)
  - The contents of an intervention that is effective and cost-effective.
  - Any adverse or unintended (positive and negative) effects of the intervention

For cost-effectiveness, primary outcomes were broadly any related to the economic assessment of interventions.

For both effectiveness and cost-effectiveness, if a study met the inclusion criteria, then data on any other outcomes considered relevant were extracted. As such, secondary outcomes were decided iteratively on a case by case basis.

Distinction was made between the primary and secondary outcomes of the study and the primary and secondary outcomes relevant to this referral. This was achieved by presenting data in evidence tables by the primary and secondary outcomes of the study (e.g. see Appendix 11: Effectiveness evidence tables) and in the findings sections of this report by the primary and secondary outcomes for the referral (e.g. see Section 4 Effectiveness Findings).

## 2.5 Complex Studies

A number of the effectiveness studies (and one cost-effectiveness study) described interventions and population groups that met both the specified inclusion criteria as well as criteria that were not relevant to the part of the referral being addressed in this report. These were specifically related to:

- 
- a mixed intervention comprising components relevant to this phase of the referral and others outside it (e.g. the provision of preventative information and free sunscreen)
  - a mixed population of those who have never knowingly had skin cancer and a proportion who have had skin cancer
  - a mixed intervention containing primary prevention information and also explicitly stated detection of skin cancer information (e.g. to detect first occurrence)
  - a mixed intervention covering broader topics other than just skin cancer prevention such as combined skin cancer; smoking cessation and healthy eating information

A number of studies fell in to more than one of these categories.

After consultation with NICE about how best to deal with these included studies the following was decided:

- mixed intervention comprising components relevant to and not relevant to this phase
  - If it was possible, relevant data on information provision only compared to do nothing/usual practice or another information only message was analysed. For example, in a three arm study comprising an information plus provision of sun screen arm compared with information only arm and a do nothing/usual practice arm, only data for information only versus do nothing/usual practice was analysed
  - if a study had an information component combined with non-information component compared with only a single information component or do nothing/usual practice component it was not analysed (e.g. information vs. information plus sunscreen)

- 
- a mixed population (no previous episode of skin cancer plus previous episode of skin cancer)
    - data on the no previous cancer subset was to be analysed separately if disaggregation of the data was possible, however if this was not possible the population as a whole was analysed with appropriate cautions noted
  
  - a mixed intervention of primary prevention information and also explicitly stated detection of skin cancer information (e.g. first occurrence)
    - the study as a whole was analysed but with appropriate cautions noted
  
  - a mixed intervention covering broader topics other than just skin cancer prevention
    - if unable to disaggregate the skin cancer relevant data then the study was not analysed
    - if able to disaggregate the skin cancer relevant data the study was analysed but highlighting the possibility that other information components may have impacted on the effect of the skin cancer message

Studies containing more than one of the above issues were treated on a case by case basis to ascertain if relevant evidence could be obtained.

A list of studies that were not analysed (or only partially analysed) because of the above issues are listed in this report (see Section 3.3 and Appendix 15: Studies not analysed).

Where a controlled study was not analysed (or only partially analysed) individual arms were considered for their relevance as before and after studies.

## 2.6 Controlled before and after studies

Controlled before and after studies which met the inclusion criteria were only analysed if they either:

- were on a population – setting – intervention- comparator combination not covered by an included RCT or
- had a longer duration of follow up than a randomised controlled trial in the same population – setting – intervention – comparator combination

A list on non-analysed controlled before and after studies can be found in Appendix 15: Studies not analysed.

## 2.7 Applicability

Assessment of the external validity of included studies was based on guidance and possible applicability statements in *Methods for development of NICE public health guidance*. The latter being:

- Likely to be applicable across a broad range of populations and settings.
- Likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted.
- Applicable only to populations or settings included in the studies – the success of broader application is uncertain.
- Applicable only to settings or populations included in the studies.

Studies were subjectively assessed against these criteria by a single reviewer, based on factors relating, but not limited, to: population, setting, intervention, study

quality and whether there was sufficient level of detail reported to fully assess applicability.

For the effectiveness studies, the most appropriate statement was used to describe each study and where relevant summary findings. For the cost-effectiveness studies a broader assessment was taken using responses of applicable, partially applicable and not applicable.

## 2.7.1 Analytic framework

The analytic framework underpinning the reporting of the evidence from included studies was based on that developed for media interventions by Saraiya et al<sup>91</sup> and shown in Figure 2.

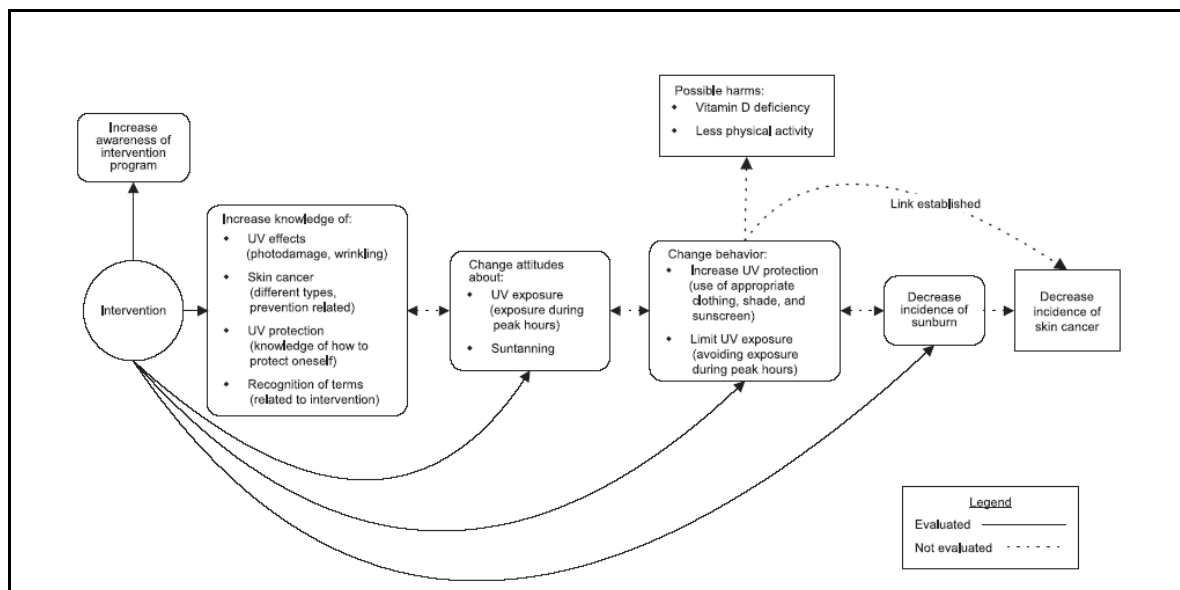


Figure 2 Analytical Framework.

Taken from: Saraiya M., et al. Interventions to Prevent Skin Cancer by Reducing Exposure to Ultraviolet Radiation: A Systematic Review. *Am J Prev Med* 2004; 27(5):422-466

The framework allows for the assessment of the effect of an intervention on knowledge, attitude (a secondary outcome for this review), behaviour and incidence of sunburn (solid lines in figure). Whilst the framework indicates a relationship between each of these intermediate outcomes and the next (dashed line) it was not the aim of this review to actively investigate such relationships.

## 2.7.2 Reporting Framework

Studies were grouped into themes by intervention category (verbal, mass media, new media, printed materials or combinations thereof) and comparator (current provision/do nothing, or one of the intervention categories) combinations. Each of these combinations was then subdivided into children or adults. Each of these subcategories was further divided by the intervention's setting (e.g. school, university, workplace etc). In the case of a school setting there was a further subdivision, where possible or evidence allowed, by age bands corresponding approximately to UK school age ranges (4-7 years, 7-11years, 11-16 years).

For example:

- Verbal advice
  - Compared to do nothing/usual practice
    - Children
      - School Setting
        - Age 4-7 years
    - Adults
      - University
      - Medical practice
  - Compared to other verbal advice



Such a reporting framework allowed for the mapping of evidence from the disparate combinations of intervention, comparator, population age and settings in studies which met the inclusion criteria

Some multi-arm studies covered more than one intervention-comparator combination.

For identification purposes, studies are named after the surname of the first author of the main/first paper (e.g. Loescher). If an author has more than one study then the year of publication is added to the designation (e.g. Buller 1994, Buller 1997). If more than one study by the same author was published in the same year then “a” and “b” are added to the study name (e.g. Buller 2006a, Buller 2006b).

A list of included studies and the papers which report on them can be found in Appendix 13: Studies analysed in the report.

## 2.8 Synthesis and formulation of evidence statements

### 2.8.1 Effectiveness studies

The results of the data extraction and quality assessment for each included effectiveness study were summarised and presented under each of the above mentioned themes and categories. Where possible a narrative summary across similar studies was undertaken. Evidence statements were generated for each study, and where possible, also for any summary across similar studies.

## 2.8.2 Cost-effectiveness studies

A similar synthesis approach to that used for effectiveness was employed and to derive evidence statements (section 2.8.1).

## 2.8.3 Deviations from protocol

The protocol was executed for the most part as planned. However, due to resource issues, particularly related to the larger than anticipated number of identified primary studies/reviews and included studies in the effectiveness review, some changes were required. These were agreed with the NICE CPHE technical team and are outlined below:

- A list of primary studies meeting the effectiveness review inclusion criteria was not submitted to identified field experts for the identification of further studies. However details of included studies were provided to the NICE technical team.
- We planned to examine reference lists of primary studies included in the evidence reviews to identify additional relevant papers. This was not undertaken.
- Data extraction from included studies was to be checked by a second reviewer. This was revised to a check of the extraction of data from 10% of included RCTs; with the provision to increase this percentage if any discrepancies were commonly found that were perceived to be a threat to the validity of the review. No such inaccuracies were found.
- Analysis of before and after studies was to be included in this report. Due to time constraints, these are now to be presented, if required, in a later report.

- 
- As indicated in section 2.6, controlled before and after studies that met the inclusion criteria were only analysed if they covered intervention, comparator, population, setting combinations not addressed by RCTs or had longer follow up than RCTs of the same combination. This was not detailed in the protocol.

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## 3 Overview of identified evidence

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### 3.1 Effectiveness

Searches identified 34589 articles potentially relevant to this review (details to be found in Appendix 7: Effectiveness study flow diagram). After applying the reference screening criteria, a total of 349 papers were identified as relevant to the clinical effectiveness of interventions on the primary prevention of skin cancer and full texts were ordered. 197 of these were excluded and 16 full papers could not be obtained. References to unobtainable and excluded papers together with a brief reason for exclusion can be found in Appendix 8: Effectiveness articles excluded with reason and unobtainable. 136 of the articles met the inclusion criteria. Of these 54 reported 49 RCTs and 18 articles reported ten controlled before and after studies that were analysed in this report. 26 before and after studies reported in 28 papers were also found but not analysed and references to them can be viewed in Appendix 15: Studies not analysed. 49 articles reported a study with a mixed intervention, e.g. a composite intervention containing elements relevant to this review but also other components, such as the provision of sunscreen. Given that the effect on outcomes could not be disaggregated for interventions relevant to this review for 34 of these papers, they were excluded from the analysis apart from the ones which had at least one non-mixed intervention arm or a non-mixed period. Details of these mixed papers are given in section 3.3. Where a non-randomised study was on the same population, setting and intervention as an RCT, but had a shorter or equal follow-up, it was not analysed, but discussed in the section 3.3.

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The coverage of the included studies with respect to intervention, comparator, population and setting is shown in Table 2, Table 3,

Table 4, Table 5, Table 6 and Table 7. Every table contains at least five comparisons: with current practice/ do nothing and with four basic intervention types (verbal advice, mass-media, printed materials and new media). For combination interventions (i.e. comprising two or three basic intervention types) a comparison is provided only if there was any evidence identified. Shaded cells indicate that a comparison is repeated in another table. Individual studies are listed together with type and internal validity assessment. If a study had more than two arms it is listed in all relevant comparisons.

Twenty three studies (17 RCTs and seven controlled before and after studies - one study was utilised as both RCT and a controlled before and after study) provided information on interventions classed as verbal advice. 17 were studies on prevention of skin cancer in children and six in adults. Most studies provided information on a comparison of verbal advice with current provision of information/do nothing – 16 in children and five in adults. Eight studies provided information on head to head comparisons (six in children and two in adults). The most frequent setting was school for children studies and university for adults. Further details are provided in Table 2 Coverage of analysed studies on verbal advice by comparator, population and setting below.

**Table 2 Coverage of analysed studies on verbal advice by comparator, population and setting**

Comparator	Current provision of information/ do nothing	Children		Adults	
			<u><i>school (age 4-7)</i></u>		<u><i>university/ college</i></u>
		2 RCT	Buller 2006a (rated -) Loescher (rated +)	3 RCT	Jackson (rated ++) Katz (rated -) Mickler (rated ++)
		1 CBA	Kidskin (rated +)		
			<u><i>school (age 7-11)</i></u>		<u><i>hospital/ medical practice</i></u>
		4 RCT	Buller 1994 (rated -) Buller 1997 (rated -) Buller 2006a (rated -) Hornung (rated +)	1 CBA	Jones 2007 (rated -)
		1 CBA	Hewitt (rated -)		
			<u><i>school (age 11-16)</i></u>		<u><i>sports venue</i></u>
		6 RCT	Buller 2006b (rated +)	1 RCT	Parrott (rated -)

	Girgis (rated -) Hughes (rated -) Kristjánsson (rated +) Mermelstein (rated -) Syson-Nibbs (rated -)	
	<b><u>community</u></b> 2 CBA   Reding (rated -) Rodrigue (rated -)	
	<b><u>domicile</u></b> 1 RCT   Turrisi (rated +)	
<b>Verbal advice</b>	<b><u>school (age 4-11)</u></b> 1 CBA   Buller 2006a (rated -)	
	<b><u>school (age 7-11)</u></b> 1 CBA   Hewitt (rated -)	
	<b><u>school (age 11-16)</u></b> 1 RCT   Hughes (rated -)	
	<b><u>community</u></b> 1 CBA   Rodrigue (rated -)	
<b>Mass-media campaigns</b>		<b><u>university/ college</u></b> 1 RCT   Mickler (rated ++)
<b>Printed materials</b>	<b><u>school (age 7-11)</u></b> 1 CBA   Barankin (rated -)	<b><u>university/ college</u></b> 1 RCT   Mickler (rated ++)
<b>New media</b>	<b><u>school (age 7-11)</u></b> 1 RCT   Hornung (rated +)	
<b>Verbal advice + printed materials</b>		<b><u>hospital/ medical practice</u></b> 1 RCT   Clowers-Webb (rated +)

Three studies evaluated the use of mass-media – all of them were RCTs in adults in a university/ college setting. Each study compared mass-media interventions with current practice/ do nothing. All of them additionally provided information on head to head comparisons. Further details are provided in Table 3 Coverage of analysed studies on mass-media by comparator, population and setting below.

**Table 3 Coverage of analysed studies on mass-media by comparator, population and setting**

Comparator		Children	Adults
	Verbal advice		<u>university/ college</u> 1 RCT   Mickler (rated ++)
	Mass-media campaigns		<u>university/ college</u> 1 RCT   Cody (rated -)
	Printed materials		<u>university/ college</u> 2 RCT   Mickler (rated ++) Mahler 2007 (rated +)
	New media		
	Mass-media + printed materials		<u>university/ college</u> 1 RCT   Mahler 2007 (rated +)

Twenty three studies (20 RCTs and three controlled before and after studies) evaluated printed materials. Four studies aimed at prevention of skin cancer in children and 20 in adults (one study was aimed at both groups). The most frequent comparisons were with current provision of information/ do nothing (two studies in children and ten in adults) and of different content of printed materials (12 in adults only and one in both children and adults). Information on head to head comparisons was reported in 15 adult studies and two studies in children (one was both in adults and children). Ten studies were conducted in a university/ college setting. Further details are provided in



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Table 4 Coverage of analysed studies on printed materials by comparator, population and setting below.

**Table 4 Coverage of analysed studies on printed materials by comparator, population and setting**

	Children		Adults	
	<b>Comparator</b>	<b>Current provision of information/ do nothing</b>	<u>Domicile</u> 1 RCT   Bauer (rated +)	<u>Workplace</u> 2 RCT   Hanrahan (rated +) Rasmussen (rated -)
<u>hospital/ medical practice</u> 1 CBA   Bologna (rated -)			<u>university/ college</u> 3 RCT   Castle (rated +) Mahler 2007 (rated +) Mickler (rated ++) 1 CBA   Greene (rated -)	
		<u>hospital/ medical practice</u> 1 RCT   Prochaska (RCT, rated -)	<u>domicile</u> 1 RCT   Richard (RCT, rated -)	
			<u>airport/ flight</u> 2 RCT   Dey (RCT, rated -) Segan (RCT, rated -)	
<b>Verbal advice</b>		<u>school (age 7-11)</u> 1 CBA   Barankin (rated -)	<u>university/ college</u> 1 RCT   Mickler (rated ++)	
<b>Mass-media campaigns</b>		<u>university/ college</u> 2 RCT   Mickler (rated ++) Mahler 2007 (rated +)		
<b>Printed materials</b>	<u>Domicile</u> 1 RCT   Buller 1998 (rated -)	<u>university/ college</u> 7 RCT   Boer (rated ++) Cho (rated -) Jones 1994 (rated -) McMath (rated -) Prentice-Dunn (rated -) Rothman (rated +) Stephenson (rated -) 1 CBA   Greene (rated -)		
		<u>domicile</u> 4 RCT   Buller 1998 (rated -) Branström (rated +) Gerbert (rated -) Richard (rated -)		
		<u>workplace</u> 1 RCT   Rasmussen (rated -)		
<b>New media</b>				

<b>Mass-media + printed materials</b>		<u>university/ college</u> 1 RCT   Mahler 2007 (rated +)

Four studies provided information on the use of new media – all were RCTs and one was a study in children. Two studies (one in adults and one in children) compared new media to current provision of information/ do nothing and three provided information on head to head comparisons (one in children, two in adults). Further details are provided in Table 5 Coverage of analysed studies on new media by comparator, population and setting below.

**Table 5 Coverage of analysed studies on new media by comparator, population and setting**

	Current provision of information/ do nothing	Children	Adults
		<u>school (age 7-11)</u> 1 RCT   Hornung (rated +)	<u>hospital medical practice</u> 1 RCT   Glazebrook (rated +)
<b>Comparator</b>	<b>Verbal advice</b>	<u>school (age 7-11)</u> 1 RCT   Hornung (rated +)	
	<b>Mass-media campaigns</b>		
	<b>Printed materials</b>		
	<b>New media</b>		<u>workplace</u> 1 RCT   Dixon (rated -)  <u>university/ college</u> 1 RCT   Bernhardt (rated +)

Twelve studies (eleven RCTs and one controlled before and after study) evaluated combination interventions. Eight were studies on prevention of skin cancer in adults and four in children. Half of them provided information on verbal advice

together with printed materials in six different settings. Four children and seven adult studies compared interventions to current provision of information/ “do nothing” and two adult studies provided information on head to head comparisons. All combination intervention studies are presented below in two separate tables: Table 6 Coverage of analysed studies on two-component interventions by intervention, comparator, population and setting and Table 7 Coverage of analysed studies on three-component interventions by intervention, comparator, population and setting.

**Table 6 Coverage of analysed studies on two-component interventions by intervention, comparator, population and setting**

		Verbal advice + Printed materials		Verbal advice + New media		Mass-media + Printed materials	
		Children	Adults	Children	Adults	Children	Adults
comparator	Current provision of information/ do nothing	<u><i>school (age 7-11)</i></u> 1 RCT   Naldi (rated +)  <u><i>recreation site</i></u> 1 RCT   Mayer (rated +)  <u><i>domicile</i></u> 1 RCT   Benjes (rated +)	<u><i>workplace</i></u> 1 RCT   Glanz (rated -)  <u><i>domicile</i></u> 1 RCT   Geller 2006 (rated -)	<u><i>school (age 7-11)</i></u> 1 CBA   Geller 2003 (rated -)			<u><i>workplace</i></u> 1 RCT   Borland (rated +)  <u><i>university/ college</i></u> 2 RCT   Mahler 2005 (rated +) Mahler 2007 (rated +)
	Verbal advice		<u><i>hospital/ medical practice</i></u> 1 RCT   Clowers-Webb (rated +)				
	Mass-media campaigns					<u><i>university/ college</i></u> 1 RCT   Mahler 2007 (rated +)	
	Printed materials					<u><i>university/ college</i></u> 1 RCT   Mahler 2007 (rated +)	
	New media						

**Table 7 Coverage of analysed studies on three-component interventions by intervention, comparator, population and setting**

		Verbal advice + Printed materials + New media		Verbal advice + Mass media + Printed materials	
		Children	Adults	Children	Adults
Comparator	Current provision of information / do nothing		1 RCT   <u>recreation site</u> Walkosz (rated ++)		1 RCT   <u>university/ college</u> McClendon (rated ++)
	Verbal advice				
	Mass-media campaigns				
	Printed materials				
	New media				

### 3.2 Cost-effectiveness

A total of 1288 articles were identified for the cost-effectiveness review of primary prevention of skin cancer. 48 of them were considered relevant and, of these, three papers satisfied the inclusion criteria<sup>21,49,58</sup>. A list of excluded articles with the reason for exclusion can be found in Appendix 10: Economic articles excluded with reason. The main reasons for exclusion were irrelevant study type (32 papers excluded); population (6 articles excluded) and intervention (5 papers excluded). One study was excluded due to being conducted in a non-OECD country, while one study was not considered due to not having access to its full text.

A flow diagram detailing the identification of included studies can be found in Appendix 9: Economic study flow diagram.

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Of the included studies, one (Carter<sup>50</sup>) was classified as of mixed intervention, combining an education strategy with activities not relevant to this review (structural changes including guidelines for workers' sun protection and downward pressure on the price of sunscreens; various sponsorships). However, due to the way the study was carried out, the reported effectiveness results could not be separated to reflect the impact of the education strategy only and thus this study was not analysed.

### 3.3 Studies not analysed in the report

Studies with a mixed-intervention comprising components relevant to this part of the referral and outside of it where it was not possible to disaggregate the data were reported in 34 effectiveness papers (RCT, controlled before and after and before and after) and one cost-effectiveness paper. References to these studies are provided in Appendix 15: Studies not analysed.

Eight controlled before and after studies were identified to be carried out in the same population – setting – intervention combination as a randomised trial and have an equal or shorter follow-up. Therefore they were not analysed. The references to these studies are provided in Appendix 15: Studies not analysed.

Before and after studies with a non-mixed intervention were included, but not analysed after consultation with NICE. They are listed in Appendix 15: Studies not analysed.

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## 4 Effectiveness Findings

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### 4.1 Theme 1: Verbal advice vs. Current provision of information/do nothing

#### 4.1.1 Studies on prevention in children

##### 4.1.1.1 School based studies in children aged four to seven years

Two randomised trials (Buller 2006a, rated - and Loescher, rated +) and one controlled before and after study (Kidskin, rated +) evaluated group-based verbal advice in children aged four to seven years in a school setting. In all studies interventions were cluster allocated. The number of participants in Buller 2006a was not clear for this age group. Loescher included 150 children and Kidskin 1221. Both randomised trials were set in the USA – Buller 2006a in Arizona and there were no details provided for Loescher. Kidskin was conducted in the Perth area, Australia. All studies evaluated a school curriculum, but they differed with regard to the time over which it was delivered. Loescher investigated an intervention delivered in three sessions of approximately 45 to 50 minutes. In the Buller 2006a study a curriculum was taught over six weeks. Kidskin investigated an educational intervention taught over the longest period of time - four years (four to six sessions each spring) and it also had the longest follow-up of six years. In the randomised studies participants were followed-up for seven weeks (Loescher) and from February to April or May of the same year (Buller 2006a).

The evidence from randomised studies seems inconsistent. Both assessed changes in knowledge and while in Loescher there was a significant increase in the intervention arm compared to the control group (both at two and seven weeks



after baseline), in Buller 2006a there was also a significant difference in changes, but in the opposite direction. Loescher also evaluated comprehension (understanding instructions) and application (ability to transfer concepts learned in one situation to another situation or setting). For comprehension there was a significantly higher increase in the intervention group compared to controls at both two and seven weeks. For application there was no significant difference between groups and only at seven weeks it appeared that the application score adjusted for baseline differences was marginally higher in the intervention group. Buller 2006a assessed changes in skin tone using a colorimeter but there was no significant difference between study arms (however for children in the control group there appeared to be less skin darkening and redness).

In the Kidskin study there was no significant difference between groups in sun exposure and suntan (measured by skin reflectance) at two years, however it appeared to be marginally lower in the intervention group compared to controls.

At four years this study evaluated the impact of the curriculum on the number of naevi developed. There was no significant difference between groups, but the number of naevi was lower in the intervention group for each anatomical site examined.

There was some statistically significant evidence of reduced naevus development, at six year follow-up, in the intervention group compared with controls in the sub-group analyses of boys. In the, pre-specified, sub-group analysis of boys at the anatomical site of the chest, naevus development was significantly lower in the intervention group compared with controls. A post-hoc, sub-group analysis of boys at the anatomical site of the back also revealed significantly lower naevus development in the intervention group compared with controls. A post-hoc, sub-group analysis of boys at the composite anatomical site of the face and arms revealed lower levels of naevus development in the intervention group compared with controls but the results were not statistically significant.

There was no statistically significant evidence of reduced naevus development, at six year follow-up, in the intervention group compared with controls in the, post-

hoc, sub-group analyses of girls at the anatomical sites of the back, and the composite of face and arms. Naevus development was very similar amongst both groups.

#### 4.1.1.1.1 Buller 2006a<sup>16</sup> - *cluster (class) RCT*

This randomised trial (rated -) assessed the effectiveness of group based verbal advice compared with a do nothing arm. It was carried out, in four elementary schools in Tucson, Arizona, USA. The year of the study was not reported, although it was probably 1996 or 1997 – based on a footnote.

The elementary schools had a minimum of 75 % of Caucasian students. Children in this study were in kindergarten up to fifth grade of elementary school (age was not reported, but was probably 5-11\*). Results were reported for three age groups: kindergarten to first grade, grades two to three, and four to five. There were 434 children in the study. Two hundred twenty seven were given the intervention and 207 the control.

The proportion of female students was not provided for the youngest group. For children in second and third grades it was 53% in the intervention and 49% in the control group. In fourth and fifth grades 54% students in the intervention and 39% in the control arm were female. Race was not reported for the youngest children. In the second and third grades 71% were white in both study arms. In the fourth and fifth grades 72% were white in the intervention group and 77% were white in the control group.

The investigated intervention (“*Sunny Days, Healthy Ways*”) was delivered during a six-week period and contained four age-appropriate units – “*Living with Sunshine*”, “*Limiting Time in the Sun*”, “*Wearing Cover-up Clothes*” and “*Using Sunscreen*” – designed to be taught in four one-hour class periods. Materials

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\* Based on the typical age in the American education system<sup>2</sup>

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included two storybooks, a limited number of activity sheets that taught curriculum content and used animated characters. Activities incorporated knowledge and skills from different areas (such as health or reading).

The kindergarten and first grade component “*contained 2 storybooks and a limited number of activity sheets that taught curriculum content.*” Kindergarten through third grade “*components included animated characters (...). The components for grades 2-3 and 4-5 contained multiple activity sheets with activities, games and puzzles; the 4-5 component included cards with UVR sensitive ink and activities using computers.*”

Researchers conducted a 1.5-hour training session for teachers prior to the commencement of the study. It included an overview of the project, research procedures and of the curriculum along with a demonstration of classroom activities.

The control group was given no intervention. Teachers in this group were trained on consenting and testing procedures.

Three different questionnaires were used to measure knowledge in children in the following groups: kindergarten to first grade, second to third grade, fourth to fifth grade. For the youngest group a four-item photographic test was used. It contained four pairs of photographs labelled “A” or “B” that were presented to children. Children were then asked to indicate which photograph demonstrated appropriate sun safety behaviours. Eleven simple questions with dichotomous answers were also added for children in randomised study arms. Questionnaires with three possible answers (“yes”, “no”, “don’t know”) were used in older children. For second and third grade children they consisted of 30 items, and for fourth and fifth – of 35 items.

Authors report that some items in questionnaires for children in second grade and older differed between study arms.

Additionally children’s skin tone was measured with a colorimeter (outside lower arm vs. inside upper arm) on 3 scales:

- 
- Light-dark (L): lower scores indicating more skin darkening and exposure to UVR,
  - Blue-yellow (b): higher scores indicating more skin darkening and exposure to UVR,
  - Red (a): higher scores indicating more skin redness and exposure to UVR.

This measure was used to provide information on sun exposure following the intervention.

Children's solar protection was assessed with 13 questions. Protective behaviour by parents was measured by 8 questions. Possible answers in both categories were: "always", "sometimes" and "never". A higher score indicated safer behaviour in both cases. Behaviour was assessed only in children from second grade or older.

This study also investigated the change in participants' attitude towards sun protection, but only in children from second grade and above. A score was constructed based on questionnaires consisting of seven items for second and third grade students and 10 items – for fourth and fifth grades (possible answers to each question were: "yes", "no", "maybe"). A higher score indicated a more favourable attitude towards sun protection.

Children were first tested in February, before the intervention, and after completion of the curriculum in April and May.

## Results

Only results for children from kindergarten through first grade are reported in this section. Results for the remaining age groups are reported in section 4.1.1.2.3.

### *Primary outcomes*

Knowledge about appropriate sun-safety behaviours score was 3.71 in the intervention and 3.30 in the control group at pre-test. At follow-up it was 3.90 and 3.79 respectively. A test for difference between mean changes provided evidence

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of a significantly ( $p=0.047$ ) smaller increase in the intervention compared to the control group. The difference between groups in the follow-up test was not significant. Authors tried to explain this counterintuitive result by suggesting that the test used in this study was not sensitive enough and/or that there was a ceiling effect, as mentioned below.

Skin tone was measured on three scales. At baseline children's average skin tone measured on the light-dark "L" scale was -5.76 in the intervention and -5.48 in the control group. At follow-up the scores indicated more skin darkening and were -7.66 and -7.16 respectively. There was no significant difference between groups in the mean change of skin tone ( $p=0.659$ ). On the blue-yellow "b" scale, children's baseline skin tone was 4.26 in the intervention and 4.30 in the control group. At follow-up it increased to 5.26 and 5.18 respectively, indicating more skin darkening (difference in change was not significant,  $p=0.721$ ). Skin tone measured on the red "a" scale was 2.77 in the intervention and 2.56 in the control group. When tested at follow-up the scores showed more redness and were 3.72 and 3.48. The difference between groups in mean change was not statistically significant ( $p=0.908$ ).

Solar protection and attitude were not measured in this age group.

### *Secondary outcomes*

No secondary outcomes relevant to this review were reported.

### **Limitations**

Internal validity was rated "-". Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

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Probably applicable only to population or setting included in the study – the success of broader application is uncertain.<sup>†</sup>

The authors stated that it is possible that the knowledge test for children from kindergarten through first grade was not sensitive enough or there was a “ceiling effect” which contributed to the counterintuitive better results in the control group. It is also suggested that follow-up might have been too short to detect changes in attitudes. Non-equivalence of some measures at baseline was stated. Several of the measures used were self-reported - only the knowledge test and colorimeter measurements can be perceived as somehow objective. Colorimeter measures are, however, subject to reliability errors which can be also viewed as a limitation to this study. Finally, authors indicate that there was a possibility of a seasonality effect, as pre-testing took place in winter and post-testing in spring when there is higher sun intensity and higher temperature, which could have had influence on reported behaviours and attitudes.

Additionally it was observed that there was no demographic information provided for children in kindergarten and first grade, therefore it is not possible to tell if groups were similar at baseline. It was not reported if an intention to treat analysis was carried out: 30 children did not complete the follow-up questionnaire, but no information is provided if they were included in the analysis. Attitude and solar protection were not measured in this age group.

Applicability of results might be limited because of the location of this study.

Classes were the unit of randomisation, hence it is possible that there might have been some contamination with children from the same school allocated to different study arms. Furthermore, reported methods of analysis do not indicate that clustering was sufficiently adjusted for.

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<sup>†</sup> Rated differently for children in kindergarten and first grade because of missing information for this group

**Evidence statement**

An American RCT (rated -) included children in kindergarten and first grade of elementary school (number of children in these two arms was not clearly stated). They were provided with “*Sunny Days, Healthy Ways*” curriculum delivered during a six-week period and containing four age-appropriate units – “*Living with Sunshine*”, “*Limiting Time in the Sun*”, “*Wearing Cover-up Clothes*” and “*Using Sunscreen*” – all designed to be taught in four one-hour class periods. Materials included two storybooks and a limited number of activity sheets. Activities incorporated knowledge and skills from different areas (such as health or reading). Outcomes were first measured in February and then in April or May.

This study provided evidence that knowledge increase in the intervention group was significantly lower than in the control group ( $p=0.047$ ). There was also a smaller change in skin tone in the control group than in the intervention arm indicating less skin darkening and redness. This difference was however not statistically significant ( $p=0.659$  for “L” scale,  $p=0.721$  for “b” scale and  $p=0.908$  for “a” scale). Probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Buller 2006a<sup>16</sup>)

#### 4.1.1.1.2 Loescher<sup>60</sup> - *cluster (class) RCT*

This study (rated +) was carried out in 12 American preschools. Further details about the location or study year were not provided.

Four to five year old children able to understand English and whose parents were able to read and understand English were included in this study. The intervention group comprised six classes with 70 children. The mean age was 4.9 years (SD 0.4) and 61% of the group was female. 60% of children in this group were white, 17% Hispanic and 23% of other race or ethnicity. In the control group there were

also six classes - with 80 children (mean age 4.7 (SD 0.4), 38% female). 69% of the children were white, 12% Hispanic and 19% were reported as other race or ethnicity.

The intervention began with education for class teachers which comprised: *“materials for the teacher that review tanning, the ultraviolet spectrum, skin, skin cancer, and skin cancer risk factors.”*

Three teaching units (45 to 50 minutes) addressing simple sun-safety concepts *“(cover up, find shade and ask for sun-safe things) were consistently structured and contained teacher information, purpose and objectives, materials available for loan, classroom and take-home activities, key words, and learning resources. Interactive activities included a puppet show, sun safety classification games, art activities, and sun safety songs and storybooks. Throughout the activities, key characters Sunny the Bear and Shadow the Frog conveyed and reinforced sun-safe messages.”* An exact duration of the program was not provided, but it was probably approximately two weeks.

The control group was given no intervention.

Children’s knowledge, defined as *“the ability to recall or remember the specifics of instruction”* was measured. Additionally comprehension (*“understanding of instruction, which was shown by making use of ideas without relating them to other situations”*) and application (*“ability to transfer the concepts learned in one situation into another situation or setting”*) was investigated. These three qualities were assumed to represent *“increasing levels of cognition”* in children.

Children were followed-up for seven weeks (with two post-intervention tests: two and seven weeks after baseline).



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## Results

Unadjusted baseline results were reported separately for children who participated in the first and in the second post-test. Comparisons between mean scores adjusted for baseline results were made for both follow-up times.

### *Primary outcomes*

Children who took part in the two-weeks post-test (52 in the intervention and 65 in the control group) had a mean baseline knowledge of sun safety score of 2.5 (SD 1.2) in the intervention and 2.1 (SD 1.3) in the control group. The follow-up mean scores were 3.1 (SD 1.2) and 2.3 (SD 1.4) respectively. The adjusted mean post-test score was significantly higher in the intervention than in the control group ( $p=0.01$ ). In children who took part in the seven week follow-up test (52 in the intervention and 57 in the control group) at baseline the mean knowledge score was 2.4 (SD 1.1) in the intervention and 2.0 (SD 1.3) in the control group. At post-test the scores were 3.2 (SD 1.2) and 2.5 (SD 1.3) respectively. After adjustment for pre-test differences, the mean knowledge score was significantly higher in the intervention than in the control group, with  $p = 0.03$ .

The mean comprehension score for children who participated in the first post-test (48 in the intervention and 56 in the control group) at baseline was 1.4 (SD 1.4) in the intervention and 1.4 (SD 1.3) in the control group. At two weeks the mean scores were 3.0 (SD 1.9) and 2.1 (SD 1.6). Adjusted mean post-test scores were significantly higher in the intervention compared to the control group ( $p=0.006$ ). The mean comprehension score in children who participated in the second post-test for the intervention group (42 children) was 1.5 (SD 1.4) at pre-test, and 3.5 (SD 2.5) at post-test, while the mean comprehension for the control group (52 children) was 1.4 (SD 1.5) at pre-test, and 2.5 (SD 1.8) at post-test. Adjusted mean comprehension of sun safety was significantly higher in the intervention than the control group, with  $p = 0.033$ .

In children who participated in the first post-test (31 intervention, 38 control group) the mean application score at baseline was 1.7 (SD 0.8) in the intervention and 1.5 (SD 0.8) in the control group. The adjusted post-test difference was not statistically

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significant ( $p=0.134$ ) and the data provided did not suggest any direction of effect. For participants in the seven week follow-up (35 intervention, 27 control) the mean baseline application score was 1.6 (SD 0.9) in the intervention and 1.5 (0.9) in the control group. At post-test the scores were 2.1 (SD 0.9) and 1.8 (SD 0.8) respectively. The adjusted mean application of sun safety score did not significantly differ between the two groups, with  $p = 0.322$ . There was a slightly higher increase in the unadjusted mean score in the intervention group than in the control group.

### *Secondary outcomes*

No secondary outcomes relevant to this review were reported.

### **Limitations**

Internal validity was rated “+”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

The authors indicated that the use of self-reported measures might be a limitation, as they are susceptible to problems of guessing and of responding to questions in a particular direction. It was also stated that there was no direct observation. There was no possibility to compare children who participated with those who did not with regard to demographic information and family health motivation.

The percentage of female students was the only characteristic that appears to differ between groups at baseline. Analysis was performed only on the sample of children who participated in at least one of the follow-up tests therefore it was not intention to treat. It was not possible to tell if results from all the sites are comparable. Applicability might be limited by the specifics of the American system and authors providing relatively little information about the interventions.

**Evidence statement**

An American RCT (rated +) in 150 children attending preschools aged four to five years evaluated three teaching units (45 to 50 minutes) addressing simple sun-safety concepts (“*cover up, find shade and ask for sun-safe things*”). The units “*were consistently structured and contained teacher information, purpose and objectives, materials available for loan, classroom and take-home activities, key words, and learning resources. Interactive activities included a puppet show, sun safety classification games, art activities, and sun safety songs and storybooks.*”

This study provided evidence of a higher adjusted post-test level of sun safety knowledge in participants in the intervention group compared to controls (p=0.01 for two weeks and p = 0.03 for seven weeks follow-up). The mean comprehension was higher in the intervention group compared to controls (p=0.006 at two weeks and p = 0.033 at seven weeks follow-up). There were no significant differences in application of sun safety at both follow-up times and only in the seven weeks follow-up it appeared that the increase in the intervention group was higher than in the control group (p = 0.322 was provided for the difference in adjusted scores only). Probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Loescher<sup>60</sup>)

#### 4.1.1.1.3 Kidskin<sup>33,34,69-73</sup> - *cluster (geographic area) controlled before and after study*

This controlled before and after study (rated +), undertaken during 1995-2001, assessed the effectiveness of group-based verbal advice provided as part of the school curriculum for first grade children. Thirty three schools with 50 or more first-grade students located within 30km of the centre of Perth, Western Australia took part.

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Children (numbers at baseline: overall=1,623; high intervention group=402 (results not assessed in this report); moderate intervention group=472; control group=749; moderate intervention group + control group=1221) were aged five to six years at baseline, approximately 47% were female and all were of European ethnicity as non-European children were excluded. Details of socioeconomic status were not reported.

Schools in the 'moderate' intervention arm are the focus of this report. These schools taught a specially designed sun-protection curriculum over four consecutive years (1995-1998). The materials taught in each grade were age-specific and included both classroom and home-based activities. They were delivered in four to six 40-minute sessions during the spring of each year. Children were encouraged to reduce their sun exposure by staying indoors during the middle of the day and by protecting themselves when outdoors by staying in the shade and wearing sun-protective clothing, hats and sunscreen.

NB: The study also had a 'high intervention' arm however, as this group were offered low-cost sun-protective swimwear, a component that could not be disaggregated, the results are not included.

Control schools taught the standard Western Australian health education curriculum.

Naevi were counted in winter to minimise confusion with freckling. Observers were trained according to the International Agency for Research on Cancer protocol for identifying and recording naevi. Under bright light, the observers counted the number of naevi on each child's face and arms. Slides of each child's back, and boy's chests, were taken using professional photographic equipment. Anatomic landmarks were marked on children's skin so that the areas on which naevi were to be counted later could be identified on the slides.

All slides of each child's trunk were projected side by side on a whiteboard. An experienced observer, blind to study group, identified and marked all pre-existing naevi on the baseline slide and new naevi on the 1999 and 2001 slides. Naevi that had disappeared from the later slide were also marked, and any excisions noted.

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The observer also indicated whether factors such as freckling or poor slide quality made counting difficult. Standard diagrams were used to assess the level of freckling on the face and arms and on the shoulders when the slides of the back were compared.

In 1999 (four-year follow-up), naevi on randomly selected pairs of slides were counted twice by the same observer, a dermatologist also counted naevi from randomly selected pairs of slides. Each time naevi on the face and arms were counted, randomly selected children were assessed twice, either by the same observer or two different observers, at least 15 minutes apart<sup>73</sup>.

In 2001 (six-year follow-up), the dermatologist counted naevi from 47 randomly selected triplets of slides. Each time naevi on the face and arms were counted, a random sample was assessed by two observers<sup>33</sup>.

The level of freckling on the face and arms was estimated whenever naevi were counted, and freckling on the shoulders was assessed when the two slides of the back were compared. Winter freckling on the face, arms, and shoulders was scored between 0 (none) and 10 (very heavy).

Skin reflectance was measured in winter 1995 on the inner surface of the arm to assess constitutional colour. To assess the degree of suntan, skin reflectance was measured on the back and dorsal surface of the forearm in February 1997 (end of 1996/1997 summer). Trained observers took two reflectance measurements (at 425nm) on each site using one of two identical reflectance spectrophotometers. Reflectance is inversely related to degree of skin pigmentation, and reflectance near this wavelength is strongly correlated with melanin density. All five observers measured reflectance on 20 randomly selected children at one school.

In late winter 1995 and at the end of the 1996/1997 summer, parents were mailed questionnaires that asked about their child's sun-related activities over the previous summer vacation. Follow-up questionnaires were mailed to parents in 1997 asking them to estimate the number of days their child went to the beach or to an outdoor swimming pool during the vacation. They were also asked about the days and times their child played outside around the home, the proportion of time

their child wore a hat or sunscreen, stayed in the shade, or had his/her back covered by clothing at each venue and the types of clothing, swimwear, and hats worn.

Two, four and six year follow-up was undertaken.

## Results

### *Primary outcomes*

Naevi were assessed at baseline, and naevus development was assessed at four and six-year follow-up.

At four-year year follow-up naevus development on the back was assessed in 86% (n=1045) of children in the moderate intervention and control groups. Similar numbers were assessed for naevus development at other anatomical sites. No significant differences were reported between the groups at four years,<sup>73</sup> see Table 8 Naevus counts at baseline and 4-year follow-up: Kidskin 1995-1999 below:

**Table 8 Naevus counts at baseline and 4-year follow-up: Kidskin 1995-1999**

Anatomic site	Control group		Moderate intervention group		p value
	No.	Value	No.	Value	
<b>Back (n=1045)</b> Adjusted mean 1995*, § Adjusted mean 1999± Ratio of means (95% CI) ¥	629	4.0 7.3	416	3.6 6.8 0.94 (0.88-1.00)	NS
<b>Chest (boys only, n=555)</b> Adjusted mean 1995§ Adjusted mean 1999± Ratio of means (95% CI) ¥	328	3.3 6.3	227	3.4 6.0 0.95 (0.87-1.04)	NS
<b>Face (n=1076)</b>	646	4.2	430	4.4	

Adjusted mean 1995#		6.0		5.4	
Adjusted mean 1999\$				0.89 (0.79-1.00)	NS
Ratio of means (95% CI) ¥					
<b>Arms (n=1075)</b>	646		429		
Adjusted mean 1995#		9.2		9.8	
Adjusted mean 1999\$		14.1		13.0	
Ratio of means (95% CI) ¥				0.92 (0.83-1.01)	NS

\* All adjusted means are geometric means of 'naevi + 1'; § adjusted for month of observation. ± Adjusted for sex, tendency to sunburn, southern European ethnicity, parental education, hair colour, inner arm reflectance, baseline naevus count, month of observation in each year, and month95 x month99. ¥ intervention group mean divided by control group mean. # Adjusted for month of observation and observer. \$ Adjusted for sex, tendency to sunburn, southern European ethnicity, parental education, hair colour, inner arm reflectance, baseline naevus count, observer in each year, month of observation in each year, and month95 x month99

At six-year year follow-up naevus development on the back was assessed in 66% (n=809) of children in the moderate intervention and control groups (numbers assessed for naevus development at other anatomical sites were not reported).

Primary analyses at six years indicated there were no significant differences between the groups in naevus development on the back, and on the face and arms combined. However the, pre-specified, primary analysis of naevus development on the chest, for boys only, indicated significantly higher naevus counts amongst the control group at six years. The authors<sup>33</sup> stated the observation of a statistically significant association at this anatomical site prompted them to undertake secondary analyses of sub groups for girls and boys at the other anatomical sites: back, and face and arms combined. These, post hoc, analyses indicated that for boys in the control group naevus counts on the back were significantly higher, but there were no significant differences at this site for girls. No significant differences were observed between the groups when the face and arms were examined in the sub-group analyses for boys and for girls. See Table 9 Naevus counts at baseline and 6-year follow-up: Kidskin 1995-2001 below:

**Table 9 Naevus counts at baseline and 6-year follow-up: Kidskin 1995-2001**

Anatomic site	Control group		Moderate intervention group		p value
<b>Primary analyses\$</b>					
<b>Back (n=809)</b>	<b>Value</b>	<b>No</b> 471	<b>Value</b>	<b>No</b> 338	
Baseline mean¥	3.5		3.0		
Mean at end¥	10.1		8.2		
Ratio of change * (95% CI)	1.0		0.94 (0.86-1.04)		NS
<b>Chest (boys only)</b>					
Baseline mean	2.7		2.5		
Mean at end	8.6		7.1		
Ratio of change (95% CI)	1.0		0.88 (0.80-0.97)		<0.05
<b>Face and arms</b>					
Baseline mean	14.7		15.3		
Mean at end	25.2		23.8		
Ratio of change (95% CI)	1.0		0.91 (0.81-1.02)		NS
<b>Secondary analyses\$\$</b>					
<b>Back (boys)</b>					
Baseline mean	3.5		3.2		
Mean at end	11.4		9.1		
Ratio of change (95% CI)	1.0		0.88 (0.87-0.97)		<0.05
<b>Back (girls)</b>					
Baseline mean	3.5		2.8		
Mean at end	9.1		7.5		
Ratio of change (95% CI)	1.0		1.00 (0.89-1.13)		NS
<b>Face and arms (boys)</b>					
Baseline mean	15.2		15.7		
Mean at end	25.7		23.0		
Ratio of change (95% CI)	1.00		0.86 (0.75-1.00)		NS
<b>Face and arms (girls)</b>					
Baseline mean	14.1		14.8		
Mean at end	24.5		25.1		
Ratio of change (95% CI)	1.00		0.98 (0.85-1.13)		NS



¥ Least-squares mean naevi + 1 from mixed model with covariate values set to baseline distribution of all participants. All models included fixed effects for melanin density of inner arm, hair colour, and sex. School level random effects included intercept alone (back: both sexes combined and chest); slope alone (back: boys); intercept, slope and covariance (all other analyses). \* Figures are relative changes from baseline to end of follow-up in the adjusted geometric mean number of naevi + 1 in the intervention group relative to that in the control group. \$ The numbers assessed for anatomical sites other than the back in the primary analyses were not reported. \$\$ The numbers assessed at each anatomical site in the secondary analyses were not reported.

Winter freckling ratings on the face, arms and shoulders were similar amongst the groups both at baseline and the four-year follow-up.<sup>73</sup> No statistically significant differences were reported, see Table 10 Winter freckling ratings at baseline and 4-year follow-up: Kidskin 1995-1999 below:

**Table 10 Winter freckling ratings at baseline and 4-year follow-up: Kidskin 1995-1999**

Year and site	Control group*		Moderate intervention group*	
	Mean	95% CI	Mean	95% CI
<b>1995</b>				
Face	2.5	2.3-2.7	2.3	2.1-2.6
Arms	1.2	1.1-1.4	1.0	0.8-1.2
Shoulders	0.1	0.07-0.15	0.05	0.0-0.1
<b>1999</b>				
Face	3.7	3.7-4.0	3.7	3.4-4.1
Arms	2.3	2.1-2.5	2.2	2.0-2.4
Shoulders	0.6	0.5-0.7	0.4	0.3-0.6

NB: Winter freckling was scored between 0 (none) and 10 (heavy). \* numbers assessed not reported

Adjusted mean percentage skin reflectance, used as measure of suntan, at 2-year follow-up,<sup>72</sup> on the two exposed anatomic sites, was not significantly different amongst the moderate intervention and control groups. See Table 11 Skin reflectance (percentage) at 2-year follow-up: Kidskin 1995-1997 below:

**Table 11 Skin reflectance (percentage) at 2-year follow-up: Kidskin 1995-1997**

	Control group (n=513)	Moderate intervention group (n=391)
<b>Forearm</b>		
Adjusted mean	22.7	23.8
Difference relative to control group (95% CI)		1.1 (-0.2 to 2.5), NS
<b>Back</b>		
Adjusted mean	34.7	36.2
Difference relative to control group (95% CI)		(1.5 (-0.1 to 3.2), NS)

NB: skin reflectance is inversely related to degree of skin pigmentation

Sun exposure index and total time spent outdoors were expressed as 'midday minute equivalents' (MMEs). Adjusted means at 2-year follow-up were not significantly different amongst the moderate intervention and control groups,<sup>72</sup> see Table 12 Sun exposure index and total time outdoors in MMEs per day at 2-year follow-up: Kidskin 1995-1997 below:

**Table 12 Sun exposure index and total time outdoors in MMEs per day at 2-year follow-up: Kidskin 1995-1997**

	Control group (n=485)	Moderate intervention group (n=347)
<b>Sun exposure index</b>		
Median (SD) 1995	18.2 (23.9)	17.2 (21.7)
Median (SD) 1997	8.0 (18.5)	6.6 (14.5)
Adjusted mean 1997	8.4	7.6
Ratio to control group (95% CI)		0.90 (0.78-1.1), NS
<b>Total time outdoors</b>		
Median (SD) 1995	117.0 (60.8)	105.6 (53.9)
Median (SD) 1997	80.2 (63.7)	69.6 (58.5)
Adjusted mean 1997	66.0	66.1
Ratio to control group (95% CI)		1.00 (0.88-1.1), NS

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### *Secondary outcomes*

No secondary outcomes relevant to this review were reported.

### Limitations

Internal validity was rated “+”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment

Applicable only to populations or settings included in the studies, the success of broader application is uncertain.

The participants may have been too old at recruitment for the Kidskin intervention to have a major impact on the development of naevi. It is possible that not enough time elapsed for behaviour change to protect against naevus development.<sup>73</sup> The study was not randomised and there were baseline differences between the groups.<sup>33</sup> Loss to follow-up at six-years may have compromised validity.<sup>33</sup>

Selection bias cannot be discounted given the non-random allocation of the control and intervention group clusters. The generalisability of the results of the study to groups other than those of European ethnicity is unclear. Substantial additional losses to follow-up between the four and six-year assessments (approximately 23%) created baseline differences amongst the groups examined in 1999 and 2001. These differences in the samples examined at four and six-years raise problems in comparing the 1999 and 2001 results. The possibility that benefits reported at six years, but not evidenced at four years, may relate to differences between the groups selected for examination at the different time points should be considered.

#### **Evidence statement**

An Australian controlled before and after study (rated +) evaluated the effectiveness of a sun-protection curriculum delivered over four consecutive years

(1995-1998) to 1221 children aged 5-6 years at baseline. The materials taught in each grade were age-specific and included both classroom and home-based activities. They were delivered in four to six 40-minute sessions during the spring of each year. Children were encouraged to reduce their exposure to the sun by staying indoors during the middle of the day and by protecting themselves when outdoors by staying in the shade and wearing sun-protective clothing, hats and sunscreen.

There was no statistically significant evidence of reduced sun-exposure, at two year follow-up, in the intervention group compared with controls. However sun-exposure was marginally lower in the intervention group.

There was no statistically significant evidence of reduced levels of suntan (assessed by measuring skin reflectance), at two year follow-up, in the intervention group compared with controls. However levels of sun tan were marginally lower in the intervention group.

There was no statistically significant evidence of reduced naevus development, at four year follow-up, in the intervention group compared with controls. However naevus development at each anatomical site examined (back, chest (boys only), face and arms) was lower in the intervention group.

There was no statistically significant evidence of reduced naevus development, at six year follow-up, in the intervention group compared with controls in the pre-specified, analyses examining both sexes together. However naevus development at each anatomical site examined (back, and a composite of face and arms) was lower in the intervention group.

There was some statistically significant evidence of reduced naevus development, at six year follow-up, in the intervention group compared with controls in the sub-group analyses of boys. In the, pre-specified, sub-group analysis of boys at the anatomical site of the chest, naevus development was significantly lower ( $p < 0.05$ ) in the intervention group compared with controls. A post-hoc, sub-group analysis of boys at the anatomical site of the back also revealed significantly lower ( $p < 0.05$ ) naevus development in the intervention group compared with controls. A post-hoc,

sub-group analysis of boys at the composite anatomical site of the face and arms revealed lower levels of naevus development in the intervention group compared with controls but the results were not statistically significant.

There was no statistically significant evidence of reduced naevus development, at six year follow-up, in the intervention group compared with controls in the post-hoc, sub-group analyses of girls at the anatomical sites of the back, and the composite of face and arms. Naevus development was very similar amongst both groups.

Applicable only to populations or settings included in the studies, the success of broader application is uncertain. (Kidskin<sup>33,34,69-73</sup>).

#### 4.1.1.2 School based studies in children aged seven to eleven years

Four RCTs (Buller 1994, rated -, Buller 1997, rated -, Buller 2006a, rated -, and Hornung, rated +) and one controlled before and after study (Hewitt, rated -) investigated the effectiveness of group-based verbal interventions in a school setting in children aged seven to 11 years. All were cluster-allocated. The number of participants in this age group in Buller 2006a was unclear. In the remaining studies the numbers of participants were: 130 in Hornung (only for two arms comparing verbal advice to do nothing), 139 in Buller 1994, 209 in Buller 1997 and 454 in Hewitt. Different curricula were evaluated in all studies apart from Buller 1997 which assessed an interactive sun safety fair. In this study children were educated both on how to prevent and detect skin cancer. Buller 1994 investigated the effectiveness of “*Sunshine and Skin Health*”, which was an earlier version of “*Sunny Days Healthy Ways*” evaluated in Buller 2006a. All randomised studies were set in Arizona, USA apart from Hornung which was carried out in North

Carolina, USA. The controlled before and after study was set in Nottinghamshire, UK. The period during which the intervention was delivered was not clear in two studies evaluating curricula and in the remaining was five (Buller 1994) and six (Buller 2006a) weeks. The health fair was held during a single day and classes visited it for 45 to 90 minutes. Follow-up differed across studies and ranged from six weeks (Hewitt) to seven months (Hornung). The remaining studies reported a follow up of: eight weeks (Buller 1994), three months (Buller 1997) and from February to April or May (Buller 2006a).

All randomised studies evaluating curricula reported a significant increase in knowledge in intervention groups compared with controls. In the controlled before and after study there was also a significant positive effect on knowledge compared to the control group, but only in children whose education was based on a workbook and not on a computer program (there was however a non-significant increase). In two randomised trials the change in self-reported behaviours was not significant (there was no obvious direction of effect in Buller 2006a and in Hornung it appeared that the score in the control group was more favourable). In Buller 1994 there was a significant improvement in the curriculum arm in five out of 11 evaluated behaviours, this was however not consistent across immediate post-test and the end of the study. Buller 2006a measured changes in skin tone using a colorimeter, there was however no consistent direction of effect.

The sun safety fair (Buller 1997) was reported to increase children's knowledge compared to the control condition. There was no significant difference for self-reported sun protective behaviours. Child-reported parent behaviours adjusted for baseline were significantly more sun protective in the sun fair arm immediately after the intervention, but not three months later.

#### 4.1.1.2.1 Buller 1994<sup>18</sup> - *cluster (school) RCT*

One hundred and thirty nine children in grades four to six in two public elementary schools in Mesa, Arizona, USA were enrolled in this trial (rated -) which took place in 1992.

Age was not reported, but was probably 9-11<sup>‡</sup>. Gender and race/ ethnicity were not stated. The authors did not provide numbers of participants allocated to study arms.

*“Sunshine and Skin Health”, which in a later publication was referred to as an earlier version of “Sunny Days Healthy Ways” curriculum<sup>15</sup>, consisted of five multidisciplinary units (one unit taught each week over five weeks) “that synthesise material from science, history, social studies, health and geography into a comprehensive cause and-consequence presentation about man’s relationship with the sun. The properties of the sun, the composition of human skin, historical attitudes toward tanning, skin cancer, and sunlight awareness strategies (skin cancer prevention) are covered in an interactive lesson/activity format. Each unit contains lesson material, in-class activities, take-home activities, a glossary of key terms, a quick review, and a student-parent newsletter. Suggestions for spreading the sun-safety message throughout the school are presented. The time needed to present the lesson material and in-class activities for each unit is approximately one hour. The times to complete take-home activities and school projects vary according to the activities.”*

*“The comprehensive and academically-oriented curriculum was developed through the collaboration of health communication experts, dermatologists, teachers, and curriculum consultants.”*

A two-hour training session for teachers took place before implementing the intervention.

The comparator was not reported – probably do nothing/ current practice.

An 84-item questionnaire which took approximately 20 minutes to complete was used to measure study outcomes. It included questions on: knowledge of the

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<sup>‡</sup> Based on the typical age in the American education system<sup>2</sup>

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relationship between exposure to sunlight, preventive behaviour, and skin cancer (35 items), attitudes towards preventive behaviour (11 items), implementation of favourable behaviour (14 child-behaviour items on 11 behaviours and eight parent-behaviour items), vocabulary recognition (10 items), and demographic characteristics (seven items).<sup>§</sup>

The study was carried out from January to May 1992. Children were first tested one week before the intervention. The first post-test was conducted at the end of the intervention and the second - eight weeks later.

## Results

Although participants were tested before the intervention was delivered, only results for two post-tests (at the end of the intervention and eight weeks later) were provided. Authors did not report results for all investigated outcomes. When results were reported without division by grade, only information on significant effects ( $p < 0.05$ ) of the curriculum was provided. However when the results were stratified by grade, no clear explanation was given for choosing certain outcomes, therefore stratified data is not discussed in this section, but can be found in Table 29 Buller 1994.

### *Primary outcomes*

Knowledge was reported to have significantly increased in the intervention group compared to controls. The average number of correct answers to 35 questions was 28.94 in the first post-test in the intervention and 19.37 in the control arm. Eight weeks later the results were 28.86 and 20.32 respectively.

Out of the ten vocabulary items students recognised a mean of 9.70 in the intervention and 7.66 in the control arm immediately after the intervention. At the second post-test the mean in the intervention group was 9.68 and 8.11 in the control group.

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<sup>§</sup> The numbers of items reported actually add up to 85



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Results for only six out of 11 sun protective behaviours were provided. Wearing sunscreen in winter was significantly increased in the intervention compared to the control condition (1.40 in intervention and 1.25 in control at first post-test, 1.51 and 1.33 at second post-test). In the first post-test students in the intervention group were less likely to lie out in the sun to get a tan (1.57 in the intervention group and 1.93 in the control group) – a significant difference that was however not observed eight weeks later. Only in the second post-test was lip balm used more often in the curriculum group (3.85 in the intervention and 3.46 in the control group). Wearing protective clothing in the summer was reported for the first post-test only as stratified by grade. In the second post-test it was more frequently reported in the curriculum (mean 1.71) than in the control condition (mean 1.34). Wearing sandals in the summer was more frequent in the control group (mean 2.06) than in the intervention group (1.92), but only in the second post-test. Sunscreen use was reported only for the first post-test and only stratified by grade.

Parent protective behaviour was not reported.

### *Secondary outcomes*

Out of 11 items assessing attitudes related to skin cancer, results were reported only for seven (comprising four categories of outcomes). In both post-tests less students in the curriculum condition agreed that tan makes them look and feel better. They were also less likely to believe that having a tan is in style. Barriers to sunscreen use and a positive attitude to the colour of one's skin untanned were reported only stratified by grade.

### **Limitations**

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

Authors highlighted that this study relied only on self-reported measures. The sample size was relatively small and clustering effects were not taken into account.

This study did not report characteristics of participants, baseline results and numbers of participants allocated to each arm. Due to poor reporting it was not possible to tell if groups were similar at baseline, what the drop-out rate was in each arm, or if results were comparable for different sites. Intention to treat analysis was not undertaken. Another limitation of this study is that only two schools were randomised. Applicability of the results of this study might be additionally limited by choice of a location with high UV radiation levels.

#### **Evidence statement**

An American RCT (rated -) in 139 children evaluated “*Sunshine and Skin Health*” curriculum which consisted of five multidisciplinary units (one unit taught each week over five weeks) “*that synthesise material from science, history, social studies, health and geography into a comprehensive cause and-and-consequence presentation about man’s relationship with the sun.*” Children were tested one week before the intervention, immediately after the intervention and eight weeks later.

It provided evidence of a significant increase in knowledge in children in grades four, five and six of elementary school in the intervention group compared to controls in both post-tests (significance levels were not reported). It also provided evidence of increased recognition of terms in the intervention group, and a positive change in five (wearing sunscreen in winter, lying out in the sun to get a tan, lip balm use, wearing protective clothing in the summer, wearing sandals in the summer) of the 11 investigated behaviours but not always for immediate and eight week follow-up (significance levels were not reported). Although the study assessed parent protective behaviours, results were not provided. Probably

applicable only to population or setting included in the study – the success of broader application is uncertain. (Buller 1994<sup>18</sup>)

#### 4.1.1.2.2 Buller 1997<sup>17</sup> - *cluster (school) RCT investigating an intervention on prevention and detection*

This trial (rated -) was set in Tucson, Arizona, USA and carried out in 1993. Three hundred and eighteen children from fourth-grade classes in public elementary schools were enrolled. One hundred and nine participants were allocated to a mixed arm which is not in the scope of this report. One hundred and five children were randomised to have a health fair in their school and 104 to the control group.

Age was not reported, but taking into account the characteristics of the American education system it is probably nine to ten years.<sup>2</sup> Demographic characteristics were provided for all participants including the mixed arm, separately for each test. In the immediate post-test 56% participants were female and three months later – 58% were female. Race and/or ethnicity of students participating in the first and second post-test was: Asian or Oriental (4% in both), Black (2%, 1%), Hispanic (4%, 3%), Native American (2%, none), White (75%, 77%), Indian (3% in both), Other (10%, 12%).

An interactive sun safety fair was organised and classes visited it for around 45-90 minutes. It featured eight activity stations: “(1) *Sun Safety Pursuit: a life-size board game quiz*; (2) *“The Sun Cowboy and Pale Face” puppet show and activity book*; (3) *Block It Out: a physical and chemical sunblocks display*; (4) *The Truth About Tanning: a presentation of the effects of sun overexposure*; (5) *Cover-up: a game about sun-safe clothes, sunglasses and hats*; (6) *Sun Safety Videos*; (7) *Lighten Up: a presentation of the electromagnetic spectrum and ultraviolet light using prisms, a rainbow projector, and slides*; and (8) *Skin Check: a dermatologist-taught skin type and skin self-examination.*” Although the programme was

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evaluated only in fourth-graders, *“the school principal required that all grades be invited to the health fair, so some age-appropriate stations were included for younger students (e.g. puppet show, videos).”*

Students had to participate in at least six stations to be eligible for the drawing of three prizes. They were given “passports” to collect stamps at each visited station. When leaving the fair they turned in their “passports” and received an attendance certificate.

*“The fair was held in the school’s Learning Resources Centre (LRC) from 9:00 am to 2:00 pm...”* It needs to be highlighted that apart from receiving information on causes and ways to prevent skin cancer, children were also taught how to perform a skin self-examination.

The comparator was not reported but was probably do nothing/ current practice.

The *“Sunshine and Your Skin Questionnaire”* was used to evaluate the effectiveness of this intervention – an age-appropriate questionnaire consisting of: *“a 10-item term recognition scale (...) and 35-item true/false knowledge scale(...). The knowledge scale addressed environmental factors (e.g., ultraviolet radiation, latitude, sun intensity, tanning booths), skin (type, layers, moles), and skin cancer (screening, treatment, and prevention strategies). The attitude scale also contained 11 items measuring attitudes towards tanning (...), barriers to sunscreen use (...), and stylishness of tans (...). Thirteen questions measured intentions to reduce sun exposure through sunscreen use (...), lip balm use (...), and hat use (...). Finally, children reported parental preventive behaviour on an eight-item scale, which was summed into a single index (...).”*

Students were first tested immediately after being exposed to the intervention and then after three months.

## Results

This study compared only post-test results between groups. They were however adjusted for baseline responses. Significance levels were calculated for all three groups (including mixed) therefore they need to be considered with caution.

### *Primary outcomes*

This study showed a significantly higher ( $p < 0.05$ ) adjusted level of skin cancer knowledge in the intervention group compared to controls immediately after the intervention (26.04 and 21.63) and three months later (26.96 and 23.79). The sun fair group had also a significantly ( $p < 0.05$ ) higher adjusted recognition of terms score at the first post-test (9.02 and 8.09) and at the second one (9.32 and 8.54).

None of the skin cancer related behaviours that children reported were found to differ significantly ( $p > 0.05$ ) between groups in either post-test. These behaviours included: hat use, sunscreen use in summer, SPF of the last sunscreen used, extent of sunscreen application and lip balm use. Reporting for this outcome was not entirely clear and it was not possible to tell if there was a direction of effect.

Parents were reported to be doing more to protect their children from the sun in the intervention group immediately after the intervention (16.36 and 15.51,  $p < 0.05$ ), but not in the second post-test (16.72 and 16.16,  $p > 0.05$ ).

### *Secondary outcomes*

Immediately after the intervention participants in the experimental group had a less positive attitude towards tanning than the controls. This effect was however not significant three months later.

There was no significant difference in barriers to sunscreen use and believing that tan is in style in either of the post-tests.

Significantly more parents were reported to perform a skin examination on their children in the intervention group compared to controls in the first post-test. In the second post-test this difference was no longer significant.

## Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

Authors highlighted possible confounding, as only one school was randomised to each arm therefore results may be heavily influenced by the specifics of schools. Authors also pointed out that *“reliability of the recognition of terms, hat use, and barriers to sunscreen use were lower than in an earlier study. (...) The measurement error in these scales attenuated observed effects of the interventions.”*

Individual students were used as unit of analysis and there was no indication of adjustment for clustering effects (only stated that there were very few differences between classes in schools). All outcomes were based on participant reports, which could have biased the results. This could be the reason for student-reported parent behaviour being significantly more in accordance with what was taught during the fair than three months later. Furthermore it was not possible to tell if the groups were similar at baseline, if the only difference was the intervention and if intention to treat analysis was carried out. Significance levels were calculated for all three groups (including mixed) and therefore may not represent actual differences between the two groups relevant to this report. Standard deviations were not reported and therefore it was not possible to calculate the significance of between-group differences. The drop-out rate was high with only 159 children (out of the 232 who attended the pre-test) participating in the three months follow-up test. This study was set in a part of the USA with a high UV radiation level which might limit the applicability of its results.

**Evidence statement**

An American cluster RCT (rated -) investigated the effectiveness of a health fair in 209 fourth grade children in an elementary school compared to controls. Classes took 45 to 90 minutes to visit the fair. It featured eight activity stations and topics included sun safety, sunblocks and skin checking. The activities were: games, a puppet show, videos, a presentation and skin self examination taught by a dermatologist. The first post-test was carried out immediately after the intervention and the second three months later.

It provided evidence of higher adjusted level of knowledge and recognition of terms both immediately after the intervention and at three months follow-up ( $p < 0.05$ ) in the intervention group compared with controls. There was no significant difference between groups in self-reported behaviours ( $p > 0.05$ ) and due to reporting issues it was not possible to tell if there was any direction of effect. Participants in the health fair group immediately after the intervention reported that their parents protected them from the sun more frequently than those in the control group ( $p < 0.05$ ). This difference was however not present three months later ( $p > 0.05$ ). The significance levels were calculated for both intervention arms including a mixed one. Probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Buller 1997<sup>17</sup>)

**4.1.1.2.3 Buller 2006a<sup>16</sup> - *cluster (class) RCT***

This study (rated -) was already discussed in section 4.1.1.1.1. It was carried out in the USA, probably in 1996 or 1997. The population comprised children from kindergarten through fifth grade of elementary school (age was not provided). There were more female students in the experimental than in the control arm. Children's race was predominantly white.

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The intervention (Sunny Days, Healthy Ways) was delivered during a six-week period and contained four age-appropriate units designed to be taught in four one-hour class periods.

Students were first tested in February, before the intervention, and after completion of the curriculum in April and May.

## Results

### *Primary outcomes*

The knowledge score at baseline in second and third grade students was -0.09 in the intervention and 0.11 in the control arm. The post-test scores were 1.17 and 0.40 respectively. The scores in fourth and fifth grade children at baseline were -0.04 in the curriculum and 0.03 in the control condition. At follow-up they were 1.31 and 0.25 respectively. The increase in knowledge in children from second to fifth grade was reported to be significant with  $p=0.0001$ .

Skin tone was measured on three scales as an indicator of exposure to the sun. For children in the second and third grade the average score on the light-dark "L" scale at baseline was -6.85 in the experimental and -6.61 in the control arm. Post-test it was -8.89 and -8.56 respectively. In fourth and fifth graders it changed from -7.68 to -9.89 in the intervention group and from -7.95 to -9.89 in the control group. Decreasing scores suggested more skin darkening in the post-test. The difference in the mean change between study arms in grades second to fifth was not significant ( $p=0.541$ ).

Skin tone in children from second and third grade measured on the blue-yellow "b" scale was 5.18 in the intervention arm and 4.66 in the control arm at baseline and at follow-up it increased to 5.71 and 5.58, indicating more skin darkening. In the oldest age group the "b" score at baseline was 5.48 in the experimental and 5.52 in the control condition. Post-test scores were 6.17 and 6.43 respectively. The



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difference in mean change in children from second to fifth grade was not significant with  $p=0.0697$ .

Chromameter scores on the red “a” scale in second and third grade children at baseline were 3.22 in the intervention and 3.14 in the control arm and increased at follow-up to 3.89 and 3.85 respectively, indicating more skin redness. The oldest children had a baseline score of 3.56 in the experimental and 3.75 in the control arm, which increased at post-test to 4.27 and 4.67 respectively. Differences in change of skin tone on the red “a” scale were not significant in second through fifth grade ( $p=0.490$ ).

Average self-reported solar protection in the experimental arm did not change significantly from baseline compared to controls in second to fifth grade children ( $p=0.529$ ). In the second and third grades it was 2.09 in the intervention and 1.99 in the control group at baseline and 2.08 and 1.96 at follow-up. In fourth and fifth grade children at baseline this score was 2.00 in the intervention and 1.95 in the control group. At follow-up it was 2.01 and 1.98 respectively.

The mean parent solar protection score reported by second and third grade children decreased in the intervention group from 2.04 to 1.92 and in the control group from 1.91 to 1.85. The mean score reported by fourth and fifth grade children changed marginally in the curriculum group from 1.98 to 1.97 and in the control group from 1.80 to 1.82. Overall parent solar protection reported by children in grades second to fifth did not change significantly in the curriculum condition compared to controls with  $p=0.308$ .

### *Secondary outcomes*

In second and third graders the attitude score rose in both groups, indicating a change towards a more sun protective behaviour. A similar tendency was observed in the intervention arm of the fourth and fifth graders. In the control group however the mean attitude score fell. The difference in changes in attitudes in participants in second to fifth grade was not statistically significant with  $p=0.363$ .

## Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment

Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted.\*\*

Further details are provided in section 4.1.1.1.1.

### Evidence statement

An American RCT (rated -) included children (the exact number in this age group was not clear) from second to fifth grades of elementary school. They were provided with “*Sunny Days, Healthy Ways*” curriculum delivered during a six-week period and containing four age-appropriate units – “Living with Sunshine”, “Limiting Time in the Sun”, “Wearing Cover-up Clothes” and “Using Sunscreen” – all designed to be taught in four one-hour class periods. Materials included “*multiple activity sheets with activities, games and puzzles; the 4-5 [grade] component included cards with UVR sensitive ink and activities using computers.*” Participants were followed-up from February to April or May.

This study provided evidence that knowledge increase in the intervention group was significantly higher than in the control group ( $p=0.0001$ ). There was no statistically significant difference in change in skin tone – when measured on the “L” scale there was slightly more skin darkening in the intervention group ( $p=0.541$ ), on the “b” scale there was more skin darkening in the control group ( $p=0.0697$ ) and measurements on the “a” scale indicated slightly more skin redness in the control arm ( $p=0.490$ ). Children’s sun-protective behaviours did not differ significantly between study arms and there was no visible direction of effect ( $p=0.529$ ). For parent behaviours reported by children there was also no obvious direction of effect and the difference between groups was not statistically

\*\* Study was rated differently for this population as different levels of demographic data were provided

significant ( $p=0.308$ ). Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted. (Buller 2006a<sup>16</sup>)

#### 4.1.1.2.4 Hornung<sup>50</sup> - *cluster (class) RCT*

This study (rated +) was set in a public elementary school in North Carolina, USA. Study year was not reported. Seventy nine children (from three classes) were randomised to use a CD-ROM in the classroom, 53 (from two classes) were allocated to be taught a curriculum and 77 (from three classes) to the control arm.

The mean age was 8.76 years (SD 0.75) in the first and 8.89 years (SD 0.73) in the second intervention group. The mean age in the control arm was 8.49 years (SD 0.63). 42% and 43% of the intervention arms and 48% of the control group were female. This study did not report race or ethnicity. Authors observed that age and grade were not equally distributed between study arms.

All teachers received written and verbal advice on how to conduct the study protocol. They were also given printed materials about skin cancer (skin cancer prevention pamphlets produced by the American Academy of Dermatology and an information sheet written by one of the authors).

Teachers in the first group were then asked to use a CD-ROM in the classroom setting via large-screen projection and student volunteers were asked to take turn navigating through the program for the class. The CD-ROM took approximately 18 minutes to complete. It contained colourful animation as well as digital audio and video. Three different cartoon characters modelled 3 different sun safety behaviours: extremely protective, overly risky and appropriate.

In the second intervention arm they were then asked to teach about skin health as per their normal protocol. Since there was no teaching standard for skin cancer

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prevention, they were instructed to supplement their lessons with the previously received information.

Children in control groups were given no intervention. Teachers however were given the same materials on skin cancer prevention as those in the intervention group.

Knowledge, attitude and behaviour (as well as all the other outcomes in this study) were measured with a shortened questionnaire (55 items) originally developed by Arizona Cancer Center with responses assessed on a three-point Likert scale or formulated as “fill in the blank”. Higher scores indicated more favourable results. Surveys were distributed in the classroom and teachers read the questions aloud. Completion took approximately 20-25 minutes.

Participants were first post-tested immediately after the intervention and then seven months later.

## Results

Results are not provided for baseline, however the immediate post-intervention and follow-up scores are adjusted for baseline knowledge and demographic characteristics.

### *Primary outcomes*

The mean adjusted post-intervention knowledge score was 59.5 in the intervention group and 55.0 in the control group, and was marginally higher, but did not reach statistical significance with  $p=0.053$ . The mean knowledge score in the seven months follow-up was 66.5 in the intervention group and 57.4 in the control group. This time the difference was significant with  $p=0.0168$ .

The mean post-intervention behaviour score was 39.0 in the intervention group, and 42.3 in the control group. The mean behaviour score at seven months follow-up was 38.8 in the intervention group, and 42.6 in the control group. The

difference was not significant in any of the tests (significance levels were not reported).

### *Secondary outcomes*

The mean post-intervention attitude score in the intervention group was not significantly higher compared to the control group in any of the post-tests.

### **Limitations**

Internal validity was rated “+”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment

This study is probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted.

As authors reported, all outcome measures depended on self reporting which made information bias possible. Children could have also underreported certain behaviours to answer “correctly”.

Surveys included questions about sunburns in the previous month which is probably not a good measure of effect in an immediate post-test. As the baseline testing was carried out in autumn and the seven months follow-up in spring there might have been a different opportunity for sun exposure. Classes from one school were randomised to different study arms, making contamination likely.

Furthermore groups were not similar at baseline. It was also not possible to tell if intention to treat analysis was carried out. Applicability can be limited by the study’s location.

### **Evidence statement**

An American RCT (rated +) compared class-taught sun protection to do nothing in 130 third and fourth grade children. Teachers taught sun protection based on the

materials that were provided by researchers. Participants were post-tested twice: immediately after the intervention and seven months later.

Adjusted knowledge level was significantly higher in the intervention group seven months after baseline ( $p=0.0168$ ), and not significantly higher directly after the intervention ( $p=0.053$ ) in comparison with the control group. In both tests there was no significant difference in self-reported behaviour score, however the intervention group scored lower than the control group indicating a less favourable behaviour (significance levels were not reported). This study is probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted. (Hornung<sup>50</sup>)

#### 4.1.1.2.5 Hewitt<sup>47</sup> - *cluster (school) controlled before and after study*

This controlled before and after study (rated -), undertaken in 1998, assessed the effectiveness of group based verbal advice provided at school. Sixteen state maintained primary and junior schools located within the boundaries of Nottinghamshire Health District, UK took part. Schools already involved in a project covering the same topic were excluded.

Children ( $n=454$ ) were aged 10-11 years. Details of the participant's sex, ethnicity and socioeconomic status were not reported. No exclusion criteria for the children attending the participating schools were reported.

Sun-safe was offered as either a computer-based or workbook-based resource. Both resources were designed for use in class-based topic work. The class teacher selected pairs of children to work together. Poor readers were paired with readers for peer support. The broad objectives of the two resources were: to clarify key messages on skin cancer prevention; to provide information on the effects UV

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radiation on the skin; and to encourage responsible attitudes and behavioural intentions in relation to skin cancer prevention.

### 1. The Sun-safe teaching computer-based resource

The core of the Sun-safe computer-based teaching resource was an interactive computer programme for children aged 10-11 years. The interactive programme uses colour, sound and movement. The story follows the adventures of a central character 'Dillo', the Armadillo who loses his protective armour and has to learn how to protect himself from the harmful effects of the sun before reaching his final destination, the 'Sun City' theme park. To progress through the 20 minute programme the children have to correctly answer questions on a searching screen. By answering questions relating to four key sun-safe messages the children collect objects, such as SPF 15+ sun cream, that Dillo can use to protect himself the sun. Methods of sun protection are reinforced on a second page where the children tick off items on a packing list for Dillo's trip. Background information pages on tanning and fashion follow, along with a screen on the potentially harmful effects of UV radiation. A second screen invites users to click on relevant sun-safe objects from a beach scene. Finally Dillo arrives in Sun City where users apply their knowledge by identifying who is 'Most at Risk from the Sun' in a scene of children at a fun park on a hot sunny day.

### 2. The Sun-safe workbook

The Sun-safe workbook version of the story was developed to ascertain the effect of the interactive computer programme as a medium for learning. The workbook contained the same text and still images from the computer programme, it was given the same introduction by the teachers and designed to meet the same objectives.

No intervention was provided to the control group.

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Effectiveness was measured in changes in levels of knowledge, attitudes and behavioural intentions.

The lessons were taught and supervised by the teachers in the presence of a researcher. The researcher acted as an observer and administered a questionnaire before the intervention. The children were asked complete the questionnaire (referred to in the lesson as a quiz). They were advised not to confer. Children with reading difficulties were encouraged to seek help from the teacher but this did not extend to explanations of the meaning of the terms used in the test. The day after the pre-test questionnaire and intervention the teachers went through the answers in the workbook and computer programme and the first post-intervention questionnaire was administered. The second post-intervention questionnaire was administered six weeks later. The control schools completed the questionnaires at the same time points.

Participants were followed-up for six weeks.

## Results

### *Primary outcomes*

#### Knowledge

Mean  $\pm$  SD pre-intervention scores for the three groups were as follows: computer,  $8.23 \pm 2.07$ ; workbook,  $7.65 \pm 2.27$ ; control,  $8.54 \pm 2.22$ .

Mixed-model analysis revealed significant increases in all three groups (computer: 1.73, 95% CI 1.00 to 2.46; workbook: 2.36, 95% CI 1.66 to 3.05; control: 0.93, 95% CI 0.11 to 1.74) but only the workbook group was significantly better than the control group (1.43, 95% CI 0.36 to 2.50) and there was no significant difference between the intervention groups (0.63, 95% CI -0.8 to 1.63).

### *Secondary outcomes*

#### Attitudes



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Mean  $\pm$  SD pre-intervention scores for the three groups as follows: computer,  $10.41 \pm 3.14$ ; workbook,  $9.82 \pm 3.17$ ; control,  $9.86 \pm 3.31$ .

Mixed-model analysis revealed significantly greater increases in both intervention groups compared with the control group but no significant differences between them (computer: 1.92, 95% CI 0.76 to 3.09; workbook: 2.37, 95% CI 1.27 to 3.47; control: -0.01, 95% CI -1.28 to 1.27).

### Behavioural intentions

Mean  $\pm$  SD pre-intervention scores for the three groups were as follows: computer,  $6.71 \pm 1.72$ ; workbook,  $5.91 \pm 1.76$ ; control,  $6.19 \pm 1.79$ .

Mean increases in behavioural intentions scores were small. However mixed-model analysis revealed significantly greater increases in both intervention groups compared with the control group with no significant differences between the intervention groups (computer: 1.11, 95% CI 0.70 to 1.51; workbook: 0.66, 95% CI 0.26 to 1.05; control: 0.08, 95% CI -0.37 to 0.52).

### Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Applicable only to populations or settings included in the studies, the success of broader application is uncertain.

Authors stated that cluster randomisation was used with schools randomly allocated to the two intervention arms of the study however as the control schools were self selected the study design did not totally adhere to a randomised controlled trial.

Losses to follow-up at six weeks were between 18 & 23% and as an ITT analysis was not undertaken the impact of selection bias on the final results needs to be taken into account. Also based on the numbers finally assessed the study seemed

to lack sufficient statistical power to detect a difference between the treatment groups.

**Evidence statement**

A UK controlled before and study (rated -) evaluated the effectiveness of computer-based and work-book based resources, designed for use in topic work, in 454 children aged 10-11 years at school. The interactive 20-minute computer-based resource followed the adventures of a fictional character who has to learn how to protect himself from the harmful effects of the sun. The workbook version of the story was developed to ascertain the effect of the interactive computer programme as a medium for learning. It contained the same text and still images from the computer programme.

There was no statistically significant evidence of increased knowledge, at six week follow-up, amongst the group receiving the computer-based intervention compared with controls. However knowledge increased to a greater extent in this intervention group.

There was statistically significant evidence of increased knowledge, at six week follow-up, amongst the group receiving the work-book based intervention compared with controls ( $p < 0.05$ ).

Applicable only to populations or settings included in the studies, the success of broader application is uncertain (Hewitt<sup>47</sup>).

#### 4.1.1.3 School based studies in children aged eleven to sixteen years

Six cluster randomised studies (Buller 2006b, rated +, Girgis, rated -, Hughes, rated -, Kristjánsson, rated +, Mermelstein, rated - and Syson-Nibbs, rated -) were

found to evaluate curricula in children aged 11 to 16 in a school setting. The numbers of participants analysed in these studies varied and were: 145 in Syson-Nibbs, 184 in Kristjánsson, probably 543 in Hughes (however it was not entirely clear), 612 in Girgis, 1703 in Mermelstein and 1788 in Buller 2006b. Two studies were set in the UK – in Liverpool, Rotherham, Rugby, London, Essex and Kent (Hughes) and in Derbyshire (Syson-Nibbs) and the latter utilised materials evaluated in the first one. Two studies were conducted in the USA – Buller 2006b in Colorado, New Mexico and Arizona and Mermelstein in Chicago. The remaining trials were set in Australia (Girgis) and Stockholm County, Sweden (Kristjánsson). The period over which the intervention was delivered varied from a single-session class (Kristjánsson, Mermelstein) to four (Girgis) and six weeks (Buller 2006b). The shortest follow-up was two weeks (Mermelstein) and the longest eight months (Girgis). In remaining studies follow-up was not always clearly stated, but was approximately three to five months.

An important issue when analysing these studies is that not all of them measured or accounted for baseline data in the analysis (Hughes, Mermelstein). The Syson-Nibbs study measured outcomes at baseline, however it performed only analyses of within-group changes over time. Girgis only reported a regression analysis to identify predictors of solar protection.

The trials which compared an increase in knowledge between study arms (Buller 2006b and Kristjánsson) reported a significant positive effect of the intervention. Syson-Nibbs provided information of a significant increase in knowledge within the intervention arm (and no significant change in the control arm). Hughes and Mermelstein did not take into account baseline scores and these studies reported significantly higher levels of knowledge in the curriculum condition compared with controls.

Sun protective behaviour was evaluated in various ways in four trials. Girgis found, in a regression analysis, that the intervention was a predictor of solar protection both at five weeks and eight months after baseline. The difference between intervention and control groups in behaviour assessed in self-reports indicated a significant beneficial effect in Buller 2006b and was not significant in Hughes

(authors did not provide further details). Buller 2006b however also assessed participants' sun protective behaviour at school using diary reports and found no significant difference between groups (no direction of effects was observed).

Sunburn in the previous month was assessed only in Buller 2006b and was not found to significantly differ between study arms.

#### 4.1.1.3.1 Buller 2006b<sup>15,85</sup> - *cluster (school) RCT*

This study (rated +) was carried out in 2038 six to eight grade students (only 1788 were analysed after excluding a pair of schools) in 30 middle schools in Colorado, New Mexico and Arizona, USA between 2001 and 2003.

The mean age in both the intervention and control arm was 12.9 years. Female participants comprised 57.2% of the sample used in the analysis. 78% of the analysed students were white, 24.8% Hispanic, 6.5% Black/ African American, 6.5% American Indian/ Alaska Native and 2.9% Native Hawaiian/ Other Pacific Islander. The percentages do not add up to a 100% as the categories are not mutually exclusive.

Numbers of participants allocated to study arms were not provided.

The "*Sunny Days, Healthy Ways Curriculum*" comprised six 50-minute lessons implemented over six weeks. It was intended "*to increase perceived personal risk for skin damage and cancer, positive outcome expectations about sun protection to reduce personal risk, and self-efficacy expectations for performing sun protection in a variety of situations. It taught the following skills: selecting and applying sunscreen, selecting sun protective clothing, hats and sunglasses, using shade, and minimizing time in the sun. It contained activities to help children set goals for sun protection, monitor progress towards them, and overcome barriers to*

*sun protection. Each unit was designed to be presented on its own or in 15- or 30-minute segments over several classes.*” Before implementing the intervention, teachers attended a two-hour training sessions.

The comparator was not reported, but was probably do nothing/ current practice.

A diary measure recording *“time outside, mostly in sun/shade, wearing a head covering, wearing clothing that covered legs, and wearing sunscreen”* was used to assess the effect of the intervention on behaviour. Children completed diaries for times they were outdoors, while at school. *“A weighted body coverage measure was created for each time outdoors, ranging from 0 to 15.”*

Additionally behaviour was assessed using five-point frequency items regarding *“how often children applied sunscreen with sun protection factor (SPF) of  $\geq 15$ , wore clothes covering most of the body, wore a hat, limited time in the sun during midday, stayed in the shade, and wore sunglasses.”* A mean score was then calculated across all these items.

A scale ranging from one – “not important” to four – “very important” was used to evaluate: frequency of lying out in the sun to get a tan and using a self-tanning cream, being sunburned during the past month and in the last summer, the SPF of sunscreen used, and the perceived importance of having a tan.

Sun-safety knowledge was assessed with ten true-false questions.

Attitudes towards sun exposure and sun protection were assessed with 17 questions on a five-point Likert scale.

The study also evaluated self-efficacy expectations with four three—point items ranging from one – “not sure” to three – “sure”.

Participants were also asked about barriers to use sunscreen, barriers to sun-protection and negative normative perceptions of sun-safety.

Follow-up was not clearly stated. Students were first tested in February and March. Post-testing was carried out at the end of the school year in May.

## Results

All results are provided as post-test results adjusted for baseline variables.

### *Primary outcomes*

There was no significant difference between groups in sunburns experienced in the previous month with an adjusted OR of 1.23 (95% CI: 0.87 to 1.74). It was not clearly stated if this score indicates more or less sunburns in the intervention group.

Knowledge level assessed as number of correct answers to a ten-item test was significantly higher in the intervention group (mean 8.07, SE 0.14) than in the control group (mean 6.65, SE 0.14). The estimated difference was -1.42 (SE 0.18) with  $p < 0.0001$ .

Based on diary reports, there was no significant difference between groups in sun-protective behaviour. During lunch mean body coverage score was 8.91 (SE 0.185) in the experimental and 8.75 (SE 0.182) in the control group with an estimated difference of -0.15 (SE 0.260),  $p = 0.5687$ . This score during physical education class was 9.34 (SE 0.996) in the intervention and 7.10 (SE 1.256) in the control arm. The estimated difference was -2.23 (SE 1.450) and was not significant with  $p = 0.2430$ . For recess the mean body coverage score in the curriculum arm was 8.86 (SE 0.197) and in the control arm 8.90 (SE 0.240) with an estimated difference of 0.036 (SE 0.331),  $p = 0.9275$ .

Rating of sun protection when outside for more than 15 minutes in the past month provided a significant difference of 0.13 (SE 0.029),  $p = 0.0035$ . The score in the experimental group was 3.43 (SE 0.020) and in the control group - 3.56 (SE 0.021).

There was no difference in mean sun exposure in the past month which was reported based on three items: laying out in the sun to get a tan (estimated

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difference of 0.13,  $p=0.0974$ ), using a self-tanning cream (estimated difference of 0.01,  $p=0.9129$ ) and getting sunburned (estimated difference of 0.06,  $p=0.4222$ ).

This study also investigated behaviours in relation to sunscreen use. The adjusted OR of sunscreen use was 2.16 (95% CI: 1.54 to 3.01) indicating that participants in the intervention group used sunscreen more often. There was however no significant difference in the SPF of the sunscreen used ( $p=0.2035$ ).

### *Secondary outcomes*

This study also evaluated participants' perception of barriers to sun-protective behaviour. For barriers to sunscreen use there was a significant difference of 0.15 (SE 0.047),  $p<0.0046$ . The scores in each group were: 2.36 (SE 0.034) in the experimental and 2.51 (SE 0.035) in the control group. The differences in barriers to sun protection (estimate 0.08, SE 0.038,  $p=0.0662$ ) and social norms as barriers (estimate 0.04, SE 0.042,  $p=0.4331$ ) were not statistically significant.

The difference in composite perceived self-efficacy expectations (-0.08, SE 0.038) was approaching statistical significance with  $p=0.0577$ .

### **Limitations**

Internal validity was rated "+". Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted.

The authors indicated that the difference between the diary measure and the frequency rating of sun protection might be caused by the diary covering only the part of the day spent in school. Furthermore composite measures included behaviours which can be partial substitutes (i.e. using sunscreen and staying in the shade). With regard to evaluating the effects of the curriculum, the use of only self-reported measures is an important limitation.

Furthermore the requirement of active parental consent could have introduced selection bias. Setting the study in three states with a relatively high level of UV radiation can seriously limit its generalisability.

Groups were not similar at baseline. Only 1788 of the original 2038 students were included in the final analysis, as two schools were excluded after the study commenced. It is not possible to tell if results of this study were comparable across different sites.

### **Evidence statement**

An American RCT (rated +) in 1788 sixth to eighth grade children evaluated the effectiveness of the “*Sunny Days, Healthy Ways*” Curriculum comprising six 50-minute lessons implemented over six weeks. It was intended to change participants perceptions about personal risk and measures of sun protection, as well as to teach them sun-protective skills. *“It contained activities to help children set goals for sun protection, monitor progress towards them, and overcome barriers to sun protection. Each unit was designed to be presented on its own or in 15- or 30-minute segments over several classes.”* Students were first tested in February and March. Post-testing was carried out at the end of the school year in May.

This study did not provide evidence of a significant difference between groups in the odds of experiencing sunburn in the previous month (OR=1.23 – not clearly stated if indicates more or less sunburns in the intervention group; 95% CI: 0.87 to 1.74). It provided evidence of an increase in knowledge in the curriculum condition compared to controls ( $p < 0.0001$ ). The level of self-reported sun protection when outside for more than 15 minutes in the past month was significantly higher in the intervention group ( $p = 0.0035$ ). However, when measured using a diary there was no significant difference between groups and the score in the intervention group was slightly higher for measurements relating to lunch time ( $p = 0.5687$ ) and physical education ( $p = 0.2430$ ) and lower for recess ( $p = 0.9275$ ). Probably likely to



be applicable across a broad range of populations and settings, assuming it is appropriately adapted. (Buller 2006b<sup>15,85</sup>)

#### 4.1.1.3.2 Girgis<sup>41</sup> - *cluster (school) RCT*

In this study (rated -) 648 students (612 after excluding those with missing data) from 11 government primary schools in Australia were randomised: 247 to intensive intervention, 180 to standard intervention and 185 to control. Only the largest schools in the region were chosen. The year of the study was not reported.

Participants were from the fifth and sixth year of primary school and were aged nine to 11 years. 13% of the intervention group were aged nine, 82% ten and 5% eleven. In the control group the relevant percentages were: 10%, 79%, 11%. Race and ethnicity were not reported. 53% of the intervention and 51% of the control condition were female. Socioeconomic status was measured in terms of father's occupational status. It was rated high in 19% of the intervention and 16% of the control arm and low in 23% and 36% respectively. For the remaining students data was missing.

Two variants of the intervention were investigated in this study: an intensive and a standard one. However, in the standard intervention arm sunscreen was distributed to students, therefore only results from the intensive condition are discussed in this report.

The SKIN SAFE programme was "*developed by the New South Wales (NSW) Cancer Council in collaboration with the NSW Department of School Education (...). During the 4 weeks in which the programme was incorporated into the curriculum, cooperative learning techniques, student participation and problem-based learning strategies were utilised in an attempt to promote an awareness of the problems and potential solutions associated with solar exposure; and to*

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*encourage the students to develop some responsibility for their own welfare by critically examining and improving their own environment. The SKIN SAFE booklets were delivered to participating teachers in the intensive intervention group by NSW Cancer Council education officer. The teachers then implemented the programme simultaneously over the next 4 weeks across a number of curriculum areas. The actual number of hours allotted to the programme depended on the extent to which teachers incorporated the programme within their curriculum. The booklets provided teachers with background information, programme aims and objectives, and suggested teaching strategies and activities. Comprehensive instructions are given for both the teacher and the student for undertaking each of the eight steps of the programme. (...) Teachers were encouraged to contact the education officer if any queries arose in the use of the programme.”*

Students in the control group received no intervention.

A questionnaire was developed and pilot tested on a group of children in the target age group. It contained 19 knowledge and 19 attitude items. “*Students were required to respond to each item by circling “True”, “False” or “Don’t know”.*” Four attitude subscales were derived and they included: perceived barriers to solar protection, benefits of using solar protection, desirability and attractiveness of a suntan, susceptibility to skin cancer. “*Six items did not fit into any of the subscales.*”

“*A score for each student was calculated by adding up the factor scores on individual items within each subscale, with a low score on a subscale indicating that students were more likely to agree with the belief that was being measured by the subscale. The scores for each factor were included as variables in the logistic regression analysis.*”

Solar protection behaviour was measured with a validated Solar Protection Behaviour Diary completed by students over five consecutive school days. Teachers explained methods of completing the diary with the use of overhead transparencies.

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*“Students completed diaries by circling the number corresponding with their answer in each category.”* A score was calculated for every opportunity available for protection (student being outdoors in the periods of recess or lunch during fine weather). It was completed for five school days during recess, first and second half of lunch (a total of 15 possible opportunities). Protection level was calculated for each of the body regions. The points assigned to each region were weighted (to reflect the risk of that region developing skin cancer) to calculate the overall protection level. The maximum was 16 points. Participants scoring 12 or more were classified as having a high level of protection.

Post-testing took place five weeks and eight months after baseline.

## Results

Results were reported only as regression analysis to identify predictors of high solar protection.

### *Primary outcomes*

In the first post-test high baseline solar protection (OR=4.55, 95% CI: 2.79 to 7.40) and the intensive intervention compared to no intervention (OR=2.45, 95% CI: 1.37 to 4.38) were found to be predictors of high solar protection.

In the second post-test the following predictors of high solar protection were reported: adequate baseline protection (OR=2.39, 95%CI: 1.43 to 3.99), intensive intervention compared to control (OR=3.06, 95% CI: 1.33 to 6.99), number of opportunities to use protection (OR=0.74, 95% CI: 0.60 to 0.91) – with the result indicating that with each additional opportunity students were less likely to protect themselves.

### *Secondary outcomes*

No secondary outcomes relevant to this review were reported.

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## Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

Reliance on self-reported measures was an important limitation to this study indicated by the authors. There were significant differences in baseline sun protection. Children were required to wear standard school uniforms, which could have limited the influence of the intervention on wearing sun-protective clothing.

It also needs to be stated that results for the outcomes measured were not provided, only results of a regression analysis. Intention to treat analysis was not used with 36 students excluded from the analysis because of missing data.

Authors provided no information on how many schools were allocated to each study arm. It was not possible to tell if the only difference between the groups was the intervention.

### **Evidence statement**

An Australian cluster RCT (rated -) in 612 nine to eleven year old children investigated the effectiveness of a school-based programme. *“During the 4 weeks in which the programme was incorporated into the curriculum, cooperative learning techniques, student participation and problem-based learning strategies were utilised in an attempt to promote an awareness of the problems and potential solutions associated with solar exposure; and to encourage the students to develop some responsibility for their own welfare by critically examining and improving their own environment.”* Teachers implemented the programme simultaneously *“across a number of curriculum areas. The actual number of hours allotted to the programme depended on the extent to which teachers incorporated*

*the programme within their curriculum.*” Post-testing took place five weeks and eight months after baseline.

This study reported that the intervention was a predictor of high solar protection compared to the control group both five weeks (OR=2.45, 95% CI: 1.37 to 4.38) and eight months (OR=3.06, 95% CI: 1.33 to 6.99) after baseline. Probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Girgis<sup>41</sup>)

#### 4.1.1.3.3 Hughes<sup>51</sup> - *cluster (class) RCT*

This study (rated -) was conducted in the UK, in seven schools in Liverpool, Rotherham, Rugby, London, Essex and Kent, and evaluated the effectiveness of class-taught sun protection with the use of various materials. The study was carried out in 1990 and included 35 classes. The number of participants is unclear – it is only reported that 543 took part in the first post-test and 466 in the second.

The students' age ranged from 12 to over 16 years. 51% in the first post-test and 61% in the second were female. Race and ethnicity was not reported. Numbers of students in each arm are unclear.

*“The educational material consisted of: (i) a colour leaflet “Suncool” which was an attempt to make covering-up look desirable, and also provided tips about avoiding sun exposure; (ii) a workbook containing basic information about the sun and ultraviolet radiation and skin cancer, particularly melanoma, which could easily be photocopied by the schools; (iii) a video called “Suncool” in which the actress Melanie Hill (from the television programme “Bread”) discusses the concepts of sun and skin cancer with a class of children.”*

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The first intervention group “*read through the text of the workbook and took home “Suncool”* (this probably refers to the leaflet, but was not clearly stated).

Interventions in the following groups included the same components as in the first group and additional materials or activities. The second intervention group additionally watched the video. The third one was given homework to design posters for public education. The fourth one additionally had a discussion later in the week about the issues raised.

*“Teachers at the school were asked to supervise the project, and add identification to the questionnaires, so that the results from the two questionnaires could be paired.”*

The control group received no special education.

Knowledge was tested only in July in a 33-item questionnaire and the total number of correct answers was counted. The maximum possible score was thus 33. If a participant did not answer at least six questions, their score was classed as missing.

Attitude was assessed in a questionnaire consisting of 15 statements that participants could mildly or strongly agree or disagree with. For a correct attitude one point was given and for an incorrect one – zero. Half a point was given for weak positive answers (either mild agreement or disagreement with a statement – depending on the context). If children did not answer to at least six questions, their score was classed as missing. The maximum score was 15.

After the summer break students were additionally asked about their sun-protective behaviour during holidays.

The study commenced in May (there was no baseline survey) and tests were carried out in July and September.

## Results

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This study did include pre-testing of students. Therefore it is not possible to establish if the results represent effects of the intervention or underlying differences between clusters.

### *Primary outcomes*

Knowledge in all four intervention groups was significantly higher than in the control group ( $p < 0.001$ ). There was however no significant difference between intervention groups. The mean scores were:

- in the group which “*read through the text of the workbook and took home “Suncool”*” the mean score was 21.2 (SD 3.3),
- in the group which additionally watched the video: 22.6 (SD 3.0),
- in the group which was given homework to design posters: 22.8 (SD 4.8),
- in the group which additionally had a discussion: 20.5 (SD 5.9),
- in the control group: 19.5 (SD 3.3).

Results for behaviour during summer holidays were not provided, however the authors stated that there was no significant difference between groups.

### *Secondary outcomes*

Attitude score in the control group was significantly lower than in the remaining four study arms ( $p < 0.01$ ). There was no significant difference between the intervention groups. Authors report that scores from both questionnaires “*gave essentially the same results. There was a reasonable correlation between attitude in July and September, suggesting retention of reported attitudes after the summer holiday.*” Therefore only mean scores for July were reported and they can be found in Table 51 Hughes.

### Limitations

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Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

Authors highlighted that results were based on self-reported measures which could have introduced bias. Authors were also critical about the questionnaire they used, as it “*contained a number of questions which did not provide useful information.*” Furthermore, “*alteration of classes following the summer holiday made it difficult in some schools to use the same group of children.*” The research did not closely supervise the project in schools and “*in one school it was noted that the physical education teachers who supervised the project were conspicuous by their sunbathing during lunch-breaks.*”

There was no baseline outcome measurement therefore it is not possible to establish if the results represent effects of the intervention or underlying differences between clusters. As classes from the same school were allocated to different interventions, there is a possibility of contamination. Classing questionnaires with less than six answers as missing might have an impact on the estimate of the effectiveness of interventions.

Intention to treat analysis was not conducted. It is not possible to establish if groups were similar at baseline, if the only difference between them was the intervention, what was the drop-out rate and if results are comparable across different sites.

#### **Evidence statement**

A British cluster RCT (rated -) in probably 543 children (numbers not clear) aged 12 to over 16 years evaluated verbal advice together with different types of educational materials: “(i) a colour leaflet “Suncool” which was an attempt to make covering-up look desirable, and also provided tips about avoiding sun exposure;



(ii) a workbook containing basic information about the sun and ultraviolet radiation and skin cancer, particularly melanoma, which could easily be photocopied by the schools; (iii) a video called "Suncool" in which the actress Melanie Hill (from the television programme "Bread") discusses the concepts of sun and skin cancer with a class of children." The first intervention group "read through the text of the workbook and took home "Suncool"" (this probably refers to the leaflet, but was not clearly stated). Interventions in the following groups included the same components as in the first group and additional materials or activities: watching the video, being given homework to design posters for public education and having a discussion later in the week about the issues raised. The study commenced in May (there was no baseline survey) and post-tests were carried out in July and September.

This study provided evidence of a significantly higher level of knowledge in intervention arms compared to controls ( $p < 0.001$ ). Authors reported that there was no difference between groups in behaviour (no further details were provided). An important limitation of this study is lack of any baseline assessment. Probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Hughes<sup>51</sup>)

#### 4.1.1.3.4 Kristjánsson<sup>57</sup> - cluster (class) RCT

This randomised study (rated +) was carried out in schools in Stockholm County, Sweden. Study year was not reported. Five schools (268 students at baseline, 184 analysed) were enrolled and classes in each school were randomised to study arms: 97 students were analysed in the intervention and 87 in the control group.

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The age of participants ranged between 13 and 15. There were 41% female in the experimental and 55% in the control condition. Race and ethnicity was not reported.

The study arms appeared to be similar with regard to most characteristics, however the *“intervention group had a higher proportion of students who were able to progress in their readiness to give up sunbathing ( $p=0.01$ ).”* The experimental group also *“had more favourable attitude towards sunbathing and tanning.”*

The intervention was implemented by the students' regular teacher or the school nurse during one lesson (45 min). The educational package contained: a manual for teachers, ten overhead transparencies with animated comic figures, a seven minute video tape and recommendations and instructions on how to behave in the sun – with the suggestion to photocopy and give them to the students to take home. Teachers were recommended to allow their students to work in groups and do several exercises. Prior to the intervention, teachers in this study received verbal and written instructions.

The comparator was not reported, but was probably do nothing or current practice.

Knowledge was tested using 15 statements, with a score based on the number of correct answers (possible responses were: yes, no, don't know).

This study also evaluated participants' readiness to change the following skin cancer related behaviours: using clothes for sun protection, avoiding sun between 11am and 3pm, staying in the shade for sun protection, using sunscreen and giving up sunbathing.

Attitudes towards sunbathing and tanning were investigated using a questionnaire with answers on a five-point Likert scale. Higher scores indicated a more sun-safe attitude.

Post-testing took place three months after the intervention.

## Results

### *Primary outcomes*

In the intervention group the knowledge score increased from 8.6 (SD 2.8) to 10.3 (SD 2.6),  $p < 0.001$ . In the control group from 9.0 (SD 3.7) to 9.7 (SD 3.3),  $p = 0.043$ . The mean increase was 1.7 in the intervention and 0.7 in the control arm,  $p < 0.05$ .

### *Secondary outcomes*

Changes in attitudes were only measured as within group differences between baseline and follow-up. For most statements the changes in attitudes were not significant. The exceptions were: “sunbathing feels nice and warm” with a significant change towards a more sun-safe attitude in both groups and “sunbathing makes me feel close to nature” – a significant change towards a more sun-safe attitude only in the experimental arm.

Progression in stages of change related to five sun-protective behaviours was reported as follows:

- Using clothes for sun protection: 18% progressed in the intervention and 11% in the control group; the proportion ratio was 1.7 (95% CI: 0.8 to 3.7),
- Avoiding sun between 11am and 3 pm: 26% in the intervention and 13% in control group; proportion ratio was 1.9 (95% CI: 1.0 to 3.8),
- Staying in the shade: 13% in intervention and 8% in the control group, with the proportion ratio of 1.7 (95% CI: 0.7 to 4.2),
- Using sunscreen: 6% in the intervention and 4% in the control group with the proportion ratio 1.4 (95% CI: 0.4 to 5.8),
- Giving up sunbathing: 12% in the intervention and 13% in the control group; the proportion ratio was 0.9 (95% CI: 0.4 to 2.1).

Ratios of proportions in intervention and control group were not statistically significant for any of the behaviours.

## Limitations

Internal validity was rated “+”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted.

There was a possibility of contamination across school classes, as the authors observed. Two schools including six classes were eliminated from the study for procedural reasons. The study enrolled a relatively small number of participants.

The follow-up was relatively short. Outcomes did not directly evaluate behaviour change. The measures of effect used were based on self-reports.

The groups were not entirely similar at baseline. Intention to treat analysis was not used. Clustering effects were not accounted for in the analysis.

### **Evidence statement**

A Swedish cluster RCT (rated +) investigated in 184 students aged 13 to 15 the effectiveness of a lesson on sun protection implemented by the students' regular teacher or the school nurse during one lesson (45 minutes). The educational package contained: a manual for teachers, ten overhead transparencies with animated comic figures, a seven minute video tape and recommendations and instructions on how to behave in the sun – with the suggestion to photocopy and give them to the students to take home. Teachers were recommended to allow their students to work in groups and do several exercises. Participants were tested three months after the intervention.

This study provided evidence of a significantly higher mean increase in the level of knowledge in the experimental group compared to controls ( $p < 0.05$ ). Probably

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likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted. (Kristjánsson<sup>57</sup>)

#### 4.1.1.3.5 Mermelstein<sup>67</sup> - *cluster (school) RCT*

This study (rated -) included 1703 students from suburban high schools in Chicago, USA area. Ten schools were randomly assigned to a class on sun protection or control – with five schools in each arm and numbers of students not provided. Study year was not reported.

83% were White, 7.6% Asian, 5% Hispanic, 1.1% Black and 3.3% were reported as other. Female students constituted 53% of the sample. Age was not reported, but was probably 14-16 years.<sup>2</sup> Authors stated that there was no significant difference between groups in knowledge and perceived susceptibility at baseline.

*“A one-session (45 min) class consisting of a 12-min videotape explaining the dangers of skin cancer, the risk factors, and ways to take precautions, followed by an elaboration the important facts presented in the video. The students used worksheet to help them assess their personal risk of skin damage caused by sun exposure. Last, barriers to taking precautions were discussed. The intervention was conducted by one of the authors.”*

The control group received no intervention. Two questionnaires were administered to this group approximately two weeks apart.

Skin type was assessed. Sun exposure was measured as the average number of daylight hours spent outside during the summer and a weighed score was calculated using questions about summer holidays, weekends and weekdays. Sunscreen use was evaluated by asking how often sunscreen or sunblock was

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used when outside (possible answers ranged from 1 – “never” to 4 – “always”) and the SPF of sunscreen or sunblock. A scale from 1 for “0 times” to 5 for “21 times” was used for indoor tanning frequency.

Knowledge scores at baseline were derived from a nine-item scale and included true/false and multiple-choice items asking about risk factors, SPF numbers and sunscreen use and seriousness and prevalence of skin cancer. Five items were added to the follow-up questionnaire however no further details were provided.

Likelihood of taking precautions was evaluated using a seven-item scale measuring how likely it would be for participants to take precautions in the sun. All items were measured on 4-point scales from 1 “not at all likely” to 4 “extremely likely”.

Attitude items were measured on four-point scales ranging from 1 “definitely disagree” to 4 “definitely agree”. Three subscales were reported in the article: perceived susceptibility (11 items), perceived benefits of sun exposure (14 items) and awareness of changing social norms (two items).

Both groups received two questionnaires. The intervention group one week before and after the class and control group two weeks apart.

## Results

Results were provided for only some of the outcomes assessed.

### *Primary outcomes*

The percentage of correct answers in the follow-up knowledge test was reported as 82% of the intervention group and 56.8% of the control group. The difference between groups was significant with  $p < 0.0001$ . When stratified by grade the percentages were in ninth grade students 78.1% and 46.7% and in tenth grade 85.3% and 62.1% respectively.

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### *Secondary outcomes*

Perceived susceptibility was significantly higher in the intervention compared to the control group. There was no significant difference in perceived benefits of sun exposure and likelihood of taking precautions.

### Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to settings or populations included in the study.

The authors stated that this study had a short follow-up and no behavioural data was collected.

Numbers of participants allocated to groups were not provided. Some demographic characteristics were missing. Authors did not provide attrition details. It was not reported if intention to treat analysis was used. Baseline data was not reported for study groups. The intervention was not described in sufficient detail. Results were not completely reported for all outcomes assessed. There was no indication if clustering was considered.

### **Evidence statement**

An American RCT (rated -) in 1703 high school students evaluated “*a one-session (45 min) class consisting of a 12-min videotape explaining the dangers of skin cancer, the risk factors, and ways to take precautions, followed by an elaboration the important facts presented in the video. The students used worksheets to help them assess their personal risk of skin damage caused by sun exposure. Last, barriers to taking precautions were discussed. The intervention was conducted by one of the authors.*” Students in the intervention group were tested one week

before and one week after the intervention. In the control group two tests were undertaken two weeks apart.

This study provided evidence of a higher knowledge level (measured as percentage of correct answers) in the intervention arm compared to controls ( $p < 0.0001$ ). Probably applicable only to settings or populations included in the study. (Mermelstein<sup>67</sup>)

#### 4.1.1.3.6 Syson-Nibbs<sup>94</sup> - *cluster (tutor groups) RCT*

This RCT (rated -) investigated the effectiveness of class-taught sun protection in 200 eight-year pupils in a secondary school, in a rural area of Derbyshire, UK. The analysis included 145 students: 70 in the intervention and 75 in the control arm. Study year was not reported.

Age of the participants was not stated. Half of the pupils analysed in the experimental group were female and 55% in the control group. Race and ethnicity was not reported.

The intervention was similar to that in Hughes 1992,<sup>51</sup> as one of the aims of this study was to test the applicability of its findings. The materials used consisted of:

- a 'Suncool' leaflet which promoted covering up in the sun and also provided information about sun exposure
- "a workbook containing information about the sun, ultraviolet radiation and cancer which could be photocopied by the school"
- "a 'Suncool' video in which the actress Melanie Hill (from the television programme 'Bread') discusses attitudes to sunbathing and skin cancer with a school class."



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The author, supported by each group's tutor led three 40-minute educational sessions. In the first one students completed the baseline questionnaire, and then watched the 'Suncool' video. Afterwards participants could ask questions. *"They were encouraged to read the 'Suncool' leaflet and to take it home, to share with parents and carers."* Several weeks later a second session was carried out. Students read through the workbook in the classroom and discussed issues raised in the video. *"In session three, three months later, after the summer holidays, children again completed the original questionnaire."*

In the control group *"pupils (...) completed the questionnaire at the same time as the immediate intervention groups, but received no educational information until after the second questionnaire."*

A questionnaire based on a previous study (Hughes 1992<sup>51</sup>) was used. It contained 29 questions assessing knowledge and 15 assessing attitude.

Further details were not provided.

Follow-up was not clear, however it was longer than three months, which was the time between the second and third session.

## Results

Results were analysed only within groups and not compared between groups.

### *Primary outcomes*

The increase in knowledge was statistically significant ( $p < 0.0005$ ) in the experimental group. The mean baseline knowledge score was 18.5 (SD 3.2) and in the post-test it was 24.0 (SD 3.2). The increase observed in the control group from 18.9 (SD 2.9) at baseline to 20.00 at follow-up was not statistically significant (p value not reported).

### *Secondary outcomes*

Out of the 15 questions assessing attitude there was a statistically significant improvement in the experimental arm with regard to the following three items: avoiding trying to go out in the sun when it is hottest, a lot of sun throughout life ages the skin, there is little chance that the respondent will get skin cancer. There were no statistically significant changes in the control arm.

## Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted.

The author indicates that the pre-intervention knowledge scores were generally high, which could have limited the impact of the intervention. There also might have been some variation in the way the intervention was delivered to groups as the author had other duties apart from conducting the study. Pupils arrived for the intervention from a variety of other classes, such as physical education which meant more time was necessary for them to settle down. Differing classroom environments could have influenced the results. In school pupils had to spend every midday break in the playground where there was minimal shade possibly this influenced their attitudes about avoiding midday sun

The study had a high loss to follow-up with only 145 out of the initial 200 participants analysed. This also meant that intention to treat analysis was not used. Evaluation of effectiveness was based on self-reported outcomes. There was no comparison of between-group differences for any of the results.

There was a possibility of contamination with classes from the same school allocated both to intervention and control groups. Clustering effects were not accounted for.

There is too little information provided to decide if groups were similar at baseline and if the only difference between them was the intervention.

#### **Evidence statement**

A British cluster RCT (rated -) evaluated verbal advice with use of other materials in 145 eight-year secondary school children. The study author, supported by each group's tutor led three 40-minute educational sessions. In the first one students completed the baseline questionnaire, and then watched the 'Suncool' video. Afterwards participants could ask questions. *"They were encouraged to read the 'Suncool' leaflet and to take it home, to share with parents and carers."* Several weeks later a second session was carried out. Students read through the workbook in the classroom and discussed issues raised in the video. *"In session three, three months later, after the summer holidays, children again completed the original questionnaire."*

This study provided evidence of an increase in skin cancer knowledge in the intervention group ( $p < 0.0005$ ) but not in the control group (p value not reported). There were no between-group comparisons undertaken. Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted. (Syson-Nibbs<sup>94</sup>)

#### 4.1.1.4 Community based studies

Two controlled before and after studies assessed provision of verbal advice in a community setting (Reding and Rodrigue, both rated -). They were both set in the USA – Reding in Wisconsin and Rodrigue in Florida. The first study investigated an intervention delivered directly to children during summer camps and spring

monthly meetings of a children's association. The second one tried to educate Caucasian mothers to better protect their children (in a 90-minute educational session) without specifying the site. This study had two intervention groups: a comprehensive prevention programme and information only arm. Reding assessed outcomes immediately after completion of the intervention and Rodrigue followed-up participants for two and 12 weeks.

In Reding children provided with the intervention had answered seven out of ten questions testing knowledge significantly better compared to the control group. For the remaining questions there was a non-significant difference in favour of the intervention group. In Rodrigue for mothers provided with verbal advice (in both intervention groups) there was a significant increase in knowledge and protection of their children from the sun compared with the control arm.

#### **4.1.1.4.1 Reding<sup>84</sup> - *controlled before and after study***

This controlled before and after study (rated -), undertaken in 1992, assessed the effectiveness of group based verbal advice provided in a community setting in two rural counties in northern Wisconsin, USA.

Children aged 5-7 years participated, numbers evaluated were not reported. Details of their sex, ethnicity and socioeconomic status were not reported and no exclusion criteria were stated.

The 4-H Youth Development project has an emphasis on family involvement, with a mix of adult and youth volunteers working together and coalition to increase the visibility and scope of programmes.

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The 4-H coalition included county and state 4-H youth agents; the youth education assistant director from the American Cancer Society (ACS), Wisconsin division; and Wisconsin Farmers' Cancer Control Programme (WFCCP) staff.

This project targeted the Cloverbud programme, an introduction to the 4-H programme for children aged 5-7 years. The 4-H coalition developed a booklet, 'Hands-on Activities', with a sun-protection theme to be used with the Cloverbuds. The booklet includes family surveys, science projects, arts activities, and board games to be used by the family and club leaders. Educational sessions were provided by WFCCP staff to 4-H leaders with a packet of information on skin cancer and sun protection and methods to deliver the education. The 'Children's Guide to Sun Protection K-3' curriculum developed by the ACS in conjunction with the American Academy of Dermatology (AAD) was used along with the 'Hands-on Activities' booklet.

The 'Cloverbuds' participated in the sun protection exercises from the 'Hands-on Activities' booklet at spring monthly meetings or summer day camps. Due to the organisational structure of 4-H, it was not possible to standardise delivery of the interventions, and the children received the education module in different ways.

NB: This study evaluates the impact of attending the one-day summer camp.

Participants in the control group received no intervention.

For some of the intervention groups, presentations were made to the Cloverbuds at a one-day summer camp. Surveys were given before and after this session. Control groups received only pre-post surveys (times surveyed not reported). Knowledge gain was measured using a ten-question sun protection knowledge survey. A knowledge gain was defined as a correct response on the post-survey after an incorrect response on the pre-survey.

Follow-up was immediate for those receiving the educational session. However the time frame for pre-post assessment of the control group was not reported.

## Results

### *Primary outcomes*

Pre-post evaluation of the intervention and control sites demonstrated a significant pre-post knowledge gain in the pilot intervention groups ( $p < 0.01$ ). The intervention group displayed significantly higher knowledge gains ( $p < 0.01$ ) than the control group in their answers to the following questions:

1. When should you protect yourself from the sun (summer only, spring and summer, or the whole year)? Intervention 70% vs. control 0%
2. What is the best lotion to use to protect yourself from the sun (baby oil, sunblock or tanning lotion)? Intervention 85% vs. control 13%
3. What is the correct sunblock number to wear when outside (10, 12 or 15 or greater)? Intervention 90% vs. control 14%
4. What does A mean in the ABC of skin protection (away, after or above)? Intervention 88% vs. control 10%
5. What does B mean in the ABC of skin protection (block, baby oil or burn)? Intervention 81% vs. control 0%
6. What SPF number should be on the sunblock your family buys (10, 12 or 15 or greater)? Intervention 90% vs. control 18%
7. Which of the three items, long sleeved shirt, baby oil or sunblock, does not provide sun protection? Intervention 80% vs. control 27%

Non significant improvements in knowledge were seen in the following items amongst the intervention group compared with the control group:

1. At what time of day is the sun at its strongest (early morning, noon, or late afternoon)? Intervention 78% vs. control 33%
2. What skin type needs the most protection (light, medium or dark coloured skin)? Intervention 50% vs. control 15%

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3. What does C mean in the ABC of skin protection (check, colour or cover-up)? Intervention 68% vs. control 26%

(NB figures read from chart)

### *Secondary outcomes*

No secondary outcomes relevant to this review were reported.

### Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment

Applicable only to populations or settings included in the studies, the success of broader application is uncertain.

The authors stated that the long-term effects of the study are unknown. There is no guarantee that short-term knowledge gain will translate to desired behaviour. Long term follow-up is needed to observe a decrease in skin cancer incidence rates.

Key information, such as the numbers assessed in the pilot study, is not reported. The authors did not explicitly state who (children, parents) completed the pre-post evaluations.

### **Evidence statement**

An American controlled before and after study (rated -) evaluated the effectiveness of a one-day summer camp of sun protection activities for children aged five to seven years. The number of participants in this study was not clearly stated. The control group received no intervention.

It provided evidence of statistically significant improvements in knowledge in seven of the ten items tested, immediately after the intervention, amongst those receiving the intervention compared with the control group ( $p < 0.01$ ). Non-statistically significant improvements in knowledge were also seen amongst the intervention group in comparison with controls for the remaining three items tested.

Applicable only to populations or settings included in the studies, the success of broader application is uncertain. (Reding<sup>84</sup>).

#### 4.1.1.4.2 Rodrigue<sup>87</sup> - *controlled before and after study*

This controlled before and after study (rated -) assessed the effectiveness of group based verbal advice, provided in a community setting (evening meetings were held at two schools), to mothers who were targeted as agents of change for their children. The study year was not reported. Sixty six mothers who were affiliated to the Parent-Teacher Association of 'local' county schools took part. We assume the schools were 'local' to the research centre in Gainesville, Florida, USA, however precise details are not reported.

The mean ( $\pm$ SD) age of the children was 6.4 ( $\pm$ 2.5) years. All mothers were Caucasian due to the higher incidence of skin cancer amongst individuals with light complexions, non-Caucasian mothers were excluded. Details of the participant's socioeconomic status were not reported.

Participants were assigned to the comprehensive prevention programme (CPP), an information only condition (IOC) or a no information control (NIC).

Both interventions lasted 90 minutes. Both the comprehensive prevention programme (CPP), and information only condition (IOC) intervention included a didactic component but parents in the CPP arm also engaged in an experimental



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session designed to focus on changing behaviour patterns, attitudes and beliefs related to skin cancer prevention.

The didactic component involved the presentation of information regarding skin cancer facts and myths, risk factors and precautionary actions one can take to reduce risk. Special emphasis was placed on children as a high risk group.

An additional 45-minute experimental component for parents in the CPP arm included videotapes designed to encourage discussion, role playing the proper application of sunscreens on children, and discussion of the barriers to preventive behaviours and ways to overcome them. Family discussions about the value of skin cancer prevention measures were encouraged and the group was led in a discussion of ways to incorporate them in family activities. Additionally a young female adult with a history of malignant melanoma was present to discuss her personal experience of cancer.

For parents in the IOC arm the remaining 45 minutes involved viewing an informational videotape describing other common types of cancer, their aetiology, symptoms and treatments.

No information was provided on the control group.

Changes in knowledge of skin cancer and sun exposure, sun-safe behaviours, and attitudes and beliefs were examined using three questionnaires (KQ, SSBQ & SEAB) which were administered to the mothers at baseline, two weeks post-intervention and 12 weeks post-intervention. In addition to responding to items based on their own attitudes, beliefs, and behaviours, mothers were asked to identify one child in their family between the ages of six months and ten years who would serve as the target child for purposes of responding to some of the questionnaire items.

KQ is a 26-item questionnaire designed to capture respondents' knowledge of the seriousness and prevalence of skin cancer, risk factors for skin cancer, and knowledge of sunscreen use. To test the hypothesis that the CPP and IOC groups would show improvements in knowledge of skin cancer and sun exposure relative

to the NIC group, a 3 (Group) x 3 (Assessment Time) ANOVA with assessment time as a repeated measure was conducted.

SSBQ was developed as a retrospective measure of sun protection and skin cancer prevention behaviours exhibited by parents on behalf of their children. A 3 (Group) x 3 (Assessment Time) ANOVA, with assessment time as a repeated measure was conducted to test the hypotheses that the CPP group report more sun-safe behaviours post-intervention compared with the other groups and these behaviours would be maintained over time.

SEAB (Sun Exposure Attitudes & Beliefs) was designed to assess various constructs deemed important within the health belief model, self-efficacy theory, and response motivation theory. Mothers responded to questions twice (for self & child). 3 (Group) x 3 (Assessment Time) ANOVAs, with assessment time as a repeated measure were conducted for both sets of responses.

Participants were tested at two and 12 weeks.

## Results

### *Primary outcomes*

#### Knowledge

Mean (SD) KQ scores for the three groups were as follows:

baseline: CPP: 14.7(2.7) vs. IOC: 13.5(2.2) vs. NIC: 13.8(2.6)

2-weeks post-intervention: CPP: 21.8(3.0) vs. IOC: 20.9(2.9) vs. NIC: 14.0(2.2)

12-weeks post-intervention: CPP: 21.6(2.6) vs. IOC: 20.9(2.8) vs. NIC: 14.3(1.9)

The 3 x 3 ANOVA on KQ total score revealed a significant effect for Time,  $p < 0.001$ , and a significant effect for Group,  $p < 0.0001$ , modified by a significant Group x Time interaction,  $p < 0.0001$ . Simple effects of assessment time were significant for the CPP & IOC groups,  $p < 0.0001$ . Post hoc tests showed

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significantly more knowledge in the two groups between baseline assessment and both the 2-week and 12-week post-intervention assessments. Also the CPP & IOC groups showed significantly more knowledge than the NIC group at both two and 12 weeks,  $p < 0.0001$ .

## Behaviour

Mean (SD) SSBQ scores for the three groups were as follows:

baseline: CPP: 23.7(4.4) vs. IOC: 21.3(3.2) vs. NIC: 21.9(3.3)

2-weeks post-intervention: CPP: 32.6(8.8) vs. IOC: 26.6(8.7) vs. NIC: 19.8(2.9)

12-weeks post-intervention: CPP: 42.2(7.3) vs. IOC: 23.7(5.9) vs. NIC: 19.4(2.8)

The 3 x 3 ANOVA on SSBQ total score revealed a significant effect for Time,  $p < 0.0001$ , and a significant effect for Group,  $p < 0.0001$ , modified by a significant Group x Time interaction,  $p < 0.0001$ . Simple effects of assessment time were significant for the CPP group,  $p < 0.0001$ ; IOC group,  $p < 0.0001$ ; and NIC group,  $p < 0.01$ . Post hoc tests showed significant improvements in sun-safe behaviours from the baseline assessment to the two-week post-intervention assessment for both the CPP & IOC groups; however the CPP group showed continued improvements in sun-safe behaviours from the two-week post-intervention assessment to the 12-week post-intervention assessment, whereas the IOC group showed a significant decline. The NIC group reported significantly fewer sun-safe behaviours from the baseline assessment to both the two and 12-week assessments. Regarding group effects, post hoc analyses revealed that at the two-week post-intervention assessment the CPP & IOC groups reported more sun-safe behaviours than the NIC group and the CPP group had higher scores than the IOC group,  $p < 0.001$ . The similar between-groups pattern was observed at 12 weeks.

## *Secondary outcomes*

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## Sun Exposure Attitudes & Beliefs

Mean (SD) SEAB-mother total scores for the three groups were as follows:

baseline: CPP: 43.8(10.8) vs. IOC: 43.4(9.6) vs. NIC: 43.4(9.2)

2-weeks post-intervention: CPP: 61.0(9.0) vs. IOC: 50.0(8.0) vs. NIC: 44.0(10.3)

12-weeks post-intervention: CPP: 66.8(8.5) vs. IOC: 47.7(10.4) vs. NIC: 42.6(9.2)

The 3 x 3 ANOVA on SEAB-mother total score revealed a significant effect for Time,  $p < 0.0001$ , and a significant effect for Group,  $p < 0.001$ , modified by a significant Group x Time interaction,  $p < 0.0001$ . Simple effects of assessment time were significant for the CPP & IOC groups,  $p < 0.0001$  and  $p < 0.001$  respectively. Post hoc tests revealed significant differences in the CPP & IOC groups between the baseline assessment and both the two-week and 12-week post-intervention assessments. Regarding group effects, the CPP group differed significantly from both the IOC & NIC groups at the two-week post-intervention,  $p < 0.0001$ , and at the 12-week post-intervention assessment,  $p < 0.0001$ .

Mean (SD) SEAB-target child total scores for the three groups were as follows:

baseline: CPP: 39.3(8.3) vs. IOC: 39.2(7.9) vs. NIC: 43.8(9.9)

two-weeks post-intervention: CPP: 59.7(6.9) vs. IOC: 48.8(7.8) vs. NIC: 42.9(10.4)

12-weeks post-intervention: CPP: 64.8(8.9) vs. IOC: 48.3(9.1) vs. NIC: 42.6(7.8)

The 3 x 3 ANOVA on SEAB-target child total score revealed a significant effect for Time,  $p < 0.0001$ , and a significant effect for Group,  $p < 0.001$ , modified by a significant Group x Time interaction,  $p < 0.0001$ . Simple effects of assessment time were significant for the CPP & IOC groups,  $p < 0.0001$ . Post hoc tests revealed significant differences in the CPP & IOC groups between the baseline assessment and both the two-week and 12-week post-intervention assessments, and significant differences for the CPP group between the two-week and 12-week post-intervention assessments. Post hoc analyses indicated that at the two-week post-intervention assessment the CPP group differed significantly from both the

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IOC & NOC groups and the IOC group differed significantly from the NIC group,  $p < 0.0001$ . Also the CPP group differed significantly from both the IOC & NIC groups at the 12-week post-intervention assessment,  $p < 0.0001$ .

### Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Applicable only to populations or settings included in the studies, the success of broader application is uncertain.

As the authors reported, the study relied on mothers' report of sun-safe behaviours. The study was limited by its relatively small sample size. The demographic parameters of the study preclude generalisation of its findings beyond this highly self-selected sample (i.e. white, well-educated, and very well motivated mothers of young children).

The review team had nothing to add with respect to limitations.

### **Evidence statement**

An American controlled before and after study (rated -) evaluated the effectiveness of group-based verbal advice, provided in a community setting to 66 mothers who were targeted as agents of change for their children (mean age 6.4). Participants were assigned to a comprehensive prevention programme (CPP) intervention, an information only condition (IOC) intervention or a no information control (NIC). Both interventions lasted 90 minutes. Both CPP and IOC interventions included a didactic component but parents in the CPP arm also engaged in an experimental session designed to focus on changing behaviour patterns, attitudes and beliefs related to skin cancer prevention.

There was statistically significant evidence, at two and 12 week follow-up, of increased knowledge amongst the groups receiving the CPP intervention and IOC intervention in comparison with controls ( $p < 0.0001$ ).

There was statistically significant evidence, at the two and 12 week follow-up, of a greater improvement in sun-safe behaviour amongst the groups receiving the CPP intervention and IOC intervention in comparison with controls ( $p < 0.001$ ).

Applicable only to populations or settings included in the studies, the success of broader application is uncertain. (Rodrigue<sup>87</sup>).

#### 4.1.1.5 Studies set in the place of domicile

Only one study was identified to evaluate this intervention in the place of domicile. Details of this study are provided below.

##### 4.1.1.5.1 Turrisi<sup>95,96</sup> - *RCT*

This randomised study (rated ++) investigated the effectiveness of parent-taught sun protection in elementary and middle school children aged nine to 12 in specific regions (Boise, Idaho, and Johnson City, Tennessee) in the USA. The study year was not reported. 51% of the children were female and for 94% race was reported as white. In 5% of families the socio-economic status was reported as much higher than in most families, in 29% as moderately higher, in 50% about average, and in 7% as much lower.

A sample of 469 parent-child pairs was randomised to receive the intervention with baseline and follow-up tests (234), the intervention and a follow-up test (106) and no intervention (129).

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There were two intervention groups which differed by outcome assessment – in the first one tests were carried out at baseline and follow-up and in the second - only at follow-up. Parents in both intervention groups were given materials at the start of the study, and were then asked to read them and implement the intervention with their children (for which they were given 30 days). The materials contained a handbook of approximately 25 pages with an introduction to the problem of skin cancer and UV exposure. *“It also helped motivate parents to talk with their children by emphasising that such discussions could make a difference in both improving their relationship and reducing their child’s susceptibility to skin cancer.”*

Parents in the control group were given no materials.

Participants in this study were asked to estimate the number of times in 30 days when their skin had become red because of sun exposure which was the basis of calculating sunburn frequencies. Sunburn severity was assessed by four items inquiring: the general severity of the sunburn, the degree that sunburn peeled, pain associated with sunburn, and the difficulty the child had sleeping due to the sunburn. All items were measured in a four-point scale (1 – “not at all”, to 4 – “extremely”).

Sunbathing tendencies were evaluated using six items related to intentional sunbathing, lying out in the sun to get a tan, and lying out in the sun to get colour in the skin

A number of measures were used to investigate the impact of the information on attitudes associated with sun exposure and prevention of skin cancer. Appearance attitudes were assessed using nine items evaluating how much a child associated a tanned complexion with attractiveness. All items were measured on a five-point scale ranging from “strongly disagree” to “strongly agree”. Attitudes towards tanning were assessed using five items about approval or disapproval of tanning and sunbathing activities. Attitudes about sunscreen use were assessed using five items asking how a child would feel about wearing sunscreen if outside for two hours in five different climate situations. All items were measured on a five-point

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scale ranging from “very bad” to “very good”. Attitudes about using sunblock were assessed using five items which asked how a child would feel about wearing sunblock if outside for two hours in five different climate situations. All items were measured on a five-point scale ranging from “very bad” to “very good”.

Parental willingness to implement the content of the intervention was measured as a secondary outcome in this study.

Participants were followed-up for 45 days.

## Results

The results are presented only as differences between groups at follow-up. Baseline information is not taken into account. No distinction was made between two intervention groups. Results in the original papers were presented with confidence intervals and p-values were not included.

### *Primary outcomes*

Sunburn frequency was lower in the intervention group with a mean of 0.816 (SD 1.53), in the control group the mean was 1.74 (SD 3.13). The mean difference between groups (-0.923, with 95%CI: -1.45 to -0.401) was statistically significant and indicated a lower sunburn frequency in the intervention group.

Sunburn severity was also lower in the intervention group with a mean of 1.82 (SD 6.09), in the control group it was 1.97 (SD 0.723). The mean difference was statistically significant and was -0.152, with 95%CI: -0.288 to -0.015.

The result for sunbathing tendencies also indicated a more sun-safe behaviour in the intervention group, with a mean of 1.12 (SD 0.890). In the control group the mean was 1.49 (SD 1.08). The mean difference between groups was statistically significant: -0.365, with 95%CI: -0.560 to -0.170.



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### *Secondary outcomes*

Attitudes in the intervention group were more favourable towards sun-safe behaviour than in the control arm. These included: appearance attitudes, attitudes about tanning, attitudes about sunscreen use, attitudes towards sunscreen use and attitudes about sunblock. Exact scores are reported in Table 78 Turrisi.

### Limitations

Internal validity was rated “++”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

The authors stated that this study only evaluated short-term effects of the parent-taught intervention and did not look at any subgroups.

This was a well conducted study. It was not, however possible to establish if the results were comparable across all sites.

The study was carried out in the USA in school children. Outcomes were reported by children who possibly wanted to please both researches and their parents. No results were reported for baseline and it is not possible to tell if the results were due to the intervention or baseline dissimilarities.

### **Evidence statement**

An American RCT (rated ++) in 469 parent-child pairs investigated the effectiveness of parents teaching their nine to twelve year old children about skin cancer prevention. Parents were given materials at the start of the study, and were then asked to read them and implement the intervention with their children (for which they were given 30 days). The materials contained a handbook of

approximately 25 pages with an introduction to the problem of skin cancer and UV exposure. *“It also helped motivate parents to talk with their children by emphasising that such discussions could make a difference in both improving their relationship and reducing their child’s susceptibility to skin cancer.”* Children were post-tested 45 days after distribution of the materials.

This study compared only post-test results between groups and therefore it is not possible to tell if it measures actual effects of the intervention or the underlying differences between groups. Children in the experimental group were found to report significantly less sunburns (95%CI for mean difference: -1.45 to -0.401) and significantly less severe ones (95%CI for mean difference: -0.288 to -0.015) than in the control group. There was also a significant difference indicating less sunbathing tendencies in the intervention group (95%CI for mean difference: -0.560 to -0.170). Probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Turrisi<sup>95,96</sup>)

## 4.1.2 Studies on prevention in adults

### 4.1.2.1 Studies in a university/ college setting

Three randomised studies were identified to evaluate verbal advice in university or college students. Two studies evaluated a group-based intervention (Jackson, rated ++ and Katz, rated -) and one an individual nurse-led session (Mickler, rated ++). All studies were carried out in the USA – only Jackson provided a more exact location: Arizona. Katz and Mickler reported that interventions addressed both prevention and detection of skin cancer. Some participants in Mickler had a history of skin cancer, however exact data was not provided. Jackson included only female students. Katz used a “do nothing” control group and the remaining two trials delivered interventions not relevant to skin cancer (stress management in Jackson and peer leadership in Mickler). In Mickler participants were followed-up for three weeks, while in the remaining two trials they were tested immediately

after completing the intervention (in Katz there was a two-week follow-up, but the control group was given the intervention after the first post-test). Only Jackson measured outcomes at baseline.

Jackson provided evidence of a higher adjusted post-test mean level of knowledge. The remaining two trials indicated a higher post-test level of knowledge in the intervention arm compared to controls (baseline data was not collected). Other primary outcomes of this review were not assessed.

#### 4.1.2.1.1 Jackson<sup>52</sup> - *RCT*

This study (rated ++) set at Arizona State University in Phoenix, USA investigated the effectiveness of educational sessions about sun protection in female Introductory Psychology students. The year of the study was not provided.

Two hundred and eleven non-Hispanic Caucasian women were recruited. One hundred and five were allocated to the intervention and 106 to the control group. Their age ranged between 18 and 25 years with a mean of 19.46 (SD 1.3). One percent of the participants in the experimental and 2.9% in the control group had a personal history of skin cancer.

Educational sessions about sun protection were delivered by a trained presenter to groups of three to fifteen participants (mean number was eight). The presentation comprised three segments dealing with different issues. The first one covered the threat of skin cancer and photoaging and concentrated on susceptibility and severity of skin cancer. It included a videotaped testimonial of a woman from the same university diagnosed with skin cancer. The second segment targeted sun protection and contained a discussion of effectiveness of sun protection measures and barriers to using sunscreen. It included advice on buying sunscreen and a visualisation task on imagining “*purchasing sunscreen, placing it*

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*in a visible location and using it daily.*” Image norms were covered in the third section. Changing norms for sunbathing from the 1970s to the 1990s were discussed.

It was emphasised that sun protection is important and that women can look attractive without a tan, but participants were not specifically instructed not to sunbathe to minimise reactance.

Participants were given a sunscreen sample after completing the first post-test – hence results of the follow-up survey are not reported.

A session on stress management was conducted with the control group.

Knowledge was measured as the number of correct answers to a ten-item test.

Psychosocial scales were also used to evaluate perceived:

- Susceptibility (six items),
- Severity (four items),
- Benefits of sun protection (four items),
- Barriers to sun protection (seven items),
- Self-efficacy (eight items),
- Advantages of tanning (seven items),
- Descriptive norms for sun protection (four items),
- Descriptive norms for sunbathing (five items),
- Image norms with regard to society and media’s views on paleness (five items),
- Intention to sunbathe (five items),

- Intention to sun protect (six items).

Participants were first post-tested immediately after completion of the intervention. After this assessment participants were given a sample of sunscreen. Therefore the results of the second post-test which took place two weeks later are not discussed in this report.

## Results

### *Primary outcomes*

Knowledge score increased in the intervention group from 6.04 at baseline to 8.35 after the intervention. In the control group scores were 6.07 at baseline and 6.11 at follow-up. A test for post-test differences adjusted for baseline scores provided evidence of a significant difference with  $p < 0.01$ .

### *Secondary outcomes*

There was a significant ( $p < 0.01$ ) adjusted post-test difference in most of psychosocial scales in favour of the intervention. The experimental group increased their perceived susceptibility to skin cancer and photoaging, severity of photoaging (but not skin cancer), benefits of sun protection with respect to both skin cancer and photoaging, self efficacy to sun protect and intentions to sun protect. Participants in the intervention arm also saw less advantages of tanning, changed their image norms to more favourable towards paleness and decreased their intentions to sunbathe. There was no difference between groups in perceived barriers to sun protection. Results for descriptive norms for sun protection and sun bathing were not reported.

## Limitations

Internal validity was rated “++”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

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Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

As the authors stated this study was conducted in Arizona which has 300 or more days of sunshine. Messages highlighted dangerous daily sun exposure and this content might not be transferable to a different climate. Participants were a very narrowly defined group (white, non-Hispanic women, college students) which might limit generalisability. In other contexts messages like “pale is beautiful” could be considered racist. Reliance on self-reports could have introduced bias.

The study had a short follow-up, especially since the results from the mixed phase could not be used. It was not possible to tell if intention to treat analysis was used, as losses to follow-up were not reported. However with such a short study duration it is likely that no participants dropped-out. A small proportion of participants had a history of skin cancer.

#### **Evidence statement**

An American RCT (rated ++) in 211 female college students (aged 18-25 years) evaluated an educational session about sun protection delivered by a trained presenter to groups of three to fifteen participants (mean number was eight). The presentation comprised three segments. The first one covered the threat of skin cancer and photoaging and included a videotaped testimonial of a woman from the same university diagnosed with skin cancer. The second segment targeted sun protection and contained a discussion of effectiveness of sun protection measures and barriers to using sunscreen. It included advice on buying sunscreen and a visualisation task on imagining “*purchasing sunscreen, placing it in a visible location and using it daily.*” Changing image norms from the 1970s to the 1990s were covered in the third section.

This study provided evidence of a higher mean post-test level of knowledge adjusted for baseline in the intervention group compared to controls ( $p < 0.01$ ).

Probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Jackson<sup>52</sup>)

#### 4.1.2.1.2 Katz<sup>55</sup> - *RCT on prevention and detection of skin cancer*

This American study (rated -) tested the effectiveness of a presentation to delivered to college students seeking extra course credit. The year of the study was not stated.

The total number of participants is unclear and was probably 40 to 43 students. Seventeen students were analysed in the intervention and 23 in the control arm.

No demographic characteristics were provided.

The presentation took 25-30 minutes and covered four main topics: “(1) *the skin*; (2) *cancer, the disease*; (3) *basic facts about skin cancer, which include risk factors, myths, the different types of skin cancer*; and (4) *preventive measures*. *The latter stressed the importance of using sunscreens with SPF of at least 15, how to properly apply sunscreens, avoiding excessive sun exposure and tanning booths, how to conduct a self-examination of the skin, and prompt diagnosis by a dermatologist if any warning signs are noted. The presentation was primarily by a lecture, followed by a brief question and answer period. Slides were used to illustrate different types of skin cancer (basal cell, squamous cell, and malignant melanoma). The “ABCDs” of melanoma [asymmetry, borders, colour, diameter(...)] were also described to help the subjects discriminate between a normal and cancerous mole.”*

No intervention was provided to the control group before the first test and the same intervention as in the experimental group was delivered before the second test two weeks later.

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Knowledge was tested in a questionnaire developed in cooperation with dermatologists. It was piloted on a sample of 251 college students and questions which were not problematic for them were removed. The final questionnaire contained 29 questions on knowledge and one which was a self-rating of knowledge level. The majority of the questions were either true-false or multiple choice. Two required short written answers. The possible scores ranged from 0 to 37 and the questionnaire took about 10 minutes to complete.

Students were followed-up for up to two weeks. However only the immediate post-test can be used to compare groups as the control group was given the intervention before the second test.

## Results

There was no baseline outcome measurement.

### *Primary outcomes*

The mean knowledge level in the first test was 30.5 (SD 2.9) in the presentation and 18.8 (SD 3.5) in the control condition. The difference between groups was statistically significant with  $p < 0.0001$ .

In the second test – after the intervention was delivered to the control group the means knowledge scores were: 25.9 (SD 3.8) in the group which was given the intervention before first test and 30.7 (SD 3.5) in the initial control group. The improvement in the students who were given the presentation before second testing was statistically significant ( $p < 0.0001$ ). There was also a statistically significant ( $p < 0.0001$ ) decrease in knowledge in the group that was educated before the first test. This score was however still significantly higher than the one from the first test in the control group ( $p < 0.0001$ ).

### *Secondary outcomes*

No secondary outcomes relevant to this review were reported.



## Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to setting or population included in the study.

Authors highlighted that this study did not investigate how education translates into behaviour.

A major limitation of this study is the lack of a clearly stated aim. It was furthermore very poorly reported and very little characteristics of participants were provided. No baseline testing was done. It is therefore not possible to establish if groups were comparable at baseline. It is also not possible to tell if the study measures the effect of the intervention or underlying differences between study arms. No information was provided about drop-outs. Methods of data analysis were not reported.

### **Evidence statement**

An American RCT (rated -) in college students evaluated a presentation which took 25-30 minutes and covered four main topics: *“(1) the skin; (2) cancer, the disease; (3) basic facts about skin cancer, which include risk factors, myths, the different types of skin cancer; and (4) preventive measures.(...) The presentation was primarily by a lecture, followed by a brief question and answer period. Slides were used to illustrate different types of skin cancer (...). The “ABCDs” of melanoma [asymmetry, borders, colour, diameter(...)] were also described to help the subjects discriminate between a normal and cancerous mole.”*

The study provided evidence of a higher level of knowledge in the intervention group immediately after the intervention ( $p < 0.0001$ ) in comparison with controls. Since no pre-testing was undertaken, it is not possible to establish if any actual

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effect of information is measured. Providing control students with the same intervention significantly increased their knowledge ( $p < 0.0001$ ). There was also a significant decrease in knowledge level observed two weeks after the intervention ( $p < 0.0001$ ). Probably applicable only to setting or population included in the study. (Katz<sup>55</sup>)

#### **4.1.2.1.3 Mickler<sup>68</sup> - RCT including participants with history of skin cancer on prevention and detection**

This American randomised study (rated ++) evaluated three methods of teaching skin self-examination and skin cancer prevention skills. The year of the study was not reported. One hundred and forty three undergraduate psychology students were enrolled: 39 to the video, 35 to the brochures, 33 to the nurse led and 36 to the control arm.

Students' age ranged from 17 to 31 years with a mean of 18.47 (SD 1.80). 59.4% were female. Caucasian participants constituted 76.2% of the sample. 14.7% were Hispanic-American, 2.1% African-American and 7.0% Asian-American. Family history of skin cancer was reported by 28% of participants. Authors also indicated that some of the students had a personal history of skin cancer, however exact numbers were not provided.

In the videotape group participants watched "Skin Cancer: Preventable and Curable", "*which included information about skin cancer, how to recognise it, and different skin types and their vulnerabilities to the sun. The videotape also included a demonstration of how to do a total-body skin exam and tips on prevention.*"

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In the brochures arm *“participants received several commonly used written materials and were instructed to read them thoroughly. These brochures included “The Many Faces of Malignant Melanoma”, “Skin Cancer: If You Can Spot It, You Can Stop It”, “Basal Cell Carcinoma: The Most Common Cancer”, and “Squamous Cell Carcinoma: The Second Most Common Skin Cancer”.*”

Participants in the nurse-led condition were provided with a one-to-one training. They were instructed on how to perform skin self-examination and recognise skin cancers. Students could practice *“and receive feedback about their self-examination skills, and they were provided with the same brochures as those in the Brochures Condition.”* To ensure comparability of conditions, *“a script was developed from the videotape described above. The nurse rehearsed the presentation of the scripted information in several training sessions prior to the start of the study and received corrective feedback until she achieved three perfect presentations of the material. She was periodically observed during the study to ensure maintenance of treatment integrity.”*

All interventions were reported as lasting 15 to 20 minutes.

Control students were placed on a control list and given information about peer leadership skills development to control for the time spent with participants in other arms. They were informed in advance that they will receive a skin cancer intervention, the type was however not specified. At the end of the study they were given nurse-led education.

Skin cancer knowledge was measured in a 20-item questionnaire. Seven questions were multiple choice and 13 true/false. The questionnaire was based on the measure initially reported in the Katz<sup>55</sup> study and was *“designed to measure participant’s knowledge about the seriousness and prevalence of skin cancer, skin cancer risk factors, and prevention techniques. Good internal consistency, 2 week test-retest reliability, and construct validity have been reported.”*

A Visual Picture Test containing 14 pictures was used to assess participants’ ability to identify skin cancer. Responses were classified as correct or incorrect. *“Pictures were selected by a licensed dermatologist to reflect “common” benign*

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*growths and early-stage skin cancers and to differ along the following dimensions: asymmetry, border regularity, colour, and diameter (...). Of the 14 pictures, 7 reflect benign growths and 7 are early stage skin cancers.”*

A Self Examination Rating Scale was developed for this study. Participants conducted a skin self-examination and a 28-item (pass/fail) scale was “*used by an observer to assess proficiency of the skin self-examination.*” This scale was developed based on American Cancer Society materials and other research. It was reviewed by a listed dermatologist and “*three dermatology professionals were then asked to describe a typical skin examination given to their patients.*” On the basis of the above, the instrument “*required no revisions and was determined to have good construct validity.*”

At baseline participants completed a demographic questionnaire, outcomes were however not assessed. The first post-test was carried out immediately after completion of the intervention and the second three weeks later.

## Results

In this section only results comparing nurse-led education with the control group are reported. It needs to be highlighted that as outcomes were not measured at baseline the results might be measuring not only the effects of the intervention, but also differences between groups.

### *Primary outcomes*

The mean knowledge score in the nurse-led intervention was 14.63 (SD 2.01) at the first post-test and 15.37 (SD 2.13) at the second one. In the control group it was 13.54 (SD 2.22) and 14.15 (SD 1.82) respectively. Authors report that participants in all intervention arms had significantly more knowledge than those in the control group.

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### *Secondary outcomes*

Students in the experimental arm had better results in the Visual Picture Test than the control group. Their self-examination skills were also rated higher than the wait-list. Exact results for both outcomes are provided in Table 65 Mickler.

### Limitations

Internal validity was rated “++”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

Authors stated that no pre-testing was undertaken, as it could focus participants’ attention on specific information. Participants were followed-up for a relatively short time. Characteristics of the population might limit generalisability. Two of the measures used were developed for the purpose of this study and were not validated in a wider population.

The study did not measure skin cancer related behaviours. There was little information on the interventions and an exact location was not provided. Numbers of participants in study arms were relatively low. Intention to treat analysis was not undertaken.

#### **Evidence statement**

An American RCT (rated ++) investigated the effectiveness of nurse-led one-to-one training in 69 undergraduate students (aged 17-31 years). They were instructed on how to perform skin self-examination and recognise skin cancers. Students could practice *“and receive feedback about their self-examination skills,”* and they were provided with information about skin cancer and its prevention.

This study provided evidence that the knowledge level was higher in the experimental group than in the control group both at immediate post-test and three weeks later (significance levels were not provided). No baseline measurement of outcomes was carried out. Probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Mickler<sup>68</sup>)

#### 4.1.2.2 Studies in a hospital/ medical practice setting

Only one study was identified to evaluate this intervention in a hospital/ medical practice setting. Details of this study are provided below.

##### 4.1.2.2.1 Jones 2007<sup>53</sup> - *controlled before and after study*

This controlled before and after study (rated -) assessed the effectiveness of verbal advice and literature provided individually to patients attending a dermatology outpatient clinic at Our Lady of Lourdes Hospital in Drogheda, Ireland. Details of the study year were not reported.

All dermatology patients (not only those with skin cancer or sun-related complaints) were included regardless of their presenting condition. Newly referred and follow-up patients were included. Two hundred adults participated, 7% of the intervention group and 11% of the control group had prior skin cancer. The mean age was 51.2 years and 66% were female. Details of the patients' ethnicity and socioeconomic status were not reported and no exclusion criteria were stated.

At the time of their review in clinic patients were given a written education sheet outlining cause, misconceptions, and general information about skin cancer and

sun protection. They were also given verbal information from a doctor in the dermatology clinic.

The control group were not given any information until after completion of the study

Questionnaires, assessing changes in knowledge (seven questions) and sun protection behaviour, were administered before the patient's initial review at the clinic (September to November), and posted to all participants within the following three months (December to February) with an enclosed postage-paid envelope.

Participants were followed-up for three months

## Results

### *Primary outcomes*

Correct responses (%) to the 7 knowledge questions amongst the education and control groups at baseline and 3 months follow-up were as follows:

1. Sun exposure is a major risk factor for skin cancer  
Baseline: 90% education vs. 86% control  
Post-intervention: 93.3% education vs. 90.1% control;  $p=0.556$
2. Sun beds are not a safe way to tan  
Baseline: 95% education vs. 96% control  
Post-intervention: 100% education vs. 98.6% control;  $p=1.0$
3. Skin cancer is the most common cancer in Ireland  
Baseline: 26% education vs. 30% control  
Post-intervention: 72% education vs. 35.2% control;  $p<0.001$
4. Melanoma does not only occur on skin regularly exposed to the sun  
Baseline: 66% education vs. 58% control  
Post-intervention: 80% education vs. 59.2% control;  $p=0.023$

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5. SPF 60 sunscreen is more effective than SPF 30 & 15 sunscreens

Baseline: 80% education vs. 81% control

Post-intervention: 85.3% education vs. 80.3% control;  $p=0.814$

6. The sun can cause damage to your sun in all seasons

Baseline: 72% education vs. 71% control

Post-intervention: 90.7% education vs. 71.8% control;  $p=0.009$

7. The sun can cause damage to your skin on an overcast day

Baseline: 81% education vs. 89% control

Post-intervention: 93.3% education vs. 87.3% control;  $p=0.335$

Reported frequency of sunscreen application amongst the education and control groups at baseline and 3 months follow-up was as follows:

○ Daily:

Baseline: 17% education vs. 14% control

Post-intervention: 18.7% education vs. 15.5% control

○ Once or twice weekly:

Baseline: 2% education vs. 4% control

Post-intervention: 5.3% education vs. 5.6% control

○ Summer only:

Baseline: 22% education vs. 29% control

Post-intervention: 30.7% education vs. 26.8% control

○ Summer days only:

Baseline: 29% education vs. 28% control

Post-intervention: 29.3% education vs. 31% control

○ Only when going to the beach:

Baseline: 16% education vs. 11% control

Post-intervention: 5.3% education vs. 8.5% control



- Never:

Baseline: 13% education vs. 14% control

Post-intervention: 10.7% education vs. 9.9% control

Education had no statistically significant effect on sunscreen use in the follow-up survey.

### *Secondary outcomes*

At baseline 44% stated they never examined their skin for changes, whereas 35% made checks on at least a monthly basis. The change in skin lesion most were concerned about was an increase in the size of a naevus (96.5%). The changes participants were least concerned about were a scaly area on the face (67.5%), a red patch on the face or body (66.5%), and a lesion that was itchy or bleeding (72.5%).

Education had no statistically significant effect on skin examination practices or skin lesion concerns in the follow-up survey.

### **Limitations**

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Applicable only to populations or settings included in the studies, the broader application is uncertain.

The authors indicated that as the second survey took place over the winter months in Ireland, sun protection practices would understandably be limited at that time of year. A higher response to sun protection practices may have occurred if the follow-up survey had occurred during summer months. Also skin self-examination is more likely to take place at times in the year when patients are less covered up.

Participant selection, i.e. patients attending a dermatology clinic (albeit those with and without skin cancer, or sun-related complaints) limits the extent to which the study results might be generalisable to the population as a whole.

**Evidence statement**

An Irish controlled before and after study (rated -) in 200 patients (aged 51.2 years) evaluated the provision of verbal advice and literature to adults attending a dermatology outpatient department. At the time of their review in clinic, patients were given a written education sheet outlining cause, misconceptions, and general information about skin cancer and sun protection. They were also given verbal information from a doctor in the dermatology clinic.

There was weak evidence that the intervention may increase patient's knowledge at three months follow-up. Against some initially high levels of knowledge statistically significant improvements ( $p < 0.05$ ) were seen in only three of seven areas tested for those in the intervention group compared with controls.

There were no statistically significant improvements in sunscreen use, at three months follow-up, amongst the intervention group compared with controls, nor was there any discernable trend.

Applicable only to populations or settings included in the studies, the broader application is uncertain (Jones 2007<sup>53</sup>).

#### 4.1.2.3 Studies in a sports venue setting

Only one study was identified to evaluate this intervention in a sports venue setting. Details of this study are provided below.

#### 4.1.2.3.1 Parrott<sup>79</sup> - *RCT including participants with history of skin cancer on prevention and detection*

The impact of an educational campaign for coaches of young soccer players was assessed in this American study (rated -) set in the coast of Georgia between South Carolina and Florida. Twelve coaches, 50 parents and 61 youths were enrolled. Six coaches were randomised to seminar or control. No information was provided on the numbers of parents and youths in groups. Study year was not provided.

Coaches' mean age was 43 years and ranged from 33 to 64. All were Caucasian, none had a history of skin cancer and 25% were female. Ten coaches had an annual income equal or over \$50,000. Parents' age was not reported. 98% of parents were Caucasian, 12% had a history of skin cancer and 66% were female. Two parents had an income between \$22,000 and \$35,000 and 38 equal or more than \$50,000. Baseline comparisons were not reported.

A seminar about sun protection was conducted and "*a booklet of prevention strategies and information about skin cancer and youth's risk*" was distributed.

The topics covered included skin cancer facts, skin cancer and youth, sun-smart strategies for soccer teams, how parents can protect youths' skin, sunscreen use, skin cancer prevention resources, skin cancer definitions, how to conduct a self-examination, and youth activities. The programme included information on how to choose and use sunscreen, and the difference between sports sunscreen, waterproof sunscreen, and water-resistant sunscreen.

No further details were provided.

The comparator was not reported – probably do nothing or current practice.

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In coaches and parents knowledge, outcome expectancies, self-efficacy and behaviour relating to sun protection were measured. Youths were asked about coaches' and parents' efforts to promote sun protection.

Follow-up was not reported.

## Results

Exact results for study arms were not reported.

### *Primary outcomes*

*“Post-test all six coaches in the intervention condition demonstrated understanding of the need to apply sunscreen 20 to 30 minutes before going into the sun. No change was observed in knowledge about sun-protective clothing. Nor did changes occur in understanding about the recommended frequency of obtaining a clinical skin exam. Not surprisingly, parents showed similar results, as the coaches' knowledge guided efforts to communicate with parents and youths about sun protection.”*

Findings of repeated-measures ANOVAs *“revealed no differences between control and intervention conditions; the only significant result occurred with regard to pre-test post-test differences for knowledge,  $F(1,35)=9.67, p<0.01$ .”* No indication if this change was in parents and/or coaches.

### *Secondary outcomes*

No secondary outcomes relevant to this report were provided.

## Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

It was possible, as authors stated, that there was a contamination of the control group. The sample was small and only 75% of coaches and 76% of parents participated in the follow-up survey. Only self-reported data was used. The setting, a soccer field with other teams present could limit the effectiveness of the intervention.

Results were not reported for study arms. Clustering (parents and youths) was not accounted for.

The setting of this study in a region with high UV radiation might limit the applicability of results.

#### **Evidence statement**

An American RCT (rated -) in 12 soccer coaches (aged 33 to 64 years ) assessed the effectiveness of a seminar about sun protection and distribution of “*a booklet of prevention strategies and information about skin cancer and youth’s risk*”. The topics covered included skin cancer facts, skin cancer and youth, sun-smart strategies for soccer teams, how parents can protect youths’ skin, sunscreen use, skin cancer prevention resources, skin cancer definitions, how to conduct a self-examination, and youth activities. The programme included information on how to choose and use sunscreen, and the difference between sports sunscreen, waterproof sunscreen, and water-resistant sunscreen. Follow-up was not reported.

No differences between intervention and control arms were found – the study measured knowledge and sun protective behaviour (p-values were not reported).

Probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Parrott<sup>79</sup>)

## 4.2 Theme 2: Mass-media vs. Current provision of information/do nothing

### 4.2.1 Studies on prevention in children

No studies were found to evaluate mass-media campaigns in children.

### 4.2.2 Studies on prevention in adults

#### 4.2.2.1 Studies in a university/ college setting

Three randomised studies (Cody, rated -, Mahler 2007, rated + and Mickler, rated ++) evaluated mass-media interventions using videos in a university/ college setting. One of them used cluster allocation (Cody). Cody was set in Newcastle, Australia and the remaining two in the USA. Intervention times were similar in Cody and Mahler 2007 (11 to 12 minutes) and 15-20 minutes in Mickler. Mahler included 68 participants (aged 18 to 44 years) in this comparison, Mickler – 75 (aged 17 to 31 years) and Cody 114 (aged 17 to 48 years). The Australian study used two different types of a video: an emotional and informational one. In two studies the control group received information irrelevant to skin cancer: on dietary recommendations to prevent heart disease (Cody) and on peer leadership (Mickler). Mahler 2007 probably used a “do nothing” control group. Participants were tested immediately upon completion of the intervention (Mahler 2007) or followed up for three (Mickler) to ten weeks (Cody). Some of the participants had a history of skin cancer in Cody (8%) and Mickler (not clearly stated). These two studies addressed both prevention and detection of skin cancer. None of the studies assessed or accounted for baseline outcome measures.

In Mahler 2007 results were not provided for study arms and therefore are not reported. In the remaining two trials there was a significantly higher post-test

knowledge level in the intervention compared to the control arm. In Cody this was however only true for participants shown an informational video. For the emotional video there was also a higher knowledge level, but it was not statistically significant.

#### 4.2.2.1.1 Cody<sup>25</sup> - *cluster (class) RCT including participants with history of skin cancer on prevention and detection*

Three hundred and twelve first-year psychology students at the University of Newcastle, Australia were enrolled in this study (rated -). One hundred and fourteen participants from six classes were shown an informational video and 108 from six classes an emotional one. Ninety students from five classes were in the control arm. Study year was not reported.

Participants' mean age was 20 years and ranged from 17 to 48. 58% were female. 8% of participants had a history of skin cancer. It was stated that "*none was Negro, Polynesian, or Aboriginal ethnic origin.*" It was reported that groups significantly differed on some variables at baseline.

The informational video was "*a 12-minute presentation entitled "Skin Deep" obtained from the New South Wales Cancer Council. A female gave an informative talk covering the causes, consequences, and incidence rates of skin cancer and suggested skin protection, skin examination, and treatment-seeking behaviour.*"

The emotional video "*comprised two interviews with local people diagnosed as having malignant melanoma. One was dying, while the other had fully recovered. The two interviews went a total of 8 min. The emotional video finished with the last 4 min of "Skin Deep", which comprised a succinct overview of topics covered in*

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*the first 8 min of “Skin Deep” video. This ensured that subjects were exposed to the same information.”*

The control video *“addressed the issue of dietary recommendations for the prevention of heart disease. It also ran approximately 12 min.”* After the second post-test, participants were offered to watch both intervention videos.

The baseline questionnaire collected demographic data. It also assessed health beliefs: perceived susceptibility to skin cancer (four items), perceived severity (four items), perceived benefits (seven items) and perceived barriers (seven items).

Behaviour was assessed using a modified version of New South Wales Cancer Council questionnaire. It included two items on sun exposure while at the beach (defining at risk behaviour *“as spending more than 2 hr at the beach for three or more times a week”*) and ten items on skin protection and examination behaviour.

Knowledge was assessed using ten items devised by the New South Wales Cancer Council.

The post-video questionnaire assessed health beliefs and knowledge with items identical as at baseline. Behavioural intentions were assessed using questions identical to the baseline questionnaire, only using future tense. One item was added for treatment seeking intentions.

The follow-up questionnaire assessed health beliefs, knowledge and behavioural intentions with questions identical to the post-video survey. Two items were added for skin-examination behaviour. Treatment seeking was assessed only in participants who thought they had skin cancer.

Participants were assessed at baseline, immediately after watching the video and ten weeks later.



## Results

### *Primary outcomes*

The only difference in knowledge between groups that was reported as significant was that post-test scores in the informational group were significantly higher than in controls (significance levels were not reported). In the informational video group mean knowledge scores increased from 7.6 (SD 1.5) at baseline to 8.5 (SD 1.0) immediately after watching the video and slightly decreased to 8.3 (SD 1.1) ten weeks later. The mean baseline knowledge score in the emotional video group was 8.0 (SD 1.4) and increased to 8.4 (SD 1.2) in the first post-test and to 8.6 (SD 1.1) in the second. The control group's mean scores were 7.8 (SD 1.3), 7.8 (SD 1.5) and 8.1 (SD 1.6) respectively.

### *Secondary outcomes*

*“At the post-test, the [skin protection behaviour] intentions of the informational and emotional group were significantly higher than the controls. At follow-up, intentions had decreased significantly from post-video for both the informational and control groups but not for the emotional group.”*

There was a significant increase in perceived severity within both intervention arms in both post-tests compared to baseline. Immediately after the intervention the emotional video group had significantly higher scores than the control group. There was also a significant increase from baseline in perceived benefits in both intervention groups, but not in the control arm.

For other secondary outcomes no significant differences between groups were reported. Exact results can be found in Table 38 Cody.

## Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

As the authors stated, self-reported outcome measures which can be unreliable were used. Reported increased skin protection intentions might be caused by demand effects. Severity questions had a low internal reliability.

Groups significantly differed at baseline with respect to some variables. *“Drop-outs reported significantly lower skin protection intentions and higher scores on perceived barriers at the post-video assessment. The use of intention to treat analysis was not reported.”* Significance levels were not clearly stated for between-group and within-group comparisons. Clustering was not reported as accounted for. There was a possibility of contamination after the first post-test as students were all from psychology at the same university.

#### **Evidence statement**

An Australian RCT (rated -) in 114 students (aged 17 to 48 years) evaluated an informational video (in which *“a female gave an informative talk covering the causes, consequences, and incidence rates of skin cancer and suggested skin protection, skin examination, and treatment-seeking behaviour.”*) and an emotional one (which *“comprised two interviews with local people diagnosed as having malignant melanoma. One was dying, while the other had fully recovered.”*) It finished with *“the last 4 min of “Skin Deep”, which comprised a succinct overview of topics covered in the first 8 min of “Skin Deep” video”*) in psychology students. The control group was given a video unrelated to skin cancer. Participants were assessed at baseline, immediately after watching the video and ten weeks later.

Immediately after completion of the interventions participants provided with an informational video had a significantly higher knowledge score compared to controls (significance level not provided). It slightly decreased ten weeks later. In the emotional group there was a small non-significant increase in both post-tests and in the control group only in the second one (significance levels not provided).

Probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Cody<sup>25</sup>)

#### 4.2.2.1.2 Mahler 2007<sup>63</sup> - RCT

A videotaped slide show and an UV photograph were evaluated in this American RCT (rated +). Study year was not reported. One hundred and thirty three undergraduate students from University of California, San Diego were randomised: 34 to watch the video, 35 to receive the photo, 30 to watch the video and receive the photo, 34 to the control group.

The age of participants ranged from 18 to 44, with a mean of 20.13 (SD 3.38). Female students constituted 80% of the sample. Participants reported their own race and/or ethnicity as: Caucasian 45%, Asian 35.3%, Hispanic 11.3%, Asian and Caucasian 1.5%, Hispanic and Caucasian 0.8%, Asian and Hispanic 0.8% and Other 5.3%. Family history of skin cancer was reported by 27.1% of participants. No one had a personal history of skin cancer.

In the video condition photoaging information “*was presented via an 11-min videotaped slide show (...). The video depicted photoaging (including graphic photos of extreme cases of wrinkles and age spots), described how sun exposure and UV radiation from any source leads to photoaging, and discussed effective practices for minimising photoaging (e.g., wearing protective clothing and applying a sunscreen with a sun protection factor [SPF] of at least 15 to protect against both UVB and UVA rays). The video also provided general information about sunscreen, such as the meaning of the SPF number, when to use sunscreen, and how much to apply.*”

In the UV photograph group a picture was “*taken with instant Polaroid camera modified to include a 315- to 390-mm UV filter. (...) A photograph taken with a UV filter dramatically highlights the nonuniform epidermal pigmentation that results*

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*from chronic UV exposure. Each person who had a UV photo taken also had a natural light, instant photograph taken for comparison. In all cases, participants were first shown the natural-light, black-and-white photograph and were told that it depicted what can be seen with the naked eye. Then the UV photograph was placed adjacent to the natural-light photo. Participants were told that any “dark, freckled, or pitted areas” in the UV photo that did not appear in the natural light photo indicate existing underlying skin damage that would continue to get worse if they continued their current sun exposure levels without additional sun protection.”*

The third group was both shown the video and had their UV photograph taken.

All groups were given a sample of sunscreen after completion of the first post-test.

The comparator was not reported, probably do nothing or current provision of information.

Participants were asked about their future intentions to use sun protection.

Cognitive mediators were assessed on five-point scales ranging from 1 – “strongly disagree” to 5 – “strongly agree”. These were:

- perceived rewards of sunbathing/ tanning (ten items),
- costs of using sun protection (12 items),
- perceived susceptibility to photoaging (nine items),
- sun protection intentions (18 items).

The final score was calculated as an average of all items.

Participants were tested immediately after the intervention. Afterwards sunscreen was distributed and they were again tested one year later. The results from the second post-test are not reported due to sunscreen distribution.

## Results

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No interaction was found between the UV photo and video interventions.

Therefore results are provided for:

- Participants who received the photograph (including the photograph and video group)
- Participants who did not receive the photograph (including the video group)
- Participants who received the video (including the photograph and video group)
- Participants who did not receive the video (including the photograph group)

These results are not assessing the allocated interventions and therefore are not included in this report. They can be however found in Table 60 Mahler 2007.

#### *Primary outcomes*

Not reported for study arms.

#### *Secondary outcomes*

Not reported for study arms.

#### **Limitations**

Internal validity was rated “+”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

The authors stated that the study was carried out at one site with relatively high level of UV radiation. Specific characteristics of the sample (mainly women, no African-Americans) could limit generalisability.

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Results were not reported for groups to which participants were randomised. Outcomes were not measured at baseline. Self-reported measures were used. The non-mixed stage of this study was very short duration. Sample size was rather small and groups were not entirely similar at baseline.

**Evidence statement**

An American RCT (rated +) evaluated a videotaped slide show in 68 undergraduate students (aged 18-44).

It did not however provide results for groups that participants were randomised to. Results are probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Mahler 2007<sup>63</sup>)

#### 4.2.2.1.3 Mickler 1999<sup>68</sup> - *RCT including participants with history of skin cancer on prevention and detection*

This American study (rated ++) was already described in section 4.1.2.1.3. It evaluated three methods of teaching skin self-examination and skin cancer prevention skills. One hundred forty three undergraduate psychology students were enrolled: 39 to the video, 35 to the brochures, 33 to the nurse led and 36 to the control arm.

#### Results

In this section only results comparing the video with the control group are reported. It needs to be highlighted that as outcomes were not measured at baseline the

results might be measuring not only the effects of the intervention, but also differences between groups.

### *Primary outcomes*

The mean knowledge score in the video group was 16.28 (SD 1.89) at the first post-test and 15.94 (SD 2.25) at the second one. In the control group it was 13.54 (SD 2.22) and 14.15 (SD 1.82) respectively. Authors report that participants in all intervention arms had significantly more knowledge than those in the control group.

### *Secondary outcomes*

Students in the experimental arm had better results in the Visual Picture Test than the control group. Their self-examination skills were also rated higher than the wait-list. Exact results for both outcomes are provided in Table 65 Mickler.

### Limitations

Internal validity was rated “++”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted.

Further details are provided in section 4.1.2.1.3.

### **Evidence statement**

An American RCT (rated ++) investigated in 75 students (aged 17 to 31) the effectiveness of watching a videotape (*“which included information about skin cancer, how to recognise it, and different skin types and their vulnerabilities to the*

*sun. The videotape also included a demonstration of how to do a total-body skin exam and tips on prevention.”) in undergraduate students.*

It found that the knowledge level was higher in the experimental group than in the control group both at immediate post-test and three weeks later (significance level not provided). No baseline measurement of outcomes was carried out. Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted. (Mickler<sup>68</sup>)

### 4.3 Theme 3: Printed materials vs. Current provision of information/do nothing

#### 4.3.1 Studies on prevention in children

##### 4.3.1.1 Studies set in the place of domicile

Only one study was identified to evaluate this intervention in the place of domicile. Details of this study are provided below.

##### 4.3.1.1.1 Bauer<sup>4</sup> - RCT

This study (rated +) assessed the effectiveness of printed material on prevention of skin cancer in children. It started in 1998 and was carried out in Stuttgart and Bochum, Germany. One thousand two hundred and ten children from 53 daycare centres were randomised: 593 to the intervention and 617 to the control group.



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Although the aim of the intervention was prevention of skin cancer in children, printed materials were sent to their parents.

Eligible children were two to seven years old with I-IV Fitzpatrick skin type (100% were Caucasian). 48.6% of the analysed children were female. The authors report that *“at baseline there were no statistically significant differences between intervention and control groups.”*

Parents were given an initial educational session. Afterwards they *“received an educational letter 3 times yearly (Easter, Pentecost, and summer holidays) with more detailed information on proper sunscreen use and sun protection than the educational session provided at study commencement; they also received information brochures from public melanoma prevention campaigns with detailed information.”*

*“After the initial educational session no more information or educational sessions were provided”* to the control group.

Baseline assessment was carried out after the initial educational session.

The primary outcome in this study was the number of newly developing (incident) melanocytic naevi – assessed in a physical examination by two dermatologists.

Parents were also interviewed about *“sun exposure of their child playing at home, duration and destination of holiday, history of sunburns, sunscreen use and education and ethnicity of parents.”* Measures based on this interview included:

- weeks on holidays in sunny climates,
- score of country of holiday (0-16, higher score indicating higher risk from UV radiation),
- home activity score (0-7, higher score indicating more outdoor activities),
- sunburn experience,
- use of sunscreen,

- use of sun protective clothing while on beach or at swimming pool.

Children were followed-up for three years.

## Results

### *Primary outcomes*

No significant difference was observed in incident melanocytic naevi developed, with a median of 26 (IQR 16 to 41) in the intervention and 27 (IQR 17 to 40) in the control arm. At baseline all children in all groups had a median of 8 naevi (IQR: 5 to 14).

With regard to the results of the parental interview, authors observed that some of the differences between groups were significant, but did not follow a uniform pattern that would indicate a trend in any direction. Results for individual items are reported in Table 22 Bauer.

### Limitations

Internal validity was rated “+”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted.

The authors found that an unexpectedly high proportion of children were already using sunscreen - 98% and 79% almost always used sunscreen when in the sun. Furthermore the educational session with all the parents before randomisation could have reduced the effects of the investigated intervention. The study had a relatively high drop-out rate: 224 children were lost to follow-up in the intervention and 219 in the control arm. The scoring system used to quantify holiday sun exposure might have been too simplified.

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Intention to treat analysis was not carried out.

**Evidence statement**

In a German cluster RCT (rated +) parents of 1210 children aged two to seven years in both the intervention and control group were given an initial educational session. Afterwards only parents in the intervention arm “*received an educational letter 3 times yearly (Easter, Pentecost, and summer holidays) with more detailed information on proper sunscreen use and sun protection than the educational session provided at study commencement; they also received information brochures from public melanoma prevention campaigns with detailed information.*” Participants were assessed at baseline. Children aged two to seven years were followed-up for three years.

This study provided no evidence of a difference in the number of incident melanocytic naevi after three years (significance levels were not provided). There was also no clear direction of effect. The interview with parents about child protection and sun exposure did not indicate a consistent trend (significance levels were not provided). Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted. (Bauer<sup>4</sup>)

#### 4.3.1.2 Studies in a hospital/ medical practice setting

Only one study was identified to evaluate these interventions in the hospital setting. Details of this study are provided below.

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#### 4.3.1.2.1 Bologna<sup>8</sup> - *controlled before and after study*

This controlled before and after study (rated -), undertaken in 1989, assessed the effectiveness of the provision of printed materials to mothers of infants born at Yale-New Haven, Connecticut, USA hospital. The mothers (n=275) were targeted as agents of change for their new born infants.

46% of the infants were female, 94% were classed as White and the sample limited the inclusion of Blacks and Hispanics to 10%. Details of socioeconomic status were not reported.

Mothers receiving the low-level intervention are the focus of this report. The low-level intervention group received at enrolment a sheet of simple guidelines on minimising sun exposure making the following points:

1. Prevent sunburns in your children. Begin using sunscreens at age 6 months and allow sun exposure with moderation. Before the age of 6 months, use bonnets and sun umbrellas or put your baby in the shade when outdoors for a long time.
2. Teach children sun protection early. Sun damage adds up over the years and the majority of sun exposure occurs by age 20 years.
3. Decrease sun exposure during the hours 11am to 3pm when the sun is strongest. Try to plan outdoor activities for the early morning or the late afternoon.
4. Both children and adults should put on sunscreen before sun exposure, and again at least every 2 hours, as long as you stay in the sun. The sunscreen should be applied again after swimming or perspiring heavily. A sunscreen with an SPF of 15 is recommended.
5. Don't forget to use your sunscreen on cloudy days. The sun's rays can be as strong on cloudy, hazy days as they are on sunny days.

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6. If you have a reaction to your sunscreen, change sunscreens.
  7. Beware of things that reflect! Sand, snow, concrete, and water can reflect as much as half the sun's rays onto your skin.

Although not explicitly stated the materials appear to have been provided at the maternity hospital.

In addition, during August the participants received a postcard with the message: 'Just a reminder from the Yale Newborn Skin study... Keep your baby's skin healthy! A SUNBURN HURTS IN MORE THAN ONE WAY!'

NB: The study also had a high-level intervention group however, as this group were offered sunscreen samples and sun protective clothing, components which could not be disaggregated, we have only included the results reported for the control group and low-level intervention group

The control group received standard care. Prior to the start of enrolment, attending paediatricians at the hospital were sent a letter informing them of the study and requesting they not change their routine advice on sun exposure.

Participants were interviewed by telephone by two of the authors from September to December 1989 when a standard questionnaire was used to elicit the following information:

1. the amount of exposure to direct sunlight for the newborn and mother during summer weekdays and weekends;
2. the amount of time spent outdoors in the shade;
3. sunscreen use by the mother;
4. use of physical barriers to the sun for the newborn.

Participants were followed-up for approximately seven months.

## Results

### *Primary outcomes*

Parental reports of behavioural practices in the low-level and control groups at follow-up (approximately seven months) were as follows:

Compared with the control group, the infants and their mothers spent significantly less time in direct sunlight (hours/week):

Infants:

Controls: none (0%),  $\geq 5$  hrs (99%)

Low-level: none (75%),  $\geq 5$  hrs (22%)

$P < 0.001$

Mothers:

Controls: none (0%),  $\geq 5$  hrs (85%)

Low-level: none (15%),  $\geq 5$  hrs (42%)

$P < 0.001$

In comparison with the control group the low-level intervention group spent less time in direct sunlight, less time in the shade, and significantly less time outdoors altogether (direct sunlight plus shade),  $p < 0.001$ .

The number of mothers who used sunscreen was similar in both groups. But, when the groups were controlled for sunscreen use, the low-level intervention group spent significantly less 'unprotected' time (hours/week) in the sun ( $p < 0.05$ ):

Controls: none (0%),  $\geq 5$  hrs (35%)

Low-level: none (8%),  $\geq 5$  hrs (18%)

$P < 0.001$

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There were no significant differences between the control vs. low-level intervention groups in the use of hats (96% vs. 90%), stroller hoods (49% vs. 42%), umbrellas (5% vs. 8%), and loose fitting clothing (2% vs. 3%).

### *Secondary outcomes*

The mother's recollections at follow-up of advice given to them by their paediatricians with regard to sun exposure for their newborns were similar in the low-level intervention and control groups ( $p=0.45$ ).

### Limitations

Internal validity was rated "-". Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Applicable only to populations or settings included in the studies, the success of broader application is uncertain.

The authors reported that data was collected via a survey and based on recall that may be inaccurate. The possibility of social acceptability bias should be considered given the method used to obtain parental reports of sun-protective practices (telephone interviews) at follow-up.

The non-random allocation of the groups raises the possibility of selection bias.

### **Evidence statement**

An American controlled before and after study (rated -) evaluated the effectiveness of the provision leaflets to 275 mothers of newborn infants whilst on the maternity ward.

It provided evidence of statistically significant improvements amongst the intervention group in comparison with controls for some of the behavioural practices examined at seven month follow-up. Compared with the control group,

the infants and their mothers spent significantly less time in direct sunlight and less time outdoors ( $p < 0.001$ ). The number of mothers who used sunscreen was similar in both groups. But, when the groups were controlled for sunscreen use, the intervention group spent significantly less 'unprotected' time in the sun ( $p < 0.05$ ). The use of sun protective clothing and equipment for the infants was not significantly different between the groups and there was no discernable trend.

Applicable only to populations or settings included in the studies, the success of broader application is uncertain (Bologna<sup>8</sup>).

### 4.3.2 Studies on prevention in adults

#### 4.3.2.1 Studies in a workplace setting

Two randomised trials assessed printed materials in a workplace setting (Hanrahan, rated + and Rasmussen, rated -). Hanrahan was carried out in Newcastle, Australia and covered a wide range of occupations. Rasmussen was set in industrial companies in Scotland, UK. Hanrahan included 368 participants aged 45 to 65 years and Rasmussen 171 aged 18 to 73 years. Participants in Hanrahan were provided with materials aimed at males over 45 years. Rasmussen evaluated positive and negative messages. Control groups in both studies did not receive any information relevant to skin cancer (not entirely clear in Hanrahan and describing the common cold in Rasmussen). The Australian study followed-up participants for 20 weeks and the British one did not report follow-up. Hanrahan was both on prevention and detection of skin cancer and included some participants with a history of skin cancer (exact numbers were not reported).

None of the studies compared differences between groups, but rather within-arm changes were analysed. Hanrahan reported that participants in the intervention, but not in the control arm significantly increased their level of knowledge.

Rasmussen reported that likelihood of using sunscreen significantly increased in



participants provided with the intervention (both positive and negative information), but not in the control group.

#### 4.3.2.1.1 Hanrahan<sup>46</sup> - *RCT including participants with history of skin cancer on prevention and detection*

Men over 45 years old who were employees of The Broken Hill Propriety Co Ltd and its subsidiary in Newcastle were enrolled in this Australian study (rated +) evaluating the use of two brochures to increase knowledge about skin cancer. The year of this study was not reported. 368 employees were randomised: 110 to receive the brochures, 108 to receive no information and only a post-test, 96 to receive no information and pre- and post-test.

The age of participants ranged between 45 and 65 years with a median of 55 in the intervention and 53 and 54 in the control groups. Female employees were excluded. Race and ethnicity were not reported. History of skin cancer in some participants was indicated, but no exact information was given. In terms of employment categories, the largest groups were: plant operators 26%, labourers 20%, trade-persons 18% and professionals 15%. There were also clerical and sales workers 9%, paraprofessionals 7%, managers and administrators 5%. Authors reported that groups did not differ significantly at baseline.

Participants were given two brochures to retain for three weeks.

The brochures were: *“The many faces of melanoma”, prepared by the New York Skin Cancer Foundation, and a booklet especially designed for men over the age of 45. The former contained 24 coloured photographs illustrating melanomas at different stages and general information about melanoma. The second brochure was designed to provide answers to questions contained in the questionnaire. It included facts about melanoma, changes they should look for on their skin,*

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*instructions for self-examination and photographs of benign pigmented lesions (freckles, naevi, atypical naevi, seborrhoeic keratoses) and both early- and late-stage melanoma. This booklet was developed after consultations with many professionals. The language was simple and direct and the booklet was in question-and-answer format. It was tested in pilot studies in 50-year-old males in a "club" setting and found to be understood by this target group."*

There were two control groups. None of them was provided with information materials about skin cancer. The first one was only post-tested and the second one was tested both at baseline and follow-up.

A seven-part questionnaire was used. The first six parts included general questions about melanoma and the last one used eight photographs which tested ability to distinguish between pigmented skin lesions which required to be seen by a doctor and harmless ones. *"Most questions were in a "yes, no, don't know" format. Each question was given a score of 1 and the sum of correct scores in each part was used to derive an overall score which was converted to a percentage."*

*"The self-examination body chart included demonstrations of self-examination techniques and body outlines of the areas (trunk and arms) in which pigmented lesions were to be counted. Participants were instructed to document the number of pigmented lesions greater and less than 1cm in diameter on their trunk and arms. The chart contained separate rows for distinguishing between moles and other pigmented lesions, such as seborrhoeic warts."*

Examinations by doctors were carried out after the first post-test and they included only the trunk and arms.

This study was carried out over a period of 20 weeks. During the first week consent was obtained. Baseline assessments (questionnaire and self-examination) took place during second and third week. Participants retained brochures for the fourth to sixth week. The first post-test was conducted in weeks 10 and 11, followed by an examination by doctors at week 12. The second post-test took place at week 20.

## Results

### *Primary outcomes*

At baseline the mean knowledge level was 52.4 in the intervention arm and 53.1 in the control group that took baseline measures. At the first post-test there was a significant ( $p < 0.0001$ ) increase in the intervention arm to 62.8 and a non-significant increase in the control arm to 53.8. In the control arm in which participants were distributed the questionnaire for the first time, the knowledge score was 52.0.

At the end of the study there was a further increase in knowledge in the intervention arm to 66.8. Compared to baseline this was reported significant with  $p < 0.001$ . There was no significant increase in any of the control groups. Participants who were not tested at baseline achieved a score of 57.4 and the other control group: 57.6.

### *Secondary outcomes*

In both control groups there was a statistically significant correlation between the counts of pigmented lesions by participants at the end of the study and doctors ( $p = 0.027$  and  $p = 0.01$ ). In the intervention arm the correlation was not significant with  $p = 0.908$ .

Perceptions about melanoma and frequency of self-examinations are reported in Table 48 Hanrahan.

### Limitations

Internal validity was rated "+". Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

The authors observed that their study included more blue collar workers and less managers than the general population. They also highlighted high losses to follow-up, especially at the second post-test.

Results were reported in groups and not compared against each other. Demographic information was not provided in sufficient detail. Only self-reported measures of effectiveness were used. Intention to treat analysis was not carried out.

Applicability can be limited by the study being set in a location with high UV radiation levels.

#### **Evidence statement**

An Australian RCT (rated +) in 368 male employees aged over 45 years evaluated the effectiveness of two brochures on sun protection and self examination that participants retained for three weeks. The first brochure illustrated melanomas at different stages and the second was designed for men over the age of 45 and *“was designed to provide answers to questions contained in the questionnaire. It included facts about melanoma, changes they should look for on their skin, instructions for self-examination and photographs of benign pigmented lesions (freckles, naevi, atypical naevi, seborrhoeic keratoses) and both early- and late-stage melanoma.”* Participants were first post-tested nine to ten weeks and then 19 weeks after baseline.

It provided evidence of a significant increase in knowledge in the intervention group ( $p < 0.0001$  in the first post-test and  $p < 0.001$  in the second post-test). There was no significant change in control participants (exact significance levels were however not reported). Probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Hanrahan<sup>46</sup>)

#### 4.3.2.1.2 Rasmussen<sup>83</sup> - RCT

This trial (rated -) was conducted in the UK and participants were recruited from two industrial companies in central Scotland. A total of 171 employees were randomised to receive positive information (62 participants), negative information (55 participants) or control (54 participants).

The mean age was 41.25 (SD 12.38), ranging from 18 to 73 years. 58% of participants were female. Race and ethnicity were not reported. There were significant baseline differences between groups in the likelihood of using sunscreen.

Positive information included description of the efficacy of sunscreen use, the different types of sunscreens and how a history of sunscreen usage can dramatically reduce skin cancer risk.

Negative information outlined the problems with sunscreen usage and that most sunscreens still allow some UV rays through.

The intervention period was not reported.

Participants in the control group received sunscreen irrelevant information describing the characteristics of the common cold.

Likelihood of sunscreen use was expressed as reflected logs, therefore, a lower score represented higher sunscreen use. At baseline, those who agreed to take part were provided with basic information about the prevalence of skin cancer and then asked to give ratings anticipated likelihood of using sunscreen (decision 1). After intervention, the two experimental groups were asked a second rating about the likelihood of using sunscreen in the future (decision 2). Afterwards participants

were asked to rate ten replies to a statement relevant to each group, they were asked again to rate likelihood of using sunscreen (decision 3).

Likelihood of sunscreen use was also measured in subgroups (e.g. males and females).

Follow-up was not reported.

## Results

### *Primary outcomes*

There was a significant main effect of decision (decision 1 versus decision 2 versus decision 3,  $p < 0.001$ ), suggesting that there was a significant increase in ratings of likelihood of using sunscreen.

There was a main effect of group: individuals in the negative group indicated a lower likelihood of using sunscreen than individuals in the positive group,  $p < 0.05$ .

There was a significant increase in the likelihood in both intervention groups. However in the negative group there was a decrease in decision 3. The control arm did not significantly change their likelihood.

There was a main effect of gender: females had higher likelihood of using sunscreen than males,  $p < 0.05$ .

### *Secondary outcomes*

No secondary outcomes relevant to this report were reported.

## Limitations

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Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to populations or settings included in the study – the success of broader application is uncertain.

As authors stated, outcome measurement was based on self-reports. Participants had prior knowledge about skin cancer prevention and therefore impact of different types of messages could be limited.

Groups were not similar at baseline with respect to using sunscreen. Attrition details were not provided. It was moreover not possible to tell whether intention to treat analysis was performed and if results from different locations were comparable. Participants within the same company were allocated to different interventions which makes contamination possible (unless the follow-up test was carried out immediately after the intervention). Raw scores for each group were not reported.

The study was carried out in industrial companies in Scotland. Little information was provided about the demographic characteristics of the population.

Interventions were not described in detail.

#### **Evidence statement**

A British RCT (rated -) investigated the effects of positive (including a description of the efficacy of sunscreen use, the different types of sunscreens and how a history of sunscreen usage can dramatically reduce skin cancer risk) and negative information (outlining the problems with sunscreen usage and that most sunscreens still allow some UV rays through) compared to information irrelevant to skin cancer in 171 employees (aged 18 to 73 years) of industrial companies in Scotland.

There was a significant increase in likelihood of using sunscreen in both intervention arms and no significant change in the control arm (significance levels

not reported). Probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Rasmussen<sup>83</sup>)

#### 4.3.2.2 Studies in a university/ college setting

Three randomised trials (Castle, rated +, Mahler 2007, rated + and Mickler, rated ++) and a controlled before and after study (Greene, rated -) evaluated printed materials in university and college students. Castle was set on the south coast of England, UK and the remaining studies in the USA. Castle and Mickler evaluated leaflets or brochures containing information on skin cancer and its prevention. Mahler 2007 assessed the influence of UV facial photographs (showing damages to the skin caused by sun exposure, invisible in natural light). Greene evaluated printed materials with messages focusing on problems associated with tanning beds presented either in a statistical or a narrative format (however the type of the materials was not specified). Studies differed on the type of the control group with Mickler providing participants with information on peer leadership and the remaining studies probably using a “do nothing” control group. Castle and Greene included only female participants. Follow-up ranged from an immediate post-test (Mahler 2007) to one week (Castle) and three to four weeks (Mickler, Greene). Only Castle and Greene measured outcomes at baseline.

Mahler 2007 did not present results for the arms to which participants were randomised and therefore these results are not analysed in this review. The remaining two RCTs indicated a significant increase in knowledge in the intervention group compared to control group (Castle) or a higher post-test knowledge level in the brochures arm (Mickler). Castle assessed sun-protective behaviour, but no results were provided. Other primary outcomes were not assessed.

The controlled before and after study provided evidence of a significant decrease in tanning bed use in participants given statistical information compared to the



control group. There was no significant effect of the narrative message compared to the control group.

#### 4.3.2.2.1 Castle<sup>22</sup> - RCT

In 1996 112 students from a College of Further Education on south coast of England, UK took part in this randomised study (rated +). Their age ranged from 16 to 19 years (mean 17.5, SD 2.1). All of them were female. Race and ethnicity were not reported. 66 participants were randomised to the intervention and 33 to the control group.

In the experimental group there were significantly more smokers and “*women with sensitive skin that burns easily but tans eventually.*” The experimental group also had a higher knowledge score at baseline.

Health Education Authority leaflet “If you worship the sun, don’t sacrifice your skin” containing “*information on identifying your skin type and appropriate sun screen factor number, tips on sensible sun exposure, the information on melanoma.*”

The comparator was not reported, but probably was do nothing.

Knowledge about skin cancer was assessed with 19 questions (possible answers: yes/no, multiple choice and open-ended). Possible scores ranged from 0 to 30.

Participants reported their skin cancer related behaviours: suntanning, sunburns and protective measures.

Stage of change (pre-contemplative, contemplative, preparation for action, action, maintenance) was assessed for each participant. For the purpose of this study they were classified as either action (action or maintenance) or non-action (remaining stages) stages.

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Additionally health belief model constructs were assessed. These included:

- Benefits of suntanning for: mood, attractiveness, healthiness, sociability,
- Costs of sun protection,
- Perceived susceptibility to skin cancer,
- Severity (“*rating the statement “I could die from skin cancer”*”).

Individual differences were also explored using “*Big Five personality dimensions: Extroversion, Agreeableness, Emotional Stability, Conscientiousness, and Intellect.*”

Participants were followed-up for one week.

## Results

### *Primary outcomes*

Knowledge significantly increased in the experimental group compared to controls ( $p=0.001$ ). At baseline the mean knowledge score was 14.23 (SD 3.81) in the experimental and 11.87 (SD 3.50) in the control group. At follow-up the scores were 16.09 (SD 4.91) and 12.03 (SD 3.76) respectively.

Changes in behaviour were not reported.

### *Secondary outcomes*

There was a significant ( $p=0.003$ ) difference in numbers of participants who moved from action to non-action stage of change. In the control group numbers of participants in each stage of change remained constant with 26 in action and 5 in non-action stage of change. In the experimental group at baseline 49 participants were in an action and 8 in non-action stage of change. At follow-up eight participants moved to a non-action stage.

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There was no significant difference for any of the health belief model constructs.

### Limitations

Internal validity was rated “+”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted.

Authors stated that the number of participants was relatively small and there were fewer students in the control arm. Follow-up was relatively short. Men were excluded from the analysis.

This study was carried out in adolescents and young adults in the UK in 1996. All of them were students which might limit the applicability of the results. Groups were not similar at baseline. Participants who did not read the leaflet were excluded from the analysis possibly introducing selection bias. Intention to treat analysis was therefore not carried out.

### Evidence statement

A British RCT (rated +) evaluated in a population of 99 female students aged 16 to 19 years a Health Education Authority leaflet “If you worship the sun, don’t sacrifice your skin” containing “*information on identifying your skin type and appropriate sun screen factor number, tips on sensible sun exposure, the information on melanoma.*” Participants were followed-up for one week.

This study provided evidence of a higher increase in mean knowledge score in the intervention group compared to the control arm ( $p=0.001$ ). Although the study reported measuring changes in behaviour, the results were not reported. Probably

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likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted. (Castle<sup>22</sup>)

#### 4.3.2.2.2 Mahler 2007<sup>63</sup> - RCT

A videotaped slide show and an UV photograph were evaluated in this American trial (rated +). One hundred and forty three undergraduate students from University of California, San Diego were randomised: 34 to watch the video, 35 to receive the photo, 30 to watch the video and receive the photo, 34 to the control group.

Further details to be found in section 4.2.2.1.2.

#### Results

No interaction was found between the UV photo and video interventions.

Therefore results are provided for:

- Participants who received the photograph (including the photograph and video group)
- Participants who did not receive the photograph (including the video group)
- Participants who received the video (including the photograph and video group)
- Participants who did not receive the video (including the photograph group)

These results are not assessing the allocated interventions and therefore are not included in this report. They can be however found in Table 60 Mahler 2007.

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### *Primary outcomes*

Not reported for study arms.

### *Secondary outcomes*

Not reported for study arms.

### Limitations

Internal validity was rated “+”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

Further details to be found in section 4.2.2.1.2.

### **Evidence statement**

An American RCT (rated +) evaluated a facial UV photograph in 69 undergraduate students (aged 18 to 44).

It did not however provide results for groups that participants were randomised to.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Mahler 2007<sup>63</sup>)

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#### 4.3.2.2.3 Mickler<sup>68</sup> - *RCT including participants with history of skin cancer on prevention and detection*

This American randomised study (rated ++) evaluated three methods of teaching skin self-examination and skin cancer prevention skills. One hundred and forty three undergraduate psychology students were enrolled: 39 to the video, 35 to the brochures, 33 to the nurse led and 36 to the control arm.

Further details are provided in section 4.1.2.1.3

#### Results

In this section only results comparing the video with the control group are reported. It needs to be highlighted that as outcomes were not measured at baseline the results might not be measuring not only the effects of the intervention, but also differences between groups.

#### *Primary outcomes*

The mean knowledge score in the brochures group was 16.00 (SD 1.76) at the first post-test and 16.02 (SD 1.72) at the second one. In the control group it was 13.54 (SD 2.22) and 14.15 (SD 1.82) respectively. Authors report that participants in all intervention arms had significantly more knowledge than those in the control group.

#### *Secondary outcomes*

Students in the experimental arm had better results in the Visual Picture Test than the control group. Their self-examination skills were also rated higher than the wait-list. Exact results for both outcomes are provided in Table 65 Mickler.

#### Limitations

Internal validity was rated “++”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment

Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted.

Further details are provided in section 4.1.2.1.3

#### **Evidence statement**

An American RCT (rated ++) investigated in 71 undergraduate students (aged 17 to 31 years) the effectiveness of “*several commonly used written materials and were instructed to read them thoroughly. These brochures included “The Many Faces of Malignant Melanoma”, “Skin Cancer: If You Can Spot It, You Can Stop It”, “Basal Cell Carcinoma: The Most Common Cancer”, and “Squamous Cell Carcinoma: The Second Most Common Skin Cancer”.*” The first post-test was carried out immediately after completion of the intervention and the second three weeks later.

This study provided evidence that the mean knowledge level was significantly higher in the experimental group than in the control group both at immediate post-test and three weeks later (significance levels were not provided). No baseline measurement of outcomes was carried out. Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted. (Mickler<sup>68</sup>)

#### 4.3.2.2.4 Greene<sup>45</sup> - *controlled before and after study*

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This controlled before and after study (rated -) assessed the effectiveness of different message formats in reducing the use of tanning beds amongst Caucasian female college students at a midsized South-Eastern University in the USA. Precise details of the venue and the study year were not reported.

One hundred and forty one Caucasian female college students participated in the study outside class time, and received extra credit for participation. The participants were brought up primarily in the southeast (72%), and most had previously visited a dermatologist (60%). The students were aged 19-26 years. Details of socioeconomic status were not reported. The study excluded males and non-Caucasian females.

The study explored messages which may be effective in reducing the use of tanning beds amongst Caucasian college females, specifically by increasing perceived susceptibility to skin cancer and sun damage.

After providing written consent, participants were placed in a room with up to seven other people and given a survey to complete (approximately 20 minutes).

Surveys were identical with the exception of the presence or absence of one of two types of evidence format (statistical, narrative or no message), and the presence or absence of a self-assessment to calculate personal risk for skin cancer (3 x 2 design).

There were three message evidence conditions focusing on problems associated with tanning, tanning beds, and sun exposure. One message was statistical in format, providing statistical proof or evidence about the risk of use of tanning beds and information about skin cancer. The second message used a narrative format that told the history of a young woman who used tanning beds and later developed facial skin cancer. The statistical and narrative messages contained identical arguments (quality and number) and sources, but were presented in different evidence formats. Participants in the control condition received no message (and no message perception ratings).



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Upon completion of the survey all participants were given a modified debriefing form (to not contaminate the post-test). A telephone survey contacted 98.6% of the initial participants three to four weeks later.

Participants were followed-up at three to four weeks.

## Results

### *Primary outcomes*

Tanning bed use ( $M=3.06$ ;  $SD=6.32$ ) was measured at the pre-test with the question 'How many times have you used a tanning bed in the past month?'

Tanning bed change ( $M= -1.67$ ;  $SD=5.11$ ) between the pre-test and post-test was measured by telephone callback. Subjects were asked to answer the question 'Would you please estimate how many times you have used a tanning bed in the past month?' Behaviour change was measured by subtracting each subject's use of tanning beds in the month following the pre-test from their month prior to the pre-test. A positive score indicated a reduction and a negative score an increase in tanning bed use. Prior tanning behaviour was measured with a single item, 'How many times have you used a tanning bed in the past year?'

Participants who read the statistical message reported decreased tanning behaviour (or change) ( $F(2,136)=2.87$ ,  $p<0.05$ ,  $\eta^2 =0.05$ ) compared with those who did not read any message (the effect of the narrative message was not significantly different). For tanning bed use one month post message, the statistical message was significantly better ( $F(2, 136)=3.02$ ,  $p<0.05$ ,  $\eta^2 =0.04$ ) than either the narrative or no message.

### *Secondary outcomes*

Perceptions of the message (narrative or statistical) were measured by ten Likert-type items with five-point responses ranging from 'strongly agree' to 'strongly disagree'.

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There were significant differences between the statistical or narrative messages in mental effort ( $t(98) = -0.47$ ,  $d=0.05$ ) or message reflectiveness ( $t(98) = 0.14$ ,  $d=0.01$ ).

The narrative message ( $M=3.89$ ;  $SD= 0.56$ ) produced greater ratings of realism ( $t(98)= 2.29$ ,  $p<0.05$ ,  $d=0.23$ ) than the statistical message ( $M=3.57$ ;  $SD=0.52$ ).

The statistical message ( $M=3.10$ ;  $SD= 0.76$ ) produced greater ratings on information value ( $t(98)= 2.85$ ,  $p<0.01$ ,  $d=0.31$ ) than the narrative message ( $M=2.69$ ;  $SD=0.79$ ).

This was measured at the pre-test using six Likert-type items with five-point responses ranging from 'strongly agree' to 'strongly disagree'.

For intention to use tanning beds, both messages ( $F(2,136)= 3.93$ ,  $p< 0.05$ ,  $\eta^2 =0.05$ ) were significantly better than the no message condition.

Perceived susceptibility to skin cancer and sun damage was measured at pre-test using eight Likert-type items with five-point responses ranging from 'strongly agree' to 'strongly disagree'.

For susceptibility, all three messages differed significantly from each other ( $F(2,136) = 3.17$ ,  $p<0.05$ ,  $\eta^2 =0.06$ ), with the statistical message resulting in the most susceptibility and the no message condition the least.

There were no significant differences by message evidence format in intentions to protect skin ( $F(2, 136)= 0.96$ ,  $\eta^2 =0.05$ ).

## Limitations

Internal validity was rated "-". Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Applicable only to populations or settings included in the studies, the success of broader application is uncertain.

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Authors stated, that the study was conducted during the six weeks prior to the spring break which is a popular time for students to use tanning beds with the aim of developing a 'base tan' before going on vacation. Participants who reported tanning prior to the spring break may have considered a base tan a preventive behaviour to decrease the likelihood of burning during the spring break but this possibility was not explored in the data. This trend of tanning bed use before the spring break was reflected in the call back surveys, which indicated an increase in tanning during the month following the survey compared to the month before the survey. The self-reported nature of the data has inherent limitations. The sample size and geographic location prevent broad generalisation.

As participants were surveyed by telephone at follow-up social acceptability bias may have influenced their responses.

**Evidence statement**

An American controlled before and after study (rated -) evaluated the effectiveness of two message formats (statistical and narrative) in reducing the use of tanning beds amongst 141 Caucasian female college students aged 19 to 26.

There was statistically significant evidence, at three to four week follow-up, that information provided in a statistical format led to greater reduction in tanning bed use in comparison with no intervention ( $p < 0.05$ ).

There was no evidence that information provided in a narrative format led to a statistically significant reduction in tanning bed use in comparison with no intervention.

Applicable only to populations or settings included in the studies, the success of broader application is uncertain. (Greene<sup>45</sup>).

#### 4.3.2.3 Studies in a hospital/ medical practice setting

Only one study was identified to evaluate this intervention in a hospital/ medical practice setting. Details of this study are provided below.

##### 4.3.2.3.1 Prochaska<sup>82</sup> - *cluster (medical practice) RCT*

This American trial (rated -) enrolled 3834 patients at risk for sun exposure: 1822 in the intervention and 2012 in the control arm. They were part of a bigger study including 5407 participants which investigated the effectiveness of reports on risky behaviours (sun exposure, smoking, high-fat diet and relapse from regular mammography screening) accompanied by encouragement to change it. Only information on the patients at risk for skin cancer is reported as it is relevant to this review.

Participants were patients in one of 79 primary care practices randomised to study conditions. Demographic characteristics were reported for all participants including those not at risk for sun exposure. The mean age was 44.7 years (SD 12.7). 69.9% of participants were female. Most patients were White 96.7%. Remaining races/ ethnicities were: African American 1.1%, Asian 0.4%, Hispanic 1.3%, other 1.8%. It was not stated if groups were comparable at baseline.

Participants were mailed “*three computer generated reports at 0, 6, and 12 months for each at-risk behaviour.*” The first report was generated based on a telephone survey. Each report was three- to five-page long and provided patient’s stage of change and readiness to change, the pros and cons of changing behaviour, and feedback “*on the participants’ use of up to six change processes relevant to their stage of change.*” Participants were also compared to peers in the

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same stage of change who were successful in changing their behaviour. In the last two reports participants were also compared to their own prior assessment. Advice on how to enhance self-efficacy in the most tempting situations was also provided. *“Strategies for taking small steps to progress to the next stage”* were presented. *“The reports also referred participants to sections of an integrated multiple risk behaviour stage-matched self-help manual that were most relevant to their individual progress.”*

No intervention was provided to participants in the control arm.

The Sun Protection Behaviour Scale was used which consists of two scales: Sunscreen Use and Sun Avoidance. This scale is *“strongly related to stage of change and sensitive to the effects of interventions for both adults and adolescents.”* No further details were provided.

No other measures relevant to sun exposure were reported in this study.

Questionnaires were mailed at 12 and 24 months. The intervention group additionally received a survey at six months.

## Results

### *Primary outcomes*

Mean avoidance of sun exposure score was similar in both groups at baseline (12.7 (SD 3.6) in the intervention, 12.4 (SD 3.7) in the control group). At 12 months these scores increased to 13.5 (SD 3.5) and 12.9 (SD 3.6) and at 24 months they were 13.7 (SD 3.5) and 12.9 (SD 3.6) respectively. This study did not provide any estimates of effect or significance test results. In the discussion, however, authors mentioned that there was a significant difference in avoidance of sun exposure indicating a more sun-protective behaviour in the intervention group.

Mean sunscreen use was also similar at baseline with a score of 8.6 (SD 3.9) in the intervention and 8.5 (SD 3.9) in the control arm. 12 months later in both groups

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there were higher mean scores (9.8 (SD 3.8) in the intervention and 8.9 (SD 3.9) in the control arm. There was a further increase at 24 months with a mean score of 10.0 (SD 3.9) in the intervention and 9.2 (SD 3.9) in the control arm. Estimates of effect or significance test results were not reported. In the discussion it was mentioned that mean sunscreen use was significantly higher in the intervention group.

### *Secondary outcomes*

No secondary outcomes relevant to this report were provided.

### Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Applicable probably only to population or setting included in the study – the success of broader application is uncertain.

Authors reported that recruitment rate was rather low with 69% of contacted patients being enrolled in the trial. Participants were recruited from practices participating in a trial testing policy-changing interventions. Physicians enrolled in the trial were volunteers and might represent a subset of practices active in promoting cancer prevention.

Skin cancer was only one of four cancers targeted by this study and only results for a subsample of participants were used. Similarity of groups at baseline was not investigated. Some measurements were made only in the intervention group to generate intervention reports. Only self reported measures were used. Loss to follow-up in the entire study (including participants at risk for other factors) was relatively high with 71% of participants in the intervention and 78% in the control arm still in the trial at 24 months. It was not reported if clustering was taken into account.

**Evidence statement**

An American cluster RCT (rated -) in 3834 patients (number relevant to prevention of skin cancer component) from primary care practices investigated the effectiveness of three computer generated reports that were mailed “*at 0, 6, and 12 months*”. Such a report (three to five pages) included participant’s stage of change and readiness to change. It discussed pros and cons of changing behaviour, comparison with peers successful in changing their behaviour and participant’s own prior assessments (when possible). Advice on ways to change behaviour and to cope with the most tempting situations was also provided. The control group received no intervention. Questionnaires were mailed to participants at 12 and 24 months. The intervention group additionally received a survey at six months.

This study indicated that participants in the intervention arm avoided the sun and used sunscreen more, however this was not supported with results of statistical tests. Applicable probably only to population or setting included in the study – the success of broader application is uncertain. (Prochaska<sup>82</sup>)

#### 4.3.2.4 Studies set in the place of domicile

Only one study was identified to evaluate this intervention in the place of domicile. Details of this study are provided below.

#### 4.3.2.4.1 Richard<sup>86</sup> - *RCT on prevention and detection*

This RCT (rated -) evaluated three types of leaflets (humoristic, threatening and neutral) in adults. It was set in the Region Provence-Alpes-Côte d'Azur in the South of France. Representative samples "were selected using data from IPSOS (a French survey institute)." The study took place in 1996.

There were three intervention and one control arm. Each selected sample comprised 300 participants. Demographic characteristics were not reported.

*"Three different leaflets were designed by a panel of medical experts, a psychologist, a publicist and a graphic art specialist. The three types of leaflet contained exactly the same message. This was a concise and simple information about what melanoma is, describing the early signs which should prompt consultation, how to assess one's sun sensitivity on the basis of one's skin type, how to assess one's melanoma risk (on the basis of number of naevi and skin type), and how to adapt one's sun exposure and sun protection measures to one's risk. The title, the presentation and the tone of the leaflet, including drawing, figures, colour and vocabulary were chosen to be funny in the H-leaflet, worrisome and foreboding in the A-leaflet and as neutral as possible in the N-leaflet. In the H-leaflet multiple bright colours, funny slogans and comic strips were used and the word cancer was never mentioned in the information text. The slogan was "some skins cannot stand a quick cooking". In the A-leaflet only purple colour was used, anxiety and worry were suggested by a blurred photograph of a mother protecting her child and the word cancer was repeated in each title. The slogan was "2 times more skin cancers than 10 years before". In the N-leaflet the slogan was "a sun for each skin"."*

Leaflets were mailed in easily identifiable pink envelopes of the National Health Insurance to avoid them being taken for commercial advertisements.

The control group received no leaflet.



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Two weeks after mailing the leaflets, a telephone interview was conducted to assess: participants' phenotype, knowledge and intention to change behaviour towards sun. They were also asked if they consider their sun exposure low, normal or excessive in relation to their skin type. The interviewer enquired if they received the leaflet and if they have shown it to any other family member.

Participants were interviewed two weeks after mailing the leaflets. No baseline assessment was undertaken.

## Results

It needs to be highlighted that the results for participants in the intervention groups are only reported for those who said they read the leaflet.

### *Primary outcomes*

Eighty two (64%) of respondents who read the worrisome leaflet, 98 (63%) who read the neutral leaflet and 86 (54%) who read the humoristic brochure were able to define melanoma. This was also true about 128 (42%) participants in the control group. This percentage was significantly ( $p < 0.0001$ ) higher in all intervention compared to control.

Early signs of melanoma were known to 31 (24%) participants who read the worrisome leaflet, 44 (28%) who read the neutral brochure, 44 (28%) who read the humoristic one and 39 (13%) in the control arm. The percentage was again significantly higher with  $p < 0.0001$ .

At least three melanoma risk factors were identified by 45 (35%) participants in the worrisome group, 58 (37%) in the neutral arm, 62 (39%) in the humoristic one and 86 (29%) in the control condition. The difference between all intervention and control groups was significant with  $p < 0.02$ .

It needs to be highlighted that if non-compliers were included in the analysis, results would probably not be so favourable for the intervention arms.

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### *Secondary outcomes*

24% (107/443) participants who read any of the leaflets intended to change their behaviour and 20% (87/443) participants to have their skin examined by a physician. Significance levels were not provided.

Percentages for ability to evaluate one's skin type, risk and whether one's behaviour is adapted to one's skin type are reported in Table 72 Richard. Significance of these results was not stated.

### **Limitations**

Internal validity was rated "-". Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

No limitations were reported by the study authors.

Outcomes were assessed only in participants who have read the leaflets in the intervention groups who were possibly different from the ones who did not read materials. This was not done in accordance with intention to treat principles. There were no baseline measurements. Generally the study was poorly reported. No demographic characteristics were provided.

<p><b>Evidence statement</b></p>
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<p>A French RCT (rated -) tested three different leaflets (neutral, worrisome and humoristic) containing the same information on melanoma, early signs, skin type assessment and preventive behaviour in adults. Leaflets were mailed to 900 participants and 300 participants did not receive an intervention. Participants were</p>
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interviewed two weeks after mailing the leaflets. No baseline assessment was undertaken.

This study provided evidence of a higher level of knowledge about melanoma definition ( $p < 0.0001$ ), early signs ( $p < 0.0001$ ) and risk factors ( $p < 0.02$ ) in the intervention arms compared to controls. A serious limitation of this study is that in intervention arms only participants who read the leaflet were analysed. Probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Richard<sup>86</sup>)

#### 4.3.2.5 Studies on airports and/or flights

Two cluster randomised studies assessed the effectiveness of leaflets distributed to passengers departing for holiday (Dey and Segan, both rated -). In Dey leaflets were distributed in Air UK Leisure flights departing from Manchester. Participants in Segan were departing for the south or north coast of Queensland. The control groups did not receive any information on prevention of skin cancer. Dey assessed outcomes in 12385 participants aged 0-97 years (median 32 years) and Segan in 373 participants (mean age 32.2 years in the intervention and 33.4 in the control group). Follow-up was unclear in both studies – in Dey questionnaires were distributed on return flights to a cross-section of participants (no indication of time) and in Segan they were sent for participants to complete after returning home.

Both studies assessed sunburn during holidays and none of them found a statistically significant difference between groups (however in Dey there appeared to be less sunburns in the intervention group). Segan also asked participants about their sun protective behaviours. A composite measure of behaviour did not indicate a significant difference between groups (and no direction of effect) and out of six behaviours assessed, only for number of days outside for at least two hours between 10 am and 2 pm there was a significantly more positive result in the intervention arm. There was no trend observed for the remaining five behaviours.

#### 4.3.2.5.1 Dey<sup>28</sup> - *cluster (flight) RCT with cross-sectional outcome assessment*

This randomised trial (rated -) included “*holidaymakers travelling on Air UK Leisure flights from Manchester airport during August 1993.*” No indication of how many passengers were on these flights was provided.

No baseline assessments were made and demographic information was only collected from a cross section of 12385 passengers returning to Manchester. Their age ranged from 0 to 97 with a median of 32 years in the intervention group and from 1-88 with a median of 33 in the control group. 52.2% of the intervention arm and 52.9% of the control arm were female. Race and ethnicity were not reported.

The intervention group included 16 long haul and 62 short haul flights with 6276 passengers responding to the questionnaire. In the control arm there were 15 long haul and 62 short haul flights and 6109 passengers returned questionnaires.

“*The Health Education Authority leaflet “If You Worship the Sun, Don’t Sacrifice Your Skin” was placed in seat pockets on flights.*” The authors did not provide any further information.

No leaflet was provided on the control flights.

“*Cabin crew distributed questionnaires to passengers on Air UK Leisure return flights to Manchester.*” It asked if passengers experienced sunburns and if they were associated with: “*redness of skin, blistering of the skin, pain for less than a day, pain for more than a day. Adults completed the questionnaire for children.*”

“*The study endpoint, severe sunburn, was defined as any episode of sunburn which was either painful for more than a day or resulted in blistering.*”

Follow-up was not reported.

## Results

### *Primary outcomes*

Severe sunburn was experienced by 16.1% of the passengers in the intervention and 17.2% in the control arm. The difference in proportion was not significant ( $p=0.392$ ). Stratification by short and long haul also did not provide a statistically significant difference.

### *Secondary outcomes*

No secondary outcomes relevant to this review were reported.

## Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

Passengers were not asked if they had seen or read the leaflet as this might have influenced their response to the questionnaire.

In general this study was very poorly reported. No baseline data was collected, therefore it is not possible to tell if groups were comparable. This study measures the differences between groups (or rather passengers who responded to the questionnaire) – not changes due to information. It was not stated how many passengers were on the flights from Manchester and what percentage later answered the questionnaire. No indication on flight destinations and their UV levels was provided.

**Evidence statement**

A British RCT (rated -) assessed the impact of the Health Education Authority leaflet “*If You Worship the Sun, Don’t Sacrifice Your Skin*” placed in seat pockets on flights in 12385 passengers (aged 0 to 97 years, median 32 years). The control group received no leaflets. Follow-up was not reported.

This study did not provide evidence of a difference in severe sunburn between intervention and control groups ( $p=0.392$ ). The percentage of participants reporting severe sunburn in the intervention arm was however lower. This result needs to be treated with caution as the questionnaire was distributed only to a cross-section of passengers on return flights. Probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Dey<sup>28</sup>)

**4.3.2.5.2 Segan<sup>92</sup> - cluster (flight) RCT**

This RCT (rated -) was set in Australia in 1993. Tourists were recruited in gate lounges at Melbourne Airport across 21 flights. Three hundred seventy three adults departing to the southern or northern coast of Queensland for spring holiday were enrolled: 168 from 10 flights to the intervention group and 205 from 11 flights to the control arm.

The mean age in the intervention group was 32.2 years and in the control condition – 33.4 years. Holidaymakers looking 50 years old or older were not approached. 64% of all the participants were female. Race and ethnicity was not reported.

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The leaflet was “a full-colour six-page (21 cm-square) fold-out brochure entitled “The SunSmart Holiday Guide: How to enjoy your holiday in the sun without getting burnt”. The target audience for the brochure was all fair-skinned tourists holidaying in northern Australia. The brochure was designed, and focus group pre-tested, to ensure that it particularly appealed to young people (...) while also having a broad appeal. This was achieved via the use of young models within the brochure. The front cover promised answers to a series of “burning” questions: “Will I burn more quickly up north? What’s the most dangerous time to be in the sun? If I use a SPF 15 sunscreen, can I stay in the sun all day without burning? Can I get burnt if it’s cloudy or cool? Will I still get a suntan?” Inside, answers to questions presented factual information in conjunction with sun-protection strategies reflecting the solution-oriented rather than warning-oriented approach. Of particular emphasis was the “SunSmart Siesta Plan”: to wear SPF 15+ sunscreen and stay out of the sun for at least two hours between 10am and 2 pm. This strategy was developed to enable tourists to maximise their time outdoors, while minimising the risk of sunburn (...). Sun-protection hints were also provided for risky situations (such as all-day boat trips) and a highlighted section was devoted to getting the most out of your sunscreen. The treatment of sunburn was also addressed.”

“The brochure’s approach was one of harm minimisation as some sun exposure is intrinsic to the holiday experience.”

No information was the comparator.

“The pre-holiday questionnaire assessed:

- length and destination of the holiday (south vs. north Queensland),
- whether eight prompted reasons for holiday applied,
- sun tanning aspirations (none, light, moderate, dark),

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- *dichotomous measures of whether a hat and sunscreen have been packed for the holiday,*
  - *a four-point rating of how careful respondents generally are to protect themselves from the sun, and*
  - *a five-point rating of how often they will take steps to protect themselves from the sun while on holiday.”*

Post-holiday measures differed from baseline and included:

- frequency and location of sunburn (*“any amount of reddening of the skin after being in the sun”*),
- eight-point sunburn measure taking into account: number of times burnt (range 0 – “no burn” to 3 – “three or more burns”), extent (“strip” 0, “in-between area” 1, “large area” 2) and severity of the worst burn (“red not tender” 0, “red and tender” 1, “blistered” 2),
- reasons for sunburn,
- suntan acquired (none, light, moderate, dark),
- number of days with more than two hours in the sun between 10am and 2pm (every, most, half, few, no days), and
- frequency of sun-related behaviours (wearing a hat, using sunscreen, using shade, wearing covering clothing, wearing less clothing so as to expose skin) when outside for more than 15 minutes between 10am and 2pm – each measured on a five point scale (never, rarely, sometimes, usually, always) – mean outdoor sun protection was calculated after reversing the deliberate skin exposure measure.



Follow-up depended on the length of holiday (probably from three to up to over 30 days). Tourists were sent a questionnaire home so that it would wait for them when they return from holiday.

## Results

Even though questionnaires were distributed at baseline, their scope did not overlap with the follow-up surveys. Therefore groups are only compared post-test with respect to the outcomes of interest.

### *Primary outcomes*

There was no difference in sunburn between the two groups (intervention mean 1.61, control mean 1.57;  $p=0.99$ ). There was also no difference in whether respondents were trying to protect themselves when they were sunburnt ( $p=0.35$ ).

Tourists in the intervention arm reported significantly less ( $p<0.001$ ) days outside for at least two hours between 10am and 2pm. The average number of such days in the experimental group was 3.24 and in the control condition 3.71. There was no significant difference between groups with respect to other behaviours related to skin cancer: wearing a hat, using SPF 15+ sunscreen, using shade, wearing clothes covering most of the body, deliberately wearing less to expose skin to the sun. There was also no difference in composite outdoor sun protection. Exact results are reported in Table 13 Skin cancer related behaviours in participants in Segan below.

**Table 13 Skin cancer related behaviours in participants in Segan<sup>92</sup>**

Outcome	Intervention group mean	Control group mean	Significance level for F test comparing both groups
days outside for at least two hours between 10am and 2pm	3.24	3.71	$p<0.001$
frequency of wearing a hat	3.47	3.56	$p=0.51$
frequency of using SPF 15+ sunscreen	3.97	4.01	$p=0.72$
frequency of using shade	3.38	3.47	$p=0.33$
frequency of wearing clothes	2.13	2.26	$p=0.25$

covering most of the body			
frequency of deliberately wearing less to expose skin to the sun	2.69	2.82	p=0.21
<i>composite outdoor sun protection</i>	3.26	3.30	p=0.47

### *Secondary outcomes*

No secondary outcomes relevant to this report were reported.

### Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

The authors stated that it is possible that the reported differences did not reflect actual behaviour as reading the brochure might have had impact on awareness of time spent in the sun. Social desirability also needs to be taken into account with self reported behaviour. There were differences between groups at baseline. The investigated sample was not representative of all the tourists to Queensland as they may have used alternative transport means. Participants lost to follow-up could have differed from responders. The Australian population was already exposed to the SunSmart campaign. For most of the outcomes no significant difference was observed.

Participants in the intervention arm were given the baseline questionnaire and brochure (in a sealed envelope) together with instructions to first answer the questionnaire and then read the leaflet – it is possible that some participants first read the leaflet and then completed the baseline questionnaire. A potential clustering effect was not investigated. Intention to treat analysis was not carried out.

**Evidence statement**

An Australian RCT (rated -) investigated the effectiveness of a leaflet distributed on an airport to 373 tourists (mean age 32.2 years in the intervention and 33.4 years in the control group). It was targeted at fair-skinned people, especially the young. It provided answers to questions on sun protection by presenting *“factual information in conjunction with sun-protection strategies reflecting the solution-oriented rather than warning-oriented approach.”* It also provided hints for risky situations (*“such as all-day boat trips”*). *“The brochure’s approach was one of harm minimisation as some sun exposure is intrinsic to the holiday experience.”* Tourists were sent a questionnaire home so that it would wait for them when they return from holiday (up to over 30 days).

This study did not provide evidence of any difference between the intervention and control group with regard to sunburn ( $p=0.99$ ) and no direction of effect could be concluded. Out of six behaviours related to skin cancer only for days outside for at least two hours between 10am and 2pm was there a significant difference indicating a more sun-safe behaviour in the experimental arm ( $p<0.001$ ). For the remaining behaviours there was no consistent trend. There was also no difference in composite outdoor sun protection ( $p=0.47$ ) and no direction of effect could be concluded. Probably applicable only to population or setting included in the study – the success of broader application is uncertain.(Segan<sup>92</sup>)

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## 4.4 Theme 4: New media vs. Current provision of information/do nothing

### 4.4.1 Studies on prevention in children

#### 4.4.1.1 School based studies in children aged seven to eleven years

Only one study was identified to evaluate this intervention in a school setting in children aged seven to eleven years. Details of this study are provided below.

##### 4.4.1.1.1 Hornung<sup>50</sup> - *cluster (class) RCT*

This study (rated +) was conducted in an elementary school in North Carolina, USA. Seventy nine children (from 3 classes) were randomised to use a CD-ROM in the classroom and 77 (from 3 classes) to the control arm.

Full details to be found in section 4.1.1.2.4.

#### Results

Results are not provided for baseline, however the immediate post-intervention and follow-up scores are adjusted for baseline knowledge and demographic characteristics.

#### *Primary outcomes*

The adjusted mean post-intervention knowledge score was 75.2 in the intervention group, and 55.0 in the control group. The mean post-intervention knowledge score in the intervention group was significantly higher compared to that in the control group. The mean knowledge scores at seven months follow-up was 70.9 in the intervention group (significantly higher compared to the control group with  $p < 0.001$ ), and 57.4 in the control group.

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The mean post-intervention behaviour score was 45.8 in the intervention group, and 42.3 in the control group. The mean behaviour scores at seven months follow-up were 42.0 in the intervention group and 42.6 in the control group. The difference between groups was not statistically significant at any follow-up.

### *Secondary outcomes*

The mean post-intervention attitude score in the intervention group was significantly higher compared to that in the control group both immediately after the intervention and seven months later.

### Limitations

Internal validity was rated “+”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

This study is probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted.

Full details to be found in section 4.1.1.2.4.

### **Evidence statement**

An American RCT (rated +) evaluated in 156 third and fourth grade children a computer program used in the classroom setting via large-screen projection with student volunteers asked to take turns navigating through the program for the class. It took approximately 18 minutes to complete. It contained colourful animation as well as digital audio and video. Three different cartoon characters modelled three different sun safety behaviours: extremely protective, overly risky and appropriate. The control group received no intervention. Participants were first post-tested immediately after the intervention and then seven months later.

Adjusted knowledge level was significantly higher in the intervention group than in the control group both immediately (significance level not reported) and seven months after baseline ( $p < 0.001$ ). There was no significant difference in self-reported behaviours at both follow-ups, although it appeared that there was a positive trend in the intervention group in the immediate follow-up (significance levels not reported). This study is probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted. (Hornung<sup>50</sup>)

## 4.4.2 Studies on prevention in adults

### 4.4.2.1 Studies in a hospital/ medical practice setting

Only one study was identified to evaluate this intervention in a hospital/ medical practice setting. Details of this study are provided below.

#### 4.4.2.1.1 Glazebrook<sup>44</sup> - *RCT on prevention and detection*

This randomised study (rated +) was carried out in Family Practices in Nottinghamshire, UK in 1998 in patients identified to have at least one risk factor of melanoma based on a chart of characteristics (red hair, multiple moles, history of sunburn as a child, freckling, family history of melanoma, fair sun sensitive skin). It included a total of 589 patients from ten practices. Two hundred and fifty nine patients from five practices were allocated to the intervention and 330 patients from five practices to the control arm.

The mean age was 38.2 (SD 14.3) in the intervention and 38.4 (SD 15.2) in the control arm. More than half of the participants were female: 82.6% in the intervention and 78.5% in the control condition. Race and ethnicity was not reported.

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Skinsafe computer program designed to be completed in a single sitting (10-15 minutes) was prescribed to patients in the experimental arm. It used animation, photographs and simple text to inform users about the dangers from excessive sun exposure, how to protect the skin from the sun, characteristics of skin at risk, early signs of melanoma, how to reduce risk from melanoma, how to check skin for suspicious lesions. The final section prompts the user concerning personal risk factors and gives individualised feedback of relative risk.

The prescription resembled a standard one.

The Skinsafe program which was operated by a trackball device, was sited at a dedicated workstation either in a separate room or in a quiet corner of the waiting room. It was self-directed, but an illustrated instruction sheet attached to the workstation provided additional operating instructions.

The comparator was not reported, but was probably do nothing or current provision of information.

Outcomes were measured using a three-part Melanoma Questionnaire, which covered:

- knowledge on how to reduce risk from melanoma, risk factors for melanoma and early signs of melanoma; the maximum score was 12;
- behaviour during the previous year (six months for follow up): shade seeking, use of high factor sunscreen (SPF 15+), wearing a hat and covering skin, sunbathing, sunburn, skin self-examination and examination by others every few months; the maximum score was 8, with a higher score indicating a more sun safe behaviour;
- perceived risk of skin cancer rated on a five point scale compared to general population.

Participants were followed-up for six months.

## Results

### *Primary outcomes*

The mean knowledge score increased in the intervention group from 2.90 (SD 1.55) at baseline to 3.71 (SD 1.71) six months later. In the control group there was also a slight increase from 2.75 (SD 1.65) to 3.03 (SD 1.64). The mean difference between groups adjusted for baseline scores was 0.51 (95% CI: 0.30 to 0.72) and was statistically significant. The estimated effect size was also significant ( $p < 0.001$ ) and 0.31.

There was also a statistically significant positive effect of the intervention on skin protective behaviour. The baseline score was 4.60 (SD 1.82) in the intervention and 4.66 (SD 1.55) in the control arm. At follow-up the scores were 5.36 (SD 1.72) and 5.06 (SD 1.59) respectively. The mean difference between groups adjusted for baseline scores was 0.30 (95% CI: 0.10 to 0.51) and was statistically significant. The estimated effect size 0.18 was also significant ( $p = 0.004$ ).

### *Secondary outcomes*

Perceived risk in groups did not change significantly over time. However the number of participants checking their moles increased significantly with an OR of 1.67 (95% CI: 1.04 to 2.70). Further details to be found in Table 46 Glazebrook.

## Limitations

Internal validity was rated “+”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment

Probably likely to be applicable across a broad range of populations and settings.

Authors stated that selection bias was possible with lower recruitment in the control group. Outcome measurement was based on self-reports. Practitioners did not keep a record of prescribing rates so it is not clear, what was the reason for the low percentage of men in the sample.



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A possible additional source of selection bias was that patients were prescribed Skinsafe and when they intended to use it – they were invited to participate in the study. 45 patients in the intervention and 85 in the control arm did not respond to the follow-up questionnaire.

**Evidence statement**

A British RCT (rated +) in 589 patients (mean age 38.2 years in the intervention and 38.4 in the control group) evaluated Skinsafe, a computer program designed to be completed in a single sitting (10-15 minutes) available in a medical practice. It used animation, photographs and simple text to inform users about the dangers from excessive sun exposure, how to protect the skin from the sun, characteristics of skin at risk, early signs of melanoma, how to reduce risk from melanoma, how to check skin for suspicious lesions. The final section prompted the user concerning personal risk factors and gave individualised feedback of relative risk. Details of the control group were not reported. Participants were tested at baseline and followed-up for six months.

The study provided evidence of an increase in knowledge in the intervention group compared to controls, as the mean difference in knowledge between groups adjusted for baseline scores was significant (95% CI: 0.30 to 0.72). There was also evidence on a positive influence on skin protective behaviour in the intervention group compared to controls and the mean difference between groups adjusted for baseline scores was statistically significant (95% CI: 0.10 to 0.51). Probably likely to be applicable across a broad range of populations and settings. (Glazebrook<sup>44</sup>)

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## 4.5 Theme 5: Combination interventions vs. Current provision of information/do nothing

### 4.5.1 Verbal advice and printed materials in children

#### 4.5.1.1 School based studies in children aged seven to eleven years

Only one study was identified to evaluate these interventions in a school setting in children aged seven to eleven years. Details of this study are provided below.

##### 4.5.1.1.1 Naldi<sup>75,76</sup> - *cluster (school) RCT*

One hundred and twenty two Italian elementary schools with 11230 children attending second and third years were included in this study (rated +). A pilot phase with 51 schools was carried out between 2001 and 2003 and a second phase with 71 schools in 2002-2004. 62 schools (5676 children) were allocated to the intervention arm and 60 (5554 children) to the control arm. In a subsample of children naevi were counted – this included 2852 children in the intervention and 2069 in the control arm.

The mean age of participating children was eight years (SD 0.7). There were 2765 (48.7%) female students in the intervention group (for 47 children this characteristic was missing); and 2740 (49.3%) in the control group (for 24 children this characteristic was missing). Race or ethnicity was not reported. “*Skin, hair, and eye colour distributions were similar in the two study arms.*” It appears there was no significant difference in baseline results as well.

*“The educational intervention was developed with the help of pedagogues and epidemiologists and was conducted during the first year of study. It involved the distribution of educational material to parents and their children, the development of a short curriculum at school, based on a resource developed for health*

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*teachers, and the projection of a short video at school.*” It is unclear over what period the intervention was delivered, but possibly this was one year.

No intervention was provided in the control arm.

Difference in sunburns (defined as “*an episode of intense erythema, with or without blisters, causing pain and discomfort lasting for at least 3 days*”) in children between the year preceding and following the intervention was reported by their parents. Melanocytic naevi on upper limbs of a subsample of classes selected by the local investigator was counted. A secondary outcome was parents’ knowledge concerning sun effects and sun exposure, and behaviour of their children.

Participants were followed-up for 14-16 months.

## Results

### *Primary outcomes*

At baseline “any sunburns” of children over the previous year were reported by 783 parents (for 82 it was “unknown”) in the intervention group and 764 (86 “unknown”) in the control group. At follow-up parents reported respectively: 579 (125 unknown) and 565 (102 unknown). Adjusted OR was 0.97 (95% CI: 0.84-1.13) which suggested no evidence of difference between groups.

“One to two sunburns” were reported at baseline for 574 children in the intervention group and for 570 in the control group. At follow-up 418 children in the intervention arm, and 415 in the control arm experienced one or two sunburns. The adjusted OR was 0.96 (95% CI: 0.81-1.13) again indicating no difference between groups.

“Three or more sunburns” were reported for 87 children in both groups at baseline. At follow-up they were 74 in the intervention and 68 in the control arm. Adjusted OR was 1.10 (95% CI: 0.75-1.62) and the result was not statistically significant.

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For the naevi count authors reported that “*no differences emerged between the subgroups analysed. At baseline, the geometric mean of nevus count was 5.1 in both the intervention and the control group. At follow-up, the geometric means were 6.8 in the intervention and 6.4 in the control group. The ratio of relative change was 1.06 (95% confidence interval (CI) 1.02-1.10).*”

“Child experience of intense sun exposure” last year at baseline was reported by 4484 parents (145 “unknown”) in the intervention group and 4355 (163 “unknown”) in the control group. At follow-up the numbers were 3562 (172 “unknown”) and 3297 (137 “unknown”) respectively. The adjusted OR was 0.88 (95% CI: 0.77-1.01).

The number of parents at baseline who believed that their child was adequately protected from the sun during the previous year was 4937 (111 “unknown”) in the intervention and 4762 (118 “unknown”) in the control group. At follow-up these numbers were 3863 (136 “unknown”) and 3622 (131 “unknown”) respectively. The adjusted OR was 0.86 (95% CI: 0.71-1.04).

Parents were also asked if the child regularly used sunscreen while in the sun during the previous year. At baseline in the intervention group 4059 parents reported that always, 930 sometimes and 546 occasionally/never. In the control group 3925 parents claimed that their children always used sunscreen, 967 sometimes and 577 occasionally/never. The follow-up results for the experimental condition were: 3284 always, 699 sometimes, 444 occasionally/ never and for the no intervention group: 3026 always, 771 sometimes, 384 occasionally/ never. The adjusted OR of sometimes using sunscreen was 0.86 (95% CI: 0.75-0.98) and of occasionally/ never 1.11 (95% CI: 0.92-1.32). Always using sunscreen was considered a reference category.

For “child usually wore a hat while in the sun during the previous year” at baseline: 2154 always, 2263 sometimes and 1147 occasionally/never in the intervention group; 2082 always, 2188 sometimes, 1202 occasionally/never in the control group. At follow up children in the experimental group were reported: 1525 to always, 1884 sometimes and 1020 to occasionally/ never wear a hat. In the control

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arm the numbers were: 1404, 1819 and 958 respectively. Adjusted OR of sometimes wearing a hat was 0.96 (95% CI: 0.86-1.08) and of occasionally/ never OR = 1.021 (95% CI: 0.89-1.17). Always wearing a hat was considered a reference category.

For “child usually wore a long-sleeved shirt while in the sun last year” – reported in the experimental group at baseline: always 1126, sometimes 2339, occasionally/ never 2072 and at follow-up: always 901, sometimes 1902, occasionally/ never 1626. In the control arm at baseline children were reporting as wearing long-sleeved shirt: 1089 always, 2356 sometimes, 2026 occasionally/never and at follow-up: 776 always, 1821 sometimes and 1584 occasionally/ never. The adjusted OR for sometimes wearing a long-sleeved shirt was 0.91 (95% CI: 0.79-1.04) and for occasionally/ never 0.90 (95% CI: 0.78-1.03). Always wearing long-sleeved shirt while in the sun was considered a reference category.

### *Secondary outcomes*

No secondary outcomes relevant to this review were reported.

### **Limitations**

Internal validity was rated “+”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted.

Rate of sun protection was already high in the examined population and authors expected a large effect. Drop-outs could be a limitation, as some schools were not able to comply with study requirements. Sunburn history was reported by parents and this was not an objective measure. The intervention might have been too short

to produce desired effects. Behavioural attitudes, reduction in sunburn cases and sun exposure are surrogate outcomes of incidence and mortality from skin cancer.

Intention to treat analysis was not carried out with drop-outs being excluded. In the intervention arm three schools did not return the follow up questionnaires. One thousand two hundred and forty six children were lost to follow up (580 from the naevi count subsample). In the control group six schools and a total of 1373 children (408 from the naevi count subsample) were lost to follow up.

The study was carried out in Italy which might limit applicability to other countries. Few demographic characteristics were reported.

#### **Evidence statement**

An Italian RCT (rated +) in 11230 children was set in elementary schools and evaluated the effectiveness of *“distribution of educational material to parents and their children, the development of a short curriculum at school, based on a resource developed for health teachers, and the projection of a short video at school.”* The control group was given no intervention. Participants were tested at baseline and followed-up for 14 to 16 weeks.

It provided no evidence of a difference in adjusted OR of any sunburns experienced during the previous year (95% CI: 0.84 to 1.13) and the direction of effects was inconsistent for the number of sunburns experienced in the previous year. There was no significant difference in sun protective behaviours and it is difficult to indicate any trend in the data, as groups were compared only for “sometimes” or “occasionally/ never” behaving in a certain way (“always” was considered a reference category). The adjusted OR of intense sun exposure in the previous year indicated less sun exposure in the intervention group, but was not statistically significant (95% CI: 0.77 to 1.01). The adjusted odds ratio of parents believing that children were adequately protected from the sun during the previous year indicated less sun protection in the intervention group, but was not statistically significant (95% CI: 0.71 to 1.04). The ratio of relative change in the

number of melanocytic naevi measured in a convenience subsample of the population indicated more naevi in the intervention group (95% CI: 1.02-1.10). Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted. (Naldi<sup>75,76</sup>)

#### 4.5.1.2 Studies set in the place of domicile

Only one study was identified to evaluate these interventions in the place of domicile. Details of this study are provided below.

##### 4.5.1.2.1 Benjes<sup>5</sup> - RCT

This randomised study (rated +) investigated the effectiveness of a telephone call followed by printed materials in increasing mothers' sun protection of their newborn children. It was carried out in Falmouth, USA in 1998-1999.

One hundred and eight mother-child dyads were randomised to the intervention or control with 54 allocated to each arm.

Mothers' ethnicity was not reported. Age was only reported for mothers who completed the follow-up questionnaire. Most mothers were in the 25-34 age group – 62% of the intervention and 55% of the control arm. 22% of the experimental and 30% of the control group were aged 35-45 and the percentage of mothers aged 17-24 was 16% and 15% respectively. Demographic differences between both groups were reported as generally moderate.

Before the baseline test, 24 to 48 hours after delivery a maternity nurse in Falmouth Hospital counselled mothers about solar protection of their children.

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In the spring of 1999, mothers received a telephone call of at least 15 minutes and two four-page *RayBuster* newsletters. Highlights of the telephone call and materials included health benefits of sun protection, specific instructions for use of sunscreen and protective clothing, solutions to mothers' specific difficulties with sun protection, and personalised sun protection suggestions from the study director. Materials were created based on needs identified in the baseline survey and were tested with five mothers of young children who were not involved in the study.

No additional information beyond that provided by the maternity nurse was given to participants in the control arm.

The primary aim of this study was prevention of skin cancer in children. It also measured some outcomes in relation to sun protection of mothers. With regard to protection of children - mothers' practice of a series of behaviours for their child (wearing a hat, wearing a long sleeve shirt, staying in the shade, and using sunscreen) was assessed. Mothers reported of their child's sun burning and tanning as well. Mothers' own protective behaviours for themselves, their knowledge and attitudes regarding protection for themselves and for their child and mothers' vigilance in protecting their child from the sun were investigated.

Participants were followed-up for 12 months starting with a baseline questionnaire (children aged six months) and finishing with a follow-up questionnaire (children aged 18 months).

## Results

### *Primary outcomes*

For every sun protective behaviour the difference between groups in percentage change from baseline was not statistically significant ( $p > 0.05$ ). The percentage of children wearing a hat decreased from 73% in the intervention and 84% in the control arm to 64% in both groups. At baseline 73% children in the intervention



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and 80% in the control group wore a shirt. At follow-up this was 62% and 67% respectively. In the beginning of the study 89% of children in the experimental condition and 83% controls stayed in the shade. Twelve months later it was only 56% and 57% respectively. 36% of mothers allocated to the experimental and 33% to the control arm applied sunscreen to their children at the commencement of the study. This increased to 98% and 89% respectively.

At baseline any child skin damage was reported by 20% mothers in both groups. Twelve months later this increased to 52% in the experimental and 63% in the control arm. Any child burn was reported by 7% of mothers during the pre-test. At follow-up it was reported by 14% of mothers in the intervention and 28% in the control arm. Significance levels were not provided.

Rates of child tanning increased from 14% to 45% in the intervention group and from 17% to 37% in the control group. No significance test was reported for this outcome.

Vigilant sun protection of children was measured only at follow up and was reported by 82% of intervention group mothers, and by 61% in the control group. This difference was statistically significant with  $p=0.02$ .

### *Secondary outcomes*

No overall difference between groups in mothers' sun protection was observed. Routine sunscreen use among intervention mothers increased by 11% compared with 3% in controls. No difference between groups in mothers' reporting of personal sunburns or tanned skin was found.

### **Limitations**

Internal validity was rated "+". Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted.

Authors highlighted that parental vigilance was assessed only post-test. The effects of the intervention are likely to be limited due to the earlier community-wide education efforts.

Groups were not similar at baseline (authors reported that differences were generally moderate) and an intention to treat analysis was not undertaken.

This study was carried out in the USA. Results were based on the behaviours reported by mothers. The counselling by maternity nurse at baseline could have influenced the results.

#### **Evidence statement**

An American RCT (rated +) assessed in 108 mother-child pairs the effectiveness of a telephone call of at least 15 minutes and two four-page *RayBuster* newsletters. Highlights of the telephone call and materials included health benefits of sun protection, specific instructions for use of sunscreen and protective clothing, solutions to mothers' specific difficulties with sun protection, and personalised sun protection suggestions. Mothers in both the intervention and control group received verbal education from a maternity nurse before baseline assessment. The control group received no further education. Participants were followed-up for 12 months starting with a baseline questionnaire (children aged six months) and finishing with a follow-up questionnaire (children aged 18 months).

This study provided no evidence of more sun protective behaviour in the experimental arm compared to controls ( $p > 0.05$ ). Results for individual behaviours did not appear to follow any trend. Mothers in the intervention arm reported a higher post-test level of vigilant protection of their children ( $p = 0.02$ , no baseline measurements were taken). There was also a smaller increase in child skin damage and sunburn and a higher increase in child tanning in the intervention

group, significance levels were however not provided. Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted. (Benjes<sup>5</sup>)

#### 4.5.1.3 Studies set in a recreation site

Only one study was identified to evaluate this intervention in a recreation site in children. Details of this study are provided below.

##### 4.5.1.3.1 Mayer<sup>64</sup> - RCT

Prevention of skin cancer in children aged six to nine years was investigated in this RCT (rated +). It was conducted in 1995 in aquatic classes in four YMCAs in San Diego, California, USA. 169 children were allocated to the intervention (84 children) or control (85 children). If one sibling was in a control class and the other in an intervention class, the control class sibling was excluded.

The mean age of children was 7.6 years. 49.7% were female. With regard to race/ethnicity 79.8% were white non-Hispanic, 6.5% were Hispanic, 7.7% Asian/ Pacific Islander, 5.3% African American and 0.6% Native American. Annual household income as reported by parents was <\$30K in 15% of families, \$30-49K in 18%, \$50-69K in 26%, \$70-89K in 22% and equal or above \$90 in 20%. It was reported that there were no statistically significant differences between the groups on key demographic, selected skin cancer risk related, or outcome variables at baseline.

The intervention contained a UV reduction curriculum that was presented at poolside by YMCA aquatics instructors and home-based activities for children and their parents. This intervention was implemented for a period of six weeks.

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The content was “centered around four topic areas: sunscreen, protective clothing, shade, and peak sunlight hours. At each of four aquatic lessons, a 5-min SUNWISE lesson was incorporated at the beginning. The aquatic instructor began the lesson with a photograph that depicted an animal engaged in “sunwise behaviour”. (...) At each lesson the instructor (a) solicited information from the children about what the animal was doing; (b) modelled sun protection behaviour (...) and (c) rewarded verbally and with stickers the children’s use of sun protection. Each behaviour targeted at a lesson was also included in subsequent lessons.”

In the beginning of the intervention parents were given a manual about skin cancer prevention, information about the project and materials and instructions for home activities. “Activities for children  $\leq 7$  years included coloring a picture to indicate on which body parts the children should wear sunscreen, a connect-the-dots to illustrate protective clothing, a word search to indicate items that provide shade, and a coloring assignment to indicate which clocks show peak vs nonpeak sunlight hours. Activities for children 8 years and older included letter unscrambling to spell words associated with body parts requiring sunscreen, a fill-in-the-blanks with names of protective clothing, a more challenging word search for shade items, and a more challenging clock task for peak hours. Family activities included a special calendar with reward stickers given for days sunscreen was used; selecting sun protective clothing for different outdoor activities; making a map of the family’s yard, emphasizing areas of shade; and an activity-planning session to reduce time spent outdoors during peak sunlight hours. Parents were instructed to send the associated activity sheets with the child to the subsequent swimming lesson, to be collected by the aquatics instructor. Following Lesson 4, several additional materials for child and family activities were mailed to the participants, including SUNWISE “Jeopardy” game and a UVR meter.”

The control group was current information provision or do nothing.

Change in skin colour dimensions was measured objectively pre- and post-intervention using a portable colorimeter, the Chroma Meter (CR-300; Minolta). Two colour dimensions,  $L^*$  and  $b^*$ , were measured.  $L^*$  indicates the colour’s

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lightness from black to white, with the value increasing as the colour lightens (i.e., becomes less tan).  $b^*$  assesses blue to yellow, with the value increasing as the colour becomes more yellow (i.e., more tan).

Composite solar protection habit score ranging from 0 to 16 was used with a higher score indicating more protection. The child's specific use of sunscreen and protective clothing obtained from parents was evaluated using a modified version of the Solar Protection Behaviour Diary.

General use of several skin protective strategies provided by parents, including wearing hats and using sunscreen  $\text{SPF} \geq 15$  was assessed. For each item, a five-point Likert-type scale was used, ranging from 1 for "never" to 5 for "always."

Children were followed-up for six to eight weeks.

## Results

### *Primary outcomes*

The mean adjusted for baseline post-test  $L^*$  was 55.05 in the control group, and 55.46 in the intervention group, they were not significantly different with  $p=0.19$ . The adjusted post-test  $b^*$  was 16.16 in the control group, and 15.75 in the intervention group, they were not significantly different with  $p=0.084$ .

The mean composite solar protection score adjusted for baseline differences was 11.38 in the control group, and 12.11 in the intervention group, they were not significantly different with  $p=0.15$ .

The mean hat wearing score adjusted for baseline was 2.52 in the control group and 2.84 in the intervention group, they were significantly different with  $p=0.029$  (0.049 adjusted for age and gender).

The mean adjusted score of using of  $\text{SPF} \geq 15$  sunscreen, was 3.41 in the control group and 3.52 in the intervention group, they were not significantly different with  $p=0.44$  (0.53 adjusted for age and gender).

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Unadjusted baseline and post-test values are provided in Table 61 Mayer.

### *Secondary outcomes*

No secondary outcomes relevant to this review were reported.

### Limitations

Internal validity was rated “+”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted.

Authors highlighted that all the results, apart from colorimeter measurements, were reported by parents. There was no comparison of responders and non-responders undertaken.

Losses to follow-up were relatively high and differed depending on outcome. For adjusted post-test L\* and b\*, 20 subjects were lost in the control, and 11 in the experimental group. For composite solar protection habit score 17 participants dropped-out in the control, and 20 in the intervention arm. For wearing a hat and use of SPF  $\geq$  15 sunscreen the losses to follow-up were nine and eight respectively. An intention to treat analysis was not undertaken.

This study was conducted in a region of the USA with relatively high UV radiation level.

### **Evidence statement**

An American RCT (rated +) in 169 children (mean age 7.6 years) evaluated a UV reduction curriculum that was presented at poolside during the first five minutes of aquatic classes by YMCA instructors (including presenting a picture of an animal

engaged in sun protective behaviour, discussion of this behaviour and modelling sun safe behaviours by instructors) and home-based activities for children and their parents (including age-appropriate games to teach children sun protective behaviours). The intervention was delivered over six weeks to children aged six to nine years. No details of the control group were provided. Participants were tested at baseline and followed-up for six to eight weeks.

This study provided evidence that in the intervention group the adjusted score for frequency of wearing a hat was higher than in the control group ( $p=0.029$ ). In the intervention group there was a slightly higher adjusted score for frequency of using sunscreen with SPF 15+, but the difference was not statistically significant ( $p=0.44$ ). The intervention group had a higher adjusted solar protection score than the control group (the difference was not significant with  $p=0.15$ ). There was a non-significant positive trend in the intervention group compared to controls in the change of skin colour ( $p=0.19$  for  $L^*$  scale and  $p=0.084$  for  $b^*$  scale). Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted. (Mayer<sup>64</sup>)

## 4.5.2 Verbal advice and printed materials in adults

### 4.5.2.1 Studies set in workplace

Only one study was identified to evaluate these interventions in a workplace setting. Details of this study are provided below.

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#### 4.5.2.1.1 Glanz<sup>42</sup> - RCT

The purpose of this study (rated -) was to educate on sun protection group leaders responsible for children six to eight years old at recreation sites in Hawaii, USA.

This study was carried out in 1996. 176 group leaders were enrolled, but numbers allocated to study arms (which included intervention, control and a mixed intervention arm which was not included in this report) were not reported.

60.9% of the participants were female. The mean age was 20.9 (SD 7.7). 5.3% of them were White, 22.8% Hawaiian or part-Hawaiian, 31% Japanese, 9.4% Filipino, 5.8% Chinese and 25.7% were reported as other race or ethnicity. At baseline 11 demographic variables were measured and of these age and gender significantly differed between groups. These two factors were adjusted for in the analysis.

Participants were given a “60-90 minute staff training, a leader’s guide for staff, on-site activities, and educational materials for children aged six to eight years and their parents” and incentives for children including “logo lunch sacks, school supply kits, magnets, temporary SunSmart tattoos, logo hats, and logo T-shirts.”

After the initial training leaders delivered interventions for children over the following six weeks

Participants in the control group did not receive any intervention until the last test. An abbreviated educational package was provided after the last follow-up test

Knowledge about skin cancer prevention and attitudes were assessed, but no information about the questionnaires used was provided.

Sun protection habits were assessed with scores which “were calculated on the basis of a composite of five sun protective behaviours (wearing a shirt with sleeves, wearing sunglasses, seeking shade, using sunscreen and wearing a hat).”



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An index evaluating norms for sun protection was created by adding up responses to three statements about whether most staff used sunscreen, wore hats, and covered up when outdoors.

All staff were followed-up for eight weeks and staff who agreed to be mailed a questionnaire – for three months.

## Results

### *Primary outcomes*

At baseline knowledge score in the intervention group was 4.46 and it increased to 5.02 at the first post-test. The adjusted difference was 0.79 (SE 0.27) and was significant with  $p < 0.01$ . In the control group there was a slight decrease in the mean score (from 4.67 to 4.57), the significance of this change was however not reported. The adjusted difference between changes in the intervention and control arm was 0.46 (SE 0.30) and was not statistically significant. Results are also provided for the three months follow-up (4.92 intervention, 4.55 control), but no statistical testing was reported.

Sun protection habits followed a similar pattern with a significant ( $p < 0.05$ ) increase in the adjusted difference between baseline and first post-test in the intervention group (0.37, SE 0.12) and a non significant adjusted difference between changes in the intervention and control arm (0.06, SE 0.15). Significance testing for the change within the control group was not reported. The mean scores at baseline were 2.39 in the intervention group and 2.33 in the control group. In the first post-test they were 2.49 and 2.33 and at 3 months follow-up – 2.30 and 2.25 respectively.

Mean staff sunscreen use score was 2.18 in the intervention arm and 2.08 in the control arm at baseline. It increased after eight weeks in both groups to 2.46 and 2.44 respectively. The adjusted increase in the intervention arm (0.35, SE 0.22) was reported to be non significant and was not reported for control participants.

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The adjusted difference between changes in groups (0.18, SE 0.40) was also reported to be not significant. At three months mean scores were slightly lower in both groups (2.40 intervention, 2.39 control), however significance was not reported.

### *Secondary outcomes*

There was a statistically significant adjusted increase in the intervention group with regard to perceived norms (0.51, SE 0.25,  $p < 0.05$ ) – probably indicating a more sun safe attitude, although a clear statement was not provided. No testing for the control group or between-group comparison was reported.

### Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

Authors highlighted that the effectiveness of this intervention was assessed using only self-reported measures. Some participants did not respond to the survey both at baseline and both follow-ups. There was possibly a selective drop-out. The time frame of this study was limited.

Groups were not similar at baseline. 144 of the initially enrolled 176 participants responded to the first follow-up survey and 66 to the second one. Intention to treat analysis was not undertaken.

This study was carried out in a location with a relatively high level of UV radiation. The demographic characteristics of the population might significantly differ from these of the UK population.

**Evidence statement**

An American RCT (rated -) evaluated an intervention in staff of recreation sites (mean age 20.9 years) who were later to deliver education to children. There were 176 participants in the study, however this number included a mixed arm that was not analysed and further details were not provided. Participants were given a “60-90 minute staff training, a leader’s guide for staff, on-site activities, and educational materials for children aged six to eight years and their parents” and incentives for children including “logo lunch sacks, school supply kits, magnets, temporary SunSmart tattoos, logo hats, and logo T-shirts.” The control group received no intervention. Staff were tested at baseline and followed-up for eight weeks and staff who agreed to be mailed a questionnaire – for three months.

It did not provide evidence of any effect of the intervention compared to control on knowledge, sun protection habits and sunscreen use. Only for knowledge was there a consistent pattern with an increase in the intervention group ( $p < 0.01$ ) and a decrease in the control group (reported as non-significant, no p-values provided) at eight weeks. At three months there was a decrease in knowledge in both groups, but the knowledge level in the intervention arm was still higher than at baseline (statistical significance not reported). Probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Glanz<sup>42</sup>)

#### 4.5.2.2 Studies set in the place of domicile

Only one study was identified to evaluate these interventions in the place of domicile. Details of this study are provided below.

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#### 4.5.2.2.1 Geller 2006<sup>35,38</sup> - *cluster ("sibship") RCT on prevention and detection*

Adult siblings of melanoma patients from four Boston, USA area teaching hospitals were enrolled in this study (rated -) which was conducted between 1998 and 2000. Four hundred and ninety four consenting siblings of 298 patients were randomised to either a combination intervention 237 or usual care 257. "Sibship" was used as the unit of randomisation.

55.7% of participants in the intervention arm and 60.6% in the control arm were aged 50 years or less. Slightly more than half of the participants were females (51.9% intervention, 54.9% control). All participants were Caucasian.

The intervention commenced with a motivational and goal-setting telephone session with a health educator. *"Computer-generated tailored print materials were sent at 1, 3, and 5 months after randomisation. The materials were tailored based on responses to the baseline; materials were tailored to level of participation in each of the three target behaviours (skin self-examination, physician screening, and sun protection), self efficacy, and beliefs."* Three telephone calls of approximately 10-15 minutes using a motivational interviewing style followed receipt of the materials. Participants were also provided with *"linkages to free screening programmes."*

The intervention was designed to address: knowledge and attitudes, barriers to change, risk perception and self-efficacy for improving skin cancer risk behaviours.

Participants in the control arm were given what was considered standard practice. No intervention was provided until the completion of the last survey. Patients were advised to notify family members about their diagnosis and make appointments for first-degree relatives to be screened.

*"Knowledge was tested with true/ false questions on shape, colour, and risk factors for melanoma."*

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Participants were asked to rate their degree of tanning at the end of the summer.

It was enquired if siblings had “*a skin cancer screening examination by a dermatologist within 12 months after completion of the baseline survey,*” conducted a personal skin self-examination at least once after baseline, always or often used “*sunscreen with SPF 15 or greater when outside in the sun for more than 15 minutes during the previous summer*” (assessed at 12 months).

Psychosocial variables measured on five-point Likert scales were used to assess participant’s self-efficacy regarding: completion of a skin self-examination, having a spouse or a friend examine the participant’s skin, seeing a dermatologist, and wearing sunscreen.

Barriers scales were constructed using a sum of responses to statements (ranging from 1 “strongly disagree” to 5 “strongly agree”. Separate scales were used for: early detection (two statements, range 2-10), sun protection (six statements, range 6-30), skin self-examination (three statements; range 3-15).

Participants were tested six and 12 months after baseline.

## Results

### *Primary outcomes*

Knowledge about melanoma was assessed using four true/false statements. At six months only for two of them there was a significant increase in percentage of siblings providing correct answers in the intervention compared to the control arm. These statements concerned melanoma being found mostly on face and arms (OR = 1.90, 95% CI: 1.19 to 3.05) and melanoma being a round brown or black spot (OR = 2.10, 95% CI: 1.37 to 3.22). For lots of moles increasing the risk of melanoma (OR = 1.35, 95% CI: 0.86 to 2.13) and having freckles increasing the risk of melanoma (OR = 0.99, 95% CI: 0.58 to 1.67) the results were not statistically significant. Knowledge levels at 12 months were not reported.

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In the intervention arm 55.9% declared routine use of SPF 15+ sunscreen at baseline, 66.7% at six months and 67.4% at the end of the study. In the control group there was also an increase from 56.6% at baseline to 64.4% at six months and 66.1% at 12 months. The increase in the intervention group did not differ significantly from the control group at 12 months with an OR of 0.96 (95%CI: 0.67 to 1.38).

At 12 months there was also no significant difference between groups with regard to being tanned at the end of last summer (OR=0.72, 95%CI: 0.47 to 1.09). In the intervention arm the percentage dropped from 41.7% at baseline to 36.8% at six months and 25.7% at 12 months. In the control group there was no consistent pattern and the observed percentages were 37.2%, 38% and 35.6% respectively.

### *Secondary outcomes*

At 12 months in the intervention compared to the control arm there was a significant increase in the percentage of participants who within the previous year had an examination of all their moles and compared all their moles to see if one stands out. There was no difference with regard to participants who within the last 12 months had an examination by a dermatologist, asked a family member or friend to look at their moles or used a picture of moles as help in looking.

Out of seven items assessing attitudes only in two was there a significant change towards more sun protection in the intervention compared to control group. These items were: confidence to see a dermatologist and intentions to have a dermatological examination.

### **Limitations**

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Applicable probably only to population or setting included in the study – the success of broader application is uncertain.

One of the limitations stated by authors was that only self-reported measures were used. Furthermore the sample might not be representative for siblings of melanoma patients in the general population. No cost-benefit analysis was undertaken. No comparison with other high risk populations was made.

Participants were enrolled at different times of the year which makes recall bias about sun tanning during the previous summer possible. There were also large loss to follow-up (84% were followed up at six months and 64% at 12).

Some variables were not similar in both groups at baseline. Intention to treat analysis was not undertaken.

#### **Evidence statement**

An American cluster RCT (rated -) in 494 siblings of melanoma patients investigated the effectiveness of *“computer-generated tailored print materials (...) sent at 1, 3, and 5 months after randomisation”* and telephone calls. *“The materials were tailored based on responses to the baseline; materials were tailored to level of participation in each of the three target behaviours (skin self-examination, physician screening, and sun protection), self efficacy, and beliefs.”* Three telephone calls of approximately ten-15 minutes using a motivational interviewing style followed receipt of the materials. Participants were also provided with *“linkages to free screening programmes.”* The control group received standard intervention. Participants were tested at baseline. Follow-up tests were carried out six and 12 months after baseline.

At six months there was a significant increase in the intervention compared to control group in the percentage of participants providing correct responses to two questions about melanoma (95% CI: 1.19 to 3.05 and 1.37 to 3.22). For two remaining questions there was no significant difference between the groups and no consistent trend. The study did not provide evidence of a difference between groups or a visible effect direction at 12 months in change in routine use of SPF 15+ sunscreen. There was a decrease in the percentage of participants who

reported being tanned at the end of last summer in the intervention group compared to controls, but there was no statistically significant difference between groups (OR=0.72, 95%CI: 0.47 to 1.09). Findings are applicable probably only to population or setting included in the study – the success of broader application is uncertain. (Geller 2006<sup>35,38</sup>)

### 4.5.3 Verbal advice and new media in children

#### 4.5.3.1 School based studies in children aged seven to eleven years

Only one study was identified to evaluate these interventions in a school setting in children aged seven to eleven years. Details of this study are provided below.

##### 4.5.3.1.1 Geller 2003<sup>36,37,39</sup> - *cluster (school) controlled before and after study*

This controlled before and after study (rated -), undertaken during 2002, assessed the effectiveness of group-based verbal advice and new media information provided at school. The study years were 1999-2002. Most of the results were analysed as a before and after study and are reported in a separate document.

The intervention evaluated, the SunWise School Programme, was already available across the USA. All public and private elementary and middle schools in the USA were eligible to participate. A sample of 156 schools (5,625 children) was chosen to participate in surveys assessing its effectiveness (1999-2002). The assessment of these results was essentially a pre-test/post-test before and after comparison. Children (n=5,625) assessed in the pre-test/post-test before and after comparison were aged 5-15 years (grades K-8).



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In the year 2000, all nine elementary schools in Framingham, MA served as controls (n=1,285) and provided no education during spring months. The students in the control schools were compared with the nationwide profile of children in similar grades receiving SunWise education in spring 2000 (the precise composition of the intervention group was not reported).

The Framingham control group (n=1,285) comprised fourth to fifth grade students with a mean age of ten years. Details of sex, ethnicity and socioeconomic status were not reported and no exclusion criteria were stated.

The cross-curricular, standards-based classroom lessons were contained in an activity guide and later expanded in the SunWise Tool Kit. Lessons focused on three key areas: 1) the effects of UV radiation, 2) risk factors for overexposure, and 3) sun-protection habits. Each lesson consisted of a variety of developmentally-appropriate activities meeting prescribed educational standards that combined education about sun protection and the environment with other aspects of student's regular learning on sciences, social studies, health, and mathematics. At least one or two hours were spent on the activities. There were at least 30 activities for faculty to choose from. Other activities were supplemented by the SunWise web-site which offered schools the opportunity to check for the UV index, report, chart, and compare UV measurements, and play educational games.

In the year 2000, all nine elementary schools in Framingham, MA served as controls (n=1,285) and provided no education during spring months. The students in the control schools were compared with the nationwide profile of children in similar grades receiving SunWise education in spring 2000.

The effect of classroom lessons on students' knowledge, attitudes, practices, and intended practices was evaluated using identical, self-administered pre-test surveys distributed in September-March (autumn-spring) and post-test surveys distributed immediately after teaching the SunWise educational programme, generally in May-June (spring-summer). Surveys were collected and individually analysed each year from 1999-2002.

For the students (fourth and fifth grades only) in the Framingham control/no intervention schools, school nurses conducted pre-tests in November and post-tests in June. Students in the control schools were compared with the nationwide profile of children in similar grades receiving SunWise education in spring 2000.

Participants were followed-up for approximately four to five months.

## Results

### *Primary outcomes*

During the school year the fourth and fifth grade students (n=1,285) in the control schools showed no improvement in knowledge from pre-test to post-test.

Changes in knowledge were more likely in experimental schools (no of students not reported) than control schools. Statistical significance not reported.

### *Secondary outcomes*

Students in the control group showed no improvement in beliefs about tanning, and reported fewer intentions to play in the shade from pre-test to post-test.

Overall changes attitudes and intentions were more likely in experimental schools (no of students not reported) than control schools: intentions to play in the shade improved by 5% in the experimental schools and dropped 8% in the control schools ( $p<0.05$ ); the attitude that people look healthier with a tan dropped in experimental schools, but rose in control schools ( $p<0.05$ ).

## Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

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Applicable only to populations or settings included in the studies, the success of broader application is uncertain.

Authors stated that school nurses and teachers volunteering to participate in the SunWise programme may have strong personal interests. The positive changes in knowledge and attitudes that occurred during the 4-5 months between pre-tests and post-tests may have occurred elsewhere.

The authors state 'students in the control schools were compared with the nationwide profile of children in similar grades receiving SunWise education in spring 2000'. However the composition of this intervention group is unclear.

**Evidence statement**

An American cluster allocated controlled before and after study (rated -) evaluated the effectiveness of a cross-curricular classroom based intervention including group based verbal advice and access to a website for fourth and fifth grade students (mean age ten years). The control group received no intervention. Participants were followed-up for four to five months.

There was evidence indicating knowledge was more likely to increase amongst children receiving the intervention in comparison with controls. However statistical significance not reported.

Applicable only to populations or settings included in the studies, the success of broader application is uncertain. (Geller 2003<sup>36,37,39</sup>).

## 4.5.4 Mass-media campaigns and printed materials in adults

### 4.5.4.1 Studies set in workplace

Only one study was identified to evaluate these interventions in a workplace setting. Details of this study are provided below.

#### 4.5.4.1.1 Borland<sup>9</sup> - *cluster RCT with cross-sectional outcome assessment on prevention and detection*

In this Australian RCT (rated +) six Telecom districts (covering the Melbourne metropolitan area and Geelong) were randomised to receive a video and printed material or no intervention. The study took place between 1989 and 1990.

Participants were teams of outdoor staff. Further characteristics were not provided.

*“The (...) programme was titled “Cover yourself against skin cancer” and used a well known Australian (Olympic gold medallist Dawn Fraser) as a role model.”*

A set of materials for each depot, and a folder for each worker was provided. Depot materials contained: four posters encouraging sun protection and early detection, a video entitled “Goodbye sunshine” about a young man dying of melanoma and instructions for distribution of the materials. *“Posters were put up in a predetermined pattern, with different posters or combinations of posters being displayed each week.”*

The individual folders were distributed to staff in the beginning of the campaign. They contained: a brochure introducing the campaign and a letter from management, four lapel buttons and several Anti-Cancer Council of Victoria brochures on protection and detection of skin cancer. *“Staff were encouraged to use protective hats and clothing, to use maximum protection sunscreen and to*

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*avoid the sun when possible between 11 a.m. and 3 p.m. The resources were complemented by input from occupational health nurses who were also provided with extra information on skin cancer.”*

The intervention started in early December 1989 and lasted until early March 1990, which was about three months according to the authors.

Normal occupational health and safety care was the comparator.

*“Senior line staff under the supervision of occupational health nurses were designated to act as observers using a checklist.”* Observations were made between 11 a.m. and 3 p.m. The unit of observation was a work team (consisting of one to four people). The following outcomes were measured:

- Hat use – mean level for the whole team, taking into account the protective properties of different types of hats (score ranged from 1 – “total protection” to 0 – “no protection”)
- Shirt use - mean level for the whole team, taking into account the protective properties of different types of shirts (score ranged from 1 – “total protection” to 0 – “no protection”)
- *“Shade use – a categorical variable with three levels defined across the team as a whole (total shade, partial shade, minimal shade)”*
- *“Protection overall – includes weighing for the use of shade. Total shade gives a score of 1.0 regardless. Partial shade adds 0.33 to the protection measure, or takes it to 1.0 whichever the lesser. No shade leaves the index unchanged.”*

The observers also recorded: time and place of observation, weather conditions, subjective temperature and availability of shade (including both availability and use by team).

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Post-test assessments were made approximately three months after baseline. This study did not follow individual participants or teams, but rather assessed outcomes in two cross-sections of the population.

## Results

### *Primary outcomes*

*“Before the campaign the intervention group had a significantly higher protection index than the control group ( $t=2.32$ ,  $df=523$ ,  $p<0.05$ ) (...); the intervention group significantly increased their superiority in protection after the campaign as compared with the control group.”* There was a 6% increase in the intervention group. If a non-significant decrease in the control group is taken into account – the difference would be 11%.

With regard to individual items which contributed to this score:

- The intervention group had a higher hat use before and after the intervention (0.39 vs. 0.28,  $p<0.0001$ ); this results did not change after the intervention in any of the groups.
- It was also reported that the intervention group increased shirt cover relative to the controls after the campaign; the interaction between group and time of survey was significant ( $p=0.02$ ); no further data was provided.
- *“There was no significant change in use of shade as a function of experimental condition.”*

### *Secondary outcomes*

No secondary outcomes relevant to this review were reported.

## Limitations

Internal validity was rated “+”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to setting or population included in the study.

Authors highlighted that groups were not equivalent at baseline with the intervention group having a significantly higher level of sun protection. Telecom had an ongoing sun protection campaign – the one investigated in this study was just added to it. There was also an ongoing SunSmart community-based campaign. There were weather differences between both surveys (average temperatures during the second survey were slightly lower) which could have influenced scores. Observers were not blinded which could have introduced bias.

Reporting was rather poor both for participant characteristics and results.

Outcomes were assessed in two cross-sections of the population. The methods of analysis are unclear. Clustering was not reported as taken into account.

### **Evidence statement**

An Australian RCT (rated +) in outdoor employees (age was not reported) evaluated a campaign combining materials supplied to depots (four posters and a video “Goodbye sunshine”) with individual folders for employees (a brochure introducing the campaign and a letter from management, four lapel buttons and several Anti-Cancer Council of Victoria brochures on protection and detection of skin cancer). The campaign lasted for approximately three months. The control group was allocated to standard practice. Baseline and follow-up evaluations were carried out as direct observations of cross-sectional samples (numbers of participants in samples not reported). Post-test evaluations were undertaken three months after baseline.

This study provided evidence, that “*before the campaign the intervention group had a significantly higher protection index than the control group ( $t=2.32$ ,  $df=523$ ,*

*p<0.05) (...); the intervention group significantly increased their superiority in protection after the campaign as compared with the control group.”* The intervention group had a higher hat use before and after the intervention ( $p<0.0001$ ); and there was no change in any of the groups at follow-up. The intervention group increased shirt cover relative to the controls after the campaign; the interaction between group and time of survey was significant ( $p=0.02$ ). *“There was no significant change in use of shade as a function of experimental condition.* Participants were not followed-up in this study, but two cross-sectional samples were taken. Probably applicable only to setting or population included in the study. (Borland<sup>9</sup>)

#### 4.5.4.2 Studies in a university/ college setting

A mass media intervention together with printed materials in a university setting was evaluated in two RCTs (Mahler 2005 and Mahler 2007, both rated +). Mahler 2005 evaluated the intervention in 100 participants (aged 17 to 44 years) and Mahler 2007 in 64 (aged 18 to 44 years). Both trials were located in California, USA. In both studies participants were first shown a video on photoaging (11 to 12 minutes) and then a UV facial photograph was taken. Control groups were probably given no intervention. Participants were post-tested immediately after completion of the intervention. 1.4% of participants in Mahler 2005 had a history of skin cancer.

No primary outcomes of this review were assessed in Mahler 2005 and Mahler 2007 did not provide results for study arms.



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#### 4.5.4.2.1 Mahler 2005<sup>62</sup> - RCT including participants with history of skin cancer

This American study (rated +) enrolled 54 undergraduates from the University of California, San Diego and 92 undergraduates from California State University, San Marcos. They were randomised: 50 to a video and a facial UV photograph, 46 to additionally receive sunless tanning lotion and 50 to control. The study arm with provision of tanning lotion will not be analysed in this report. The study year was not stated.

Age ranged between 17 and 44 with a mean of 22.21 (SD 4.66). 78% of all the participants were female. Race and/or ethnicity was reported as: White 67.8%, Asian 16.4%, Hispanic 6.8%, African American 2.1%, Other 6.9%. 1.4% of participants had a personal history of skin cancer.

*“The intervention consisted of a 12-minute video and UV facial photograph taken with an instant camera. The video defined photoaging (premature wrinkles and age spots due to UV radiation) and discussed ways to reduce the effects of UV exposure (using a sunscreen with an SPF of at least 15 and avoiding the sun between the hours 10am and 2 pm). The video also provided general information about sunscreen, for example, explaining what the SPF means and how much sunscreen to use.”*

*“The UV facial photographs were taken with a single-lens reflex camera equipped with Polaroid 667 professional black-and-white instant film (Weltham, Mass) and a UV filter. (...) The resulting black-and-white photograph highlights clearly and dramatically the nonuniform epidermal pigmentation that has resulted from chronic sun exposure. Each person who had a UV photograph taken also had a natural-light instant photograph taken for comparison. In all cases the natural-light black and white photograph was shown to participants first, followed by the UV photograph. Participants were told that any “dark, freckled, or pitted areas” in the UV photograph (that did not appear in the natural-light photograph) indicated*

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*existing underlying skin damage that would continue to worsen if they did not engage in greater sun protection behaviours (than they currently did)."*

Participants viewed their photographs for only a few minutes and were not allowed to take them home.

After completing the session participants were given a free sunscreen sample. Therefore the second post-test is not included in this report.

Participants in the control arm were given no intervention.

At baseline UV exposure and protection as reported by participants were recorded.

Intentions to use sunscreen in the future were assessed in the post-test with nine items rated on five-point scales (with possible answers ranging from 1 "strongly disagree" to 5 "strongly agree").

Photoaging and sun protection perceptions were assessed by the level of agreement (1 "strongly disagree" to 5 "strongly agree") on items concerning:

- perceived rewards of sunbathing and being tan (ten items),
- costs of using sunscreen (12 items),
- perceived susceptibility to photoaging (eight items),
- perceptions of the severity of photoaging (four items), and
- perceived response efficacy of sunscreen use for the prevention of photoaging (four items).

Self-efficacy for regular sunscreen use was evaluated using 12 separate ten-point scales (1 "certain I could not do" to 10 "certain I could do") to indicate how confident participants were that they could motivate themselves to use sunscreen despite obstacles.

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First post-test immediately after the intervention and the second one a month later (not reported as participants were given sunscreen after the first one).

## Results

In this study significance tests compared results from the two intervention groups (including mixed) together to the control arm. Therefore they are not reported in this review.

### *Primary outcomes*

This study did not report any outcomes primary to this review.

### *Secondary outcomes*

Scores for intentions to use sunscreen, photoaging and sun protection perceptions, as well as self-efficacy for regular sunscreen use are reported in Table 59 Mahler 2005.

## Limitations

Internal validity was rated “+”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

Authors highlighted that this study was set in a location with high rates of incidental sun exposure. Self-reported measures were used. The sample size was relatively small and participants were followed-up for a short time.

Outcomes were not measured at baseline. Groups were not similar at baseline. Significance tests were not conducted for each intervention group separately. Two participants were excluded from the analysis based on criteria not defined before

commencement of the study (one had a medical condition requiring daily sunscreen use and the other reported hours of sunbathing more than 35 SDs above the mean). The study did not follow an intention to treat approach.

#### **Evidence statement**

An American RCT (rated +) evaluated a video on photoaging and ways to reduce sun exposure and a facial UV photograph exposing skin damage invisible in natural light in 100 undergraduates (aged 17 to 44) from two universities. Participants were tested immediately after completion of the intervention.

It did not provide evidence on any of the primary outcomes of this review. Its results are probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Mahler 2005<sup>62</sup>)

#### **4.5.4.2.2 Mahler 2007<sup>63</sup> - RCT**

A videotaped slide show and an UV photograph were evaluated in this American RCT. Undergraduate students from University of California, San Diego were randomised: 30 to watch the video and receive the photo and 34 to the control group.

Further details to be found in section 4.2.2.1.2.

#### **Results**

No interaction was found between the UV photo and video interventions. Therefore results are provided for:

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- Participants who received the photograph (including the photograph and video group)
  - Participants who did not receive the photograph (including the video group)
  - Participants who received the video (including the photograph and video group)
  - Participants who did not receive the video (including the photograph group)

These results are not assessing the allocated interventions and therefore are not included in this report. They can be however found in Table 60 Mahler 2007.

#### *Primary outcomes*

Not reported for study arms.

#### *Secondary outcomes*

Not reported for study arms.

#### Limitations

Internal validity was rated “+”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

Further details to be found in section 4.2.2.1.2.

#### **Evidence statement**

An American RCT (rated +) evaluated in 64 undergraduate students (aged 18 to 44 years) photoaging information “*presented via an 11-min videotaped slide show*”

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and a UV picture taken with a modified instant Polaroid camera which revealed normally invisible skin damages. Post-test was carried out immediately after completion of the intervention.

This study did not provide results for groups that participants were randomised to. Results are probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Mahler 2007<sup>63</sup>)

#### 4.5.5 Verbal advice, mass-media and printed materials in adults

##### 4.5.5.1 Studies in a university/ college setting

Only one study was identified to evaluate these interventions in a university/ college setting. Details of this study are provided below.

###### 4.5.5.1.1 McClendon<sup>65</sup> - RCT

This American study (rated ++) assessed a lecture with a video and essays in 61 introductory psychology college students. All participants were “*Caucasians who have tanned intentionally at least once in the past year were recruited.*”

No further details were provided.

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The intervention was divided into two sessions separated by 48 hours. Each session lasted 60-75 minutes.

In the first session after completing the baseline questionnaire, participants read five-page essays containing photos of sun-induced damage to the skin and models on current magazine covers who had light skin tone. *“The message emphasized how unattractive and unhealthy a person looks with a tan in light of new social norms concerning skin tone. It also stressed the effectiveness of the two recommended behaviours (i.e. eliminating sunbathing and using sunscreen) to prevent sun-induced skin damage and contained information on the ease of sunscreen application.”*

Afterwards in groups of three to four students listed ways to avoid unpleasant consequences of the sun’s UV rays. Groups shared the results of their work.

The second session started with two videos *“from the Australian television program, 60 Minutes, which profiled a young Australian named Marc Marcellis. The first segment (11 minutes) detailed Marc’s life after the diagnosis of melanoma and his willingness to help others prevent skin damage. The second segment (7 minutes) occurs after Marc’s death and contains testimonial from people who were helped directly by Marc’s campaign.”*

*“After the videos, participants discussed possible alternatives to Marc’s earlier lifestyle and then designed a campaign for junior high students to convince them to practice sun safe behaviours. The experimenter then gave a brief lecture highlighting the themes of the two sessions.”*

After completing two questionnaires participants in the control arm were given the intervention.

Protection Motivation Theory variables were assessed: vulnerability, severity of threat, rewards, response efficacy, self-efficacy, response costs, primary intentions (directly addressed in the intervention) and supplementary intentions (not addressed directly by the intervention).

Participants were post-tested immediately after completing the intervention. The second follow-up test was carried out a month later however at this point the effects of the intervention were assessed in a before and after design, included in a separate report.

## Results

### *Primary outcomes*

No primary outcomes were assessed.

### *Secondary outcomes*

Significance of differences in Protection Motivation Theory variables between study arms was not reported. Results can be found in Table 62 McClendon.

## Limitations

Internal validity was rated “++”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to settings or populations included in the study.

Authors suggested that it was possible that there was a seasonality effect. The randomised period in this study was short.

Demographic information was not provided. No significance was reported for changes in variables. Intention to treat analysis was not reported. Baseline similarity of groups was not stated.



**Evidence statement**

An American RCT (rated ++) assessed in 61 college students (age was not reported) a combination intervention delivered in two sessions (60-75 minutes) separated by 48 hours. The intervention included participants being asked to read essays on changing image norms for tanning, which also recommended eliminating sunbathing and using sunscreen. They also watched a video about a young Australian and his "*life after the diagnosis of melanoma and his willingness to help others prevent skin damage*". It also contained testimonial from people who were helped by his campaign. Participants were asked to do some work in groups after familiarising themselves with each of the materials. In the end of the second session a lecturer highlighted main themes of both sessions. The control group received no intervention before the follow-up test. Participants were tested at baseline and immediately after the intervention.

None of this review's primary outcomes was reported. Probably applicable only to settings or populations included in the study. (McClendon<sup>65</sup>)

#### 4.5.6 Verbal advice, printed materials and new media in adults

##### 4.5.6.1 Studies based in a recreation site

Only one study was identified to evaluate these interventions in ski resort setting. Details of this study are provided below.

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#### 4.5.6.1.1 Walkosz<sup>97</sup> - *cluster (ski area) RCT with cross-sectional outcome assessment*

This randomised study (rated ++) tested a combination intervention for protection of skin cancer in “6516 adult guests at 26 western US and Canadian ski areas, who were recruited, consented, and interviewed on chairlifts.” Locations of the study were: Alaska, California, Colorado, Idaho, Montana, New Mexico, Nevada, Oregon, Utah, and British Columbia. It was conducted in 2001 and 2002.

Participants were not followed-up, but cross-sectional samples were taken: 2991 tourists were interviewed at baseline and 3525 at study end.

In the first survey 15.5% were aged 18 to 25 years, 25.6% were 26 to 35, 28% - 36 to 45, 19.3% - 46 to 55 and 11.6% were over 55. Age distribution in the second survey was similar with 16.4% aged 18 to 25 years, 24.2% - 26 to 35, 27% - 36 to 45, 18.5% - 46 to 55 and 13.9% over 55. Race and/or ethnicity was reported as white in 96% of participants at baseline and 95.4% at follow-up. 2.5% of participants in the first questionnaire and 4.2% in the second were Hispanic. Sex of participants was not reported.

Go Sun Smart was created by researchers and used “*print, electronic, and interpersonal messages.*” Messages were primarily targeted at employees, but some were communicated to guests as well. “*Guest materials included posters and brochures for ski and snowboard schools, signage at the base of chairlifts and on chairlift poles, electronic signs and grooming reports, brochures, and table tents and posters in lodges.*” Employees were encouraged to advise guests to limit sun exposure. All materials had a Go Sun Smart logo advised to wear sunscreen, sunglasses, and a hat.

“*Ski-area contact personnel received three sets of program materials at intervention areas (...) from late December to early March to rotate messages and to address the increased UVR in spring. Contact personnel met with investigators in August 2001 and received Go Sun Smart program guides. Investigators visited contact personnel in November and December 2001 to review the program*

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*implementation protocol, and Go Sun Smart was implemented from January to April 2002.*

Do nothing was the comparator.

*“Trained staff interviewed guests on chairlifts with a minimum run time of 4 minutes during 3-day periods (1 weekend day and 2 weekdays).”* Only one interview was completed per chair-ride.

To assess sun-protection behaviours participants were asked about wearing sunscreen, its type and application frequency and sun-protective balm use. Assessors also observed if the guests wore a head cover, neck cover, face cover, gloves and eyewear. *“Two unweighted summed composite scores were created: (1) sunscreen SPF 15+ and lip balm SPF 15+ (range=0-2); and sunscreen SPF 15+; lip balm SPF 15+; goggles; gloves; face cover; neck cover; and hand cover (range=0-7).”*

Participants were also asked about their sun burning while skiing or snowboarding that winter. *“Sunburn was defined as skin that was red or painful, or both, from sun exposure but not exposure to wind or cold.”*

Attitudes toward sun protection, self-efficacy expectations, sensation-seeking and scepticism were assessed using five-point Likert-type scales.

Exposure to sun-protection messages was also measured.

Participants were not followed-up, but cross-sectional samples were taken in January to April 2001 and in January to March 2002.

## Results

Raw results for outcomes were not reported. Authors only stated the result of verification of their hypotheses.

### *Primary outcomes*

The hypothesis that guests at ski areas assigned to use Go Sun Smart would report more sun protection was not supported. Results of statistical testing were not provided.

### *Secondary outcomes*

No secondary outcomes relevant to this review were reported.

### **Limitations**

Internal validity was rated “++”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

Authors observed that in the intervention areas at least 40% of guests did not encounter, pay attention to, or remember the sun-safety messages. Extent of message exposure was not randomly assigned as it depended on staff in the areas. Run times of chairlifts limited the number of measures used. The areas in which the study was set limited its generalisability. Use of self-reported measures was a possible limitation, taking into account factors such as social desirability, demand effects, and memory errors. Contamination of the control group was likely with tourists moving between resorts.

Participants were not followed-up over time, but cross-sectional samples were taken. Samples in study arms were not compared and results for individual outcomes were not provided. No numbers of participants in study arms were given. There was no indication of including clustering effects in the analysis.

**Evidence statement**

A cluster RCT (rated ++) set in ski resorts in USA and Canada evaluated a combination intervention aimed at changing the sun protective behaviours of adult guests in ski resorts. Messages were primarily targeted at employees, but some were communicated to guests as well. *“Guest materials included posters and brochures for ski and snowboard schools, signage at the base of chairlifts and on chairlift poles, electronic signs and grooming reports, brochures, and table tents and posters in lodges.”* Employees were encouraged to advise guests to limit sun exposure. All materials had a Go Sun Smart logo and advised to wear sunscreen, sunglasses, and a hat. In the control group participants did not receive an intervention. Participants were not followed-up, but cross-sectional samples were taken in January to April 2001 (2991 participants) and in January to March 2002 (3525 participants).

This study provided no evidence of increased sun protection in guests to areas assigned to the intervention, as authors report that the hypothesis that guests in the intervention areas would report more sun protection was not supported. Results of statistical testing were not provided. Probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Walkosz<sup>97</sup>)

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## 4.6 Theme 6: Head to head comparisons between intervention types

### 4.6.1 Verbal advice vs. Mass-media in adults

#### 4.6.1.1 Studies in a university/ college setting

Only one study was identified to evaluate these interventions in a university setting. Details of this study are provided below.

##### 4.6.1.1.1 Mickler<sup>68</sup> - *RCT on prevention and detection of skin cancer*

This American randomised study (rated ++) evaluated three methods of teaching skin self-examination and skin cancer prevention skills. One hundred and forty three undergraduate psychology students were enrolled: 39 to the video, 35 to the brochures, 33 to the nurse led and 36 to the control arm.

Further details are provided in section 4.1.2.1.3.

### Results

In this section only results comparing the nurse-led intervention with the video are reported. It needs to be highlighted that as outcomes were not measured at baseline and the results might be measuring not only the effects of the intervention, but also differences between groups.

#### *Primary outcomes*

Authors report that at the first post-test the video group had a significantly higher knowledge score (16.28 (SD 1.89)) than the nurse-led group (14.63 (SD 2.01)). There was no difference significance reported for seven months and the scores were 15.94 (SD 2.25) and 15.37 (SD 2.13) respectively.

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### *Secondary outcomes*

Students in the nurse-led arm had better results in the Visual Picture Test than the video group. No differences between groups were reported for self-examination skills. Exact results for both outcomes are provided in Table 65 Mickler.

### Limitations

Internal validity was rated “++”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment

Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted.

Further details are provided in section 4.1.2.1.3.

### **Evidence statement**

An American RCT (rated ++) compared a nurse-led one-to-one training (on how to perform skin self-examination and recognise skin cancers, they were also provided with two brochures) with a video (*“which included information about skin cancer, how to recognise it, and different skin types and their vulnerabilities to the sun. The videotape also included a demonstration of how to do a total-body skin exam and tips on prevention.”*) in 72 undergraduate students (aged 17 to 31 years). Both interventions lasted 15 to 20 minutes. The first post-test was carried out immediately after completion of the intervention and the second three weeks later.

It provided evidence that the knowledge level was higher in the video group compared to the nurse-led group in the immediate post-test (significance level not provided). At seven months the score in the video group was still higher, however authors provided no indication if the difference was statistically significant. No baseline measurement of outcomes was carried out. Probably likely to be

applicable across a broad range of populations and settings, assuming it is appropriately adapted. (Mickler<sup>68</sup>)

## 4.6.2 Verbal advice vs. Printed materials in children

### 4.6.2.1 School based studies in children aged seven to eleven years

Only one study was identified to evaluate these interventions in a school setting in children aged seven to eleven years. Details of this study are provided below.

#### 4.6.2.1.1 Barankin<sup>3</sup> - *cluster (school) controlled before and after study*

This controlled before and after study (rated -), undertaken in 1999, assessed the effectiveness of group based verbal advice provided at school. Sixteen schools in the Thames Valley District School Board in London, Ontario, Canada participated in the study.

Children (n=509) were aged 9-10 years. Details on sex, ethnicity and socioeconomic status were not reported and no exclusion criteria were stated.

Schools in the 'standard' intervention arm are the focus of this report. The 'standard' intervention groups received a 'Sun and the Skin' presentation from medical students that comprised a one-hour interactive slide presentation that included discussion of UV light, the harmful effects of the sun, and skin cancer risks and prevention. Sun protection strategies including sunscreen, clothing, hats, sunglasses, avoiding midday sun, and seeking shade were emphasised. Additional materials including the Rayguard activity booklet were provided before and during the presentation.



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NB: The study also had an 'enhanced' treatment group however, as this group were provided with sunscreen, a component that could not be disaggregated, we have only included the results reported for the control group and 'standard' intervention group.

The control group did not receive the presentation or its enhancements but were provided with the Rayguard activity booklets.

Changes in knowledge, attitudes and behaviour relating to sun-protection were assessed. Both parents and children were surveyed in May before the presentations, and again in June after the presentations. Modified surveys were used in September to assess behaviour and sun damage outcomes. Teachers were also surveyed about their student's knowledge, attitudes and behaviours in May and June. Details of the appraisal tools used were not reported.

Participants were post-tested at one and four months.

## Results

### *Primary outcomes*

In May all teachers except one in the standard group characterised their students as 'somewhat' aware of the consequences of excessive sun exposure. In June, 75% (3/4) of the control group and 100% (4/4) of the standard group characterised their students as being very aware of the consequences of too much sun.

Statistical significance not reported.

The number of children reporting no sunburns improved between May and September for the standard group (non-statistically significant trend). Percentages without sunburn were as follows: standard: 39.9% (May), 47.2% (September); control: 36.5% (May), 36.8% (September).

Parental reports of the number of children without sunburns showed an improvement between May and September for the standard group (non-

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statistically significant trend). Percentages without sunburn were as follows: standard: 43.6% (May), 54.2% (September); control: 43.1% (May), 42.7% (September). There was no significant difference in September in the number of multiple sunburns ( $\geq 2$ ) amongst the groups: standard 12.5%; control 10.7%.

In May and June, all but two teachers indicated that 0-25% of their students had a sunburn during the year; the other two teachers responded that 25-50% of their students had a sunburn during the year. The assessment did not differentiate between the children in the different groups.

In all three survey periods, a large proportion of children reported using sunscreen with SPF  $\geq 30$ , and more than 90% used sunscreen with SPF  $\geq 15$ . No differences were observed amongst the groups or time periods.

In May parents reported that their children were already practicing many sun protective behaviours to a high degree. 75-78.6% of parents reported that their children used an SPF  $\geq 30$  and 96% of parents reported that their children used an SPF  $\geq 15$ . Trends amongst the standard and control groups were similar. Between 90-95% of parents reported that their children 'sometimes' to 'usually' applied sunscreen 15-30 minutes before going out in the sun, reapplied sunscreen after swimming or sweating, and avoided activities during the midday sun. The use of long pants and long-sleeved shirts to protect the skin from the sun were not popular options for children. Most parents reported that their children either 'never' or 'sometimes' wore this type of clothing in the May surveys. There was no improvement in the September survey with no differences amongst the groups.

Most teachers listed 0-24% of students as wearing long pants and long-sleeved shirts in the warm weather. All teachers but one indicated that <50% of their class usually wore a hat outdoors; the hats worn were all baseball caps rather than wide-brimmed hats. In most classrooms teachers observed that <25% of students wore sunglasses outdoors, and <25% of students applied sunscreen at least once during the day. These reported behaviours were similar in May and June and there were no significant differences between the groups.

### *Secondary outcomes*

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The standard group showed a reduction in the percentage of students who wanted a tan: 31.4% (May), 15.5% (September), statistical significance not stated. The control group showed no improvement: 23.3% (May), 21.1% (September). No teachers at either time period believed their students thought that tans were 'cool' and that they believed they would want to have a tan.

### Limitations

Internal validity was rated "-". Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Applicable only to populations or settings included in the studies, the success of broader application is uncertain.

As the authors indicated, there may be some bias in the June and September surveys in that there was a noticeably lower response rate than there was in May.

The methods used to obtain information and analyse the results were poorly reported. It was not clear how the data for the different groups were compared and some of the charts were poorly labelled.

### **Evidence statement**

A Canadian controlled before and after study (rated -) compared the effectiveness of group-based verbal advice and literature (intervention) with the provision of literature only (comparator) in 509 children aged nine to ten years. The intervention group received a 'Sun and the Skin' presentation from medical students that comprised a one-hour interactive slide presentation that included discussion of UV light, the harmful effects of the sun, and skin cancer risks and prevention. Sun protection strategies including sunscreen, clothing, hats, sunglasses, avoiding midday sun, and seeking shade were emphasised. Additional materials including the Rayguard activity booklet were provided before

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and during the presentation. The comparator group were provided with the Rayguard activity booklets.

Knowledge was assessed by a teacher survey at baseline and one month follow-up. There was no evidence that the provision of group –based verbal advice along with literature provided statistically significant improvements in the knowledge in comparison with the provision of literature only, although there were improvements in both groups. Statistical significance was not reported.

Sun protection behaviour was assessed by separate surveys of the children and their parents, at baseline, one and four months follow-up, and teacher surveys at baseline and one month follow-up. There was no evidence that the provision of group –based verbal advice along with literature provided statistically significant improvements in behaviours in comparison with the provision of literature only. No differences were observed amongst the groups or time periods.

Sunburns were assessed by separate surveys of the children and their parents, at baseline and four months follow-up. There was no statistically significant evidence of a reduction in the number of sunburns amongst children receiving group-based verbal advice along with literature in comparison with the provision of literature only. However surveys of both children and parents reported the number of children without sunburns improved to a greater extent amongst those receiving the verbal intervention (non-statistically significant trend). At four month follow-up, data from parental reports indicated there was no significant difference in the number of multiple sunburns ( $\geq 2$ ) amongst the groups, however there was a higher incidence amongst the group receiving the verbal intervention.

Applicable only to populations or settings included in the studies, the success of broader application is uncertain. (Barankin 2001<sup>3</sup>).

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### 4.6.3 Verbal advice vs. Printed materials in adults

#### 4.6.3.1 Studies in a university/ college setting

Only one study was identified to evaluate these interventions in a university/ college setting. Details of this study are provided below.

##### 4.6.3.1.1 Mickler<sup>68</sup> - *RCT on prevention and detection*

This American randomised study (rated ++) evaluated three methods of teaching skin self-examination and skin cancer prevention skills. One hundred and forty three undergraduate psychology students were enrolled: 39 to the video, 35 to the brochures, 33 to the nurse led and 36 to the control arm.

Further details are provided in section 4.1.2.1.3.

#### Results

In this section only results comparing the nurse-led intervention with brochures are reported. It needs to be highlighted that as outcomes were not measured at baseline and the results might not be measuring not only the effects of the intervention, but also differences between groups.

#### *Primary outcomes*

Authors report that at the first post-test the brochure group had a significantly higher knowledge score (16.00 (SD 1.76)) than the nurse-led group (14.63 (SD 2.01)). There was no difference significance reported for seven months and the scores were 16.02 (SD 1.72) and 15.37 (SD 2.13) respectively.

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### *Secondary outcomes*

Students in the nurse-led arm had better results in the Visual Picture Test than the brochure group. Students from the brochure group however had significantly better self-examination skills. Exact results for both outcomes are provided in Table 65 Mickler.

### Limitations

Internal validity was rated “++”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment

Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted.

Further details are provided in section 4.1.2.1.3.

### **Evidence statement**

An American RCT (rated ++) compared a nurse-led one-to-one training (on how to perform skin self-examination and recognise skin cancers, they were also provided with two brochures) with brochures (*“participants received several commonly used written materials and were instructed to read them thoroughly”*) in 68 undergraduate students (aged 17 to 31). The first post-test was carried out immediately after completion of the intervention and the second three weeks later.

This study found that the mean knowledge level was higher in the brochures group than in the nurse-led group in an immediate post-test (significance level not provided). At seven months participants in the brochures group still had a higher mean level of knowledge, significance of the difference was however not provided. No baseline measurement of outcomes was carried out. Probably likely to be

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applicable across a broad range of populations and settings, assuming it is appropriately adapted. (Mickler<sup>68</sup>)

#### 4.6.4 Verbal advice vs. New media in children

##### 4.6.4.1 School based studies in children aged seven to eleven years

Only one study was identified to evaluate these interventions in a school setting. Details of this study are provided below.

###### 4.6.4.1.1 Hornung<sup>50</sup> - *cluster (class) RCT*

This study (rated +) was conducted in an elementary school in North Carolina, USA. Seventy nine children (from three classes) were randomised to use a CD-ROM in the classroom and 53 (from two classes) were allocated to be taught a curriculum.

Further details are reported in section 4.1.1.2.4.

#### Results

Results were not provided for baseline, however the immediate post-intervention and follow-up scores were adjusted for baseline knowledge and demographic characteristics.

### *Primary outcomes*

The mean adjusted post-intervention knowledge score was 59.5 in the standard intervention group and 75.2 in the computer program group which was a significantly higher score with  $p < 0.001$ . The mean knowledge score in the seven months follow-up was 70.9 in the computer program group (significantly higher compared to the standard intervention group, with  $p = 0.005$ ) and 66.5 for the curriculum group.

The mean post-intervention behaviour score was 48.8 in the computer group and 39.0 for the curriculum group. The mean behaviour scores at seven months follow-up were 42.0 and 38.8 respectively. In the first post-test the computer group scored significantly higher with  $p = 0.015$ . This difference was however not significant in the second post-test.

### *Secondary outcomes*

There was a significant improvement in the mean attitude score in the computer compared to standard condition in the immediate post-test. This tendency was however not retained in the seven months follow-up.

### **Limitations**

Internal validity was rated “+”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted.

Further details are reported in section 4.1.1.2.4.



**Evidence statement**

An American cluster RCT (rated +) in 132 third and fourth grade children compared sun protection taught by group teachers with a computer program used in the classroom setting via large-screen projection. Student volunteers were asked to take turn navigating through the program for the class. It took approximately 18 minutes to complete. It contained colourful animation as well as digital audio and video. Three different cartoon characters modelled three different sun safety behaviours: extremely protective, overly risky and appropriate. Participants were tested at baseline and then immediately after the intervention and seven months later.

Adjusted mean knowledge level was significantly higher in the computer intervention group both directly after the intervention ( $p < 0.001$ ) and seven months after baseline ( $p = 0.005$ ). In the first test the computer intervention had a significantly higher mean score for self-reported behaviours ( $p = 0.015$ ) and this difference was still present after seven months it was however not significant (significance level not provided). Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted. (Hornung<sup>50</sup>)

#### 4.6.5 Mass-media campaigns vs. Printed materials in adults

##### 4.6.5.1 Studies in a university/ college setting

Two randomised studies compared videos with brochures (Mickler, rated ++) or a UV facial photograph (Mahler 2007, rated +) in a university setting. In Mickler there were 72 participants (aged 17 to 31 years) in this comparison and in Mahler 2007 - 69 (aged 18 to 44 years). Both were American studies and Mahler 2007 was reported to be carried out in California. Mickler provided participants with information on both prevention and detection and some of the students had a

history of skin cancer. Mahler 2007 had an immediate post-test and Mickler followed-up participants for three weeks.

Mahler 2007 did not report results for study arms. Mickler provided no indication if a significantly higher knowledge level was observed in any group.

#### 4.6.5.1.1 Mahler 2007<sup>63</sup> - RCT

A videotaped slide show and an UV photograph were evaluated in this American RCT. One hundred and thirty three undergraduate students from University of California, San Diego were randomised: 34 to watch the video, 35 to receive the photo, 30 to watch the video and receive the photo, 34 to the control group.

Further details to be found in section 4.2.2.1.2.

#### Results

No interaction was found between the UV photo and video interventions.

Therefore results are provided for:

- Participants who received the photograph (including the photograph and video group)
- Participants who did not receive the photograph (including the video group)
- Participants who received the video (including the photograph and video group)
- Participants who did not receive the video (including the photograph group)

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These results are not assessing the allocated interventions and therefore are not included in this report. They can be however found in Table 60 Mahler 2007.

### *Primary outcomes*

Not reported for study arms.

### *Secondary outcomes*

Not reported for study arms.

### Limitations

Internal validity was rated “+”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

Further details to be found in section 4.2.2.1.2.

### **Evidence statement**

An American RCT (rated +) in 69 undergraduate students (aged 18 to 44 years) compared photoaging information “*presented via an 11-min videotaped slide show (...).*” with a facial UV photograph showing damage to the skin invisible in natural light. Participants were tested immediately after the intervention.

This study did not provide results for groups that participants were randomised to. Results are probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Mahler 2007<sup>63</sup>)

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#### 4.6.5.1.2 Mickler<sup>68</sup> - *RCT on prevention and detection*

This American randomised study (rated ++) evaluated three methods of teaching skin self-examination and skin cancer prevention skills. 143 undergraduate psychology students were enrolled: 39 to the video, 35 to the brochures, 33 to the nurse led and 36 to the control arm.

Further details are provided in section 4.1.2.1.3.

#### Results

In this section only results comparing the videotape with brochures are reported. It needs to be highlighted that as outcomes were not measured at baseline and the results might be measuring not only the effects of the intervention, but also differences between groups.

#### *Primary outcomes*

Difference in knowledge score was not reported for these two groups. In the immediate post-test the brochure group had a score of 16.00 (SD 1.76) and the video group 16.28 (SD 1.89). At seven months and the scores were 16.02 (SD 1.72) and 16.02 (SD 1.72) respectively.

#### *Secondary outcomes*

Students in the video arm had better results in the Visual Picture Test than the brochure group. Students from the brochure group however had significantly better self-examination skills. Exact results for both outcomes are provided in Table 65 Mickler.

## Limitations

Internal validity was rated “++”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted.

Further details are provided in section 4.1.2.1.3.

### **Evidence statement**

An American RCT (rated ++) in 72 undergraduate students (aged 17 to 31 years) compared a video (*“which included information about skin cancer, how to recognise it, and different skin types and their vulnerabilities to the sun. The videotape also included a demonstration of how to do a total-body skin exam and tips on prevention.”*) with brochures (*“participants received several commonly used written materials and were instructed to read them thoroughly”*). The first post-test was carried out immediately after completion of the intervention and the second three weeks later.

This study did not provide evidence of a significant difference between both groups. In the immediate post-test the video group had a slightly higher mean knowledge score than the brochures group, but at seven months scores in both groups were equal (no significance levels were provided). No baseline measurement of outcomes was carried out. Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted. (Mickler<sup>68</sup>)

## 4.6.6 Verbal advice and printed materials vs. Verbal advice in adults

### 4.6.6.1 Studies in a hospital/ medical practice setting

Only one study was identified to evaluate these interventions in a hospital/ medical practice setting. Details of this study are provided below.

#### 4.6.6.1.1 Clowers-Webb<sup>24</sup> - *RCT including participants with history of skin cancer*

In this study (rated +) 202 verbally consenting “*transplant recipients presenting for dermatologic consultation in the von Liebig Transplant Centre at Mayo Clinic*” were randomised to receive either a session with a physician with or without later being sent printed material (101 patients in each group).

The mean age ranged from 18 to 76 years in the intervention group with a mean of 52.8 years (SD 13.4). In the control group mean age was 55.8 (SD 12.7) and ranged from 11 to 75. Forty two females were in the group which was sent printed materials and 41 in the other one. 95% of patients were white in the combination intervention and 98% in the physician session group. There were 3% and 1% Asian/Indian and none and 1% African American participants. For two participants in the intervention group race or ethnicity was reported as unknown. 29% in the physician advice only and 28% in the other group had a history of skin cancer. Authors report that there were no significant differences between groups.

*“In the first group a laminated, pocket-sized copy of standardized verbal education guidelines was given to all recruiting physicians to ensure coverage of essential points. Patients were informed on their increased risk for and potential morbidity owing to skin cancer. An individualised risk assessment was performed, and patient-specific risk factors were discussed. Patients were instructed to use sunscreen with sun protection factor of 15 or greater on all exposed skin daily for*

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*all activities and even for short periods of sun exposure regardless of the weather. They were instructed to wear protective clothing and hats and to avoid times of peak UV light year-round. They were asked to stop intentional tanning outdoors or indoors by means of tanning lamps or at salons. Monthly skin self-examinations were recommended, with any changes reported promptly to their physician. They were given a copy of the Mayo Clinic pamphlet “Skin Cancer and Organ Transplant Recipients”, which includes this information in more detail, reviews additional risk factors for skin cancer (i.e., fair skin, personal or family history of skin cancer, and past exposure), stresses the need for general sun protection (especially sunscreen use and reapplication), and describes and illustrates the appearance of skin cancers.”*

*“At 2, 6, and 9 months after recruitment, patients in the intensive intervention group were sent a cover letter encouraging careful review of the enclosed pamphlets (at 2 months, the Skin Cancer Foundation pamphlets “Simple Steps to Sun Safety” and “Skin Cancer: If You Can Spot It, You Can Stop It”; at 6 months, the American Academy of Dermatology pamphlet “Skin Cancer – An Undeclared Epidemic” and leaflet “Stop-Look for Danger Signs in Pigmented Lesions of the Skin”; and at 9 months, the Mayo Clinic pamphlet “Skin Cancer and Organ Transplant Recipients”).”*

The second group received the same session with a physician without letters and pamphlets at two, six and nine months

The two interventions were compared with each other.

Knowledge was assessed with 18 statements which patients were asked to indicate were correct or incorrect. For each patient a knowledge score was calculated as percentage of correct answers. Only for patients who answered to at least 75% of questions the score was calculated. In a secondary analysis missing responses were considered as incorrect.

Behaviour was assessed using 17 items. Patients used a five-point scale (1 – “all of the time”, 2 – “most of the time”, 3 – “some of the time”, 4 – “rarely”, 5 – “never”) to indicate their level of compliance. A score was calculated as an average of all

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items with lower score indicating better compliance. Only for patients who responded to at least 75% of the questions, a score was calculated. Additional items were used to collect detailed information on the level of behaviour.

Three and ten months after recruitment all patients were sent a questionnaire. If no response was received, the questionnaire was mailed again a month later.

## Results

### *Primary outcomes*

The result for the knowledge score was found to be highly skewed (most patients with one or no incorrect answers) – therefore it was additionally analysed in intervals as reported in Table 37 Clowers-Webb.

The mean baseline score was similar in both arms: it was 91.5 (SD 9.3) in the investigated intervention and 92.0 (SD 7.2) in the control group. At three months the mean score in the intervention group was 93.8 (SD 7.8) and 94.1 (SD 6.1) in the control group. Difference between groups was not statistically significant with  $p=0.66$ . Ten months after commencement of the study the means were: 94.4 (SD 6.9) and 93.9 (SD 6.7) respectively. Difference between groups was not statistically significant with  $p=0.50$ .

Behaviour score was also similar at baseline with a mean of 2.9 (SD 0.6) in the physician session and leaflet arm and 3.0 (SD 0.6) in the physician session only. There was a decrease in both arms (mean 2.4 (SD 0.6) intervention, 2.7 (SD 0.7) control) at three months indicating a more sun safe behaviour. Difference between groups was statistically significant ( $p=0.006$ ) and showed that participants who were additionally sent printed material complied more with the advised behaviour. There was very little change at ten months (2.4 (SD 0.6) and 2.6 (SD 0.7) respectively). The difference was still significant with  $p=0.007$ .

### *Secondary outcomes*



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No secondary outcomes relevant to this report were provided.

### Limitations

Internal validity was rated “+”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

Authors stated that participants had a high knowledge level at baseline. A seasonal effect was possible as outcomes were measured at different times of the year. This study followed-up participant for a relatively short time. The study instrument was not formally validated.

There is a possibility that the population was self-selected as it included patients who presented for dermatologic consultation. It was very narrowly defined and the results might not be generalisable. Change in knowledge and behaviour from baseline was not calculated and compared.

At three months two participants died and further 65 questionnaires were not included in the analysis due to mailing errors and no response from patients. At ten months further two patients died and 55 questionnaires were not included in the analysis for the same reasons as in the earlier follow-up. Intention to treat analysis was not performed.

### **Evidence statement**

An American RCT (rated +) in 202 transplant patients (aged 18 to 76 years), some with history of skin cancer, compared a session with a physician followed by mailing of printed materials with a session with a physician only. The initial session covered information on increased risk of skin cancer and provided advice on sun protective behaviours and performing skin examinations. Patients were also given

a leaflet. One group was mailed at two, six and nine months additional pamphlets with covering letters. Patients were tested at baseline and three and ten months after recruitment were sent a questionnaire.

This study did not provide evidence of a significant difference in knowledge between the two groups and mean scores in the two follow-up tests did not follow a uniform pattern. It provided evidence of more sun safe behaviour in the group which was additionally mailed printed materials both at three ( $p=0.006$ ) and ten months ( $p=0.007$ ). Probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Clowers-Webb<sup>24</sup>)

#### 4.6.7 Mass-media campaigns and printed materials vs. Mass-media campaigns in adults

##### 4.6.7.1 Studies in a university/ college setting

Only one study was identified to evaluate these interventions in a university/ college setting. Details of this study are provided below.

##### 4.6.7.1.1 Mahler 2007<sup>63</sup> - RCT

A videotaped slide show together with a UV photograph were compared to the videotape only in this American RCT (rated +). 133 undergraduate students from University of California, San Diego were randomised: 34 to watch the video, 35 to receive the photo, 30 to watch the video and receive the photo, 34 to the control group.

Further details to be found in section 4.2.2.1.2.

## Results

No interaction was found between the UV photo and video interventions.

Therefore results are provided for:

- Participants who received the photograph (including the photograph and video group)
- Participants who did not receive the photograph (including the video group)
- Participants who received the video (including the photograph and video group)
- Participants who did not receive the video (including the photograph group)

These results are not assessing the allocated interventions and therefore are not included in this report. They can be however found in Table 60 Mahler 2007.

### *Primary outcomes*

Not reported for study arms.

### *Secondary outcomes*

Not reported for study arms.

## Limitations

Internal validity was rated “+”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

Further details to be found in section 4.2.2.1.2.

**Evidence statement**

An American RCT (rated +) compared a videotaped slide show on photoaging together with a facial UV photograph to a video on its own in 64 undergraduate students (aged 18 to 44 years). Participants were tested immediately after the intervention.

This study did not provide results for groups that participants were randomised to. Results are probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Mahler 2007<sup>63</sup>)

#### 4.6.8 Mass-media campaigns and printed materials vs. Printed materials in adults

##### 4.6.8.1 Studies in a university/ college setting

Only one study was identified to evaluate these interventions in a university setting. Details of this study are provided below.

##### 4.6.8.1.1 Mahler 2007<sup>63</sup> - RCT

A videotaped slide show together with a UV photograph were compared to the UV photo only in this American RCT (rated +). One hundred and thirty three undergraduate students from University of California, San Diego were randomised:

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34 to watch the video, 35 to receive the photo, 30 to watch the video and receive the photo, 34 to the control group.

Further details to be found in section 4.2.2.1.2.

## Results

No interaction was found between the UV photo and video interventions.

Therefore results are provided for:

- Participants who received the photograph (including the photograph and video group)
- Participants who did not receive the photograph (including the video group)
- Participants who received the video (including the photograph and video group)
- Participants who did not receive the video (including the photograph group)

These results are not assessing the allocated interventions and therefore are not included in this report. They can be however found in Table 60 Mahler 2007.

### *Primary outcomes*

Not reported for study arms.

### *Secondary outcomes*

Not reported for study arms.

## Limitations

Internal validity was rated “+”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

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Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

Further details to be found in section 4.2.2.1.2.

#### **Evidence statement**

An American RCT (rated +) compared a videotaped slide show on photoaging together with a facial UV photograph to a UV photograph on its own in 65 undergraduate students (aged 18 to 44 years). Participants were tested immediately after the intervention.

This study did not provide results for groups that participants were randomised to. Results are probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Mahler 2007<sup>63</sup>)

## 4.7 Theme 7: Head to head comparisons within the same intervention type

### 4.7.1 Verbal advice in children

#### 4.7.1.1 School based studies in children aged four to eleven years

Only one study was identified to evaluate this intervention in a school setting in children aged four to eleven years. Details of this study are provided below.

##### 4.7.1.1.1 Buller 2006a<sup>16</sup> - *cluster (school) controlled before and after study*

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NB: Using an RCT design, the study compared a single instruction (group B) with no-instruction (group C); using a controlled before & after design, the study compared the impact of the provision of repeated instruction (group A) with single instruction (group B). The results of the RCT component are reported in section 4.1.1.1.1 and 4.1.1.2.3. The results of the additional controlled before and after component are reported below.

The main study population and setting details are reported in sections 4.1.1.1.1 and 4.1.1.2.3.

Four hundred and thirty five children were included in the before and after comparison (rated -) of single and repeated instruction, 227 in group B (single instruction) and 208 in group A (repeated instruction). The proportion of female students was not reported for the youngest group (kindergarten to first grade), for children in second to third grades it was 58%, and for children in fourth to fifth grades it was 42%. Race was not reported for kindergarten to first grades, for children in second to third grades 75% were white, and for children in fourth to fifth grades 71% were white. Details of socioeconomic status were not reported. No exclusion criteria were reported.

Details of the initial single instruction (group B) are provided in sections 4.1.1.1.1 and 4.1.1.2.3.

The comparator group (group A) received the initial instruction (provided to group B) plus repeated instruction. For children in grades one, three and five, three two-hour age-appropriate 'booster units' were developed so that these students received novel instructional materials in a second year. These consisted of interactive activities that included reviewing the main sun safety concepts and applying and reinforcing them in individual and small and large group activities.

The effect of the repeated instruction was tested by comparing the change in outcome from pre-test (year 1) to post-test (year 2) between group A (those receiving the curriculum in 2 successive years) and pre-test/post-test change (year 2) for group B (those receiving the curriculum in the second year only). Also examined was the change in outcomes for those in group A from pre-test (year 1)

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to post-test (year 2) compared with their change over year 1 (from year 1 pre-test to year 1 post-test). Details of outcome measurement are provided in section 4.1.1.1.1.

Participants were followed-up for approximately 15 months.

## Results

### *Primary outcomes*

#### Grades K-1

Sun-safety knowledge was not improved when compared with one exposure (group B),  $p=0.369$  or when scores following the first and second exposure were compared within group A students,  $p=0.333$ .

#### Grades 2-5

Sun-safety knowledge in group A was significantly improved when compared with one exposure (group B),  $p=0.0005$ , and when the score following the first and second exposures within group A were compared,  $p=0.0381$ .

There was no significant change in skin tone amongst the children receiving repeated instruction in comparison with group B,  $p=0.593$ . Comparisons of changes across the years within group A were also not significant,  $p>0.05$ .

### *Secondary outcomes*

#### Grades K-1

There was no significant change in skin tone amongst the children receiving repeated instruction in comparison with group B,  $p=0.593$ . Comparisons of changes across the years within group A were also not significant,  $p>0.05$ .



## Grades 2-5

Children in group A displayed lighter skin tones, indicating lower exposure to UVR, than children in group B. On the 'L' scale children in group A had smaller changes when compared with those in group B,  $p=0.0001$ .

The reduced exposure amongst children in group A was also confirmed on the 'b' scale. Children in the group A showed smaller increases in skin darkening in comparison with those in group B,  $p=0.052$ .

Children in group A demonstrated a lower increase in redness on the 'a' scale than those in group B,  $p=0.0243$ , indicating less erythema.

## Grades 2-5

There were no significant differences in attitudes towards sun-protection amongst children in group A compared with group B,  $p=0.152$ . However group A expressed more favourable attitudes than the no-instruction group (group C),  $p=0.05$ .

## Limitations

Internal validity was rated "-". Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment

Applicable only to populations or settings included in the studies, the success of broader application is uncertain.

In the absence of random allocation to the two treatment groups there is a possibility of selection bias. Further details are reported in section 4.1.1.1.1.

### **Evidence statement**

An American controlled before and after study (rated -) in 435 children compared curricular based advice delivered in one school year, with provision over two

successive years. The intervention was delivered during a six-week period and contained four age-appropriate units designed to be taught in four one-hour class periods. It also included two storybooks, a limited number of activity sheets that taught curriculum content and used animated characters. Activities incorporated knowledge and skills from different areas. For those receiving extended provision in year two, three two-hour age-appropriate 'booster units' were developed. These consisted of interactive activities that included reviewing the main sun safety concepts and applying and reinforcing them in individual and small and large group activities.

There was evidence of a statistically significant improvement in knowledge, at 15 months follow-up, for children in grades 2-5 (aged approximately 7-11 years), amongst the group receiving the extended two year curriculum compared with the group receiving the intervention for one year only ( $p=0.0005$ ).

There was no evidence of a statistically significant improvement in knowledge, at 15 months follow-up, for children in grades K-1 (aged approximately 5-7 years), amongst the group receiving the extended two year curriculum compared with the group receiving the intervention for one year only ( $p=0.369$ ).

Applicable only to populations or settings included in the studies, the success of broader application is uncertain. (Buller 2006a<sup>16</sup>).

#### 4.7.1.2 School based studies in children aged seven to eleven years

Only one study was identified to evaluate this intervention in a school setting in children aged seven to 11 years. Details of this study are provided below.

#### 4.7.1.2.1 Hewitt<sup>47</sup> - *cluster (school) controlled before and after study*

This controlled before and after study (rated -), undertaken in 1998 in the UK, had two intervention groups and a control group (no intervention). Follow-up was at six weeks. This section compares the effectiveness of two variants of the 'Sun-safe' intervention, a computer-based resource and workbook based resource, both designed for use in topic work, for children aged 10-11 years at school. The main details of the study, and assessment of the effectiveness of the 'Sun-safe' interventions versus no intervention are provided in section 4.1.1.2.5.

### Results

#### *Primary outcomes*

##### Knowledge

Mean  $\pm$  SD pre-intervention scores for the 2 groups were as follows: computer,  $8.23 \pm 2.07$ ; workbook,  $7.65 \pm 2.27$ .

Mixed-model analysis revealed significant increases in both groups (computer: 1.73, 95% CI 1.00 to 2.46; workbook: 2.36, 95% CI 1.66 to 3.05) but there was no significant difference between the computer and workbook groups (0.63, 95% CI -0.8 to 1.63).

#### *Secondary outcomes*

##### Attitudes

Mean  $\pm$  SD pre-intervention scores for the 2 groups were as follows: computer,  $10.41 \pm 3.14$ ; workbook,  $9.82 \pm 3.17$ .

Mixed-model analysis revealed no significant differences between the groups (computer: 1.92, 95% CI 0.76 to 3.09; workbook: 2.37, 95% CI 1.27 to 3.47).

## Behavioural intentions

Mean  $\pm$  SD pre-intervention scores for the 2 groups were as follows: computer, 6.71  $\pm$  1.72; workbook, 5.91  $\pm$  1.76.

Mean increases in behavioural intentions scores were small. Mixed-model analysis revealed no significant differences between the groups (computer: 1.11, 95% CI 0.70 to 1.51; workbook: 0.66, 95% CI 0.26 to 1.05).

## Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Applicable only to populations or settings included in the studies, the success of broader application is uncertain.

Further details to be found in section 4.1.1.2.5.

### **Evidence statement**

A UK controlled before and after study (rated -) compared the effectiveness of computer-based and workbook based resources, designed for use in topic work, for children aged ten-11 years at school (number of children in this comparison was unclear). The interactive 20-minute computer-based resource followed the adventures of a fictional character who has to learn how to protect himself from the harmful effects of the sun. The workbook version of the story was developed to ascertain the effect of the interactive computer programme as a medium for learning. It contained the same text and still images from the computer programme.

There was no statistically significant evidence, at six week follow-up, of increased knowledge amongst the group receiving the computer-based intervention in

comparison with the group receiving the workbook based intervention. However knowledge increased significantly in both groups with a higher increase evidenced in those receiving the workbook based intervention.

Applicable only to populations or settings included in the studies, the success of broader application is uncertain (Hewitt<sup>47</sup>).

#### 4.7.1.3 School based studies in children aged 11 to 16 years

Only one study was identified to evaluate this intervention in a school setting in children aged 11 to 16 years. Details of this study are provided below.

##### 4.7.1.3.1 Hughes<sup>51</sup> - *cluster (class) RCT*

This study (rated -) conducted in the UK evaluated the effectiveness of class-taught sun protection with the use of various materials. The study was carried out in 1990 and included 35 classes. The number of participants is unclear. The students' age ranged from 12 to over 16.

Further details are provided in section 4.1.1.3.3.

#### Results

This study did include pre-testing of students. Therefore it is not possible to establish if the results represent effects of the intervention or underlying differences between clusters.

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### *Primary outcomes*

There was no significant difference between intervention groups in the mean knowledge score. The mean scores were:

- in the group which “*read through the text of the workbook and took home “Suncool”*” the mean score was 21.2 (SD 3.3),
- in the group which additionally watched the video: 22.6 (SD 3.0),
- in the group which was given homework to design posters: 22.8 (SD 4.8),
- in the group which additionally had a discussion: 20.5 (SD 5.9).

Results for behaviour during summer holidays were not provided, however the authors stated that there was no significant difference between groups.

### *Secondary outcomes*

There was no significant difference between the intervention groups in the mean attitude score. Authors report that scores from both questionnaires “*gave essentially the same results. There was a reasonable correlation between attitude in July and September, suggesting retention of reported attitudes after the summer holiday.*” Therefore only mean scores for July were reported and they can be found in Table 51 Hughes.

### Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

Further details are provided in section 4.1.1.3.3.

**Evidence statement**

A British cluster RCT (rated -) in children aged 12 to over 16 years (number unclear) evaluated verbal advice together with different types of educational materials: *“(i) a colour leaflet “Suncool” which was an attempt to make covering-up look desirable, and also provided tips about avoiding sun exposure; (ii) a workbook containing basic information about the sun and ultraviolet radiation and skin cancer, particularly melanoma, which could easily be photocopied by the schools; (iii) a video called “Suncool” in which the actress Melanie Hill (from the television programme “Bread”) discusses the concepts of sun and skin cancer with a class of children.”* The first intervention group *“read through the text of the workbook and took home “Suncool””* (this probably refers to the leaflet, but was not clearly stated). Interventions in the following groups included the same components as in the first group and additional materials or activities: watching the video, being given homework to design posters for public education and having a discussion later in the week about the issues raised. The study commenced in May (there was no baseline survey) and post-tests were carried out in July and September.

Authors reported that there was no difference between groups in knowledge (and no direction of effect indicating superiority of one group was observed) and behaviour (no further details for behaviour were provided). An important limitation of this study is lack of any baseline assessment. Probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Hughes<sup>51</sup>)

#### 4.7.1.4 Community based studies

Only one study was identified to evaluate this intervention in a community setting. Details of this study are provided below.

#### 4.7.1.4.1 Rodrigue<sup>87</sup> - *controlled before and after study*

This controlled before and after study (rated -) undertaken in the USA, had two intervention groups and a control group. Participants were assigned to a comprehensive prevention programme (CPP) intervention, an information only condition (IOC) intervention or a no information control (NIC). This section compares the effectiveness of two variants of group based verbal advice (CPP and IOC), provided in a community setting, to mothers who were targeted as agents of change for their children. Follow-up was at two and 12 weeks. The main details of the study and assessment of the effectiveness of the interventions compared with a no information control are provided in section 4.1.1.4.2.

### Results

#### *Primary outcomes*

#### Knowledge

Mean (SD) KQ scores for the two intervention groups were as follows:

baseline: CPP: 14.7(2.7) vs. IOC: 13.5(2.2)

2-weeks post-intervention: CPP: 21.8(3.0) vs. IOC: 20.9(2.9)

12-weeks post-intervention: CPP: 21.6(2.6) vs. IOC: 20.9(2.8)

The 3 x 3 ANOVA on KQ total score (also taking account of the control group) revealed a significant effect for Time,  $p < 0.001$ , and a significant effect for Group,  $p < 0.0001$ , modified by a significant Group x Time interaction,  $p < 0.0001$ . Simple effects of assessment time were significant for the CPP & IOC groups,  $p < 0.0001$ . Post hoc tests showed significantly more knowledge in the two groups between baseline assessment and both the 2-week and 12-week post-intervention



assessments. The statistical significance of the marginal difference in knowledge scores at two and 12 week follow-ups was not commented on.

## Behaviour

Mean (SD) SSBQ scores for the two groups were as follows:

baseline: CPP: 23.7(4.4) vs. IOC: 21.3(3.2)

2-weeks post-intervention: CPP: 32.6(8.8) vs. IOC: 26.6(8.7)

12-weeks post-intervention: CPP: 42.2(7.3) vs. IOC: 23.7(5.9)

The 3 x 3 ANOVA on SSBQ total score (also taking account of the control group) revealed a significant effect for Time,  $p < 0.0001$ , and a significant effect for Group,  $p < 0.0001$ , modified by a significant Group x Time interaction,  $p < 0.0001$ . Simple effects of assessment time were significant for the CPP group,  $p < 0.0001$  and IOC group,  $p < 0.0001$ . Post hoc tests showed significant improvements in sun-safe behaviours from the baseline assessment to the 2-week post-intervention assessment for both the CPP & IOC groups; however the CPP group showed continued improvements in sun-safe behaviours from the 2-week post-intervention assessment to the 12-week post-intervention assessment, whereas the IOC group showed a significant decline. Regarding group effects, post hoc analyses revealed that at the 2-week post-intervention the CPP group had higher scores than the IOC group,  $p < 0.001$ . The similar between-groups pattern was observed at 12 weeks.

## *Secondary outcomes*

### Sun Exposure Attitudes & Beliefs

Mean (SD) SEAB-mother total scores for the two groups were as follows:

baseline: CPP: 43.8(10.8) vs. IOC: 43.4(9.6)

2-weeks post-intervention: CPP: 61.0(9.0) vs. IOC: 50.0(8.0)

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12-weeks post-intervention: CPP: 66.8(8.5) vs. IOC: 47.7(10.4)

The 3 x 3 ANOVA on SEAB-mother total score (also taking account of the control group) revealed a significant effect for Time,  $p < 0.0001$ , and a significant effect for Group,  $p < 0.001$ , modified by a significant Group x Time interaction,  $p < 0.0001$ . Simple effects of assessment time were significant for the CPP & IOC groups,  $p < 0.0001$  and  $p < 0.001$  respectively. Post hoc tests revealed significant differences in the CPP & IOC groups between the baseline assessment and both the 2-week and 12-week post-intervention assessments. Regarding group effects, the CPP group differed significantly from the IOC group at the 2-week post-intervention,  $p < 0.0001$ , and at the 12-week post-intervention assessment,  $p < 0.0001$ .

Mean (SD) SEAB-target child total scores for the two groups were as follows:

baseline: CPP: 39.3(8.3) vs. IOC: 39.2(7.9)

2-weeks post-intervention: CPP: 59.7(6.9) vs. IOC: 48.8(7.8)

12-weeks post-intervention: CPP: 64.8(8.9) vs. IOC: 48.3(9.1)

The 3 x 3 ANOVA on SEAB-target child total score (also taking account of the control group) revealed a significant effect for Time,  $p < 0.0001$ , and a significant effect for Group,  $p < 0.001$ , modified by a significant Group x Time interaction,  $p < 0.0001$ . Simple effects of assessment time were significant for the CPP & IOC groups,  $p < 0.0001$ . Post hoc tests revealed significant differences in the CPP & IOC groups between the baseline assessment and both the 2-week and 12-week post-intervention assessments, and significant differences for the CPP group between the 2-week and 12-week post-intervention assessments. Post hoc analyses indicated that at the 2-week post-intervention assessment the CPP group differed significantly from the IOC groups  $p < 0.0001$ . Also the CPP group differed significantly from both the IOC group at the 12-week post-intervention assessment,  $p < 0.0001$ .

## Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Applicable only to populations or settings included in the studies, the success of broader application is uncertain.

Further details are provided in section 4.1.1.4.2.

### **Evidence statement**

An American controlled before and after study (rated -) evaluated the effectiveness of group-based verbal advice, provided in a community setting to 66 mothers (numbers in two intervention arms were not provided) who were targeted as agents of change for their children. Participants were assigned to a comprehensive prevention programme (CPP) intervention, an information only condition (IOC) intervention or a no information control (NIC). Both interventions lasted 90 minutes. Both the CPP and IOC interventions included a didactic component but parents in the CPP arm also engaged in an experimental session designed to focus on changing behaviour patterns, attitudes and beliefs related to skin cancer prevention.

Knowledge scores were marginally higher amongst the CPP group in comparison with the IOC group at the two and 12 week follow-ups (and at baseline). The statistical significance of the small difference was not commented on.

There was statistically significant evidence, at the two and 12 week follow-ups, of a greater improvement in sun-safe behaviour amongst the CPP group in comparison with the IOC group ( $p < 0.001$ ).

Applicable only to populations or settings included in the studies, the success of broader application is uncertain. (Rodrigue<sup>87</sup>).

## 4.7.2 Mass-media campaigns in adults

### 4.7.2.1 Studies in a university/ college setting

Only one study was identified to evaluate these interventions in a university/ college setting. Details of this study are provided below.

#### 4.7.2.1.1 Cody<sup>25</sup> - *cluster RCT including participants with history of skin cancer on prevention and detection*

Three hundred and twelve first-year psychology students at the University of Newcastle, Australia were enrolled in this study (rated -). Of these 114 participants from six classes were shown an informational video and 108 from six classes an emotional one.

Further details are provided in section 4.2.2.1.1.

### Results

#### *Primary outcomes*

In the informational video group mean knowledge scores increased from 7.6 (SD 1.5) at baseline to 8.5 (SD 1.0) immediately after watching the video and slightly decreased to 8.3 (SD 1.1) ten weeks later. The mean baseline knowledge score in the emotional video group was 8.0 (SD 1.4) and increased to 8.4 (SD 1.2) in the

first post-test and to 8.6 (SD 1.1) in the second. A significant difference between groups was not reported.

### *Secondary outcomes*

*“At follow-up, [skin protection behaviour] intentions had decreased significantly from post-video for both the informational and control groups but not for the emotional group.”*

No further differences between two intervention types were reported for any of the secondary outcomes. All results can be found in Table 38 Cody.

### Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

Further details are provided in section 4.2.2.1.1.

### **Evidence statement**

An Australian RCT (rated -) compared in 222 psychology students an informational video (“*Skin Deep*” in which “*a female gave an informative talk covering the causes, consequences, and incidence rates of skin cancer and suggested skin protection, skin examination, and treatment-seeking behaviour*”) with an emotional video (which “*comprised two interviews with local people diagnosed as having malignant melanoma. One was dying, while the other had fully recovered.*” It finished with an overview of topics covered in the “*Skin Deep*” video.). Participants were assessed at baseline, immediately after watching the video and ten weeks later.

No significant differences between groups in the mean knowledge score were reported and no obvious direction of effect was present. Probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Cody<sup>25</sup>)

### 4.7.3 Printed materials in children

#### 4.7.3.1 Studies set in the place of domicile

Only one study was identified to evaluate these interventions in the place of domicile. Details of this study are provided below.

##### 4.7.3.1.1 Buller 1998<sup>12-14</sup> - RCT

In this study (rated -) a random sample of 1975 parents of children aged five to 11 were chosen from a paediatric practice and 42 classes from seven elementary schools with kindergarten through fifth grades and at least 75% of Caucasian students. Eight hundred forty one parents consented to participate in the study and 768 who responded to all questionnaires were included in the final analysis. The study was set in a metropolitan area of Arizona which at the time of the trial had the highest rates of skin cancer in the USA. The study started in 1994 and finished in 1996.

Parents were randomised to receive printed materials with inductive logical structure and high or low language intensity (190 and 192 participants analysed)

or deductive logical structure and high or low language intensity (187 and 199 participants analysed).

Demographic characteristics and baseline comparisons were not reported. Authors however mentioned some characteristics in their discussion as a limitation (reported below).

Messages (newsletters and brochures containing information on sun protection) were sent to parents in the spring and summer months. Initially the study also aimed at investigating the influence of the duration of an intervention (six and three months), but in the end data was reported for both durations jointly.

*“Three persuasive prevention messages were created that presented arguments on health outcomes of sun protection, parental values and responsibilities for own health and child’s health, and importance of physical appearance of the skin. (...) Four versions of each message were produced by altering language intensity (high vs. low), using adjectives and adverbs and opinionated rejection statements, and by changing logical argument structure (deductive vs. inductive), through the presentation of evidence and conclusions...”*

The materials that were used in this study included:

- three four-page newsletters containing *“lead articles on a newsworthy sun safety topic (effectiveness of sunscreens, dangers of artificial tanning, and state of the ozone layer) with an attention-getting headline, short articles with practical sun protection advice, and a child’s page with games, projects, and suggested readings. Lead articles always continued onto the upper left-hand column of the second page; the persuasive messages were placed next to the last part of the lead article, in the upper right-hand column on page 2...”*
- three brochures containing one of the persuasive messages; on the inside flap there was a list of recommendations based on advice from the American Academy of Dermatology, the US Public Health Service, and the American Cancer Society. Recommendations were: *“(1) limit time spent in*

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*the sun; (2) avoid the sun's rays between 10am and 3pm; (3) apply a sunscreen with an SPF of 15 or greater every day of the year; (4) wear clothing that protects the skin – long sleeves and long pants, a wide brimmed hat, and sunglasses; (5) stay in the shade whenever possible – find shade trees and ramadas or bring an umbrella; (6) avoid artificial tanning from booths, beds or lamps; (7) be careful not to get sunburn; (8) examine your skin regularly; and (9) make sun safety a family habit.”*

- an initial newsletter with the description of the programme
- three magnetic “3x5” refrigerator tip cards repeating recommendations on sunscreen, protective clothing and avoiding intensive sunlight. *“Language intensity and logical structure were not altered on these materials.”*

*“Newsletters, brochures and tip cards were mailed one at a time to participating parents in rotating order, beginning with the introductory newsletter and followed by a brochure, tip card, another newsletter and so on. Mailings to parents were equally spaced across the intervention period” (2.5 weeks for six month duration and 1.25 for three month).*

Children in the elementary schools were taught the Sunny Days, Healthy Ways curriculum by their teachers in March and April (on this condition schools agreed to participate). Materials for parents were designed to be independent of the curriculum, but contained graphics and characters used in the curriculum.

Before the intervention a telephone interview lasting a mean of 20.6 minutes was conducted. First post-test telephone interviews took a mean of 23.1 minutes, however no mean time was provided for final interviews.

In the pre-test survey a 97-item questionnaire was used which asked about sources of skin cancer information, knowledge and attitudes, practice of sun safe behaviours, skin cancer risk factors and demographic information. In the first post-test a 103-item survey was used. It additionally asked about exposure to prevention messages and additional demographic characteristics. The last survey comprised 18 items.



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Behavioural intentions were measured at baseline by asking parents if they were planning to protect themselves and their children (yes/no/don't know). A single variable was created: intentions for both, for self or child, for none.

Knowledge scores were constructed as a number of correct answers.

Attitudes and self-efficacy expectations were measured on five-point Likert-type scales:

- Health Outcome Involvement,
- Physical Impression Involvement,
- Value Involvement for a tan,
- Self-efficacy expectations for engaging in more solar protection for themselves,
- Self-efficacy expectations for engaging in more solar protection for children.

It was also reported that Barriers to Self Protection and Barriers to Child Protection were measured on a "similar scale". Barriers to Child Protection included subscales: Barriers to Child Sunscreen Use, Child Complaints, and Difficulty of Protecting Child.

Sun protection was measured during each assessment as reported by parents on five-point scales ("never", "rarely", "sometimes", "often", "always") and for themselves was: frequency of using sunscreen and sunscreen with SPF 15+, wearing protective clothing or hats, avoiding the sun at midday, staying in the shade. For children it additionally measured application of sunscreen before school.

Summed scales were generated for parent and child summer and winter protection.

Behaviour was measured in relation to: current winter and previous summer at baseline, current summer and plans for winter in the first post-test and current winter in the second post-test.

Exposure to messages was measured in the first post-test only and included questions on how many different materials were received and read by parents and other members of the family.

Letters inviting to participate were mailed in October through December 1994. Baseline assessment was carried out in January and February 1995. Mail was sent to participants from March to August. Participants were first post-tested in September and October and then in February 1996 a short post-test was conducted to assess winter sun protection.

## Results

This study investigated the change in behaviour to protect both parents and children. In this section results only for child protection are reported. Results were rarely reported for groups to which participants were randomised, but grouping them by the intensity of the messages only, which means comparing pairs of intervention arms.

### *Primary outcomes*

This study tested two hypotheses: that "*high intense language would produce more compliance with sun protection recommendations than those with less intense language*" and that "*high-intensity deductive messages would be more effective than inductive ones.*" The first one was confirmed in the analysis of solar protection behaviour both for parents and children and the second in the analysis of parents' plans to protect themselves in the upcoming winter. The second one was confirmed only in relation to parent behaviour.

In the summer the mean frequency of applying sunscreen increased by 0.13 in the low intensity groups and by 0.09 in the high intensity groups. The difference

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between two intensity levels was not significant with  $p=0.474$ . Application of sunscreen with SPF 15+ was also more frequent in both groups in the follow-up assessment (0.19 in low and 0.27 in high intensity) and the difference between both groups was not significant with  $p=0.229$ . There was an increase in both groups in applying sunscreen before school – 0.38 in the low intensity and 0.42 in the high intensity group. The difference between the two was not statistically significant  $p=0.627$ . The frequency of children wearing protective clothing increased by 0.18 and 0.22 respectively, with a non-significant difference between groups ( $p=0.620$ ). The frequency of wearing a hat increased by 0.13 in both groups and the difference was not significant ( $p=0.931$ ). Limiting exposure to the midday sun was also more frequent in the post-test with an increase of 0.25 in the low and 0.27 in the high intensity group. Telling children to play in the shade was also more frequent in the post-test in both groups with an increase of 0.21 in the low and 0.31 in the high intensity message group with the difference also not significant  $p=0.245$ .

In winter the same behaviours were assessed. The frequency of applying sunscreen increased by 1.37 in the low and by 1.60 in the high intensity group. The difference between the two was significant with  $p=0.027$ . For applying sunscreen with SPF 15+ there was again a significant difference ( $p=0.020$ ) and it increased by 1.58 and 1.88 respectively. A similar significant change in frequency was observed for applying sunscreen before school (1.09 low, 1.36 high,  $p=0.003$ ), wearing protective clothing (1.00 low, 1.25 high,  $p=0.045$ ) and limiting exposure to midday sun (1.26 low, 1.49 high,  $p=0.041$ ). There was no difference in change in frequency of wearing a hat (0.86 low, 1.02 high,  $p=0.127$ ) and a difference approaching statistical significance in telling children to play in the shade (1.32 low, 1.54 high,  $p=0.051$ ).

The average time that children spent outside decreased in both groups (by 11.48 in the low and 7.94 in the high intensity group; units were not provided) and the difference between study arms was not significant ( $p=0.617$ ).

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### *Secondary outcomes*

No secondary outcomes relevant to this review reported.

### Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to settings or populations included in the study.

One of the limitations reported by authors was use of self-reported measures which is susceptible to memory mistakes, social desirability and demand effects. White parents and those with slightly higher incomes were overrepresented in the sample.

Part of the sample that was recruited in schools had children additionally provided with a curriculum. Authors observed that parents from this group did not achieve better results, therefore this is probably not a confounder. However the majority reported seeing children’s materials and discussing them at home. Demographic information and baseline equivalence of groups was not reported. Results were not always reported for groups to which participants were randomised. Intention to treat analysis was not used. Drop-out reasons were not reported.

This study was conducted in an “*area in southern Arizona, the region with the highest rates of skin cancer in the United States,*” which might also seriously limit the applicability of the results.

### **Evidence statement**

An American RCT (rated -) assessed the effects of high and low intensity printed materials (they also varied on the logical structure of arguments, but results for this factor were not reported for children) sent to parents (768 in the final analysis) in

spring and summer in changing sun-protective behaviour relating to children. The materials included three newsletters (on “*effectiveness of sunscreen, dangers of artificial tanning and state of the ozone layer*”), three brochures with recommendations on sun protective behaviour, an initial letter describing the programme and three magnetic refrigerator tip cards with recommendations (sunscreen use, protective clothing, avoiding intensive sunlight). Mail was sent to participants from March to August. Participants were first post-tested in September and October and then in February 1996 a short post-test was conducted to assess winter sun protection.

No difference between study arms was found for summer protection, although for most behaviours there was more improvement in the high intensity group: frequency of applying sunscreen with SPF 15+  $p=0.229$ , applying sunscreen before school  $p=0.627$ , wearing protective clothing  $p=0.620$  and telling children to play in the shade  $p=0.245$ . For winter protection in five of seven items there was a significantly higher improvement in the high intensity arm compared to low intensity arm: frequency of applying sunscreen ( $p=0.027$ ), applying sunscreen with SPF 15+ ( $p=0.020$ ), applying sunscreen before school ( $p=0.003$ ), wearing protective clothing ( $p=0.045$ ) and limiting exposure to midday sun ( $p=0.041$ ). For the remaining two behaviours (wearing a hat and telling children to play in the shade) there was a non-significantly higher increase in frequency in the high intensity group ( $p=0.127$  and  $p=0.051$  respectively). There was no significant difference in the average time a child spent outside, but it decreased more in the low intensity group ( $p=0.617$ ). Probably applicable only to settings or populations included in the study. (Buller 1998<sup>12-14</sup>)

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## 4.7.4 Printed materials in adults

### 4.7.4.1 Studies in a workplace setting

Only one study was identified to evaluate this intervention in a workplace setting. Details of this study are provided below.

#### 4.7.4.1.1 Rasmussen<sup>83</sup> - RCT

This trial (rated -) was conducted in the UK and participants were recruited from two industrial companies in central Scotland. A total of 171 employees were randomised to receive positive information (62 participants), negative information (55 participants) or control (54 participants). The mean age was 41.25 (SD 12.38), ranging from 18 to 73 years.

Further details are provided in section 4.3.2.1.2.

### Results

#### *Primary outcomes*

There was a main effect of group: individuals in the negative group indicated a lower likelihood of using sunscreen than individuals in the positive group,  $p < 0.05$ .

There was a significant increase in the likelihood in both intervention groups. However in the negative group there was a decrease in decision 3.

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### *Secondary outcomes*

No secondary outcomes relevant to this report were reported.

### Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to populations or settings included in the study – the success of broader application is uncertain.

Further details are provided in section 4.3.2.1.2.

### **Evidence statement**

A British RCT (rated -) compared the effects of positive (including a description of the efficacy of sunscreen use, the different types of sunscreens and how a history of sunscreen usage can dramatically reduce skin cancer risk) and negative information (outlining the problems with sunscreen usage and that most sunscreens still allow some UV rays through) in 117 employees of industrial companies in Scotland (aged 18 to 73 years).

This study provided evidence that individuals in the negative information group indicated a lower likelihood of using sunscreen than individuals in the positive group,  $p < 0.05$ . Later there was a decrease in the likelihood in the negative group (significance level not provided). Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

(Rasmussen<sup>83</sup>)

#### 4.7.4.2 Studies in a university/ college setting

Seven randomised studies (Boer, rated ++, Cho, rated -, Jones 1994, rated -, McMath, rated -, Prentice-Dunn, rated -, Rothman, rated + and Stephenson, rated -) and one controlled before and after (Greene, rated -) compared different types of printed materials in university or college students. Apart from Boer which was set in the Netherlands, all were American studies. The numbers of participants in studies and their age varied and they were: 92 participants in Stephenson (median age 21 years), 96 in Greene (aged 19 to 26 years), 136 in Jones 1994 (age 17 to 23), probably 140 in Prentice-Dunn (unclear; age not reported), 146 in Rothman (age not reported), 159 in Boer (aged 17 to 27), 208 in McMath (age not reported) and 274 in Cho (aged 18 to 37). Five studies assessed outcomes in an immediate post-test, one three to four weeks after baseline (Greene) one four weeks after baseline (Cho) and one did not report follow-up (Boer).

Although all used interventions which can be classed as printed materials, they varied both in terms of the form and content. Three studies reported evaluating essays (Jones 1994, McMath and Prentice-Dunn), two reported using “messages” (Cho and Stephenson), one pamphlets (Rothman) and one booklets containing 12 public service announcements (Boer). The issue of content tends to be more complicated, as studies had three or four arms comparing different combinations of investigated factors. For example Prentice-Dunn looked at four essays highlighting either high or low benefits of a tan and high or low efficacy of sun protection.

Five studies did not report or assess primary outcomes of this review or did not report outcomes for arms to which participants were randomised.

Boer (comparing four announcements with or without pictures and with or without textual arguments) did not report significance levels for comparisons of post-test knowledge scores. Only for announcements that did not use picture and textual arguments did the knowledge score appear to be lower.



Cho reported that participants provided with high threat messages were significantly more likely to use sunscreen four weeks after being given the intervention than those who were given low threat messages.

Greene provided evidence that participants who were given information in a statistical format reduced sunbed use significantly more than those who were given information in a narrative format.

#### 4.7.4.2.1 Boer<sup>7</sup> - *RCT*

In this study (rated ++) 159 participants were recruited from the University of Twente and a college, both located in Enschede, Netherlands. The study year was not reported. Participants were allocated to four groups and given public service announcements containing pictures and/or textual arguments. 39 participants were in an arm with pictures and textual arguments and 40 in each of the remaining three.

35% of participants were female. Mean age was 21.5 years and ranged from 17 to 27. Race and ethnicity were not reported. Authors stated that groups did not significantly differ with respect to demographic characteristics and baseline knowledge.

This study investigated public service announcements that contained a logo, slogan ("Practice safe sun tanning"), and a concrete sun protection advice, which was supported by different combinations of pictures and textual arguments:

- picture + textual arguments,
- picture + no textual arguments,
- no picture + textual arguments,

- no picture + no textual arguments.

Each participant received a booklet with twelve different announcements (*“three for each of the four sun protection measures, i.e., staying out of the midday sun, wearing protective clothing, using sun screen, and wearing sun glasses”*). The announcements were presented *“in a fixed random order within each condition.”*

Judgement of public service announcements (attractiveness, credibility, comprehensibility, required amount of cognitive processing) was measured on a 5-point Likert scale (from 1 “strongly agree” to 5 “strongly disagree”).

Knowledge was defined as recall of one of four negative consequences of sun exposure (scored 0-4) and pieces of sun protection advice (score 0-4).

Perceived advantages and disadvantages and intended sun protective behaviour with respect to the following sun protection measures were also evaluated:

- sunscreen use ,
- protective clothing,
- avoiding fierce sun,
- wearing sun glasses.

They were all measured on a five-point Likert scale (from 1 “strongly agree” to 5 “strongly disagree”).

Follow-up was not reported.

## Results

Outcomes were measured only after exposure to the intervention.

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### *Primary outcomes*

Mean knowledge about sun exposure scores were: 3.1 (SD 1.0) in the picture and textual arguments group, 3.1 (SD 0.9) in the group given only pictures, 3.2 (SD 0.7) with only textual arguments and 1.8 (SD 0.8) in the remaining one. For mean knowledge about sun protection advice the scores were: 2.9 (SD 0.9), 3.1 (SD 0.9), 3.1 (SD 0.8), 2.8 (0.9). No significance testing for between-group comparisons was reported, only investigating main effects and interactions between factors.

### *Secondary outcomes*

Significance for groups on any of the outcomes was not reported, only main effects and interactions between factors. For results in groups please see Table 25 Boer.

### **Limitations**

Internal validity was rated “++”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

Authors stated that the experimental method might have limited external validity of the study results. The booklet did not reflect real life exposure to public service announcements. The study population had a higher educational background than the target population of public service announcements. Single item measures were used for opinion about the announcements while multiple item scales could provide a better indication of internal consistency.

Probably only short-term effects of the intervention were measured.

Allocation concealment was not reported. Losses to follow-up and use of intention to treat analysis were not stated.

**Evidence statement**

A Dutch RCT (rated ++) evaluated public service announcements that contained a logo, slogan (“Practice safe sun tanning”), and concrete sun protection advice supported by four different combinations of pictures (picture vs. no picture) and textual arguments (textual argument vs. no textual argument) in 159 participants (aged 17 to 27 years) recruited at a university. Each participant received a booklet with twelve different announcements (*“three for each of the four sun protection measures, i.e., staying out of the midday sun, wearing protective clothing, using sun screen, and wearing sun glasses”*). The announcements were presented *“in a fixed random order within each condition.”* Follow-up was not reported.

This study did not provide any indication if there were statistically significant differences in knowledge levels between groups. Only for announcements which contained neither pictures nor textual arguments the mean knowledge score appeared to be lower compared to the remaining three groups. Probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Boer<sup>7</sup>)

**4.7.4.2.2 Cho<sup>23</sup> - RCT**

Two hundred seventy four participants were enrolled in this American trial (rated -). The study did not report the year in which they were carried out. Numbers of participants allocated to study arms were also not reported.

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The highest percentage of female students was 60.6%. 83.9% were white. Mean age was 20 years (SD 2.1) ranging from 18 to 37. Similarity of groups at baseline was not assessed.

This study tested the effects of a high and low threat message.

High threat message which *“highlighted the facts that are pertinent to college students’ risk of skin cancer, emphasizing that college students are vulnerable to skin cancer unless they engage in preventive behaviour and that the consequence of skin cancer is severe. The fictionalised case described how a student at the university where the study was done suffered from and died of skin cancer. It also included graphic colour photos of skin cancer patients.”*

Low threat message which *“presented general facts about skin cancer. The fictionalised case described how a 52-year old farmer in New Zealand discovered and treated an early-stage skin-cancer symptom. The low threat message included colour photos conveying neutral images, such as lab test results.”*

*“At the end of both the high and low threat messages was a list of recommended behaviour, including sunscreen use, wearing a protective hat and clothing, minimising sun exposure at midday, and performing periodic skin self-examination.”*

Witte, Cameron, McKeon, and Berkowitz’s scale was used to assess:

- threat – defined as *“susceptibility to and severity of threat”* of skin cancer,
- efficacy,
- attitude towards recommended behaviour (favourable - unfavourable),
- intentions to engage in recommended behaviour,
- behaviour – self reported sunscreen use; measured at a 4-week follow up,
- defensive avoidance – items such as avoiding the thought of skin cancer while sunbathing,

- 
- message derogation – measured if participants considered the message to be exaggerated,
  - perceived manipulation – if participants thought the message was manipulative, misleading, etc.

Rippetoe and Roger's scale was also used and it measured:

- fatalism – defined as having no influence on course of events related to skin cancer,
- hopelessness – meaning the extent to which thought of cancer made participants feel staying healthy to be useless,
- wishful thinking – the level of agreement with the following statement:  
*“When faced with the prospect of developing skin cancer, it helps me to dream of a world where there are no diseases such as cancer”.*

For most questions a seven-point Likert-type scale (from 1 “strongly disagree” to 7 “strongly agree”) was used.

Participant's stage of change was assessed before randomisation and it was classified as:

- Precontemplation (P) – *“individuals have no intention to stop a risky behaviour within six months”*
- Contemplation (C) – *“individuals consider initiating preventive behaviour within six months”*
- Preparation (PP) – *“individuals plan to start preventive behaviour within a month”*
- Action (A) – *“individuals have engaged in a behaviour changes for less than six months”*
- Maintenance (M) – *“individuals regularly engage in preventive behaviour for more than six months.”*

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Confound checks were performed looking at “*perceived accuracy, clarity, objectivity, quality, understandability, and amount of learning from the message.*”

Most outcomes measured on the same day as provision of information; four weeks after the intervention behaviour change was assessed.

## Results

Outcomes other than stage of change were not assessed at baseline. The results only compare groups at post-test which could mean measuring an underlying difference between groups instead of an intervention effect. Some results were reported comparing participants in different stages of change. These are not directly relevant to this review, but can be found in Table 36 Cho.

### *Primary outcomes*

The behaviour score at four weeks was significantly ( $p < 0.001$ ) higher in the high threat group than in the low threat (mean 3.64 and 2.85 respectively) indicating more sunscreen use in the high threat arm.

### *Secondary outcomes*

The results indicated that participants in the high threat arm perceived skin cancer as a significantly more likely and severe threat. They also had significantly more intentions to engage in recommended behaviour. However they were also feeling more fatalistic and hopeless about skin cancer. No more secondary outcomes were reported for intervention groups. Exact information to be found in Table 36 Cho.

## Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

This study investigated a single forced exposure to a message which may, as highlighted by authors, differ from real-life exposure. Also what the authors called “laboratory setting” could limit generalisability of the findings. Furthermore a population of students is characterised by a relatively high socio-economic status and education level compared to an average person that age. Some confounding factors were identified (perceived message accuracy, clarity and quality) they were however controlled for in the analysis.

Outcomes were not measured at baseline. Groups similarity at baseline was not reported. The follow-up was relatively short.

The study reporting was rather poor and it was not possible to establish if allocation was adequately concealed or participants were blinded. 33 participants were lost to follow-up at four weeks. It was not reported if they were included in the analysis.

#### **Evidence statement**

An American RCT (rated -) in 274 undergraduate students (aged 18 to 37 years) compared high threat messages (which *“highlighted the facts that are pertinent to college students’ risk of skin cancer, emphasizing that college students are vulnerable to skin cancer unless they engage in preventive behaviour and that the consequence of skin cancer is severe”*) with low threat messages (which *“presented general facts about skin cancer”*). Both messages contained sun protection advice. Most outcomes measured on the same day as provision of information; behaviour change was assessed four weeks after the intervention.

This study provided evidence that participants given high threat messages were more likely to report sun safe behaviour (measured by use of sunscreen) at the four week follow up than those provided with low threat messages ( $p < 0.001$ ). This



study did not assess outcomes at baseline. Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

(Cho<sup>23</sup>)

#### 4.7.4.2.3 Jones 1994<sup>54</sup> - RCT

This study (rated -) was carried out in the USA, the year was not provided. 136 undergraduate students were randomised to read 44 a health-based, 46 an appearance-based or 46 a neutral essay about tanning.

They were 17 to 23 years old. 49% were female. All of them were reported as white. No significant differences were found between groups.

Students were asked to read one of three essays.

- The health-based essay (“Tanning: a Risk to One’s Health”) *“discussed the health risks associated with excessive tanning, offered incidence statistics for skin cancer, described types of skin cancer, and recommended that people use sunscreen.”*
- The appearance-based essay (“Tanning: a Risk to One’s Appearance”) *“discussed the deleterious effects of excessive tanning on appearance – such as excessive wrinkling, scaring, aging, and so on – and recommended that people use sunscreen.”*
- The control essay (“Tanning”) *“simply described the process by which tanning occurs but did not mention any negative effects of tanning; even so, the essay recommended that people use sunscreen to prevent burning. Thus the control essay was a minimal intervention.”*

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All essays were approximately 500 words, had similar structure, tone and beginning and concluding paragraphs.

Students were asked to rate the degree to which they were “concerned about the harmful effects of exposure to the sun” on a scale from 1 “not at all” to 12 “extremely”. How they planned to “work on getting a tan this coming summer, compared to last summer” was scored on a scale from 1 “much less” to 12 “much more”. The degree to which they intended “to use sunscreen when in the sun for prolonged periods” was assessed using a scale from 1 “not at all” to 12 “extremely”.

Quality and strength of the essays was rated using a scale from 1 to 12.

Participants were tested immediately after completing the intervention.

## Results

### *Primary outcomes*

No primary outcomes relevant to this review were provided.

### *Secondary outcomes*

*“Subjects who read the appearance-based essay (mean 8.5) or the control essay (mean 8.1) indicated that they were significantly more concerned about the harmful effects of the sun than those who read the health-based essay (mean 6.4;  $p < 0.01$ ).”*

The participants who read the appearance-based essay were more likely to use sunscreen (mean 6.7) than those who read health-based essays (mean 5.3), with  $p < 0.05$ . *“The control essay fell midway between and did not differ from the others (mean 6.1,  $p > 0.05$ ).”*

Subjects viewed all three essays as equally well written (difference  $p > 0.05$ ).

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The health-based (mean 8.0) and appearance-based (mean 7.7) were considered more convincing than the control essay (mean 6.6), with  $p < 0.01$ .

### Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

Authors reported that the intervention was investigated in a specific population, results may not be applicable to other populations. Self-reported measures of effects were used. It is possible that the responses were reflecting the intention to please investigators. This study did not assess the stability of the results outside the experimental context.

Numbers of students by gender are not equal to the total number of students by study arm. No baseline measurements were made. Very little information was provided on the population and intervention. Reporting of results was not complete.

Due to the rather poor reporting it was not possible to tell if adequate blinding or allocation concealment was used. Similarity of groups at baseline is also uncertain. Intention to treat analysis was not reported.

### **Evidence statement**

An American RCT (rated -) evaluated three essays (health-based, appearance-based and neutral) in 136 undergraduate students (aged 17 to 23 years). Students were tested immediately after completing the intervention.

No primary outcomes relevant to this review were reported. Probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Jones 1994<sup>54</sup>)

#### 4.7.4.2.4 McMath<sup>66</sup> - *RCT*

This American study (rated -) tested four types of essays with differing levels of threat and coping in undergraduates who sunbathed. The study year was not stated. 208 University of Alabama undergraduate students were enrolled, however numbers of participants in each study arm were not reported.

73.6% of students were female. Only Caucasians who had tanned intentionally in the previous year were recruited. Age was not reported. No baseline comparisons were provided.

The intervention was provided in single, one-hour sessions to groups of 12 to 20 participants who were advised the study involved health attitudes and personality. After they provided informed consent, participants completed an inclusion criteria screening questionnaire and four personality construct instruments. They were then randomly assigned to read one of four essays emphasizing the detrimental effects of the sun on appearance and the effectiveness of using sunscreen and eliminating sunbathing with an emphasis on new 'paler' norms of attractiveness. The four essays (each nine to 11 pages long) manipulated threat and coping appraisal as follows: high threat/low coping, low threat/low coping, high threat/high coping and low threat/high coping. Manipulating threat appraisal information involved the amplification or attenuation of statements concerning severity, vulnerability and the rewards associated with sun tanning. Manipulating coping appraisal involved the heightening or attenuation of efficacy (self-efficacy and response efficacy) and response costs related to reduced tanning and increased

sunscreen use. After the intervention, the participants completed a protection motivation theory questionnaire, were debriefed, thanked and dismissed.

This study measured protection motivation theory variables (i.e. rewards, severity, vulnerability, response costs, response efficacy, self-efficacy) as checks on the successful manipulation of threat appraisal and coping appraisal information in the essays. Intentions to take precautionary measures against skin cancer were also investigated.

Post-testing took place immediately after the intervention.

## Results

Results in this study were reported for different levels of threat and coping (results for study arms were not provided). These are reported in Table 63 McMath and briefly discussed below.

### *Primary outcomes*

Not reported.

### *Secondary outcomes*

Compared to those exposed to the low threat message, participants reading the high threat message reported: stronger beliefs in the severity of skin cancer; greater vulnerability to skin cancer; and lower rewards for a tanned appearance.

High coping information increasing perceptions of self efficacy and response efficacy, whilst reducing perceived response costs.

Participants exposed to the high threat message reported increased behavioural intentions, with those reading the high threat message intending to take greater precautionary measures (than those in the low threat condition. No effect of threat information was evident for either hopelessness or avoidance. Coping information was marginally effective in increasing behavioural intentions.

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Those exposed to higher levels of coping information were more likely to report precautionary intentions than their counterparts receiving low coping information. Those who received higher coping information reported less hopelessness than those reading the low coping message. There was no coping information effect on avoidance and no threat x coping information interactions for any measure.

Further details are reported in Table 63 McMath.

### Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

Authors stated that there might be an overlap in variables that were expected to be affected only by threat or coping being affected by both factors.

Due to the poor reporting it was not possible to tell if adequate concealment and blinding methods were used. It was not reported if groups were similar at baseline and if the only difference between them was the intervention. 12 participants were excluded from the analysis as they correctly identified the experimental hypothesis. An intention to treat analysis was not carried out.

Applicability of the results can be limited by the university setting and using a population of students.

### **Evidence statement**

An American RCT (rated -) evaluated essays with different levels of threat and coping in 208 undergraduate students (age was not reported). The four essays (each nine to 11 pages long) manipulated threat and coping appraisal as follows:

high threat/low coping, low threat/low coping, high threat/high coping and low threat/high coping. Post-testing took place immediately after the intervention.

The results were not provided for groups to which participants were randomised. No primary outcomes of this review were assessed. Probably applicable only to population or setting included in the study – the success of broader application is uncertain. (McMath<sup>66</sup>)

#### 4.7.4.2.5 Prentice-Dunn<sup>81</sup> - RCT

Fifty six male and 84 female undergraduate students were enrolled in this American study (rated -) on four essay types. Only data from Caucasian students was used it was however not stated if all 140 participants were Caucasian. Study year was not provided.

Students were enrolled after a testing session in which they were identified as either high or low on appearance concern. Students from each appearance group were randomised to read one of four essays.

No further details were provided.

*“A 2.5-page messages highlighted appearance-related issues such as wrinkling and leatherying of the skin from ultraviolet exposure, the development of age spots, and the unsightly appearance of cancerous skin patches that have been removed. Each essay discussed reducing sun exposure and using sunscreen as preventive measures.”*

Participants were allocated to essays with different levels of benefits of a tan and efficacy of recommended behaviour.

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*“The low-benefits message emphasised how unattractive and unhealthy one is perceived with a tan in light of new norms; how having a tan might lower one’s self-confidence because of the new public attitude toward tanning; and how unpleasant it is to work on a tan. The high-benefits message reversed this information.”*

*“The high-efficacy message highlighted the effectiveness of reducing the amount of time spent outside in the sun using sunscreen to prevent skin cancer and other skin damage. In particular, the ease of sunscreen application was emphasised. The low-efficacy message downplayed the effectiveness of such measures and the ease and convenience of putting them into practice.”*

Ten-point Likert scales were used to assess beliefs about the beneficial effects of sun tanning (five items), efficacy of preventive measures to avoid sun damage (four items), likelihood of sun tanning and using sunscreen in the future (eight items).

No further details were provided.

Post-testing took place immediately after the intervention was completed.

## Results

Participants were not analysed in groups they were randomised to, but according to certain factors (including essay type).

### *Primary outcomes*

No primary outcomes relevant to this review were reported.

### *Secondary outcomes*

Participants provided with high-efficacy messages were more convinced that the recommended actions were effective than those given low-efficacy messages.



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Participants who received low-benefits messages had significantly more intentions to take precautions than those provided with high-benefits information.

### Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to settings or populations included in the study.

Authors did not report limitations.

No baseline outcome measurements were carried out. Little demographic information was reported. Results for study groups were not provided. No attrition details were given. Authors did not state if an intention to treat analysis was used. Follow-up was relatively short.

### **Evidence statement**

An American RCT (rated -) investigated the effectiveness of essays with different levels of benefits of a tan and efficacy of recommended behaviour in probably 140 undergraduate students (number not entirely clear, age not reported) with either high or low appearance motivations. Post-testing took place immediately after the intervention was completed.

No primary outcomes relevant to this review were assessed. Probably applicable only to settings or populations included in the study. (Prentice-Dunn 1997<sup>81</sup>)

#### 4.7.4.2.6 Rothman<sup>88</sup> - RCT

This study (rated +) evaluated positively and negatively framed pamphlets in 146 undergraduate students, probably from the University of Yale, USA. Numbers of participants allocated to intervention arms were not provided. Study year was not reported.

All participants were Caucasian and a half of them was female. Participants' age was not stated. Baseline group similarity was not reported.

*“Subjects participated in groups and were seated around a large table. A female experimenter explained that the experiment concerned the evaluation of health education materials. After signing a consent form, subjects read either a positively or negatively framed pamphlet. The pamphlets were then collected, and the first set of measures distributed. For each set of questions, the experimenter read the directions and waited for every subject to finish each section before proceeding. Finally, subjects were given postcards to mail in for informational pamphlets and/or sunscreen samples.”*

*“Pamphlets were professionally designed, printed and reported.”*

A one-page pamphlet used in a previous study was converted to a four-page brochure. It contained information on incidence, aetiology, and how to detect and prevent the disease.

*“The positively framed handout described the statistics, facts, and arrangements by emphasising benefits rather than risks, and focusing on the positive aspects of being concerned about skin cancer.”*

*“The negatively framed pamphlet described the same information but emphasised losses rather than gains, and focused on the risks of not performing cancer-related behaviours.”*

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Affective reactions to pamphlets were assessed with ten items with ratings on ten-point scales (from 1 “not at all” to 10 “very much”). *A priori* three subscales were defined: negative reactions, positive reactions, interest in the pamphlet.

Risk perceptions were measured with four items and assessed perceptions of the likelihood that they or the “average Yale student” would experience or die from skin cancer. Ratings were done on five-point scales ranging from 1 “not at all” to 5 “very much”.

Knowledge about skin cancer was assessed with seven multiple-choice questions on facts presented in the pamphlets.

Participants were tested immediately after completing the intervention. Further follow-up is not reported, as after the first post-test they were given postcards which they could send requesting free sunscreen.

## Results

### *Primary outcomes*

Knowledge scores were not reported.

### *Secondary outcomes*

The group which received positively framed pamphlets reported significantly higher mean positive reaction scores and significantly lower mean negative reaction scores. There was no significant difference in the interest in pamphlets.

However the group which was given negatively framed pamphlets perceived a higher mean risk of experiencing or dying from skin cancer both to self and to others.

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## Limitations

Internal validity was rated “+”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to settings or populations included in the study.

Authors did not report limitations.

No baseline measurements were conducted. Characteristics of participants and outcome assessment were rather poorly reported. The follow-up was relatively short. Data from three participants could not be used due to investigator errors. It was not reported if an intention to treat analysis was used.

### **Evidence statement**

An American RCT (rated +) investigated the effectiveness of positively and negatively framed messages on 146 undergraduate students (age was not reported). Participants were tested immediately after completing the intervention.

Although knowledge was assessed in this study, no results were provided.

Probably applicable only to settings or populations included in the study.

(Rothman<sup>88</sup>)

#### 4.7.4.2.7 Stephenson<sup>93</sup> - RCT

Ninety two American undergraduate students from a South-western university were enrolled in this trial (rated -). They were run in groups of up to six persons

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and randomised to one of four messages with different combinations of text and pictures and efficacy levels. There were approximately 23 participants in each study arm. The year of the study was not provided.

Their median age was 21 years with only 2% of participants over 26 years. 55% were female and 13% were not White. No baseline comparisons were provided.

Participants were told that they are “*evaluating messages for skin cancer advertisement campaigns*” and their input is necessary for their refinement.

The four messages were combinations of text only vs. text and pictures and high vs. low efficacy. Only high threat messages were used, as a previous study showed that low-threat messages “*produce no effect.*”

Participants read messages consisting of two parts. The first component was a threatening message which “*emphasised (a) the target population’s susceptibility to skin cancer and (b) the severity of skin cancer with graphic language.*” Two versions of a threat message were used: containing only written text and combining written text from other messages with four pictures of individuals in advanced stages of skin cancer on the page opposite to the text.

As a second component a message about the effectiveness of skin-protective behaviours was “*tagged to the end of the high threat base message.*” There were two efficacy versions of this part. The high efficacy message emphasised “*the effectiveness of sun block in preventing skin cancer, as well as the ease with which sun block can be used.*” The low efficacy message “*discussed detection, specifically stating that while sun block is effective in preventing any future skin damage, it is impossible to undo any past skin damage.*”

Before the study messages were validated in a pilot evaluation. A description of the validation process provides some information on the use of five high threat pictures. Four showed “*individuals with red, open skin, yellow infected excretions on the forehead, an exposed nasal cavity and eye socket where the skin cancer has eaten away the skin, and an ear that is infected with dark, black scars and is*

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*decaying away.*” The fifth was a before-after picture of Bridgette Bardot: showing her young and unwrinkled next to very wrinkled, with damaged and leathery skin.

Perceptions were assessed on seven-point Likert-type scales. Threat was measured by severity (three items) and susceptibility (three items) and combined into a single score.

Efficacy was measured by self-efficacy (four items) and response efficacy (three items) and combined into a single score.

Fear was assessed *“by having participants rate (“not at all” to “extremely”) the following five mood adjectives: frightened, tense, anxious, comfortable, nervous.”*

Dependent variables were measured on seven-point Likert-type scales and were: attitudes toward skin protective behaviours, intentions to use skin protective behaviours, defensive avoidance, perceived manipulation and message derogation.

Participants were post-tested immediately after completing the intervention.

## Results

Results of this study were reported as confirming or no four study hypotheses.

### *Primary outcomes*

No primary outcomes were reported.

### *Secondary outcomes*

The first hypothesis that high threat and high efficacy messages lead to danger control was confirmed by results of the study. Participants reading a high efficacy message had more positive attitudes towards protective behaviours than those reading low efficacy ones. High efficacy groups had also stronger intentions to follow recommended behaviours.

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For the hypothesis that high threat low efficacy lead to fear control no clear statement was provided. Low efficacy groups perceived more manipulation and more derogation than high efficacy. The difference in levels of defensive avoidance was not significant.

The hypothesis that perceived threat motivates action was generally confirmed by results. However it is not relevant to this review.

For the hypothesis that pictures are more persuasive no clear statement was provided. Participants reading the message with text and pictures perceived higher levels of fear than reading text only. Message with text and pictures was associated with similar level of threat as text only. Text and pictures message was associated with more favourable attitudes toward skin protective responses and with significantly more perceived manipulation. It also made individuals feel the message was more derogated.

### Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

Authors highlighted that long-term effects were not assessed. Setting as well as the investigated student population can limit study applicability.

Baseline comparisons were not reported. It was also not stated if an intention to treat analysis was undertaken.

### **Evidence statement**

An American RCT (rated -) evaluated high-threat messages with text and pictures or text only containing different levels of efficacy in 92 students (median age 21 years). Participants read messages consisting of two parts. The first component

was a threatening message which “*emphasised (a) the target population’s susceptibility to skin cancer and (b) the severity of skin cancer with graphic language*” (and contained either text and pictures or pictures only). As a second component a message about the effectiveness of skin-protective behaviours was “*tagged to the end of the high threat base message.*” There were two efficacy versions of this part. Participants were post-tested immediately after completing the intervention.

This study provided no information on this review’s primary outcomes. Probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Stephenson<sup>93</sup>)

#### 4.7.4.2.8 Greene<sup>45</sup> - *controlled before and after study*

This controlled before and after study (rated -) undertaken in the USA, had two intervention groups and a control group. The study explored messages which may be effective in reducing the use of tanning beds amongst Caucasian college females, specifically by increasing perceived susceptibility to skin cancer and sun damage. Follow-up was at 3-4 weeks.

This section compares the effectiveness of the two variants of printed material. The main details of the study and assessment of the effectiveness of the interventions compared with no information are provided in section 4.3.2.2.4.



## Results

### *Primary outcomes*

Tanning bed use ( $M=3.06$ ;  $SD=6.32$ ) was measured at the pre-test with the question 'How many times have you used a tanning bed in the past month?'

Tanning bed change ( $M= -1.67$ ;  $SD=5.11$ ) between the pre-test and post-test was measured by telephone callback. Subjects were asked to answer the question 'Would you please estimate how many times you have used a tanning bed in the past month?' Behaviour change was measured by subtracting each subject's use of tanning beds in the month following the pre-test from their month prior to the pre-test. A positive score indicated a reduction and a negative score an increase in tanning bed use. Prior tanning behaviour was measured with a single item, 'How many times have you used a tanning bed in the past year?'

For tanning bed use one month post message, the statistical message was significantly better ( $F(2, 136)=3.02$ ,  $p<0.05$ ,  $\eta^2 =0.04$ ) than the narrative message.

### *Secondary outcomes*

Perceptions of the message (narrative or statistical) were measured by ten Likert-type items with five-point responses ranging from 'strongly agree' to 'strongly disagree'.

There were significant differences between the statistical or narrative messages in mental effort ( $t(98) = -0.47$ ,  $d=0.05$ ) or message reflectiveness ( $t(98) = 0.14$ ,  $d=0.01$ ).

The narrative message ( $M=3.89$ ;  $SD= 0.56$ ) produced greater ratings of realism ( $t(98)= 2.29$ ,  $p<0.05$ ,  $d=0.23$ ) than the statistical message ( $M=3.57$ ;  $SD=0.52$ ).

The statistical message ( $M=3.10$ ;  $SD= 0.76$ ) produced greater ratings on information value ( $t(98)= 2.85$ ,  $p<0.01$ ,  $d=0.31$ ) than the narrative message ( $M=2.69$ ;  $SD=0.79$ ).

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This was measured at the pre-test using six Likert-type items with five-point responses ranging from 'strongly agree' to 'strongly disagree'.

Perceived susceptibility to skin cancer and sun damage was measured at pre-test using eight Likert-type items with five-point responses ranging from 'strongly agree' to 'strongly disagree'.

For susceptibility, the two messages differed significantly from each other ( $p < 0.05$ ), with the statistical message resulting in more susceptibility than the narrative message.

There were no significant differences by message evidence format in intentions to protect skin.

### Limitations

Internal validity was rated "-". Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Applicable only to populations or settings included in the studies, the success of broader application is uncertain.

Further details are provided in section 4.3.2.2.4.

### **Evidence statement**

An American controlled before and after study (rated -) evaluated the effectiveness of two message formats (statistical and narrative) in reducing the use of tanning beds amongst 96 Caucasian female college students (aged 19 to 26 years).

There was statistically significant evidence, at 3-4 week follow-up, that information provided in a statistical format led to greater reduction in tanning bed use in comparison with information provided in a narrative format ( $p < 0.05$ ).

Applicable only to populations or settings included in the studies, the success of broader application is uncertain. (Greene<sup>45</sup>).

#### 4.7.4.3 Studies set in the place of domicile

Four randomised studies compared different content and types of printed materials in the place of domicile (Buller 1998, rated –, Branström, rated +, Gerbert rated – and Richard, rated -). Materials were mailed to 768 participants in Buller 1998, 900 in Richard (age was not reported), 981 in Gerbert (aged 20 to 89 years) and 1743 in Branström (aged 18 to 37). Buller 1998 and Gerbert were set in Arizona and San Francisco Bay Area, USA, Branström in Stockholm County, Sweden and Richard in south of France. Studies differed with respect to the factors the impact of which they tested – it was for example language intensity, source or type of message. Therefore the comparability of their results is seriously limited. Follow-up was clearly stated only in Richard where participants were tested two weeks after being sent leaflets. In Buller 1998 participants were followed-up from January/February to February of the following year and in Branström from May till autumn of the same year. Gerbert did not report follow-up.

Although Branström measured knowledge and frequency of sunbathing, sunburn and sun protection – no information was provided if results were significantly different between groups. Groups received: two brochures and a UV intensity indicator, one brochure and a UV intensity indicator, two brochures and the fourth group – only one brochure. It appears that participants who were given two brochures had the highest level of knowledge and sun protection and the lowest sunbathing frequency. The lowest sunburn frequency was observed in the group which was given one brochure and a UV intensity indicator.

Buller 1998 randomised participants to four groups which received messages with different language intensity (high or low) and argument structure (inductive or deductive). This study indicated that out of six summer protective behaviours

participants who received high intensity messages limited their exposure to midday sun compared to participants who received low intensity messages – this did not take into account argument structure. In the remaining behaviours there was a tendency for more sun protection in the high intensity group. For six winter protective behaviours there was no significant difference with respect to language intensity (although the high intensity group tended to report more sun-protective behaviours). Low intensity inductive messages tended to be associated with more sun protective behaviours than high intensity inductive messages (significance not reported). Participants receiving high intensity deductive messages compared to low intensity deductive messages were reported to have significantly increased the frequency of applying sunscreen, applying sunscreen with SPF 15+ and wearing protective clothing. It was reported that there was no significant difference between groups in the overall change of SPF of sunscreen used (however in the low intensity group the score was marginally higher).

Gerbert measured activation of participants to start sun protective behaviour as dialling a toll-free number (messages varied on the source and content) and found no significant differences between study arms. The highest percentages of activated participants received a message from their own physician (as compared to received from their own Health Maintenance Organisation and a junk mail organisation) and highlighting the risk of skin cancer (compared to ageing and wrinkling with or without a book on the topic).

Richard indicated that participants provided with a humoristic leaflet had a significantly lower knowledge of the definition of melanoma compared to participants who were sent neutral or threatening materials. There was however no significant difference between groups in knowledge of early signs and risk factors of melanoma.

#### 4.7.4.3.1 Buller 1998<sup>12-14</sup> - RCT

In this study (rated -) a random sample of 1975 parents of children aged five to 11 were chosen from a paediatric practice and 42 classes from seven elementary schools with kindergarten through fifth grades. 768 parents who responded to all questionnaires were included in the final analysis. The study was set in a metropolitan area of Arizona which at the time of the trial had the highest rates of skin cancer in the USA. The study started in 1994 and finished in 1996.

Further details are provided in section 4.7.3.1.1.

#### Results

This study investigated the change in behaviour to protect both parents and children. In this section results only for parent protection are reported. Results were rarely reported for groups to which participants were randomised, but grouping them by the intensity of the messages only, which means comparing pairs of intervention arms.

#### *Primary outcomes*

The study hypothesis that “*high intense language would produce more compliance with sun protection recommendations than less intense language*” was confirmed in solar protection behaviour both for parents and children.

The second hypothesis, that “*high-intensity deductive messages would be more effective than inductive ones*” was reported as confirmed by the analysis of parents’ plans to protect themselves in the upcoming winter.

Out of six protective behaviours in the summer there was a significant difference between groups given high and low intensity messages only for limiting exposure to the midday sun. This behaviour frequency increased more in participants who received high intensity messages (mean 0.40) than in those who received low

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intensity (mean 0.24) with  $p=0.029$ . There was no significant difference for mean change in the frequency of applying sunscreen (0.18 low intensity, 0.22 high intensity,  $p=0.610$ ), applying sunscreen with SPF 15+ (0.32 low intensity, 0.34 high intensity,  $p=0.804$ ), wearing protective clothing (0.05 low intensity, 0.12 high intensity,  $p=0.377$ ), wearing a hat (0.20 low intensity, 0.30 high intensity,  $p=0.291$ ) and staying in the shade (0.18 low intensity, 0.28 high intensity,  $p=0.135$ ).

For sun protective behaviour in winter there was no significant difference between the effects of high and low intensity messages on any of the behaviours. There were however significant interactions between the intensity and style of messages for most behaviours and differences for those are reported below. The increase in the frequency of applying sunscreen did not differ significantly for intensity of messages (0.94 low intensity, 1.11 high intensity,  $p=0.114$ ). For inductive messages significance of the difference was not reported and it was an increase by 0.99 in low and 0.96 in high intensity. For deductive messages the frequency of applying sunscreen in winter increased significantly more ( $p=0.049$ ) in the high intensity group (mean 1.26) than in low intensity (mean 0.89). The frequency of applying sunscreen with SPF 15+ increased both in participants provided with low (mean 1.14) and high (mean 1.35) intensity messages, the difference was not significant with  $p=0.093$ . Inductive messages increased the frequency of applying sunscreen with SPF 15+ by 1.23 in low and by 1.14 in high intensity groups (significance of difference was not reported). Deductive messages increased this frequency by 1.06 in low and 1.55 in high intensity groups and the difference was significant with  $p=0.012$ . Frequency of wearing protective clothing increased by 0.79 in low and by 0.93 in high intensity groups with  $p=0.323$ . In groups provided with inductive messages the mean increase was 0.89 and 0.76 respectively and no significance level was provided. In participants who were sent deductive messages frequency of wearing protective clothing in winter increased by 0.69 and 1.12 with the change in the high intensity arm significantly higher ( $p=0.038$ ). Increase in frequency was similar in both groups for wearing a hat (0.78 in low and 0.76 in high intensity,  $p=0.864$ ) and for limiting exposure to midday sun (0.94 in low and 1.09 in high intensity,  $p=0.227$ ). There was no interaction between intensity and style for both behaviours. The mean increase in the frequency of

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staying in the shade was 0.89 in low and 1.12 in high intensity groups and the difference was approaching statistical significance with  $p=0.051$ . For inductive messages the mean increase was similar (0.98 low and 1.01 high intensity,  $p$  not reported), and for deductive ones the increase in high intensity (mean 1.22) was not significantly higher than in low (mean 0.80),  $p=0.073$ .

The mean SPF of sunscreen used most often increased by 3.56 in participants provided with low and 2.64 with high intensity messages. The difference was not significant with  $p=0.294$ .

### *Secondary outcomes*

The mean change in self-efficacy for self protection, perceived susceptibility to skin cancer and barriers to sun protection was not significantly different in groups who received different intensity messages. Participants provided with deductive low intensity messages significantly increased their perceived susceptibility compared to high intensity deductive group.

### Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to settings or populations included in the study.

Further details are provided in section 4.7.3.1.1.

### **Evidence statement**

An American RCT (rated -) in 768 parents assessed the effects of high and low intensity inductively or deductively structured printed materials sent in spring and summer in changing sun-protective behaviour. The materials included three newsletters (on “*effectiveness of sunscreen, dangers of artificial tanning and state*”).

of the ozone layer”), three brochures with recommendations on sun protective behaviour, an initial letter describing the programme and three magnetic refrigerator tip cards with recommendations (sunscreen use, protective clothing, avoiding intensive sunlight). Mail was sent to participants from March to August. Participants were first post-tested in September and October and then in February 1996 a short post-test was conducted to assess winter sun protection. In most cases groups with the same language intensity were analysed together without taking into account the argument style.

For summer protection six items were assessed and only in one there was evidence of a significant difference - participants who received high intensity messages limited their exposure to midday sun more than low intensity ( $p=0.029$ ). It also appears that for the remaining behaviours participants provided with high intensity messages increased the frequency of sun protection more (frequency of applying sunscreen  $p=0.610$ , applying sunscreen with SPF 15+  $p=0.804$ , wearing protective clothing  $p=0.377$ , wearing a hat  $p=0.291$ , staying in the shade  $p=0.135$ ).

For winter protection there was no difference with respect to high and low intensity in the six assessed behaviours. However results predominantly indicated more frequent sun safe behaviours in the high intensity group (applying sunscreen  $p=0.114$ , applying sunscreen with SPF 15+  $p=0.093$ , wearing protective clothing  $p=0.323$  and staying in the shade  $p=0.051$ ). There were significant interactions between intensity and message style for some behaviours. For inductive messages no significance levels were provided, but scores generally indicated that participants who received low intensity inductive messages increased the frequency of sun-safe behaviours more. Participants who received deductive high intensity messages significantly increased their mean frequency of applying sunscreen ( $p=0.049$ ), applying sunscreen with SPF 15+ ( $p=0.012$ ) and wearing protective clothing ( $p=0.038$ ) compared to those who got deductive low intensity materials.

There was no evidence of a significant difference in the change of SPF of sunscreen used between groups provided with different language intensity messages. However participants in the low intensity group appeared to have



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increased their mean sunscreen SPF more ( $p=0.294$ ). Probably applicable only to settings or populations included in the study. (Buller 1998<sup>12-14</sup>)

#### 4.7.4.3.2 Bränström<sup>10</sup> - *RCT*

This study (rated +) enrolled 1743 individuals from census registry in Stockholm County, Sweden. It took place in 2001. Participants were randomised to four arms which received different combinations of two brochures and an UV radiation intensity indicator. Clear numbers on how many participants were randomised to each arm were not provided.

Participants were aged 18-37 years and 57% were female. Race and ethnicity was not reported. Authors stated that there were no significant differences between groups at baseline - data was however not reported.

Participants were sent one of the following combinations of materials: both brochures and UVR intensity indicator, brochure 1 and UVR intensity indicator, both brochures, brochure 1 only. The brochures were similar in size, shape and layout. Brochure 1 contained information about UVR and sun protection (was produced by Apoteksbolaget AB, Sweden). Brochure 2 provided information about UVR and the UV index and recommendations on how to protect oneself from the sun; description of the daily UV forecast and illustrative descriptions of variations in UVR intensity, depending on the latitude and time of the year (was developed for the purpose of the study). The UVR intensity indicator was a credit card sized, commercially available product (Teraco, Inc., USA) which gives a rough indication of the UVR intensity after a few seconds exposure to sunlight; it indicates by colour change if the UVR levels are moderate, high, or extreme; instructions of use were printed on the card.

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Scores relating to different areas were derived based on a 47-item questionnaire investigating: sun exposure (score range 3-15), sunburn (score range 1-25), use of sun protection (score range 6-20), intention to change sunbathing behaviour (score range 3-18), knowledge (score range 0-9), beliefs and perception of risk related to sun exposure (items measured on 1-6 or 1-4 scales). Use of information packages was also evaluated. It was not reported if higher scores indicated a more of less sun-protective behaviour.

Participants were followed-up from May 2001 to autumn 2001.

## Results

Significance for within or between group differences was not reported. Authors only provided the mean of the difference between pre-test and post-test scores in groups.

### *Primary outcomes*

Mean knowledge score increased in all groups. In participants who received both brochures and the UV intensity indicator form 8.67 to 8.84, in those who received the first brochure and the UV indicator from 6.95 to 7.36, in participants who were sent both brochures from 6.89 to 7.42 and in participants who were given only the first brochure from 6.96 to 7.35. Mean of the difference between pre-test and post-test scores in groups was statistically significant with  $p < 0.001$ .

Mean sunbathing frequency score decreased in all groups. In the group that was sent all materials it decreased from 10.65 at baseline to 9.84 at the end of the study. In participants who received the first brochure and the UV indicator there was a fall from 10.61 to 9.87. The baseline score in the group which received both brochures was 10.69 and it was 9.86 at follow-up. In the arm who received only the first brochure it was 10.70 and 9.96 respectively. Mean of the difference between pre-test and post-test scores in groups was statistically significant with  $p < 0.001$ .

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Mean sunburn frequency score also decreased in all groups. In the arm which got all the materials there was a change from 4.73 to 3.32, in the group which got the first brochure and the indicator – from 5.04 to 3.49, in the group which was sent both brochures – from 4.73 to 3.40 and in the group which got only the first brochure – from 4.71 to 3.47. Mean of the difference between pre-test and post-test scores in groups was statistically significant with  $p < 0.001$ .

Mean sun protection frequency score increased in all groups. At pre-test it was 15.58 in the arm which got all the materials, 15.83 in the group which got the first brochure and the indicator, 15.54 in the group which was sent both brochures and 15.59 in the group which got only the first brochure. In the post-test scores were 15.99, 16.34, 16.21 and 16.13 respectively. Mean of the difference between pre-test and post-test scores in groups was statistically significant with  $p < 0.001$ .

### *Secondary outcomes*

Mean of the difference between pre-test and post-test scores in groups was statistically significant with  $p < 0.001$  for intention to change (increased score in all groups), positive attitude towards having a tan (decreased score in all groups) and positive attitude towards being in the sun (decreased score in all groups). There was an increase in the score for behavioural control with a mean of the difference between pre-test and post-test scores in groups statistically significant with  $p < 0.01$ . A non significant result was reported for risk perception.

### **Limitations**

Internal validity was rated “+”. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted.

Authors highlighted that the study did not investigate the potential effects of widespread media broadcasting of the UV index. Moreover the response rate

suggests a possibility that non-responders were less interested in health issues (results might be difficult to generalise). It is also possible that responders might have given answers that they thought would please the researchers (minimised by using mailed questionnaires).

Probably there was an age restriction. Only 1301 participants returned the second questionnaire. Intention to treat analysis was not reported. Blinding and allocation concealment were not reported. Significance levels were reported only for difference between all groups.

#### **Evidence statement**

A Swedish RCT (rated +) investigated different combinations of materials: brochure 1 (containing information about UVR and sun protection) and 2 (providing information about UVR and the UV index and recommendations on how to protect oneself from the sun; description of the daily UV forecast and illustrative descriptions of variations in UVR intensity, depending on the latitude and time of the year) and UVR intensity indicator (a credit card sized, commercially available product which gives a rough indication of the UVR intensity after a few seconds exposure to sunlight), brochure 1 and UVR intensity indicator, both brochures, brochure 1 only. 1743 participants (aged 18 to 37 years) were followed-up from May 2001 to autumn 2001.

Reporting of the results (tests only for within group changes from baseline showing significant difference within all groups with  $p < 0.001$  for each outcome) made it impossible to tell which intervention was the most effective one with respect to knowledge, sunbathing frequency, sunburn and sun protection. It appears that participants who received both brochures increased their knowledge and sun protection and decreased sunbathing frequency more than participants in remaining groups. The sunburn frequency score decreased most in the group which received brochure 1 and the UV intensity indicator. Probably likely to be

applicable across a broad range of populations and settings, assuming it is appropriately adapted. (Bränström<sup>10</sup>)

#### 4.7.4.3.3 Gerbert<sup>40</sup> - RCT

This study (rated -) was conducted in the San Francisco Bay Area, USA (study year was not reported). It randomised 981 patients to nine groups with 109 in each. Each group received a cover letter coming from one of three sources and emphasizing a different reason to protect their skin.

Demographic characteristics were measured only in 66 responders and 75 non-responders. The age in the first group ranged from 21 to 88 (mean 50.5, SD 17) and from 20-89 (mean 48.6, SD 13.6) in the second. Female participants were 72.7% of the activated and 65.3% of the non-activated group. There was a higher percentage of Caucasian participants in the activated group (86.4% vs. 80%), marginally lower of African American (3% vs. 4%), lower of Asian (7.6% vs. 12%) and slightly lower classed as other (3% vs. 4%).

All participants were sent a Skin Cancer Questionnaire (including respondents concerns about skin cancer and factors related to the risk of skin cancer) which enabled them to calculate their own scores. The last page contained a toll-free number patients were invited to contact regardless of their score.

Each questionnaire was accompanied by a cover letter signed by:

- their own physician,
- their own Health Maintenance Organisation (HMO), or

- a fictitious junk mail organisation named Safe Sun

and emphasised the effects of UV rays on:

- the risk of skin cancer,
- aging and wrinkling of the skin, or
- aging and wrinkling further emphasized by a book on these harmful effects of the sun (*How to Outsmart the Sun*, Michael J. Martin MD)

Nine types of packages corresponding to various combinations of both factors were created.

The primary outcome measured was patients calling a toll-free number to report their skin cancer risk scores and request free sunscreen.

Additionally risk score was collected from patients who called the toll-free number. Activated participants were also asked additional 26 questions assessing: susceptibility, severity, barriers, cues to action, and preventive behaviours with higher scores indicated endorsement of attitudes and behaviours consistent with skin cancer prevention.

Analysis of a random sample of non-responders (75 out of 128 with whom contact was attempted) was also undertaken.

Follow-up was not reported.

## Results

Results are not reported for groups that participants were randomised to, but according to certain factors. Therefore most of them were reported in Table 43 Gerbert only.

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### *Primary outcomes*

A total of 66 (7%) patients called in and completed the interview. 51% of the activated patients after receiving the letter from their physician, 35% from the HMO and 14% from the junk mail organisation. When classified by emphasis, 41% received a package highlighting skin cancer risk, 33% appearance and 26% highlighting appearance and accompanied by a book.

### *Secondary outcomes*

Secondary outcomes reported in Table 43 Gerbert.

### Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted.

The authors applied a very specific definition of activation. It is impossible to tell if patients were affected in any other way than calling the toll-free number.

The calls were answered by an investigator for only 30 hours a week between 9am and 5pm on weekdays (seems inconsistent) – callers outside of these hours were asked to leave a message, but they could have been missed.

The hours in which the calls were answered might bias against individuals in full time employment or education.

It was not possible to tell if groups were similar at baseline, if allocation was appropriately concealed or if there was any blinding.

A relatively low percentage of the initial sample was included in the analysis. Intention to treat analysis was not utilised.

**Evidence statement**

An American RCT (rated -) investigated messages from different sources (their own physician, their own Health Maintenance Organisation, or a fictitious junk mail organisation named Safe Sun) stressing different reasons for sun protection (the risk of skin cancer, aging and wrinkling of the skin, or aging and wrinkling further emphasized by a book on these harmful effects of the sun) in patients. Information was sent to 981 participants (aged 20 to 89 years). Follow-up was not reported.

This study did not provide evidence of a significantly higher activation (defined as calling a toll free number to report their skin cancer risk scores and request free sunscreen) in any of the groups. The highest activation was observed in participants who received the materials from their own physician or highlighting the risk of skin cancer (significance levels were not provided). Probably likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted. (Gerbert<sup>40</sup>)

**4.7.4.3.4 Richard<sup>86</sup> - RCT on prevention and detection**

This RCT (rated -) evaluated different types of leaflets in adults in the “Region Provence-Alpes-Côte d’Azur” in the South of France. Representative samples of 300 participants were selected for each arm using data from IPSOS (a French survey institute).

Further information on this study is provided in section 4.7.4.3.4.



## Results

It needs to be highlighted that the results for participants in the intervention groups are only reported for those who read the leaflet.

### *Primary outcomes*

82 (64%) of respondents who read the worrisome leaflet, 98 (63%) who read the neutral leaflet and 86 (54%) who read the humoristic brochure were able to define melanoma. The percentage was significantly ( $p < 0.05$ ) lower in the humoristic leaflet group compared to the remaining two.

Early signs of melanoma were known to 31 (24%) participants who read the worrisome leaflet, 44 (28%) who read the neutral brochure and 44 (28%) who read the humoristic one. No indication if there was a significant difference between groups was provided.

At least three melanoma risk factors were identified by 45 (35%) participants in the worrisome group, 58 (37%) in the neutral arm and 62 (39%) in the humoristic one. There was no indication if the percentage was significantly higher in any of the groups.

### *Secondary outcomes*

Percentages for ability to evaluate one's skin type, risk and whether one's behaviour is adapted to one's skin type are reported in Table 72 Richard. Significance of these results was not reported.

## Limitations

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

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Further information on this study is provided in section 4.7.4.3.4.

**Evidence statement**

A French RCT (rated -) compared three different leaflets (neutral, worrisome and humoristic) containing the same information on melanoma, early signs, skin type assessment and preventive behaviour mailed to 900 adults (age was not reported). Participants were interviewed two weeks after mailing the leaflets. No baseline assessment was undertaken.

It provided evidence of a lower level of knowledge about melanoma definition in the group given the humoristic leaflet compared to the remaining two ( $p < 0.05$ ). No significant differences were reported for knowledge of early signs and risk factors and no direction of effect was visible. A serious limitation of this study is that in intervention arms only participants who read the leaflet were analysed. There was also no baseline testing, therefore this study could be in fact measuring an underlying dissimilarity. Probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Richard<sup>86</sup>)

## 4.7.5 New media in adults

### 4.7.5.1 Studies set in workplace

Only one study was identified to evaluate these interventions in a workplace setting. Details of this study are provided below.

#### 4.7.5.1.1 Dixon 2007<sup>32</sup> - RCT

This study (rated -) evaluated three different e-mails containing a weather forecast and/or UV forecast and/or protective recommendation was carried out in adult employees of consulting firms and a university based in Melbourne, Australia. The year of this study was not reported. 557 participants were randomised to three arms: weather and UV forecast (183 participants), weather and UV forecast with protective recommendations (190 participants) and weather forecast only (184 participants).

13% of the sample was less than 25 year old, 27% was in the range of 25-29, 31% in the 30-39 range, 18% in the 40-49 range and 11% were 50 or older. 66% participants were female with small differences between groups. Race and ethnicity were not reported. Authors reported that arms did not differ significantly with respect to demographic characteristics.

On Thursday evenings participants were e-mailed: a standard weather forecast together with UV forecast and definition in the first intervention group, and standard weather forecast together with UV forecast and definition and protective recommendations in the second. In the third group participants were sent standard weather forecast with no UV forecast or recommendations.

The weather forecasts were e-mailed to participants at the end of the working week as a prompt for their sun-related activity over the weekend ahead.

The intervention was carried out for 18 weeks: from November to March with a two-week break for Christmas and New Year.

Every Monday participants were sent a questionnaire to report sun related behaviour and any sunburn experienced during the previous weekend. Participants could fill it in and submit online from Monday to Wednesday.

Additionally response rates to weekly surveys were measured and manipulation check assessing short-term reactions to a sample forecast communication were

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performed among a convenience sample of 20 office workers (however results are reported for 21 participants).

Participants were followed-up for 20 weeks (with a two-week break).

## Results

### *Primary outcomes*

Sunburns on Saturdays were reported by 10% of participants in the weather and UV forecast condition, 9% of participants additionally given recommendations and 10% of the weather forecast only group. Difference between the three groups was not significant with  $p=0.741$ . On Sundays there was also no significant difference ( $p=0.966$ ) and 14% of participants in each group reported getting sunburned.

23% of participants reported more sun protection in response to forecasts in the weather and UV forecast group, 25% in the forecast and recommendation and 19% in the forecast only group. Less protection was reported by 4% and 3% in the weather and UV and weather, UV and recommendation group. 7% of the weather forecast only arm reported less protection. For the remaining participants there was no effect reported. The difference between groups was significant with  $p=0.022$ .

For those who stayed out between 11a.m. and 3p.m. on Saturdays a wide range of behaviours was reported. Most differences were not statistically significant and the behaviours included: staying out of the sun ( $p=0.202$ ), using a peaked, narrow brim or a wide brim hat ( $p=0.149$ ), torso cover with a sleeveless, short sleeved or long sleeved shirt ( $p=0.0563$ ), lower body cover with shorts or midlength or full length trousers ( $p=0.017$ ) and sunscreen use ( $p=0.988$ ). Percentages for each outcome are reported in Table 40 Dixon.

There was no statistically significant difference between groups for any of the sun protective behaviours for those who stayed out between 11a.m. and 3p.m. on Sundays. The behaviours were identical to the ones measured for Saturday:

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staying out of the sun ( $p=0.341$ ), using a peaked, narrow brim or a wide brim hat ( $p=0.307$ ), torso cover with a sleeveless, short sleeved or long sleeved shirt ( $p=0.724$ ), lower body cover with shorts or midlength or full length trousers ( $p=0.054$ ) and sunscreen use ( $p=0.750$ ). Percentages for each outcome are reported in Table 40 Dixon.

### *Secondary outcomes*

Participants who took more precautions also reported what mostly influenced their behaviour. The UV index was most frequently reported in both experimental groups (63% in the first intervention group and 64% for the second) this also influenced 4% of the control group, which suggests that participants might have obtained UV forecasts from other sources or that results need to be treated with some caution as they are self-reported. The temperature was the second most important factor in the intervention groups (17% and 16%) and it was the most important for the control group (75%). Temperature and UV were reported to have influenced the behaviour of 10% and 15% of participants in intervention arms and 1% in the control group (again possibly UV forecast obtained from another source or self-reported measure not valid). Weather forecasted as fine/sunny influenced 10%, and 5% of intervention groups respectively and 20% of participants who took more precautions in the control group. The difference between groups was significant with  $p<0.0001$ .

All participants were also asked what influenced their sun protection over the weekends – 59% were influenced by the weather, 34% by personal habits, 7% by the forecast – the distribution of responses did not differ significantly between conditions.

### **Limitations**

Internal validity was rated “-“. Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

Authors stated that participants were likely to have a high knowledge level at baseline. Completing the survey every week might have had impact on the behaviour. Participants could have received UV forecasts from other sources (5% in the control group who reported some sun protective behaviour also reported being influenced by UV forecasts). There was possible cross-contamination (although 96% of the participants indicated they never compared forecasts with another colleague).

The study probably investigated a self-selected population as only 10% of the invited agreed to participate. Weather forecasts for Sundays were less accurate than for Saturdays which had a possible effect on sunburns and behaviour.

It was not stated if an adequate concealment method was used. Attrition details and intention to treat analysis were not reported.

#### **Evidence statement**

An Australian RCT (rated -) investigated emails containing weather and/or UV forecast and/or behaviour recommendations sent before weekends to 557 employees of consulting firms and a university (13% were less than 25 years old). Participants were followed-up for 20 weeks (with a two-week break).

There was no evidence of a statistically significant difference between study arms in sunburns and no direction of effect was observed. There was a significant difference between the groups in sun protection in response to forecasts ( $p=0.022$ ) and the group which received weather and UV forecast with recommendations reported the highest sun protection. Of five sun protective behaviours there was a significant difference for lower body cover on Saturdays ( $p=0.017$ , however the group which had the most positive results was not obvious) and none on Sundays. There was no obvious trend in results. Probably applicable only to population or

setting included in the study – the success of broader application is uncertain.  
(Dixon<sup>32</sup>)

#### 4.7.5.2 Studies in a university/ college setting

Only one study was identified to evaluate these interventions in a university setting. Details of this study are provided below.

##### 4.7.5.2.1 Bernhardt<sup>6</sup> - RCT

Participants came from undergraduate classes at a large south eastern university in the USA. The study (rated +) was carried out in 2000. Eighty three students were randomised to a tailored (47 participants) or standard (36 participants) website.

All participants had to be at least 18 years old, able to read English and have access to the Internet at home or at school. Their mean age was 21.6 (SD 2.02) and ranged from 19 to 30. 59% were female. 86% were white, 8% African American, 2% Asian and Pacific Islander, 1% Hispanic and 2% classed as other. The authors reported that “*there were no statistically significant differences between the groups by participant sex, race, age, skin tone, or personal involvement in skin protection.*”

The tailored intervention was a “*Webpage composed of more than 20 tailored messages that were derived from more than 30 pieces of data from each participant (...). The tailored messages were based on the constructs and principles of Social Cognitive Theory and focused on participants’ expected*

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*outcomes of regularly using or not using sunscreen and their perceived self-efficacy to regularly use sunscreen during the high risk sun exposure behaviours.*“

*“Additional tailored messages addressed participants’ skin cancer risk based on their self identified skin tone, their specific high risk sun exposure behaviours, barriers to wearing sunscreen, perceived risk of skin cancer, and perceived personal involvement with the issue of skin cancer. In addition, all messages were written from the point of view of a source that participants selected from a number of choices at baseline, and a gender-matched photo of the source was included on the web page adjacent to the messages. Furthermore, participants selected the headline fonts and colours that appeared on the tailored web page”* (based on findings from formative research).

Participants in the other group were randomised to *“a web page with generic sun protection intervention”*.

This study assessed: sunscreen wearing behaviours, self-efficacy to wear sunscreen and expected outcomes of wearing or not wearing sunscreen - during six activities: outdoor sunbathing, outdoor swimming activities, outdoor sports and recreation, outdoor exercising, yard work and gardening, other outdoor activities.

Questions about barriers to wearing sunscreen and perceived involvement in protecting one’s skin were also asked.

Information such as: reading information on the web page, time spent reading the information on the web page, level of liking the information source, or following links from the page was also collected.

Participants were followed-up for four to five weeks.



## Results

### *Primary outcomes*

It was stated that there were no significant differences between groups in sunscreen wearing behaviours. Exact results were not provided.

### *Secondary outcomes*

Expected outcomes of wearing or not wearing sunscreen did not differ significantly between groups. In barriers to wearing sunscreen there were no significant differences for three, however participants in the treatment group were less likely to report that it is very important for them to tan ( $p < 0.01$ ) and that they feel more attractive when they are tan ( $p < 0.05$ ). No results for perceived involvement in protecting one's skin were reported.

Results of evaluation of the websites are provided in Table 24 Bernhardt.

## Limitations

Internal validity was rated "+". Full details of quality assessment are reported in Appendix 5: Effectiveness studies - Quality Assessment.

Probably applicable only to population or setting included in the study – the success of broader application is uncertain.

Authors report that outcome measurement was based on self-reported questionnaires. A small *dose* of intervention was used. The sample size was rather small.

Baseline outcome measurements were not reported. The effect assessed was the difference between groups at follow up, not change from baseline. There were no effect estimates provided – only significance. The sample was selected from university students who were probably more educated than an average user of internet resources.

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It was unclear if groups were similar at baseline. Intention to treat analysis was not reported. Six participants did not complete the follow-up survey. One participant aged 35 was removed from the analysis as an outlier – probably this was not planned in the protocol.

**Evidence statement**

An American RCT (rated +) in 83 undergraduate students aged 19 to 30 years compared a “*webpage composed of more than 20 tailored messages*” (it “*addressed participants’ skin cancer risk based on their self identified skin tone, their specific high risk sun exposure behaviours, barriers to wearing sunscreen, perceived risk of skin cancer, and perceived personal involvement with the issue of skin cancer*”) with “*a web page with generic sun protection intervention*”.

Participants were followed-up for four to five weeks.

This study provided no evidence of a difference between participants who accessed tailored or standard websites with regard to sunscreen wearing behaviours (exact results and significance level were not provided). Probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Bernhardt<sup>6</sup>)

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## 5 Cost-Effectiveness Findings

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### 5.1.1.1.1 Hocking<sup>49</sup> - *cost-minimisation analysis, cost-benefit analysis*

This study (rated -) compared the costs associated with a marketing approach that involved provision of a poster and video material to promote protection against the sun for outdoor workers employed in an Australian telecommunication company, against a conventional approach which involved organised talks by occupational health nurses.

The author conducted a cost-minimisation analysis to establish the less costly intervention for 20,000 outdoor workers from the perspective of the employer (Telecom Australia).

The author assumed the programmes are equally effective, drawing on evidence from the Borland<sup>9</sup> study, showing that the marketing approach is at least as effective as the conventional talks programme. Costs for the conventional programme included the opportunity cost associated with the time that workers spent on attending the talks, expressed in terms of their salary (\$10 per hour per person). Costs for the marketing approach included the cost of the investment into research and development of materials (estimated at \$20,000) and the cost of the materials itself, estimated at \$60,000 for 20,000 workers. For this programme, time off work for staff to attend talks was not required, thus associated opportunity costs were not included. The author concluded that for staff numbers over 10,000 the marketing approach is more cost effective than the conventional approach.

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In addition to cost-minimisation analysis, this study reports a cost-benefits analysis, where the cost of providing the marketing approach to 20,000 outdoor workers is compared to the employers' savings resulting from reduced compensation to workers due to skin cancer cases averted. The author calculated reduced compensation by "guestimating" that 0.25 cases of skin cancer per outdoor worker could be prevented and assuming that the Telecom's compensation for a case of skin cancer is on average AU \$250 (£185). The estimated Net Present Value for this analysis is – AU \$126.79 (-£93), showing that the cost of implementing the intervention exceeds the monetary value of the benefits gained.

The study is potentially seriously biased as the estimates of effectiveness and costs are based on a series of assumptions, including assumptions on the cost of the marketing approach and the skin cancers preventable per outdoor worker, as well as of very limited applicability as the perspective of the study was that of the Australian company. Details of quality assessment of this study can be found in Appendix 6: Economic studies - Quality Assessment.

**Evidence statement**

An Australian study (cost-minimisation analysis, cost-benefit analysis; rated - ) reported that an educational approach involving provision of material (videos and posters) to outdoor workers accompanied by information provided by nurses is potentially cost saving compared to talks delivered by occupational health nurses, under certain assumptions about unit costs and size of targeted population. The results of the cost benefit analysis show that the cost per outdoor worker exceeded the benefits to the company due to reduced compensation, resulting in a net present value of – AUD \$126 (- £93) (Hocking<sup>49</sup>)

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#### 5.1.1.1.2 Kyle<sup>58</sup> - *cost-effectiveness analysis, cost-benefit analysis*

This study (rated +) aimed to assess the cost-effectiveness of the SunWise sun safety education programme. The setting for this study is elementary and middle schools in the US and the targeted population is children between the ages of 5 and 10 years.

The programme involves cross-curricular, standards-based classroom lessons, which focus on 3 areas: effects of UV radiation, risk factors for overexposure and sun protection habits. The lessons combine education about sun protection and the environment with other aspects of students' regular learning. In addition, each registered school received a SunWise tool kit that consists of story books, posters, videos and other relevant material.

Kyle and colleagues conducted a cost-effectiveness analysis to estimate costs and benefits of the SunWise programme compared with a no-intervention alternative under 3 funding scenarios: 1) the current funding scenario, in which funding for the SunWise programme continues at its current level through 2015; 2) funding is increased and 3) no funding is provided from 2008 onwards.

To assess each of these scenarios, Kyle et al followed a number of steps: 1) evaluated the effectiveness of the intervention based on pre-test and post-test surveys administered to students who received the intervention 2) used modelling to translate sun safety behavioural changes reported by students into changes in lifetime UV radiation exposure as well as lifetime UV radiation exposure into averted skin cancer cases and premature mortality 3) estimated costs averted per skin cancer prevented, QALYs saved and overall net benefit of the programme.

The cost of the intervention was measured from the perspective of the US government and included the expenditures for infrastructure and for operating the programme. The effectiveness of the programme was measured as skin cancer incidence, premature mortality and QALY losses averted.

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The results of the analysis show that SunWise results in cost savings in all the 3 funding scenarios, as the averted cost exceeds the cost of implementing the programme. The authors reported that each \$1 spent on the programme generates \$1.95 to \$4.02 in cost savings.

The major limitations of the study is that estimates of effectiveness were based on a student self-reporting survey and also, the fact that the process of translating behavioural change to outcomes such as averted skin cancer incidence and mortality introduces further uncertainty on the study results. Details of quality assessment of this study can be found in Appendix 6: Economic studies - Quality Assessment. The review team takes the view that further research is needed to quantify the relationship between exposure to UV radiation and risk of developing skin cancer.

**Evidence statement**

There is evidence from one US-based economic evaluation (cost-effectiveness analysis, cost-benefit analysis; rated +) that a classroom lesson results in improved effectiveness and reduced cost compared to no intervention, because of treatment costs saved in terms of cancers averted. (Kyle<sup>58</sup>)

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## 6 Discussion

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This discussion considers the studies included in this report and the themes which arise from them.

### 6.1 Effectiveness Studies

The effectiveness review included 136 articles but 34 of these evaluated an intervention containing elements not relevant to this referral and where relevant data could not be disaggregated.

Forty-nine RCTs, 18 controlled before and after studies and 26 before and after studies were available for analyses.

The before and after studies were not analysed in this report due to the availability of the other study designs and the time available for the review. A brief summary of these studies may be made available at a later date.

Of the controlled before and after studies only 10 were analysed in this report as the remainder covered combinations of population, intervention, comparator and settings for which RCTs were available with similar or longer follow up.

Of the RCTs included a number had one or more arms that were considered to contain interventional components outside of the referral. For these, where possible, those arms relevant to this referral were used.

Details of the studies which met the inclusion criteria but were not analysed are listed in Appendix 15: Studies not analysed.

The effectiveness studies which were analysed had a quality rating of “++” to “-“ and were classified into the following broad themes based on intervention categories:

- Verbal advice
- Mass media
- Printed Materials
- New Media

Additional themes were:

- Combination Interventions (i.e. combinations of the above interventions)
- Comparisons between interventions categories (e.g. verbal advice vs. printed materials)
- Comparisons of the same intervention (e.g. printed materials vs. printed materials)

Each theme was subdivided by adults and children and the setting in which the intervention took place. The school setting for children was further subdivided into age bands approximately corresponding to the three main UK school types.

The heterogeneity between studies with regard to study design, population, intervention, duration of intervention, outcomes measured, duration of follow up etc, in addition to under-reporting of studies in published articles, precluded combining data even at the smallest sub-theme level. As such, a narrative description of each study within a (sub) theme was undertaken and summary statements were made where possible. The heterogeneity makes drawing overall conclusions for (sub) themes problematic.

A brief summary of the evidence for the four main themes (verbal advice, mass media, printed materials, new media) compared to current practice/do nothing are given below. Methodological issues are not specifically mentioned in each theme but



are subsequently discussed in the context of all studies included in this report in section 6.2.

To aid the reader an indication of the number of studies measuring each outcome in the analytical frame work for this report (knowledge, attitude, behaviour, and markers for sun exposure) for each theme (and also subdivided by adult/children) are provided in Appendix 14: Numbers of studies reporting outcomes included in the analytical framework.

### 6.1.1 Verbal advice

#### Children

This was the theme with the most evidence relating to children. ...

Three studies (Buller 2006a, Loescher and Kidskin) rated “+” to “-“, undertaken in USA and Australia, evaluated verbal advice given to children aged four to seven years in a school setting compared to current provision/do nothing. Duration of intervention lasted from 3x45 minutes (Loescher) to four - six sessions every Spring for 4 years (Kidskin). Follow up was a couple of months (Loescher, Buller 2006a) to six years (Kidskin). Of the two studies measuring knowledge gain both found a significant difference between intervention and comparator groups however in one it favoured verbal advice, in the other the control. Two studies measured a proxy for sun-exposure. There was no significant difference for change in skin tan between groups even at two years follow up in Kidskin. This study also measured development of naevi (a marker for sun exposure) and found a non-statistically significant lower number in the intervention group at four and six years for most anatomical sites examined and a statistically significant lower number in a sub-group analysis of the backs and chests of boys at six years.

Five studies all rated “-“ except one “+” (Buller 1994, Buller 1997, Buller 2006a, Hewitt, Hornung) evaluated verbal advice led curricula given to children aged seven

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to 11 years in a school setting. All studies were set in the USA apart from one UK study (Hewitt). Duration of intervention was not clear in two studies and was 45-90 minutes in one and four or five sessions over five - six weeks in the others. Follow-up differed across studies and ranged from six weeks to seven months. All studies reported an increase in knowledge in intervention groups compared with controls. The findings for self-reported behaviours were mixed and skin tone measures undertaken in one study did not show any consistent benefit.

Six studies rate “+” to “-“ (Buller 2006b, Girgis, Hughes, Kristjánsson, Mermelstein, Syson-Nibbs) evaluated verbal advice given to children aged 11 to 16 in a school setting. Two studies were set in the UK, two studies in the USA and one each in Australia Sweden. The period over which the intervention was delivered varied from a single-session to several sessions over six weeks. The shortest follow-up was two weeks and the longest eight months. In half of the studies interpretation was hampered by the presentation of data. Setting this aside, where reported studies showed a significant benefit on knowledge gain for the intervention compared to control. From the studies that assessed sun protective behaviours there was no overall consensus of a benefit. Sunburn in the previous month was assessed one study and was not found to significantly differ between study arms.

Two controlled before and after studies rated “-“ (Reding, Rodrigue) assessed the provision of verbal advice in a community setting in the USA. One study investigated an intervention delivered directly to children (5-7 years) during 1 day summer camps and evaluated immediately after. There was a trend towards increased knowledge compared to control which reached statistical significance for 7 out of 10 questions. The second study evaluated two interventions (comprehensive programme, information only) compared to control to educate Caucasian mothers to better protect their children (90-minute session). It was evaluated up to 12 weeks later and showed that compared to control there was a significant increase in mother’s knowledge and sun protection behaviours towards their children.

One American RCT (Turrisi, rated ++) evaluated verbal advice in the place of domicile in children. Using provided materials parents taught their nine to twelve year old children about skin cancer prevention over a one month period. Follow up was

short at 45 days. The control group received no materials. Children in the intervention group reported less sunburns and less severe burning and there was also a significant difference indicating less sunbathing tendencies

Taking all of the evidence for verbal advice compared to current provision/do nothing given to children and applying it too the analytical frame work for this review indicates that the most frequent outcome measured is knowledge (n=13) and that that the frequency of measurement of outcomes in the framework decreases as we go from knowledge to attitude (n=12) to behaviour (n=9) and on to proxy measures of sun exposure such as sunburn (n=2) and naevi (n=1) (Appendix 14: Numbers of studies reporting outcomes included in the analytical framework). Simple vote counting of studies which report a statistically significant finding for a given outcome reveals that in children nearly all the studies that measure knowledge report a significant gain in favour of verbal advice. For behaviour the picture is less clear with only two out of nine studies reporting a significant benefit, and one out of two studies report a benefit on reduced sunburn.

It should be borne in mind that vote counting significant findings across heterogeneous studies (design, population, intervention, comparator, outcome measure, duration of follow up etc) is crude and can be misleading. All studies are given equal weighting irrespective of, for example, sample size and the magnitude of any effect is not considered. There may be underlying trends which are not observed using this method. However it is presented here for illustrative means given the diversity of the studies

What such an analysis does not reveal is that there may be a beneficial effect on reducing the number of naevi developed in young children (see Kidskin) depending on the body location examined and gender. This finding is particularly important given that the finding comes from the longest study in children and the sample size was relatively large.

## Adults

Five studies reported on the use of verbal advice in adults and these were aimed at college/university students (two rated “++”, Jackson, Mickler, one rated “-“, Katz), those attending a medical facility (Jones 2007, rated “-“) and football coaches (Parrott, rated -). Advice was compared to do nothing or in one study non-skin cancer related messages (or not reported). Follow up was three months in the medical facility based study, less than three weeks in one college study and immediately in the other two. Follow up was not reported for the study in football coaches.

In all bar the study on football coaches there was a trend to increased knowledge post intervention compared to control. There were no differences in self reported frequency of sunscreen use between groups in the only study to measure this.

Mapping the evidence to the analytical frame work reveals that practically all the evidence concerns knowledge gain (n=5), with attitude (n=1) and behaviour (n=2) the only other outcomes assessed (Appendix 14: Numbers of studies reporting outcomes included in the analytical framework). Numbers of studies are small and diverse in nature but there may be some benefit of verbal advice on knowledge gain. The cautions already raised about vote counting apply.

### 6.1.2 Mass Media

#### Children

No studies assessed the effectiveness of mass media in children.

#### Adults

Only three studies assessed mass media campaigns in adults and all were undertaken in a university/college setting in either the USA or Australia (Mickler, rated ++, Mahler 2007, rated +, Cody, rated -). All used videos ranging from 11-20 minutes and compared to no intervention of non-skin cancer related information. One

study did not present relevant data. For the other two follow up ranged from three to ten weeks. The only outcomes assessed relevant to the analytic framework were knowledge, with both studies that measured it showing a significant benefit of mass media compared to a non skin cancer related message, and attitude (n=1) (Appendix 14: Numbers of studies reporting outcomes included in the analytical framework).

### 6.1.3 Printed Materials

#### Children

Two studies assessed the effect of printed materials for the protection of children. One study (Bauer, rated +, German) evaluated printed materials in the place of domicile. Parents of children aged two to seven years were given an initial educational session followed by either educational letters three times a year or nothing. Children were followed-up for three years. There was no evidence of a difference in the number of incident melanocytic naevi.

The second study (Bologna, rated -, USA) assessed printed materials given to new mothers on a maternity ward. At seven months compared to control there were significant improvements for the intervention group for some behavioural practices, such as less time outdoors/in direct sunlight. There were no differences for use of protective clothing/equipment.

#### Adults

This was the theme with the most evidence relating to adults. ...

Two studies assessed printed materials in a workplace setting (Hanrahan, rated +, Australia; Rasmussen, rated -, Scotland) compared to no (relevant) information. Follow-up was 20 weeks or not stated. Neither study compared differences between groups.

Four studies (Castle, rated +, UK, Mahler 2007, rated + USA and Mickler, rated ++, USA Greene, rated -, USA) evaluated printed materials in university/college students. Two evaluated leaflets or brochures containing information on skin cancer and its prevention, one assessed the influence of photographs showing damages to facial skin caused by sun exposure and one evaluated printed materials with messages concentrating on tanning beds. Comparators were either information on peer leadership or do nothing. Follow-up ranged from an immediate post-test to four weeks. Only two studies assessed outcomes at baseline and a further study did not present results by intervention/comparator group. Two studies indicated a significant increase in knowledge in the intervention group compared to control group or a higher post-test knowledge level. The findings from the study assessing tanning bed use reported mixed findings.

One study (Prochaska, rated -, USA) investigated the effectiveness of three computer generated reports that were mailed at 0, 6, and 12 months to medical practice patients. The control group received no intervention. Questionnaires were mailed to participants at 12 and 24 months. This study indicated that participants in the intervention arm avoided the sun and used sunscreen more.

One study (Richard, rated -, France) evaluated three different leaflets (neutral, worrisome and humoristic) on prevention and detection of skin cancer sent to adults at their home. The control was sent no leaflet. Two weeks after mailing the leaflets, a telephone interview was conducted with participants. Only participants who read the leaflet were analysed and no baseline testing was undertaken. This study provided evidence of a higher level of knowledge about melanoma and risk factors in the intervention groups compared to controls.

Two studies assess the effectiveness of leaflets distributed to passengers departing for holiday (Dey and Segan, both rated -, UK, Australia). Control groups received no information. Follow-up was unclear in both studies. Questionnaires were distributed on return flights to a cross-section of participants (no indication of time) in one study and they were sent for participants to complete after returning home in the other. Both studies assessed sunburn during holiday and neither found a statistically significant difference between groups although in one there appeared to be less

sunburns in the intervention group. One study also asked participants about their sun protective behaviours. A composite measure of behaviour did not indicate a significant difference between groups (and no direction of effect), with only one of the six behaviours assessed (number of days outside for at least two hours between 10 am and 2pm) exhibiting a significantly more positive result in the intervention arm. There was no trend observed for the remaining five behaviours.

Mapping the evidence to the analytical frame work reveals that practically all the evidence concerns knowledge gain and behaviour. (Appendix 14: Numbers of studies reporting outcomes included in the analytical framework). Numbers of studies are small and diverse in nature but there may be some benefit of leaflets on knowledge gain. The cautions already raised about vote counting apply.

#### **6.1.4 New Media**

##### **Children**

Only one study (Hornung, rated +) assessed new media in children. It compared a computer programme to a do nothing control, in a school population aged seven to 11 years in the USA. Immediately after the intervention and seven months later there was significantly higher knowledge in the intervention group compared to control group. There was no long term benefit seen for self reported behaviour at seven months.

##### **Adults**

Only one study (Glazebrook, rated +, UK) evaluated new media in adults. It compared a computer program designed to be completed in a single sitting (10-15 minutes) in a medical practice. Participants were followed-up for six months. There was a significant increase in knowledge in the intervention group compared to control. There was also evidence of a positive influence on skin protective behaviour.

### 6.1.5 Cost-effectiveness

The main finding of the review of existing economic analyses was the very limited amount of existing research. Of the two studies containing relevant analyses both had limitations. Setting these limitations aside, both demonstrated the potential of prevention messages to be less costly under certain assumptions. One study assessed classroom based education plus printed and video materials compared to no intervention in 5-10 year old US children (Kyle rated +), the other the provision education including video and posters compared to standard occupational health messages in outdoor workers in the Australia (Hocking, rated -)

## 6.2 Commentary

There are a number of features/issues regarding the studies on effectiveness included in this review which warrant discussion in the context of both the internal validity of the studies and their external validity to the objectives of the review.

Below is a summary of some of these issues. Many of these issues have also previously been discussed in the context of the Guide to Community Preventative Services (GCPPS) work on sun-protection interventions for the US Centres for Disease Control and Prevention.<sup>43</sup>

### **Study Design and Quality Assessment Issues**

The studies which met the inclusion criteria for this report were either RCTs, controlled before and after studies or before and after studies (although the latter are not analysed in this report), with the most frequent being RCTs. Many studies were setting specific (e.g. school, university, workplace etc) although community-wide settings were represented. Some of the RCTs were cluster randomised studies with for example, the unit of randomisation being school, class etc. Whilst each design has merits and also limitations it is the RCT/cluster RCT which if undertaken well has



the highest internal validity. Thus where evidence comes from multiple study designs the RCT evidence should be given good credence where the studies have been undertaken well and are of sufficient duration for example. This does not mean other study designs should be disregarded where RCTs can be undertaken; for example interrupted time series studies of interventions in community settings could lead to more generalisable findings due to broader entry criteria and potentially lower opportunity for contamination between groups (no such studies were identified for this report). However, the potential for overestimation of effect by non-RCTs is an issue as indicated by the GCPS report in which comparison of effect size between RCTs and before and after studies for school based interventions suggested smaller effects in the RCTs.<sup>43</sup> No specific assessment of effect size between different studies designs was undertaken for the current report.

Sample size of studies varied considerably. This is unsurprising given that some interventions were assessed by RCT in setting specific populations and some assessed by community-wide before and after studies. Perhaps a more realistic indicator is the size of the sample in which outcomes were assessed. For the majority of the studies included in this report this sample size was greater than 100 people.

Sample size calculations were rarely mentioned in study reports (e.g. in only 9 RCTs; Benjes, Buller 2006b, Castle, Dey, Gerbert, Glazebrook, Jackson, Loescher, Naldi) and thus it is unclear if studies were appropriately powered.

The quality of the RCTs was variable to an extent. However as most of the studies (i) had a clearly focussed question, (ii) actually had random assignment, (iii) did not describe allocation concealment, (iv) could not be easily blinded and (v) were either not conducted at multiple sites or it was not possible to determine if results from multiple sites was comparable, meant that half of the questions had limited discerning power. The main theme was non/poor reporting of elements being quality assessed. Intention to treat analysis was rarely reported/ used. Very few studies

attained the highest quality rating and about half of the RCTs were in the lowest assessment category (meeting less than 60% of appropriate assessment criteria).

The quality of the controlled before and after studies analysed in this report was generally poor with 9 of the 10 meeting less than 60% of appropriate assessment criteria. As with RCTs the main theme was inadequate reporting of elements being assessed.

Given the breadth of interventions, population, settings etc. encountered within this review it became clear that a one-size-fits-all quality assessment strategy did not adequately address all studies. For example, issues around blinding could not always be assessed in the same way as blinding was not always appropriate/possible in a given study for some or all of the those who could be masked for some or all of the outcomes being assessed. Where blinding was possible, focussing assessment of blinding on the effect on the primary outcome of the study was also rarely possible given that there was either more than one such outcome or the primary outcome (as opposed to others) was infrequently indicated. Under direction from NICE it was agreed that assessing negatively against studies that were not blinded could be misleading given that blinding was not always possible and as such this was not undertaken.

Inadequate and insufficient reporting of studies, particularly methodology, interventions, outcome measures and findings limit both the assessment of study quality and the findings of studies. It has been highlighted<sup>43</sup> that the use of methods to improve the reporting and quality of studies is required in this field, particularly adherence to reporting guidance tools such as CONSORT and TREND.

### **Interventions and Comparators/Control Groups**

Included studies for the most part had a design that either compared one intervention with a no intervention/current provision or did not use a control group. A small number of studies compared different forms of the same intervention (e.g. one leaflet compared to another) or different types of intervention. A few studies used a three or four arm design. Only directly relevant arms for this review were utilised.

The interventions encountered were often multi-component within, or combinations of, the categories of verbal advice, mass media campaigns, printed materials or new media. These were treated as intervention programmes as the effect of individual components could not be assessed unless an appropriate comparator was used; which occurred in only a few cases (e.g. Mahler). Some interventions were multi-component involving additional elements beyond the remit for this project, for example the provision of free sunscreen. Where possible, disaggregation of data not contaminated by the effects of such non-relevant intervention components was planned. This was possible when a study had at least two non-mixed arms or a non-mixed phase (see 2.5 Complex Studies). The complex intervention studies that were not analysed are listed for reference in section Appendix 15: Studies not analysed.

A very common finding was that the description (e.g. content, presentation, delivery etc.) of the intervention/comparator was not very clear. This severely limits reproducibility.

Exposure to an intervention (frequency/duration) varied considerably between studies depending on the intervention category and between similar interventions. Many studies were single event activities and/or of short duration (e.g. hour(s)). Some interventions were undertaken over long periods, e.g. months. The effect of the intensity of delivery of the same intervention (single vs. multiple events; short vs. longer duration for example) was rarely assessed and there was insufficient evidence

to independently assess this point. It is debatable whether interventions of short duration/frequency are able to produce lasting long-term effects on disease prevention.

The duration of follow-up of study participants also varied considerably. Many were of very short duration, e.g. immediately after the intervention, and these appeared to include studies predominantly testing knowledge gain and attitudes, many were set in Universities. Such short studies cannot give information about the longer-term impact of messages on sun exposure practice, just the initial effect of the delivery of the message. Slightly longer studies (a few weeks/months) may be subject to seasonality effects on sun avoidance knowledge and behaviour. Some studies had follow-up of longer than one year. These included 4 RCTs (Bauer, Buller 1998, Naldi, Prochaska), but proportionally more were non-RCTs, and tended to investigate longer term interventions: e.g. Kidskin which had a curriculum delivered over several years and outcomes measure up to 6 years.

To be effective a public health campaign would need to show sustained long-term change in sun protection practice and thus robust evaluations of interventions require long follow-up, much longer than most of the studies included in this report.

Assessment of interventions aimed at changing the physical environment to reduce cancer attributable to UV exposure (e.g. construct shaded areas), interventions supplying sun-protective resources (e.g. sunscreen) and interventions to change policy or the effects of policy change (e.g. effect of introduction of UV protective school uniform) were beyond the scope of this project.

## **Outcomes and Outcome Measures**

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The analytical framework adopted for this report was taken from the work of Saraiya et al<sup>90</sup>. Whilst the specific example shown in Figure 2 was developed for “media interventions” (e.g. printed mass and new media) it seems appropriate to widen use to one: one and group verbally delivered interventions. The framework indicates a progression from knowledge gain to attitude change to behaviour adoption to UV exposure/sun burn reduction and ultimately reduced incidence of skin cancer. The evaluation of the effect of interventions on each of these components was an aim. However, the evaluation of the link between each of these components (e.g. does increase in knowledge lead to a change in attitude and by how much) was beyond the remit of this report and the data available in this review. Thus evidence was sought on the effectiveness of interventions to directly change each of these outcomes: knowledge, behaviour, exposure to UV, skin cancer incidence; (attitude was a secondary and not a primary outcome for this review).

Greater weight would obviously be placed on the findings of higher quality studies on interventions that were further along this list of outcomes. However it was clear that knowledge was by far the most common outcome measured and that few studies measured behaviour and hardly any sun exposure (or markers thereof) and none skin cancer incidence. The analytic framework forms the basis of the economic analyses on this topic contained in an ancillary report.

There are a number of issues related to the tools and methods used to measure outcomes in the included studies which warrant discussion.

One of the key ways in which outcomes were measured was through self-reporting by the individual or on their behalf (e.g. a carer). Such self-reporting is subject to a number of obvious biases (social acceptability, recall, responder, desire to please the investigator).

The main forms of outcome measurement tool used were questionnaires, either completed by the subject or through some form of interview (e.g. via telephone), most likely due to reasons of accessibility, economics and that they are simple to administer. For some outcomes, such as assessment of knowledge, questionnaires

seem appropriate but less so for others, such as behaviour. In at least one comparative study the questionnaires given to intervention and control groups were not identical (Buller 2006a). Some studies used more than one method to measure the same outcome in an aid to achieve greater weight through consistency (Buller 2006b).

However, for behavioural outcomes self reported subjective assessments were rarely supported by objective measures (Mayer, Kidskin). Of course there are potential issues with objective assessments too. A key outcome measure to support self-reported behaviour is the use of direct distant observation of behaviour at locations where sun protection practices would be expected to be employed (e.g. beaches/outdoor sports venues). This has the advantage of overcoming a number of issues with self-reporting however it raises others as it may introduce sampling bias and it only records behaviour at a single point in time which may be influenced by other factors (weather). Also such observations cannot accurately record some factors, such as sunscreen use, as it may have been applied prior to arriving at the venue.

Questionnaire tools may elicit information on multiple behaviours (use of shade, sunscreen, clothing etc.) with the potential to lead to coherence across activities. However the findings were often reported as composite scores, thus masking individual components or behaviours (see other analytical issues below).

As highlighted previously<sup>43</sup> this also would mask interactions with other variables such as demographic factors with the example given that men may wear hats more frequently while women may wear sunscreen. Furthermore, composite scores may mask substitution behaviours e.g. sitting in the shade but wearing less sunscreen, or putting on a hat and sitting less in the shade. Such compensations are potentially difficult to assess.

There is also an issue about whether a study is actually measuring routine behaviour or recent behaviour as some studies have elicited information about behaviour and/or sun exposure after a period where people are more likely to be exposed, for example

in the days following a weekend (Dixon) or on a plane returning from a holiday destination (Dey, Segan) as opposed to more general assessment.

An issue with the use of many outcome measures is the absence of evidence of validation against objective measures. As many tools are developed specifically by the investigators it is not necessarily clear how the findings relate to actual behaviours. The reporting of many outcome measures was often poor with little indication of components or details of questionnaires and a poor indication of the range of possible scores, let alone mention of what a meaningful change in a score might be or mean.

With children in mind, and particularly younger children, it is often not they who completed assessments of behaviour but carers; again little information regarding the accuracy of these assessments is available. The use of such methods in older children/teenagers may be even more problematic.

Whilst the ability to measure change in actual UV exposure of the skin using dose meters and change in colour of the skin using photometers and colorimeters is possible, it was rarely used in the studies in this review. Verification of sunscreen application by skin swabbing is possible but was not undertaken in any studies. Assessing sunscreen use by measuring the volume used and/or its availability do not equate readily to protection.

Development of melanocytic naevi (moles) in children is indicated as a marker of UV exposure and as a potential risk factor for melanoma. Naevi counts are an outcome that can and has been used in sun protection studies in children (e.g. Kidskin). However the number of studies included in this report that used it was small. This is probably due to the length of study required (years), the skills and labour required, and the associated costs.

Very importantly, outcomes looking at possible harms from interventions were not assessed and/or reported in any included study. This is an area of concern

particularly from the UK perspective given ongoing debates regarding vitamin D deficiency. Assessment of harms should be built into future studies.

### **Analytical Issues**

There are also other issues related to the reporting and analysis of outcomes in the studies.

In some studies, typically the larger community-based or population-based studies, outcomes were measured by cross sectional sampling at specified time points. Whilst this design has advantages it needs to be considered that the same sample (from intervention and/or control group) are not being assessed at each time point and thus the selection of the samples needs to be careful, consistent, and cover the whole spectrum of the population. Furthermore, migration in and out of intervention and control population and between them may affect findings. It can also be argued that as the same subjects are not studied at each time point, but different samples of the whole study population, the data may not be considered as longitudinal. Such designs are often used to evaluate mass media campaigns (but none were included in this review as non-RCTs had to have longitudinal data) but have also been used for assessing leaflets and complex interventions in outdoor workers in RCTs (Borland, Dey). In some cases only single point in time measures are taken and thus do not account for baseline characteristics. However the advantage of cross sectional sampling at multiple time points is that they avoid the problem of repeat testing of cohorts where the testing itself could lead to change in behaviour or focus attention for example leading to increase in knowledge. A compromise for large population/community studies would be to employ longitudinal assessment of nested cohorts alongside multiple time point cross-sectional assessment of population samples. This was not undertaken in any included study.

In a number of comparative studies baseline data was either not recorded or not reported. The only analysis available in such a case was between groups post



intervention. Obviously this cannot indicate change in outcomes due to the intervention as it is unclear if the groups were similar at baseline. Response rates were not frequently reported for baseline assessments but the majority reported such rates for the latest follow-up reported. Often these were below 80% for at least one study arm. It has been reported that often in sun protection studies response rates are calculated as a percentage of those responding to the previous or baseline assessments, thus raising the rates.<sup>43</sup>

Another important factor is that without adequate reporting and interpretation of baseline characteristics the scope for improvement in outcomes due to the intervention is unclear. It can be envisaged for example that as knowledge about the harms of excess UV exposure has increased over time the potential for ceiling effects may be greater in more recent studies. This is also linked to the sensitivity and validity outcome measures used.

Where it was possible studies often did not report or undertake intention to treat analysis. Often studies undertook analysis of completers/responders to follow. The effects of losses to follow-up, cross-overs and/or potential dilutions are unclear.

Cluster allocated studies are often used to assess public health interventions and if sufficient clusters are randomised even distribution of potential confounders between intervention and comparator can be achieved. Twenty-one RCTs and five controlled before and after studies employed cluster allocation. Often cluster studies are analysed incorrectly at the level of the individual rather than the cluster, without accounting for this change in unit of analysis, resulting in artificially lower p values and potential false conclusions in favour of the intervention. Very few of the cluster studies in this review applied or reported appropriate statistical analyses.

As in many studies intervention and comparator groups were in fairly close proximity or from a similar location, contamination between groups is a possibility.

As highlighted above there are a number of considerations with the included studies which have the potential to influence the findings and many of these have not been

adequately addressed or the implications considered in the study reports. Future studies should address these concerns.

### 6.3 Applicability

Limited information about the nature of populations targeted by intervention studies, detail about previous exposure to protective programmes, existing sun protective knowledge/behaviours, content and delivery of interventions, quality of the studies and time (historically/seasonally) when studies were undertaken, all restrict making generalisable comments about applicability of evidence to the UK population.

Furthermore, there are issues related to the climactic local where studies were undertaken and those that would be applicable to the UK population (at home and on vacation). A few studies were conducted in the UK (and Northern Europe). It seems highly likely that any effective interventions identified through these would be directly applicable to the UK.

### 6.4 Gaps

Most of the effectiveness evidence identified assesses the provision of one-to-one or group-based verbal advice or leaflets and other printed educational material compared to current provision/usual care, or the two interventions compared to each other or other forms of the same intervention (see section 3). The majority of the verbal advice was group-based and given to children in a school setting although there were a number of adult studies in workplace, study, sports and other settings. Leaflet studies were more commonly used in adults, also in these settings. Outside of these areas the evidence was less frequent and often isolated to an individual form of an intervention in a single setting e.g. in school children there was a single RCT on mass media interventions and this was a video presentation. Thus there are a number of gaps in the evidence base before the quality of what evidence there is, is considered. If the latter is taken into consideration along with the range of outcomes

measured and their relevance to assessing actual change in preventative behaviours and ultimately skin cancer avoided, then the gaps in current knowledge are greater.

Cost-effectiveness evidence is even more limited than the effectiveness evidence.

## 6.5 Limitations of the review

A strength of this report is the wide-ranging nature of the literature searches of bibliographic databases and the utilisation of existing systematic reviews to identify further studies. These resulted in a haul of over 34,000 articles from the effectiveness searches for primary studies. However, it is conceivable that not all relevant studies have been identified and included in the reviews. In particular the searches and the selection of studies did not consider evidence published prior to 1990, for reasons related to generalisability and applicability. Thus some older evaluations of prevention programmes may not be represented. Furthermore studies not reported in English were neither sought nor would have been included in this report. The effect of this bias is unclear. Both of these exclusions are based on guidance from NICE.

The literature searches did not attempt to specifically target high risk groups e.g. those immuno-suppressed, outdoor workers, and very few studies have been found in such populations. If high risk groups were to have been a focus then searches/inclusion criteria may have been different.

As indicated above (section 6.2) there are many issues related to the conduct and reporting of studies. The availability of important information on the nature of the interventions (and comparators), the populations targeted and detail of the findings is a key limitation. The utilisation of subjective outcomes and the limited measuring/reporting of outcomes of actual behaviour to prevent skin cancer, let alone direct measures of, or valid proxy measures for, skin cancer incidence or related mortality compounds these limitations.

For those outcomes that are more frequently reported – e.g. knowledge/self-reported behaviour – there are limitations to quantifying any effect or effect size due both to the nature of the outcomes assessment and the reporting of the findings.

The limitations in the existing effectiveness evidence base have implications for the economic evaluation of any skin cancer prevention interventions.

This maybe why there was very limited existing evidence on cost-effectiveness of prevention programmes. It was probably unlikely that any published economic studies had been missed.

The limitations above will present challenges for the de novo economic evaluation being undertaken for this referral and presented in a separate report.

Finally, as acknowledged by the NICE technical team, the volume of evidence was greater than expected for the review of effectiveness. As such the timescale was a limiting factor in undertaking this review.

## 6.6 Conclusions:

The objectives of the evidence reviews in this report were to address questions relating to what are the most effective and cost-effective ways of providing information to change people's knowledge, awareness and behaviour and so prevent the first occurrence of skin cancer attributable to UV exposure. It was also the purpose to identify what is the content of effective and cost-effective primary prevention messages.

It is clear from the studies identified that a large body of research has been undertaken on the provision of information to prevent the first occurrence of skin cancer. However, this body of evidence is also spread across a breadth of combinations of populations, interventions, comparators and settings. Furthermore there are issues relating to the quality and reporting of the available evidence and potentially about the relevance of some of the outcome measures used. This variety places limits on the conclusions that can be drawn. It is evident however that verbal interventions applied to children might lead to an increase in knowledge about exposure to, and protection from, UV. Whether such knowledge is retained and/or leads to protective behaviours is unclear.

Given the heterogeneity of evidence and that much of it has been undertaken in countries with greater potential for UV exposure than the UK, applicability is also an issue.

The possible harms from UV exposure reduction messages have not been reported and remain unknown.

Very limited evidence is available on the cost-effectiveness of the provision of information to prevent the first occurrence of skin cancer.

Further, and more robust, studies are required which build on the current evidence base.

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