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Behavioral Counseling for Skin Cancer Prevention: A Systematic Evidence Review for the U.S. Preventive Services Task Force

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Structured Abstract

Objective: We conducted a systematic evidence review to support the U.S. Preventive Services Task Force (USPSTF) in updating their recommendations on behavioral counseling for skin cancer primary prevention and on secondary prevention with skin self-exam. Our review addresses the following Key Questions (KQs):

- 1. Does counseling patients in skin cancer prevention improve a) intermediate outcomes (sunburn or precursor lesions) or b) skin cancer outcomes (melanoma, squamous cell, or basal cell carcinoma incidence, morbidity, or mortality)?
- 2. Do primary care-relevant counseling interventions improve skin cancer prevention behaviors?
- 3. What are the harms of counseling interventions for skin cancer prevention?
- 4. What is the association between skin self-examination and skin cancer outcomes (melanoma, squamous cell, or basal cell carcinoma incidence, morbidity, or mortality)?
- 5. What are the harms of skin self-examination?

Data Sources: We searched Cochrane Central Register of Controlled Trials, Medline, and PubMed to locate relevant studies for all KQs. For counseling on sun protection behaviors we searched for articles published from 2009 to March 31, 2016. For skin self-exam we searched for articles published from August 2005 to March 31, 2016. We supplemented our database searches by reviewing reference lists from recent and relevant systematic reviews. We also searched ClinicalTrials.gov and WHO International Clinical Trials Registry Platform (ICTRP), for relevant ongoing behavioral intervention trials. We updated our search on June 7, 2017.

Study Selection: We reviewed 2,100 abstracts and 355 articles against specified inclusion criteria. Eligible studies included those written in English and conducted in people of any age or in caregivers of younger children, conducted in settings affiliated with primary care. Intermediate outcomes of interest were sunburn, nevi, and actinic keratosis; health outcomes included melanoma, basal cell or squamous cell carcinoma incidence, morbidity or mortality. Behavioral outcomes of interest were sun protection behaviors (e.g., composite scores, use of protective clothing, sun avoidance, use of sunscreen), skin self-exam, or indoor tanning use. Any harm of behavioral counseling intervention was of interest. We conducted dual, independent critical appraisal of all provisionally included studies and abstracted all important study details and results from fair- and good-quality studies.

Data Analysis: Data were independently abstracted by one reviewer and confirmed by another. We synthesized the results for health outcomes and adverse events for pediatric and adult populations separately. The data did not allow for quantitative pooling due to the limited number of contributing studies and the variability of the outcomes measured. For sun protection and skin self-exam behavioral outcomes, we present forest plots showing the standardized mean differences in change between groups (using the Cohen's *d* statistic) to illustrate the range of effects seen across studies, but we do not provide pooled estimates. We summarized the overall strength of evidence for each KQ for child/adolescent populations and adult/young adult populations.

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Results: We included 21 trials that reported the impact of primary care-relevant behavioral interventions on skin cancer outcomes, sunburn, and sun protection behaviors. Six trials were conducted among child or adolescent populations (n=4252); 16 trials reported data in adult populations (n=16,309), and three of those were conducted exclusively in young adults (n=1528).

Intermediate and health outcomes. None of the six trials among children and adolescents reported skin cancer outcomes (KQ1). Three trials assessing parent-reported sunburn outcomes in children ages 3–10 generally found no intervention effect. A trial among six-year-olds (n=867) found a small intervention effect on nonsevere sunburn (effect size, -0.25 [95%, CI -0.47 to -0.04], p=0.02); but no effect on severe, blistering sunburn at 3 years. This same trial found no difference between the mean number of small or large nevi between intervention and control group children at 3-year followup.

One trial of six in adult populations found an intervention effect for sunburn outcomes. In a trial of online education for young adults (n=965, 86% fair skin), the proportion of participants reporting red/painful sunburn in the past month decreased more markedly from baseline to 3 months in the intervention group compared to two other groups (54.5% to 26.3% in the intervention group; 51.5% to 38.2% in the public website group; 56.3% to 41.2% in the assessment-only control group, p=0.014 for intervention-assessment only comparison). One trial (n=1356) assessed skin cancer outcomes at 12 months after a skin self-exam intervention, and found no difference in numbers of cancers and atypical nevi detected in intervention and control groups.

Behavioral outcomes. All six trials among children and adolescents reported the effect of interventions on composite sun protection behaviors; five of the six trials found a statistically significant benefit on parent-reported composite sun protection scores compared with controls at 3-month to 3-year followup. Standardized mean differences (Cohen's *d*) effect sizes ranged from 0 to 0.96, with the three larger trials suggesting small to moderate effect ranging from 0.16 to 0.50 (average around 0.32). Effects on sunscreen use and other individual sun protection behaviors were generally consistent within each trial, and there were no apparent trends in the effectiveness of the interventions according to intervention or population characteristics.

In 12 trials reporting sun protection behaviors among adults, evidence was mixed. One trial among young adults and five trials among adult populations found increases in sun protection composite measures compared to control groups. Standardized effect sizes ranged from -0.46 (favoring control group) to 0.57 (favoring the intervention group), and between 0.10 and 0.20 for most studies. Sunscreen use was the most commonly reported individual behavior. Only one in three trials found a significant change in self-reported indoor tanning behavior, a trial of an appearance-focused intervention among young adult female indoor tanners found an attenuated increase in mean number of indoor tanning sessions from baseline to 6 months in the intervention group (mean 4.67 to 6.8 sessions in previous 3 months) compared to a larger increase (mean 4.48 to 10.9 sessions) in the control group (p<0.001). We found no consistent patterns of intervention effectiveness by age or by intervention component, though trials of longer duration or more contacts with participants tended to find intervention effects. Evidence for skin self-exam was more consistent, with 9 of 11 trials finding significant increases in self-

reported skin self-exam compared to control conditions. Odds ratios for skin exam in intervention groups compared to control groups ranged from 1.16 to 2.64.

Harms (*adults only*). No harms were assessed in trials of children or adolescents. Only two trials reported harms in adult trials. One trial focused on skin self-exam (n=1356) found that more intervention group participants reported a skin procedure compared to the attention-control group between 0 and 6 months (8.0% vs. 3.6%, p=0.0005). However, between 6 and 12 months, the proportions were similar between groups: (3.9% and 3.3%, not significant [NS]).

In one study of single-session primary care provider counseling with risk assessment and feedback compared to no intervention (n=217), a slightly higher proportion of adults in the intervention group versus control group reported worrying about developing melanoma, but this difference was not significant (28.9% vs. 18.4%, p=0.16).

No trials met our inclusion criteria for KQ4, on the association between skin self-exam and skin cancer outcomes, or for KQ5, on the harms of skin self-exam.

Limitations: Trials of behavioral interventions used self-reported outcomes, which are subject to bias. The clinical relevance of incremental changes in composite measures of sun protection behaviors is difficult to assess. There were no new studies among children aged 0-3 or adolescents, and few studies among young adults. Skin cancer outcomes were reported only in a single study focused on skin self-exam.

Conclusions: The body of evidence on the impact of behavioral interventions has increased substantially since the previous review, and generally reaffirms its findings, adding new but limited evidence on intermediate and health outcomes and for behavioral outcomes in children aged 3–10. The current fair-to-good evidence base suggests that behavioral interventions can increase sun protection behavior with few harms in both pediatric and, less consistently, in adult populations; but there is no consistent evidence that interventions are associated with improved sunburn frequency in children or adults. Interventions can increase skin self-exam in adults relative to control conditions, but may also lead to increased skin procedures without detecting additional atypical nevi or skin cancers.

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Chapter 1. Introduction

The Agency for Healthcare Research and Quality (AHRQ) has requested an updated evidence review on behavioral counseling for the prevention of skin cancer. Behavioral counseling can refer to various preventive services designed to encourage people to engage in healthy behaviors and reduce unhealthy behaviors. The United States Preventive Services Task Force (USPSTF) will use this review to update its 2012 recommendation on behavioral counseling for skin cancer prevention^{2, 3} and its 2009 recommendation on skin self-exam for skin cancer detection. The service of the ser

Condition Definition

Skin cancer is an abnormal growth of cells that begins in the outermost (epidermal) layer of the skin. Skin cancer is broadly classified as melanoma and non-melanoma skin cancer (NMSC). Most NMSCs are keratinocyte carcinoma, which includes basal cell carcinomas (BCC) and squamous cell carcinomas (SCC).⁶ Both BCC and SCC typically develop in sun-exposed areas of the body.⁷ Melanomas arise from pigment-producing cells (melanocytes) and are the least common skin cancers, but are more likely to grow and spread if not treated.⁸ The depth of vertical growth is directly related to prognosis.⁹⁻¹¹

There are four major histologic subtypes of melanoma: ¹² superficial spreading, nodular, lentigo maligna melanoma, and acral lentiginous. Superficial spreading and nodular melanomas are the most common types. Nodular melanomas begin their vertical growth phase immediately, whereas other types may take decades. ^{13, 14} Lentigo maligna melanomas are slow-growing tumors that appear most commonly on sun-exposed areas such as the face, neck and forearms. ¹⁵ Acral lentiginous melanomas appear most commonly on the palms and soles of the feet, and are the most common subtype observed in people with dark skin. ¹⁵ Different melanoma subtypes may follow distinct progression trajectories, and researchers are beginning to integrate genetic, clinical, and histopathological insights into the melanoma literature. ¹⁶

Prevalence and Burden

Skin cancer is the most commonly diagnosed cancer in the United States. Precise estimates of basal cell and squamous cell carcinomas are not available since non-melanoma skin cancers are not required to be reported to cancer registries. Based on data from the Medical Expenditure Panel Survey, a 2015 study estimated that about 4.3 million U.S. adults were treated for NMSC annually between 2007 and 2011. This finding aligns with a 2013 study that used U.S. and Australian data to compare melanoma incidence; after accounting for population size differences, it estimated that 4.3 million NMSC cases were treated in the U.S. in 2010.¹⁷ The incidence of NMSC increases with age, ¹⁸⁻²⁰ and is more common in men than in women. ¹⁸⁻²⁰ Incidence appears to be increasing over time, possibly related to increased exposure to ultraviolet (UV) radiation, increased detection, and increased longevity. NMSC ranks fifth among the most costly cancers to treat according to Medicare claims data.²¹

Reliable estimates of NMSC mortality are not available for the U.S., but Australia has reported an average of 382 NMSC deaths per year (about 3 per 100,000 for males and 1 per 100,000 for females) for 1998–2005.²² Although NMSC mortality is elevated among immunocompromised individuals, death from these cancers is relatively uncommon in the general population.^{6, 23}

Melanoma incidence has been increasing more rapidly than most other potentially preventable cancers in the United States, but overall melanoma mortality rates have not increased significantly. An estimated 76,380 new cases of melanoma were expected in 2016. It is the fifth leading incident cancer in men, the eighth in women, and the sixth leading cancer overall. According to 2006–2012 Surveillance Epidemiology and End Results (SEER) data, the 5-year survival for melanoma is 91.5 percent, ranging from 98.4 percent for local stage disease to 17.9 percent for distant. Although only two percent of all skin cancers are melanoma, it is estimated to cause more than 80% of skin cancer deaths, with 10,130 expected in 2016. The increase in melanoma incidence has been attributed to increased UV radiation exposure and increased detection.

Melanoma incidence and mortality increase with age. Between 2008 and 2012, incidence was 12.6 cases per 100,000 in U.S. residents under age 65 compared to 83.7 cases per 100,000 in those aged 65 and older. During the same time period, observed mortality rates were 1.2 per 100,000 and 13.5 per 100,000 for <65 and ≥65 year-olds, respectively.³⁰

While the relationship between gender and melanoma incidence is complex and can vary by geographic location,³⁵ older men and younger women generally are at increased melanoma risk.³⁰ Overall age-adjusted melanoma incidence in the U.S. during 2008–2012 was 28.2 per 100,000 in men compared to 16.8 per 100,000 in women. Females aged 15–49 years had modestly higher incidence than their male counterparts, but the highest rates were observed in men aged 70 or older (116 to 188.4 per 100,000) and were more than double those of similarly-aged women (45.1 to 57.5 per 100,000). Although 5-year survival is similar for both men and women, age-adjusted melanoma mortality rates are higher in men than in women (4.1 vs. 1.7 deaths per 100,000 observed during 2008-2012).³⁰

Melanoma risk is highest among non-Hispanic whites, with an age-adjusted incidence of 30.2 per 100,000 during 2008–2012. Individuals of Hispanic ethnicity and Native Americans had a similar incidence (white Hispanics: 4.6 per 100,000; non-white Hispanics: 4.5 per 100,000; Native Americans: 4.0 per 100,000; blacks: 1.1 per 100,000). Although melanoma mortality rates are greater in whites (whites: 3.1 per 100,000 vs. blacks: 0.4 per 100,000 during 2008–2012), 5-year relative survival among individuals diagnosed during 2005–2011 was lower in blacks (69.4%) compared to whites (91.2%).³⁰

Etiology and Natural History

Basal cell carcinomas develop from the malignant proliferation of cells in the basal layer of the epidermis (basal keratinocytes) and rarely metastasize. Squamous cell carcinomas arise from keratinocytes in the mid-layer of the epidermis; a small proportion of these metastasize in the absence of treatment.³⁶⁻³⁸

Melanomas develop through a process of unregulated growth of melanocytes, melanin-producing cells found in the basal layer of the epidermis. Melanocytes may grow in a horizontal lentiginous pattern to appear on the skin as a freckle, and clusters of melanocytes may develop into nevi. Melanomas typically have metastatic potential when they infiltrate the dermis and begin a vertical growth phase into deeper layers of the skin. Although less common, thin melanomas that have not invaded the dermis or entered the vertical growth phase also can metastasize.³⁹

Important host factors include:

Sun-sensitive phenotypes. Individuals with fair skin, light-colored eyes, and red hair are at increased risk of skin cancer. ⁴⁰⁻⁴² Fair skin that sunburns easily increases risk of melanoma 2-fold compared to skin phenotypes that never burn. ⁴² Natural red hair and natural blond hair confer a 3.6-fold and 2-fold increase in melanoma risk, respectively, compared to natural dark hair. ⁴²

Nevi. Increased number of nevi and atypical nevi are associated with an increased risk of melanoma. ^{43, 44} Typical nevi are associated with increased risk in a dose-response manner based on the number of nevi present. ^{45, 46} Atypical nevi also confer risk in a dose-response relationship with number, with a 1.5-fold increased risk associated with a single atypical nevus and a more than 6-fold increased risk associated with five atypical nevi compared to none. ⁴³

History of skin cancer. Individuals with a history of NMSC are at increased risk of melanoma,⁴⁷ and a history of melanoma is associated with increased risk of developing a second primary melanoma.^{48, 49}

Family history and genetic disorders. Familial syndromes account for <7–10 percent of melanomas, ^{50, 51} with pooled estimates suggesting that family history increases melanoma risk 1.7-fold⁴² and that melanoma risk is higher among those with multiple affected relatives. ⁵² Individuals with familial atypical multiple mole and melanoma (FAMMM) syndrome have a high lifetime risk of developing melanoma, and those with basal cell nevus syndrome develop multiple basal cell carcinomas at an early age. Some evidence suggests that a family history of squamous cell carcinoma may confer increased risk of this same cancer. ⁵³ Several rare genetic conditions also confer increased skin cancer risk, including xeroderma pigmentosum and albinism. ⁵⁴

Genetic mutations. Mutations in certain known high-penetrance melanoma predisposition genes, such as *CDKN2A* and *CDK4*, are associated with an increased risk of developing melanoma. Mutations in the CDKN2A gene accounts for susceptibility in about 20-40% of melanoma families. ^{55, 56}

Immunosuppression. Patients with immunosuppression—such as those who have acquired human immunodeficiency virus infection, have undergone organ transplantation, or are on immunosuppressive therapies—are at increased risk of melanoma and non-melanoma skin cancer. ⁵⁷⁻⁶¹

Association Between UV Exposure and Skin Cancer

Ultraviolet radiation causes most skin cancers through damage to DNA,⁷ and represents the major environmental risk factor for all types of skin cancer.^{62, 63} Any tan or color to the skin after exposure signals UV damage. More severe damage presents as sunburn, a well-established risk factor for skin cancer especially when it occurs in childhood and is blistering or painful.^{64, 65} The World Health Organization's International Agency for Research on Cancer (IARC) has classified UV radiation, UV radiation-emitting devices, solar radiation, and indoor tanning devices as carcinogenic to humans (Group 1) with sufficient evidence linking these to melanoma and other skin cancers. Other Group 1 agents include tobacco, high-risk human papillomavirus, alcohol, formaldehyde, asbestos, and coal.⁶⁶ Sunlight is the major source of UV radiation; indoor tanning is also a source of exposure to UV radiation.⁶⁷

In its 2012 recommendation, the USPSTF found convincing evidence linking UV radiation exposure during childhood and youth to a moderately increased risk for skin cancer later in life; and for adults, adequate evidence linking UV radiation exposure to a small increase in skin cancer risk.⁶⁸

Our scan of observational studies published since the previous review confirms these associations and provides even stronger evidence for the risks of indoor tanning use;^{40, 69-79} continued mixed evidence on the role of ambient sun exposure in melanoma development;⁸⁰⁻⁸⁴ and new followup data from a randomized clinical trial (RCT) that suggests a protective effect for sunscreen use and melanoma development.⁸⁵

Indoor Tanning and Skin Cancer

A preponderance of recent evidence suggests indoor tanning increases risk of skin cancer, with a strong association for younger age at exposure. The previous USPSTF review found that regular indoor tanning was associated with increased melanoma risk (relative risk [RR] range 1.6 to 2.3),² and the IARC in 2006 estimated that people younger than age 35 at first indoor tanning exposure had a 1.75-fold increased melanoma risk compared with those aged 35 or older at first exposure.⁸⁶

In our scan of research published since the previous review, we found additional evidence for the risks of indoor tanning. A meta-analysis of 27 studies provides evidence for a dose-response relationship between indoor tanning in women under age 50 and melanoma risk, estimating a 1.8 percent increase in risk (95% confidence interval [CI] 0 to 3.8) for each additional session of sunbed use per year. The meta-analysis also estimated that people younger than age 35 have a 1.59-fold increased melanoma risk compared to those aged 35 or older at first exposure. Four additional studies have found a positive association between increasing indoor tanning frequency and increased melanoma risk (Odds Ratio [OR] 1.34 to 6.1). To-73

Two systematic reviews, ^{69, 74} one cohort study, ⁴⁰ and one case-control study⁷⁵ found evidence that ever versus never use of indoor tanning is associated with increased risk of squamous cell carcinoma (RR 1.67 to 2.23)^{40, 69, 74} and basal cell carcinoma (RR 1.09 to 1.29). ^{69, 74, 75}

In addition, recent research suggests indoor tanning behaviors can co-occur with other high-risk sun exposure behaviors⁷⁶ and psychotropic medication use.⁷⁷ Indoor tanning patterns resemble addiction in some users.^{78, 79} In the U.S., 43 states and the District of Columbia have laws regulating the use of indoor tanning by minors, and 15 of these states and the District of Columbia have banned minors from indoor tanning.⁸⁸

Sun Exposure and Skin Cancer

The previous USPSTF evidence review assessed 18 fair-quality studies, mainly with case control designs, examining the association between sun exposure and melanoma. The review found that total sun exposure in childhood was associated with an increased risk for melanoma (OR 1.81 to 4.4), and that occupational sun exposure may be associated with a decreased risk for melanoma. Increasing recreational sun exposure was associated with increased melanoma risk (OR 1.3 to 5.0), as was recreational sun exposure during childhood (OR 1.7 to 3.5), but neither total nor chronic sun exposure was strongly associated with melanoma risk.²

Evidence published since the previous review remains mixed about the association between ambient sun exposure and melanoma risk. Ro-83 A cohort of non-Hispanic white individuals (n=450,934) aged 50–71 in the National Institutes of Health (NIH)-AARP Diet and Health Study was examined for associations between incident cancer and UV radiation exposure, assessed by linking daily reports from NASA's Total Ozone Mapping Spectrometer (TOMS) database with each participant's census tract location between 1978–1993 and 1996–2005. At 9-year followup, increased UV radiation exposure was associated with both increased melanoma risk (highest versus lowest quartile; hazard ratio [HR] 1.22, 95% CI 1.13 to 1.32; p<0.001) and melanoma death (HR 1.13, 95% CI 1.02 to 125).

However, two large recent studies found no association between ambient sun exposure and melanoma risk. A meta-analysis of prospectively collected data of women and men aged 20 and older (n=250,151) in the Nurses' Health Study (1980–2008), the Nurses' Health Study 2 (1989–2009), and the Health Professionals Followup Study (1986–2008) confirmed an association between melanoma in situ risk and sunburn, but did not find an association between melanoma in situ risk and the ultraviolet index of the person's state of residence at birth, at age 15, or at age 30.81 Similarly, an analysis from the Women's Health Initiative (1993–2005, n=56,557) with a median followup of 11.9 years found no association between melanoma risk and ambient UV exposure during childhood and adulthood based on geographic residence.

The previous USPSTF review found evidence from 11 primarily fair-quality cohort and case-control studies that increasing intermittent or recreational sun exposure in childhood and over one's lifetime is associated with an increased risk for both squamous cell and basal cell carcinoma (OR 1.27 to 3.86). Four studies published since the previous review (two meta-analyses^{89, 90} and two cohort studies^{83, 91}) suggest an increased risk of NMSC in people with increased ambient UV radiation exposure.

Sunscreen Use and Skin Cancer

The previous USPSTF review found no clear protective or harmful association between sunscreen use and melanoma risk, based on one good-quality trial and nine observational studies.² Another systematic review of 15 pediatric studies (n=20,743 children) found that 12 of 15 studies did not suggest a protective effect of sunscreen against melanocytic nevi development in children; but 8 of 15 studies reported an association between sunscreen use and increased melanocytic nevi count.⁹²

Two recent publications suggest new evidence for a protective effect for sunscreen use and melanoma development in adults. Long-term followup data from the good-quality Nambour Skin Prevention Trial (n=1621)—which was included in the previous review^{85, 93}—and one case control study published since the previous review⁹⁴ suggest evidence for a protective effect of sunscreen against melanoma. In the Nambour trial, adults (mean age 49 years, 93.0% with fair or medium skin color) were randomly assigned to the sunscreen intervention group, which was asked to apply SPF 15 sunscreen daily, or to the control group, which was asked to continue their usual approach to sunscreen use. At 4.5 years, there were significantly fewer incident squamous cell carcinomas in the sunscreen intervention group compared with the control group, but no difference in BCC or melanoma. At 8-year followup, people randomly assigned to the sunscreen intervention group had a decreased risk only for squamous cell carcinoma compared with controls (RR, 0.65 [CI, 0.45 to 0.94]). 93 Follow up of the trial population has continued with regular questionnaires and searches of the regional cancer registry. The most recent report (2011) presented melanoma incidence estimates (n=1339, 82% of the original study population). Ten years after trial cessation (15 years since trial initiation), 11 incident melanomas had been identified in the sunscreen intervention group, and 22 in the control group. Overall melanoma risk was reduced in the sunscreen intervention group compared to controls after adjustment for sex, skin type, numbers of nevi, previous history of skin cancer, and sun exposure (adjusted HR 0.49; 95% CI 0.24 to 1.02). Risk reduction was most pronounced for invasive melanomas (3 in sunscreen intervention group versus 11 in control group; HR 0.27; 95% CI 0.08 to 0.97, p=0.045) compared with in situ melanomas (HR 0.73; 95% CI 0.29 to 1.81). Average melanoma thickness was 0.53 millimeters in the sunscreen intervention group and 1.2 millimeters in controls (p=0.08).85

The large U.S.-based case-control study (2011) published since the previous review included cases (age 29–59 at diagnosis, n=1167) and age- and gender-matched controls (n=1101). Mean scores for SPF 15+ sunscreen use and other sun protection behaviors were low but higher in the control group than in cases (p<0.05). Routine sunscreen use, but no other measures of sunscreen use, was associated with lower likelihood of melanoma (adjusted OR 0.44, 95% CI 0.23 to 0.86). Stimates of risk reduction attributed to other sun protection behaviors were similar (adjusted OR = 0.59, 95% CI 0.44 to 0.78).

Potential Harms of Sun Protection Behaviors

Potential harms of sun protection include skin reactions from sunscreen use, paradoxically increased sun exposure through false reassurance, vitamin D deficiency, reduced physical activity, and anxiety.^{2, 95-97} The previous USPSTF review found very little evidence and limited

potential harm from reduced sun exposure, including one trial suggesting that sun protection did not lead to decreased physical activity or increased body mass index in youth. ⁹⁸ We found no recent studies on reduced physical activity as a harm of sun avoidance.

Sunscreen users may experience irritant, allergic, phototoxic, or photoallergic contact dermatitis after sunscreen use;⁹⁵ one study of Australian adults over age 40 (n=603) found that 19 percent of users developed an adverse reaction based on use in 1991–1992.⁹⁹ The previous USPSTF review concluded that sunscreen with a higher SPF may increase intentional sun exposure in healthy student volunteers but in general does not promote paradoxically increased sun exposure, based on six trials.² More recently, a cross-sectional analysis of data from the National Health and Nutrition Examination Survey (NHANES) (n=3052 white adults) found that frequent sunscreen use was associated with higher odds of multiple sunburns (OR=1.23, 95% CI 1.06 to 1.42, p=0.01).⁹⁶ A 2010 Danish population-based cross-sectional study (n=3,499) of people ages 15–59 found similar results, and 66 percent of people with sunburn reported using sunscreen to prolong time in the sun.⁹⁷

Sun light is the body's main source of vitamin D, which is necessary for calcium absorption. Sun exposure is positively associated with vitamin D levels. $^{101\text{-}104}$ An analysis of NHANES 2005-2006 data (n=4495) found an overall 41.6 percent prevalence of vitamin D deficiency in adults (defined as \leq 20 ng/mL), with highest estimates in black (82.1%) and Hispanic individuals (69.2%) compared to white individuals (30.9%). The previous review identified one trial finding that sunscreen use does not significantly decrease vitamin D levels or cause vitamin D deficiency. More recently, neither a followup study of Nambour trial participants, or an analysis of NHANES data of NHANES data of the vitamin D levels associated with sunscreen use.

Minimal ambient sun exposure a few days per week in summer (5–15 minutes for fair-skinned individuals and 15–30 minutes for dark-skinned individuals) may be sufficient to sustain vitamin D concentrations. ¹⁰⁹⁻¹¹¹ The American Cancer Society, the office of the U.S. Surgeon General, and a coalition of seven U.K. medical societies have concluded that the benefits of sun protection outweigh the potential risk of vitamin D deficiency. ^{109, 110, 112} The American Academy of Dermatology recommends against obtaining vitamin D from unprotected sun exposure or indoor tanning devices. ¹¹³

Aside from sunlight, adequate vitamin D can be obtained safely from food and dietary supplements. ¹⁰⁹ Natural dietary sources of vitamin D include fatty fish and fish liver oils, and many foods and beverages in the U.S., such as milk, yogurt, and orange juice, are fortified with vitamin D. ¹⁰⁹ The USPSTF currently finds insufficient evidence to recommend for or against routine screening for Vitamin D deficiency (2014). ¹¹⁴

Association Between UV Exposure and Other Health Outcomes

In the previous review, four of seven fair- or good-quality studies suggested sun exposure in predominantly white populations may be inversely related to risk for advanced breast and prostate cancer and non-Hodgkin lymphoma.² Research into potential beneficial associations

between vitamin D and other health outcomes has increased substantially since the previous review, ¹¹⁵⁻¹²⁴ but studies of associations between UV exposure and health outcomes besides skin cancer are less common. The NIH-AARP Diet and Health Study (described above) found that despite an association with increased melanoma risk and melanoma death, increased sun exposure may reduce risk for several cancers. ⁸⁰ At 9-year followup, UV radiation exposure was inversely associated with total cancer risk (highest versus lowest quartile; HR = 0.97, 95% CI 0.95 to 0.99; p<0.001). For individual cancers, after adjustment for individual-level risk factors, UV radiation exposure was associated with decreased risk of: non-Hodgkin lymphoma (HR 0.82, 95% CI 0.74 to 0.92) colon (HR 0.88, 95% CI 0.82 to 0.96), squamous cell lung (HR 0.86, 95% CI 0.75 to 0.98), pleural (HR 0.57, 95% CI 0.38 to 0.84), prostate (HR 0.91, 95% CI 0.88 to 0.95), kidney (HR 0.83, 95% CI 0.73 to 0.94), and bladder (HR 0.88, 95% CI 0.81 to 0.96) cancers. ⁸⁰ An analysis of total deaths (n=41,425) also found a decreased risk of death from lung, prostate, and liver cancers when comparing the highest vs. lowest ambient UV radiation quartile. ⁸⁴

Association Between Skin Self-Exam and Skin Cancer Outcomes

The 2009 USPSTF review on skin cancer screening⁵ found no new evidence on the effectiveness of either skin examination by a physician or skin self-exam in reducing the morbidity or mortality of skin cancer. The authors described one fair-quality case-control study on skin self-exam published in 1996 and a subsequent followup study $(2005)^{125, 126}$ of the same participants. We identified no new studies, but identified a 20-year followup study of the same study population published in 2016 that suggests no beneficial association between skin self-exam and skin cancer death.¹²⁷

In the original study, ¹²⁵ melanoma cases diagnosed in 1987–1989 (n=650) were obtained from the Connecticut Tumor Registry (CTR), a National Cancer Institute Surveillance Epidemiology and End-Results (SEER) site. Age- and sex-matched controls (n=549) were identified from the general public through random-digit dialing. A trained nurse used a structured questionnaire to interview participants about family history, sun exposures, and history of skin examination, and the nurse also counted nevi on the participants' backs and arms. Of the 650 cases, 86 had conducted skin self-exam (13.2%). Participants were followed biannually for a mean of 5.4 years.

At followup, skin self-exam was associated with a reduced risk of melanoma diagnosis (adjusted OR 0.66, 95% CI 0.44 to 0.99). 125, 126 An analysis of cases only (n=528) assessed risk of death from melanoma. At followup, 58 people (11.0%) had died from melanoma; 24 (4.5%) from other causes. History of severe sunburn, high intermittent sun exposure, presence of solar elastosis (a histologic measure of sun damage), and skin awareness (defined as endorsement of the question: "Prior to your biopsy, did you ever think about your skin, how it looked, whether there were any changes, or whether there were any marks?") were significant predictors of melanoma death, but history of skin self-exam was not (HR 0.06, 95% CI 0.2 to 1.5). On multivariable analysis, solar elastosis and skin awareness, as well as melanoma thickness, head/neck location, and mitoses, remained independent predictors of melanoma death. 125

In the 2016 analysis, deaths were examined for the original case population (n=554) through 2007 (18–20 years from diagnosis) identified through SEER data, the National Death Index, and the Social Security Index. By 2007, 45 percent had died; 48.4 percent from melanoma (calculated percent of all cases 21.8%). Skin self-exam was not associated with melanoma death based on either univariate or multivariable analysis (adjusted HR 1.12, 95% CI 0.61 to 2.06) p=0.71). However, skin awareness remained independently associated with a decreased risk of melanoma death (HR 0.46, 95% CI 0.28 to 0.75, p<0.01). 127

Skin Self-Exam Potential Harms

Skin self-exam is self-conducted and noninvasive. Psychosocial harms, such as anxiety or cancer worry, are possible. If skin self-exam is followed by clinician investigation and biopsy, procedural harms might occur from biopsy, such as pain, infection, or cosmetic harms such as scarring. There is evidence for overdiagnosis of skin cancer, given the sharp rise in skin biopsies and melanoma incidence over the past several decades as melanoma death rates have remained steady. However, there is limited data on the role that skin self-exam might play in increased biopsies (discussed more in **Chapter 3**).

Current Prevalence of Sunburn, Sun Protection Behaviors, and Skin Self-Exam

Sun protective behaviors fall short of the Healthy People 2020 objective, which has set a target for 73.7 percent of adults aged 18 and older to follow protective measures to reduce the risk of skin cancer. ¹²⁹ An analysis of National Health Interview Survey (NHIS) data from 2010 found that 37.1% of U.S. adults aged 18 and older had experienced at least one sunburn during the past year, and sunburn prevalence was highest among adults aged 18–29 (52.0%). ¹³⁰ In a separate analysis of NHIS data for 18–29 year-olds, the highest reported use of any sun-protective behavior between 2000-2010 was 37 percent, and the prevalence of reported sunburn remained steady between 2000–2010 (49.1% for men and 51.3% for women in 2010) despite a trend of increasing sun protective behavior during the same time period. 131 National surveys conducted between 2004–2009 estimate that about 30 percent of U.S. adults routinely practice sunprotective behaviors. Less than 40 percent of adolescents report sun-protective behavior, and 69 percent of all adolescents reported sunburn in the previous summer. ¹³² An analysis of 2010 NHIS data found that in Hispanic adults with sun-sensitive skin (n=1676), 47.1 percent never or rarely used sunscreen, 16.8 percent never or rarely stayed in the shade, 60.3 percent never or rarely used sun protective clothing, and 43.1 percent reported having a sunburn in the past year. Greater acculturation was associated with fewer sun protection behaviors and higher reported sunburn. 133 Sun protection behaviors and skin self-exam were low in a sample of uninsured, minority, or immigrant individuals in Florida, as were measures of skin cancer awareness. ¹³⁴ Family members of people with melanoma report similar sun protection behaviors compared to those at average risk. 135, 136 A 2014 meta-analysis of the prevalence of indoor tanning in U.S., Europe, and Australia estimated ever-exposure to indoor tanning at 35.7 percent for adults, 55.0 percent for university students, and 19.3 percent for adolescents, based on data from 406,696 participants. 137

Estimates of skin self-exam prevalence vary widely. A systematic review of 14 studies reports between 7 percent and 61 percent of average-risk individuals engage in thorough skin self-exam either in their lifetime, within the past 3 months, or within the past month. A 1996 survey of 1000 randomly chosen U.S. residents found that 46 percent report performing skin self-exam at least once in the past year. In a 2011 survey of Hispanic adults (n=788), 17.9 percent reported ever having conducted a skin self-exam. A recent population-based study in Queensland, Australia—the region with the highest melanoma incidence in the world—reports 55.1 percent of adults aged 40 through 69 performed a skin self-exam in the past three years. Family members of people with melanoma report similar frequencies of engaging in skin self-exam compared with the general population.

Current Clinical Practice in the United States

Estimates of the frequency of clinician-provided skin cancer prevention counseling vary. The most recently published estimate used National Ambulatory Medical Care Survey (NAMCS) data from 1989–2010 and found that clinicians mentioned sunscreen at approximately 0.07 percent of patient visits to ambulatory care offices. ¹⁴⁴ The study noted clinicians were most likely to recommend sunscreen use to elderly patients and least likely to recommend sunscreen use to children. ¹⁴⁴ Two studies analyzing 1997 data found that skin cancer prevention counseling was reported at 1.0 percent to 2.3 percent of visits to primary care physicians. ^{145, 146}

Surveys of physicians and patients suggest higher self-reported rates of skin cancer prevention counseling. In a mailed survey of 3,032 female physicians, 27 percent said they were likely to provide skin cancer counseling or screening to a typical patient at least once per year, ¹⁴⁷ and a separate American Academy of Pediatrics survey found that 22.3 percent of pediatricians reported providing sun protection counseling to most patients in all age groups. ¹⁴⁸ In a nationally representative telephone survey of 1,589 adolescents and parents, 44 percent reported ever receiving sun protection counseling from a physician. ¹⁴⁹

Recommendations of Other Groups

A role for physicians in educating patients about skin cancer prevention is endorsed by the American Cancer Society, ¹¹² American Congress of Obstetricians and Gynecologists, ¹⁵⁰ the American Academy of Pediatrics, ⁶⁷ the Institute for Clinical Systems Improvement, ¹⁵¹ the Australian College of General Practitioners, ¹⁵² the U.K.'s National Institute for Health and Care Excellence, ¹⁵³ and the International Agency for Research on Cancer. ¹⁵⁴

The Community Preventive Services Task Force Recommends education and policy approaches to encourage skin-protective behaviors in child care centers, primary and middle schools, outdoor recreational sites, and outdoor occupational settings. They also recommend multi-component community-wide interventions—such as individual-level strategies, mass media campaigns, and environmental and policy changes across multiple settings within a defined geographic area—to increase UV radiation protective behaviors and prevent skin cancer. Although multi-component interventions may involve health care settings, the Community

Preventive Services Task Force focuses on interventions that target multiple settings or an entire community. 156

The American Academy of Dermatology encourages the general population to regularly examine their skin for early signs of skin cancer. ¹⁵⁷ The Skin Cancer Foundation and the American Cancer Society recommend individuals perform skin self-exam monthly. ^{8, 158} The Royal Australian College of General Practitioners recommends skin self-exam at different frequencies depending on risk (every 3 months for high-risk individuals, annually for low-risk individuals). ¹⁵⁹ Additional information about recommendations of other groups is in **Appendix A Table 1**.

Previous USPSTF Recommendations

In 2012, the USPSTF recommended counseling children, adolescents, and young adults aged 10 to 24 who have fair skin about minimizing their exposure to ultraviolet radiation to reduce risk for skin cancer (B recommendation). They found moderate certainty that counseling has a moderate net benefit, but that for adults older than age 24, evidence of the benefits of counseling is sparse and of unknown clinical significance, and the balance of benefits and harms cannot be determined (I statement). This replaced the task force's 2003 recommendation, in which the USPSTF found insufficient evidence to make a recommendation on behavioral counseling for skin cancer (I statement). 160

In 2009, in a separate recommendation statement, the USPSTF found insufficient evidence to assess the balance of benefits and harms of screening for skin cancer by primary care clinicians or by patient skin self-exam (I statement), citing the lack of studies on whether early detection of skin cancer reduces mortality or morbidity from skin cancer as a critical evidence gap.⁴ In 2016, the USPSTF updated its recommendation on physician skin examination only (finding insufficient evidence; I statement).¹⁶¹ The evidence for skin self-exam was not included in the 2016 evidence update, and is included in this report.

Chapter 2. Methods

Scope and Purpose

The USPSTF will use this evidence review to update its 2012 recommendation on behavioral counseling for skin cancer prevention. This review addresses the benefits and harms associated with counseling for the primary and secondary prevention of skin cancer.

Our review differs in structure compared to the previous USPSTF review on Skin Cancer Counseling.² The previous review did not include skin self-exam as a behavioral outcome. Skin self-exam was included in the 2009 USPSTF evidence review on Skin Cancer Screening,⁵ but was not included in the 2016 update,¹⁶² which focused solely on clinician skin exam. Also, we limited our discussion of the epidemiologic associations between sun exposure and health outcomes to contextual assessments, whereas the previous review assessed these with key questions (KQs).

Analytic Framework and Key Questions

We developed an analytic framework with five KQs based on the previous review and a scan of the research conducted since the previous review (Error! Reference source not found.).

- 1. Does counseling patients in skin cancer prevention improve a) intermediate outcomes (sunburn or precursor lesions) or b) skin cancer outcomes (melanoma, squamous cell, or basal cell carcinoma incidence, morbidity, or mortality)?
- 2. Do primary care-relevant counseling interventions improve skin cancer prevention behaviors (e.g., reduced sun exposure, sunscreen use, use of protective clothing, avoidance of indoor tanning, and skin self-examination)?
- 3. What are the harms of counseling interventions for skin cancer prevention (e.g., increased time in the sun, reduced physical activity, vitamin D deficiency, and anxiety)?
- 4. What is the association between skin self-examination and skin cancer outcomes (melanoma, squamous cell, or basal cell carcinoma incidence, morbidity, or mortality)?
- 5. What are the harms of skin self-examination?

Our final research plan stated that KQs 4 and 5 would be addressed systematically only if there is sufficient evidence from KQs 1 to 3 that behavioral counseling increases skin self-exam behavior. However, no studies met our inclusion criteria for KQs 4 and 5.

We also addressed one contextual question, which is described in Chapter 1: What is the association between sun exposure, sun protection behavior, indoor tanning, skin self-examination, and a) skin cancer incidence, morbidity, or mortality or b) other health outcomes?

Data Sources and Searches

We worked with a research librarian to develop our literature search (**Appendix B**). All search strategies were peer-reviewed by a second research librarian.

We re-evaluated all articles included in the previous USPSTF Evidence Report on Behavioral Counseling for Skin Cancer Screening and in the USPSTF Skin Cancer Screening Evidence Report published in 2009 (note: the 2009 update included literature published between 1999 and 2005). For articles published since the previous reviews, the librarian created two search strategies: one for counseling and one for skin self-exam. For counseling on sun protection behaviors we searched for articles published from 2009 to March 31, 2016. For skin self-exam we searched for articles published from August 2005 to March 31, 2016. We searched Cochrane Central Register of Controlled Trials, Medline, and PubMed, publisher-supplied to locate relevant studies for all KQs (Appendix B). Results of the literature search were imported into EndNote. We supplemented our database searches by reviewing reference lists from recent and relevant systematic reviews. We also searched ClinicalTrials.gov and WHO International Clinical Trials Registry Platform (ICTRP) for relevant ongoing trials (Appendix C). We updated our search on June 7, 2017.

Study Selection

Two reviewers independently reviewed 2,100 titles and abstracts using Covidence, ¹⁶³ an online platform, and 355 articles (**Appendix B Figure 1**) against specified inclusion criteria (**Appendix B Table 1**). We resolved discrepancies through consensus and consultation with a third investigator. We excluded articles that did not meet inclusion criteria or those we rated as poor quality.

For all key questions, the population of interest was people of any age without skin cancer, including parents/caregivers of children who would be the focus of a counseling intervention. We excluded studies where 25 percent or more of the population had a prior history of skin cancer or were otherwise under surveillance for skin cancer. We limited studies to settings with an established link to primary care and in countries categorized as "Very High" in the Human Development Index. 164 We defined primary care-relevant counseling interventions as those that were delivered in primary care settings, judged to be feasible for implementation in primary care, or available for referral from primary care. 165 We excluded studies set in the community with no link to primary care, at a worksite, within childcare or recreational settings, and mass media campaigns. We included any intervention aimed at improving sun protection behaviors or teaching skin self-exam in a primary care or primary care-linked setting, and excluded multicomponent interventions (such as a community-level intervention including media campaigns, screening days, with primary care counseling included) where the effect of primary care-relevant counseling could not be assessed. For comparison groups we included usual care, assessmentonly controls, attention-control groups using an equivalent-intensity intervention on a different health topic, or comparison groups using minimal intervention; we excluded studies comparing two equivalent-intensity skin cancer counseling interventions. For questions on behavioral counseling (KQ1, KQ2, KQ3) we included only randomized or controlled clinical trials. For skin self-exam questions (KQ4, KQ5), trials and prospective cohort studies were eligible for inclusion.

For KQ1, intermediate outcomes were defined as sunburn, nevi, and actinic keratosis, and health outcomes included melanoma, basal cell or squamous cell carcinoma incidence, morbidity or mortality. Behavioral outcomes for KQ2 could be parent- or self-reported outcomes that related to sun protective behaviors (e.g., composite scores, use of protective clothing, sun avoidance, use of sunscreen), skin self-exam, or indoor tanning use. For KQ3, we included any harm of behavioral counseling interventions or skin self-exam.

Quality Assessment and Data Abstraction

At least two reviewers critically appraised all articles that met the inclusion criteria based on the USPSTF's design-specific quality criteria for trials (**Appendix B Table 2**). We rated articles as good, fair, or poor quality. In general, a good-quality study met all criteria. A fair-quality study did not meet, or it was unclear if it met, at least one criterion but had no known important limitations that could invalidate its results. A poor-quality study had a single fatal flaw or multiple important limitations; we excluded poor-quality studies from this review. Disagreements about critical appraisal were resolved by consensus and, if needed, in consultation with a third independent reviewer.

One reviewer extracted key elements of included studies into a Microsoft Access® database (Microsoft Corporation, Redmond, Washington). A second reviewer checked the data for accuracy. Evidence tables were tailored for each KQ. Tables generally included details on study design and quality, setting and population (e.g., country, inclusion criteria, age, sex, race/ethnicity), intervention details, length of followup, measure descriptions, and outcomes.

Data Synthesis and Analysis

We synthesized results by KQ, using a standardized summary of evidence table to summarize the overall strength of evidence for each. This table included the number and design of included studies, summary of results, reporting bias, summary of study quality, limitations of the body of evidence, and applicability of the findings.

We report results for child and adolescent populations and adult populations separately. The data reported for each population and outcome did not allow for quantitative pooling due to the limited number of contributing studies and the variability of the outcomes measured, so we provided a narrative synthesis of results. For sun protection and skin self-exam outcomes (KQ2), we present forest plots showing the standardized mean differences in change between groups (using the Cohen's *d* statistic) to illustrate the range of effects seen across studies but have not provided pooled estimates given the small number of contributing studies and variability in measures.

Grading the Strength of the Body of Evidence

We graded the strength of evidence by each KQ according to AHRQ's guidance for Evidence-based Practice Centers, ¹⁶⁶ which was informed by the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group. ¹⁶⁷ For each key question we grade the evidence according to consistency (similarity of effect direction and size), precision (degree of certainty around an estimate), reporting bias (potential for bias related to publication, selective outcome reporting, or selective analysis reporting), and study quality (i.e., study limitations). These are four of the five suggested domains; we did not address the fifth required domain—directness—in the summary of evidence as directness is addressed in the design and structure of the key questions (i.e., whether the evidence links the interventions directly to a health outcome).

Consistency was rated as reasonably consistent, inconsistent, or not applicable (e.g., single study). Precision was rated as reasonably precise, imprecise, or not applicable (e.g., no evidence). Reporting bias was rated as suspected, undetected, or not applicable (e.g., when there is insufficient evidence for a particular outcome). Study quality reflects the quality ratings of the individual trials and indicates the degree to which the included studies for a given outcome have a high likelihood of adequate protection against bias. The body of evidence limitations field highlights important restrictions in answering the overall KQ (e.g., lack of replication of interventions, non-reporting of outcomes important to patients).

We provide an overall assessment of the strength of evidence for each KQ. "High" indicates high confidence that the evidence reflects the true effect and that further research is very unlikely to change our confidence in the estimate of effects. "Moderate" suggests moderate confidence that the evidence reflects the true effect and that further research may change our confidence in the estimate of effects. "Low" indicates low confidence that the evidence reflects the true effect and that further research is likely to change our confidence in the estimate of effects. A grade of "insufficient" indicates that evidence is either unavailable or does not permit estimate of an effect. Applicability assesses how the overall body of evidence would apply to the U.S. population based on settings, populations and intervention characteristics. Two independent reviewers rated each KQ according to consistency, precision, reporting bias, and overall strength of evidence grade. We resolved discrepancies through consensus discussion involving more reviewers.

Expert Review and Public Comment

A draft research plan that included the analytic framework, KQs, and inclusion criteria was available for public comment from March 17 to April 13, 2016. We made a few minor changes to our review methods based on the comments received. A final research plan was posted on the USPSTF website on June 30, 2016.

A draft version of this report was reviewed by invited content experts and federal partners, who are listed in the acknowledgements. Comments received during this process were presented to the USPSTF during its deliberation of the evidence and, subsequently, addressed in this version of the report.

AHRQ and USPSTF Involvement

The authors worked with four USPSTF liaisons at key points throughout the review process to develop and refine the analytic framework and KQs and to resolve issues regarding the scope for the final evidence synthesis. This research was funded by AHRQ under a contract to support the work of the USPSTF. AHRQ staff provided oversight for the project, assisted in external review of the draft report, and reviewed the draft report.

Chapter 3. Results

Description of Included Studies

Literature Search Results

We reviewed 2,100 abstracts and 353 full-text articles for all KQs (**Appendix B Figure 1**). We included 21 unique trials, reported in 27 articles: 6 reported results in pediatric populations (n=4252)¹⁶⁸⁻¹⁷³ and 16 reported on adult populations (n=16,309) (Error! Reference source not found.). The 6 pediatric studies, five reported results in child populations (ages 0-12) and one reported results in adolescents (ages 11-15). Of the 16 adult studies, 3 reported results in young adults (ages 17-25 or university students), and 13 studies results in adults of a broad age range (ages 18 and older). One trial (the Project SCAPE [Skin Cancer Awareness, Prevention and Education] family study by Glanz and colleagues) reported results for both adults and children. The 173

Nine trials (10 articles) reported the effect of behavioral counseling on skin cancer outcomes (KQ1), 21 trials (27 articles) reported skin cancer prevention behaviors (KQ2), and two trials (two articles) reported harms of behavioral counseling for skin cancer prevention (KQ3). We found no studies that met our eligibility criteria for the association between skin self-exam and skin cancer outcomes (KQ4), and no studies on the harms of skin self-exam (KQ5).

Articles were most commonly excluded due to ineligible study design (did not include a comparison group, compared two active skin cancer counseling interventions, or not a randomized or controlled trial) or ineligible outcomes (**Appendix B Table 1**). **Appendix C** provides a list of all excluded studies, with the main reason for their exclusion.

Quality

We rated 19 trials as fair quality and two as good quality. For trials rated as fair quality, limitations included a lack of reporting on how missing data were handled and incomplete reporting of blinding methods, randomization, allocation concealment, or followup rates. Followup rates ranged from 70.8 percent to 80.5 percent in pediatric studies, and 63.6 percent to 95.8 percent in adult trials. Less common were issues with the selection of control group, lack of reporting measures of intervention fidelity or adherence, and either baseline values or raw data not being reported.

All six pediatric trials¹⁶⁸⁻¹⁷³ and 9 adult trials^{173, 175, 177-180, 182, 185, 186} reported either process evaluation or measures of intervention adherence. Measures were heterogeneous across trials, such as participant report of receiving or using materials, mean number of phone contacts per participant, or participants' website usage. Most adherence estimates were above 70 percent and we found no measures that suggested poor fidelity or adherence.

Outcome Assessment

All trials used self-report or parent-report to assess behavioral outcomes and sunburn, but there was heterogeneity in the time frames assessed (past month to past year), individual items or scales used, reporting of individual behaviors that make up composite scores, and reporting of unadjusted or absolute values. Sun protection behaviors most commonly were assessed using heterogeneously adapted versions^{172, 173, 175, 176, 178, 182, 186, 188} of the Sun Habits Index¹⁸⁹ (**Appendix A**). Measures of skin self-exam also were heterogeneous, ranging from any or partial exam, to mole-checking, to total body exam with numbers of body parts examined

Trials typically did not supplement self-reported outcomes with direct observations or other objective measurement, though a few studies asked participants to complete sun protection diaries that were consistent with the composite measures. ^{172, 173, 175} One study included a measure of tanning using a device designed to read skin darkening, which was consistent with self-reported results. ¹⁷²

In the single pediatric study reporting nevi counts, counts were conducted by trained health care providers.¹⁷² In the single adult study reporting skin cancer outcomes, participant medical records were the data source.¹⁸⁷

Most trials timed assessments and interventions to address seasonality by choosing sunny climates as intervention sites, planning interventions to peak in spring, timing followup assessments in late summer or fall, or querying a specific time frame during assessment (e.g., most recent sun exposure). Exceptions included two older trials focused on multiple risk behaviors besides sun protection ^{183, 184} and a trial whose primary outcome was skin self-exam. The skin self-exam trial did not assess sun protection behaviors so seasonal considerations in outcome assessment are likely minimal. ¹⁸⁰

Results: Children and Adolescents

Study Characteristics

Six trials, four published since the previous review, provided data for 4,252 children or adolescents (Error! Reference source not found.). ¹⁶⁸⁻¹⁷³ All six trials took place in the United States and encompassed a generally wide age range. One trial included infants with followup to age 3; ¹⁶⁸ four trials included children between ages 3 and 10; ^{169, 170, 172, 173} and one included adolescents aged 11–15 (Error! Reference source not found.). ¹⁷¹ The four trials including children aged 3–10 all were published since the previous review. Two trials had risk-based inclusion criteria, limiting enrollment to children aged 4–10 at moderate or high skin cancer risk (n=1301; Project SCAPE family study by Glanz et al., 2013). ¹⁷³ and to children aged 12 and younger of melanoma survivors (n=340; Gritz et al., 2013). ¹⁷⁰ In the other four trials, children had varying constellations of skin cancer risk factors. The one trial that enrolled parents of infants (Kaiser Kids Sun Care by Crane et al., 2006) (n=728) reported no inclusion or exclusion criteria except the child's age (soon after birth), but parents with dark skin, eyes, and hair were informed that the program might have minimal benefit to them. ¹⁶⁸ Another included trial

randomized children aged six of all phenotypes (n=867) but reported results only for non-Hispanic white participants (n=677).¹⁷² The Sun Smart trial (Norman et al., 2007) recruited adolescents aged 11–15 (58% White) from six primary care practices in California's San Diego County, whereas the Sun Sense trial (Glasser et al., 2010) among children aged 3–10 years (45% White) recruited parent-child pairs from a University of California-Los Angeles pediatric clinic. Across all six trials, white race ranged from 43.7 percent of the study population to 100 percent; two trials further provided a gradation of "fair white" skin skin skin that does not tan after burning.

Most of the interventions focused on parents; some also provided child-appropriate materials (Error! Reference source not found.). In the one trial among adolescents, the adolescent was counseled directly. All intervention messages focused on increasing sun protective behaviors (e.g., using sunscreen, avoiding mid-day sun, wearing sun protective clothing) (Error! Reference source not found.). None of the interventions among children or adolescents focused on the use of indoor tanning or performing skin self-exam. Three of the six trials included direct, face-toface counseling plus print and/or phone support. 168, 169, 171 The most intensive trial was the Kaiser Kids Sun Care cluster RCT (Crane et al., 2006) targeting children aged 0–3. 168 In this trial, intervention clinics placed prompts in each child's medical record to remind physicians to discuss sun protection with parents during well-child visits at 2, 6, 18, and 36 months; control sites performed usual care. Educational materials, sunscreen, a hat, and sunglasses also were provided. In the Sun Sense trial (Glasser et al., 2010) among children aged 3–10, parents and children randomized to the intervention took part in one 10–15 minute counseling session with a health educator and were given child-focused educational materials (print and video) and sun protection aids (t-shirt, sunscreen, hat). 169 In the Sun Smart trial among adolescents (Norman et al., 2007), adolescents received brief (2–3 minute) tailored sun cancer risk information (based on computer-based assessment) from a primary care provider during one in-person counseling session and four followup phone calls from a health counselor. 171 Adolescents also received mailed materials promoting sun protection and sunscreen samples. The remaining three trials 170, ^{172, 173} were print-based with mailed materials directed to parents and/or children ranging from 3 mailings over 6 weeks¹⁷³ to 14 mailings over 3 years.¹⁷² Two of these print-based interventions included materials tailored to the participant's level of risk, barriers to change, self-efficacy, or other factors. 172, 173 For example, the Project SCAPE family study (Glanz et al., 2013) of children aged 4-10 and their parents involved three mailings of personalized risk feedback and recommendations, interactive skin cancer education materials, and a family fun guide about safe sun practices. ¹⁷³ All of the trials reported basing their interventions on accepted theoretical frameworks of health behavior change (e.g., Health Belief Model, Social Cognitive Theory).

Summary of Results

None of the trials among children and adolescents reported skin cancer outcomes (KQ1). Three trials, however, reported the effects of the intervention on sunburn among children aged 3–10 (n=2,508). All three trials were published since the previous review and generally found no effect of the interventions on sunburn at 4-month to 3-year followup. ^{170, 172, 173} One trial among 6-year-olds (Crane et al., 2012) found a small intervention effect on parent-reported nonsevere sunburn; but no effect on severe, blistering sunburn at 3 years. ¹⁷² This same trial found no

difference between the mean number of small or large nevi between intervention and control group children at 3-year followup.

All six of the trials among children and adolescents reported the effect of the intervention on composite sun protection behaviors (KQ2) (n=4252). No outcomes related to indoor tanning and skin self-exam were reported in the child and adolescent trials given the focus of the interventions. Five of the six trials found a statistically significant benefit of the intervention on parent-reported composite sun protection scores compared with controls at 3-month to 3-year followup. The individual items and scales measuring sun protective behaviors were highly variable across the trials and make interpretation of the absolute differences difficult (e.g., 0.7 between-group difference in change at 3 years on a 25-point scale). To assist with interpretation, we plotted standardized mean differences (Cohen's d) in change for the five trials that provided sufficient data. Effect sizes ranged from 0 to 0.96, with the three larger trials suggesting an effect ranging from 0.16 to 0.50 (average around 0.32)—a small to moderate effect (Error! Reference source not found.). Effects on sunscreen use and other individual sun protection behaviors were generally consistent within each trial. There were no apparent trends in the effectiveness of the interventions according to intervention or population characteristics. The population represented by these trials includes infants (1 trial; Crane et al., 2006) through adolescents aged 15 years (1 trial; Norman et al., 2007) with generally moderate-to-high risk based on race and/or skin type. The one trial that found no effect for both sunburn and sun protective behavior outcomes was the only trial focused on children of melanoma survivors (Gritz et al., 2013). The lack of effect in this trial may reflect the higher rates of protective behaviors in general at baseline, the relatively older age of the children included (mean age: 7.3 years), the motivation of the control group, or the lower uptake of the intervention (only 71% of intervention participants reported watching the educational DVD). None of the six trials among children or adolescents reported on harms of interventions.

Detailed Results by KQ (Children and Adolescents)

KQ1. Does Counseling Patients in Skin Cancer Prevention Improve a) Intermediate Outcomes or b) Skin Cancer Outcomes?

Neither the included study of children aged 0–3 (Crane et al., 2006)¹⁶⁸ nor the included study in adolescents (Norman et al., 2007)¹⁷¹ reported any intermediate or health outcomes (**Table 5**).

Children Aged 3–10

Sunburn. Only one of the three trials reporting sunburn outcomes in children found a statistically significant effect of the intervention. The trial by Crane and colleagues (2012) among 6-year-olds found a small intervention effect at 3 years for the odds of nonsevere sunburn in the previous year (effect size, -0.25 [95%, CI -0.47 to -0.04], p=0.02, frequencies not reported) but no effect for severe, blistering sunburn in the same time period (effect size, -0.52 [95% CI, -1.23 to 0.19], p=0.15). These results, however, were only among the 677 non-Hispanic white participants; results for all participants (n=867) were not reported. The remaining two trials found no effect. In the Project SCAPE family study by Glanz and colleagues (2013), parent-reported frequency of red/painful sunburn in the previous 12 months decreased in both groups between baseline and 4-month followup (1–5 scale of 1 sunburn per month to 5 sunburns per

month over the past year): from 1.61 to 1.27 in the intervention group and from 1.68 to 1.37 in the control group) but the between-group difference was not statistically significant, suggesting the tailored materials in the intervention group may not have improved sunburn outcomes beyond the minimal intervention given to the control group.¹⁷³ Likewise, in the study of children of melanoma survivors (Gritz et al., 2013), there was no difference in number of sunburns between groups at 4 months (frequencies not reported, adjusted treatment effect p=0.98).¹⁷⁰

Nevi. Crane (2012) also assessed the presence of nevi in study children. The mean number of small nevi (<2 mm) increased similarly in the intervention (18.3 to 35.6) and control groups (18.3 to 35.2) (between-group difference, p=0.52) between baseline and 3-year followup. The odds of having large nevi (≥ 2 mm) also were similar in both groups at followup (p=0.09). 172

KQ2. Do Primary Care–Relevant Counseling Interventions Improve Skin Cancer Prevention Behaviors?

Children Aged 0–3

The Kaiser Kids Sun Care trial by Crane and colleagues (2006) involved a comprehensive primary care-based intervention among parents of infants through 3 years of age (n=728). It found a statistically significant difference between the intervention and usual care control group in parent-reported sun protection behaviors over 3-year followup (p=0.04 group by time effect). At 3 years, mean scores on the use of 7 sun protection strategies (scale range 7–28) were 18.2 among intervention versus 17.7 among control group participants (p=0.049). Behaviors in both groups peaked at 1 year, remained steady at year 2, and declined by year 3, although the intervention group scores declined more slowly. Individual sun protective behaviors showing a difference between groups at 3-year followup were sunglasses (39.4% vs. 29.9% at 3 years, p=0.02) and hat use (57.3% vs. 47.4%, p=0.02; hats were provided as part of the intervention). Over the entire study period, only shade-seeking was significantly higher in the intervention group (72.6% vs. 65.2% at 3 years; p=0.06 at 3 years, p=0.03 overall test) (**Table 6**). ¹⁶⁸

No significant differences were apparent at the 3-year followup in sunscreen use even though sunscreen samples were provided as part of the intervention. However, very high proportions of parents in both groups reported always or frequent use of sunscreen on their child (94.2% and 93.1%, not significant [NS]) and 99 percent of the population reported intentions to use sunscreen at baseline, suggesting parents may have been educated about sunscreen before the study. ¹⁶⁸

Children Aged 3–10

Three of the four trials among children aged 3–10 reported statistically significant between-group differences for changes in sun protection behaviors and sunscreen use at 3-month to 3-year followup. ^{169, 172, 173} For example, in the good-quality Project SCAPE family study (Glanz et al., 2013) among children aged 4–10 at increased skin cancer risk (n=1301), statistically significant group by time intervention effects were found for composite child sun protective behaviors (study-reported effect size, 0.16; p<0.001), sunscreen use (study-reported effect size, 0.13;

p<0.0001), wearing a shirt (p<0.001), wearing a hat (p<0.001), and wearing sunglasses (p<0.03) following the tailored mailed intervention. No effect was seen for sun avoidance measures (i.e., staying in the shade or mid-day sun exposure). Absolute mean changes over 4 months on the composite sun protection scale (range 1–4 with higher scores equaling higher frequency) were from 2.19 (standard error [SE] 0.02) to 2.48 (SE 0.02) among the intervention group versus 2.19 (SE 0.02) to 2.34 (SE 0.02) among control group participants. Treatment effect was observed at the New York site (effect size 0.22) and not at the Hawaii site (effect size -0.02).¹⁷³

The tailored mailed intervention among 6-year-olds (n=677) reported by Crane (2012), ¹⁷² found a small, statistically significant benefit of the intervention over the 3 years of followup in the composite sun protection score (overall group by time effect, p<0.001) but there was no consistent effect of the intervention on individual sun protection behaviors over time (i.e., sunscreen use, clothing use, avoiding mid-day sun, limiting time in sun, shade use, hat use, and sunglasses use). The smaller Sun Sense trial (n=197; Glasser et al., 2010) found a statistically significant effect of the counseling intervention on composite sun protection behaviors (hat, shirt, and sunscreen use) and use of sunscreen at 3 months, but not on composite sun avoidance behaviors (considered the sun when planning activities, adjusted activities for sun avoidance, and limited time in the sun). ¹⁶⁹ This intervention, "Slip, Slop, Slap," specifically emphasized sun protection behaviors rather than sun avoidance.

The one study finding no effect on sun protection behaviors again was the trial among children of melanoma survivors (n=340; Gritz et al., 2013). Sun protection scores and sunscreen use improved among both intervention and control group participants from baseline to 4-month followup with no between-group difference. For example, mean composite sun protection scores increased from 3.41 to 3.65 (on a 5-point scale) in both groups over 4 months. The study found a statistically significant increase in wide-brimmed hat use in the intervention group compared with the control group; and both groups scored 3.9 on a 5-point scale for limiting time outdoors at baseline, suggesting this population may be already practicing sun avoidance.

Adolescents Aged 11–15

In the SunSmart study involving physicians directly counseling adolescents (Norman et al., 2007), followup phone counseling by a health educator, and print materials, sun protection composite scores were higher at 2-year followup in the intervention group compared with the control group (scores not reported; p=0.003) as was sunscreen use (52.9% vs. 45.9% p<0.05). ^{171, 190, 191} The intervention group was roughly 5 to 10 percent (exact numbers not reported) more likely to report "always" or "often" avoiding midday sun exposure, limiting midday sun exposure, using sunscreen on the face, and using sunscreen on sun-exposed areas. There were no differences between the two groups for wearing a shirt or staying in the shade.

KQ3. What Are the Harms of Counseling Interventions for Skin Cancer Prevention?

No studies.

KQ4. What Is the Association Between Skin Self-Examination and Skin Cancer Outcomes?

No studies.

KQ5. What Are the Harms of Skin Self-Examination?

No studies.

Results: Adults and Young Adults

Study Characteristics

Sixteen trials (reported in 20 articles), including 16,309 adults in total, met our inclusion criteria (Error! Reference source not found.). Ten were published since the previous review. Ten, 176, 178, 180, 182, 185-188 We rated 14 as fair quality (n=14,462) and two as good quality (n=1847). Eleven trials took place in the United States, three in Australia, one in France, and one in the United Kingdom.

Most trials included adults with broad age criteria, but three included specifically young adults aged 18–25¹⁷⁸ or university students^{179, 181} (n=1528) and one included only men over age 50 (Error! Reference source not found.). Reference source not found.). One study included parents of children aged 4–10 as part of a family-focused intervention. Study populations were predominantly white or fair-skinned (45.0% to 100%, with all but one study above 60% white) and predominantly female, with seven trials having a population that was 70 percent or more female. Reference source risk-based inclusion criteria, Reference female. Reference female included adults at moderate or high skin cancer risk as measured by risk assessment tools. Reference female for the intervention group if they had one or more melanoma risk factor and control group participants were selected to match the skin and demographic profile of intervention group participants. Two trials included only adult siblings of first-degree relatives of melanoma patients, and one study included female university students who use indoor tanning. Sample sizes ranged from 108 to 5407 with a median sample size of 568.

Interventions varied in their settings, messages, components, and delivery (Error! Reference source not found.) Error! Reference source not found.). Seven of the 16 trials were either conducted in or recruited from primary care. 175-177, 183, 185-187 Four were conducted directly in primary care settings 177, 185-187 and three recruited participants from a primary care setting but conducted their interventions by mail. 175, 176, 183 We judged the remaining interventions to be referable from or feasible for primary care. The majority of the interventions included comprehensive skin cancer prevention messages, such as general skin cancer education and strategies for reducing sun exposure (sun protection/sun avoidance behaviors). Several also included messages promoting or teaching skin self-exams, 174, 176-178, 182 and three trials included interventions focused exclusively on conducting skin self-exams. 180, 187, 188

One trial among young adults focused solely on reducing indoor tanning use (among indoor tanning users). The other two young adult trials focused on improving skin cancer prevention behaviors. One involved a tailored interactive educational web program called UV4.me, and one was an appearance-focused intervention involving personal UV facial photographs and a brief video about photoaging.

The majority of the interventions (7 trials) were strictly mail-based interventions whereby participants received print materials, videos, and/or skin cancer prevention aids (e.g., sunscreen, mirrors for skin self-exams) mailed directly to their homes. ^{173, 175, 176, 179, 180, 183, 184} Five trials included direct face-to-face or phone counseling in addition to print materials: in two trials the counseling was provided in-person by primary care physicians, ^{185, 186} and in the remaining three trials the counseling was provided by health educators or study staff either in-person ¹⁸⁷ or via phone. ^{174, 182} Four interventions were technology-based, using text messages, ¹⁸⁸ an interactive online program, ¹⁷⁸ an interactive computer module provided in a primary care setting, ¹⁷⁷ or simulated participant UV facial images to reinforce intervention messages. ¹⁸¹ All but two of the 16 trials included tailored feedback or education specific to the participant's level of risk and/or barriers to change. The other two included relatively focused populations (young adult female indoor tanners ¹⁷⁹ and men over age 50 ¹⁸⁰) that allowed for specific intervention messaging.

Interventions had varying contact with participants, ranging from a single distribution of standard print materials¹⁷⁹ to a six-month intervention involving individually tailored brief counseling from a health educator, followup phone calls, a tailored letter, educational print and video materials, and skin self-exam aids.¹⁸⁷ Five trials were limited to a single session with no reinforcement of study messages.^{177, 179, 181, 185, 186} The longest interventions, one of text messages¹⁸⁸ and two of mailed materials,^{183, 184} took place over the course of one year.

Summary of Results

Seven trials among adults (n=5315) (six fair-quality and one good-quality) reported the effects of the intervention on health or intermediate outcomes of relevance to KQ1: six trials reported the effects on sunburn and one reported on nevi and skin cancer outcomes. All seven trials reporting KQ1 outcomes represent new evidence. In general, there was no effect of the interventions on the number or frequency of sunburns at 3-month to 1-year followup. Only one trial in young adults (n=965) found a statistically significant improvement in the frequency of red or painful sunburns among intervention versus control group participants at 3-month followup. Only one adult trial (n=1356) reported skin cancer outcomes and found no difference in the number of melanomas detected between groups at 1 year after an intervention promoting skin self-exam.

In terms of behavioral outcomes (KQ2), half of the trials (6 of 12 trials) found small, statistically significant improvements in self-reported sun protection behaviors after the intervention compared to control conditions over 3-month to 2-year followup; similarly, four of seven trials reporting sunscreen use found improvements. Standardized mean differences in change (Cohen's d) in composite sun protection scores ranged from -0.46 (in favor of the control group) to 0.57 (in favor of the intervention group) although most effects were in the magnitude of a 0.10 to 0.20 effect size (Error! Reference source not found.). There were minimal data on the effects of the

interventions on indoor tanning use. Only one trial among female indoor tanners (n=430) found an attenuated increase in tanning sessions at 6-month followup relative to the control group.

The most consistent results were observed for self-reported skin self-exams. Of eleven trials (n=7771) assessing skin self-exam, nine adult trials found that interventions were associated with small, statistically significant increases in rates of total or partial skin self-exam compared to control conditions at 3-month to 1-year followup.

Harms of interventions were reported in only two studies. One study suggested an increase in skin procedures in the first six months after a skin self-exam-focused trial, but found no difference at 12 months. ¹⁸⁷ Skin cancer worry did not differ between groups in one adult study focused on risk assessment and sun protection counseling. ¹⁸⁵

Detailed Results by KQ (Adults and Young Adults)

KQ1. Does Counseling Patients in Skin Cancer Prevention Improve: a) Intermediate Outcomes or b) Skin Cancer Outcomes?

Sunburn

Only one trial found an intervention effect (**Table 7**). In the 3-group UV4.me trial by Heckman and colleagues (2016) of online education for young adults (n=965, 86% fair skin), the proportion of participants reporting red/painful sunburn in the past month decreased more markedly from baseline to 3 months in the intervention group compared to the other groups (54.5% to 26.3% in the intervention group; 51.5% to 38.2% in the public website group; 56.3% to 41.2% in the assessment-only control group, p=0.014 for intervention vs. assessment-only; NS for intervention vs. public website). 178

None of the trials among adults found statistically significant improvements in rates of sunburn following the intervention compared with control conditions.

Nevi/Skin Cancer

In the Check It Out trial promoting skin self-exam in adults recruited from primary care (n=1356; Weinstock et al., 2007), ¹⁸⁷ participants were asked to report if they had a skin procedure during the 12-month study period. For those reporting a procedure, patient medical records were examined to identify cancer outcomes, though no detail was provided on any efforts to identify skin cancer in people not reporting a skin procedure. No between-group differences in nevi or skin cancers were reported with few cases in general. In the intervention group (n=688, 55 reporting procedure at 0–6 months, 27 reporting at 6–12 months), one severely atypical nevi, seven basal cell carcinomas, three squamous cell carcinomas, and no melanomas were identified. In the control group (n=668, 24 reporting skin procedure at 0–6 months, 22 at 6–12 months), one severely atypical nevi, three basal cell carcinomas, four squamous cell carcinomas, and one melanoma were identified.

KQ2. Do Primary Care-Relevant Counseling Interventions Improve Skin Cancer Prevention Behaviors?

Sun Protection

One trial in young adults¹⁷⁸ and five adult trials^{173, 175, 177, 183, 188} found an intervention effect for sun protection behaviors, all reported as incremental changes in composite scores (**Table 8**). For example, in the good-quality Project SCAPE family study (Glanz et al., 2013) of mailed tailored materials, parents (n=1301, 68% white) in both intervention and minimal-intervention control groups saw improvements in sun protection behaviors at 4 months. Between-group differences favored the intervention group, but the effect size was small at 0.07 (1–4 scale: from 2.43 to 2.62 in the intervention group, from 2.39 to 2.53 in the control group, p=0.02).¹⁷³ In the Healthy Text study (2015) by Youl and colleagues (n=546, 65% fair skin, mean age 32), one intervention group received tailored sun protection-focused text messages and one received skin self-exam messages over 12 months; a control group received physical activity messages over the same time period. Both the sun protection message group and the skin self-exam-message group reported significant improvements in sun protection behaviors from baseline to 12-month followup compared to the attention-control group (1–4 scale where 2 is "sometimes" and 3 is "often": from 2.50 to 2.63 for sun protection group, p=0.032; from 2.50 to 2.63 for the skin self-exam group, p=0.05; from 2.46 to 2.50 in control group). ^{188, 192}

Interventions showing no effect on composite sun protection scores included a single session appearance-focused intervention with university students;¹⁸¹ the two trials including a single counseling and risk assessment session with a primary care physician, both conducted outside the U.S.;^{185, 186} a mailed intervention targeting multiple risk behaviors;¹⁸⁴ and two studies of tailored materials compared to generic materials: one among adult relatives of melanoma survivors¹⁸² and one among adults at increased skin cancer risk.¹⁷⁶

Effect sizes were reported inconsistently and were typically small, ranging from 0.07 for mailed materials¹⁷³ to 0.53 for the UV4.me tailored interactive web program (Heckman et al., 2016).¹⁷⁸ Our calculations of standardized effect sizes included 10 of the 12 studies reporting sun protection behaviors and suggested significant effect sizes for four studies; standardized effect sizes were similarly small, ranging from -0.46 (favoring control group) to 0.57 (favoring the intervention group), between 0.10 and 0.20 for most studies, and suggested a positive effect in only four studies. (Error! Reference source not found.)

Specific sun protection behaviors were reported in half (k=8) of the trials. Sunscreen use was the most commonly reported improved behavior, and increased in four of the seven trials assessing sunscreen use. ^{173, 178, 183, 184} However, only one study reported estimates of sunscreen use as the percentage reporting use in the past month (70.3% to 83.1% at followup¹⁷⁸). The other three used composite measures, and two of the three did not report any information on interpretation beyond direction of effect. ^{183, 184} The Project SCAPE family study (Glanz et al., 2013)¹⁷³ found marginal between-group differences at 4 months favoring the intervention group (1–4 scale, 2 is "sometimes," 3 is "often," and 4 is "always:" 3.06 in the intervention group and 2.94 in the minimal control group, p=0.04). No intervention effect was observed compared to control conditions for all four adult trials reporting time spent in the sun (n=2339)^{173, 175, 176, 186} (sun

protection was reported as improved in intervention versus control groups in two of these studies). The week, three studies found self-reported reductions in intentional outdoor exposure compared to control groups. Estimates of outdoor tanning practice at followup in efficacious interventions were 15.0 percent and 24.7 percent; and 90.7 percent for a measure of avoiding intentional UV exposure. Other specific behaviors reporting improvement were hat use and sunglasses use (1 study 175), shade seeking and limiting time in the sun (one study 173), and avoiding midday sun (1 study 183).

Indoor Tanning

Only one trial showed any indication of effect on indoor tanning rates. In the single-session, appearance-focused study of female university students already using indoor tanning (n=430; Hillhouse et al., 2008), mean indoor tanning sessions increased in both groups at 6 months, but between-group differences favored the intervention group (from 4.67 to 6.8 sessions in the intervention group; from 4.48 to 10.9 sessions in the control group, p<0.001).^{179, 193, 194} The UV4.me trial (Heckman et al., 2016) found no change in the proportion of participants reporting indoor tanning over 3 months, but reported rates were low in both groups (from 9.1% to 4.1% in the intervention group, from 9.3% to 5.9% in the public website group, and from 8.9% to 7.4% in the assessment-only control group, NS).¹⁷⁸ In the single study reporting indoor tanning outcomes in adults—which involved single-session PCP risk assessment and counseling (n=217; Rat et al, 2014)—there was no difference between the intervention and control groups in use of tanning beds over an unspecified time frame at 5 months (10.3% vs. 6.6%, NS).¹⁸⁵ However, this study was conducted in southwestern coastal regions of France over 5 months in summer, so low rates of indoor tanning may not be surprising.

Skin Self-Exam

Nine trials appeared to increase skin self-exam rates in adult populations over 3- to 13-month followup. ^{173-175, 177, 178, 180, 185, 187, 188} Of three interventions with skin self-exam-specific intervention messaging, all three found some effect favoring intervention conditions. 180, 187, 188 In the Check It Out trial (n=1356; Weinstock et al., 2007), total body skin self-exam increased between baseline and 12-month followup (from 18.0% to 55.0% in the intervention group, from 17.0% to 35.0% in the attention-control group, p<0.0001 at each time point); increases also were noted and sustained at 2 and 6 months. Number of body areas examined also was higher in the intervention group. 187 In the Healthy Text study (n=546; Youl et al., 2015), any skin self-exam increased more in the skin self-exam-focused text message group over 12-month followup compared to the attention-control group (from 36.9% to 63.2% in the skin self-exam group; OR 2.64, 95% CI 1.69 to 4.13, p=0.001), but total skin self-exam was similar across groups. The Skin Awareness Study (n=930; Janda et al., 2011) promoting skin self-exam in men over age 50 found increases in reported skin self-exam at 6 months in the intervention group compared to the minimal intervention control group, but by 13-month followup, rates of any, partial, and total skin self-exam were similar between groups. However, overall between-group effects for the course of the study remained statistically significant for partial skin self-exam and for any skin self-exam in intervention compared to control conditions. 180, 195 Among men reporting no history of skin excision at baseline (n=269, 29.0% of population), an intervention effect was observed for any skin self-exam (81.8% vs. 69.5% at 13 months, p=0.028). 180, 195

Our standardized estimates of odds of skin self-exam in intervention compared to control groups suggested similar, though somewhat more conservative findings. Of the nine studies that could be included, six maintained a significant impact favoring intervention. Odds ratios ranged from 1.16 (95% 1.04, 2.69) for a measure of any skin self-exam over 5 months¹⁸⁵ to 2.64 (95% CI 1.69 to 4.13) for any skin self-exam in the Healthy Text study promoting skin self-exam (Youl et al., 2015)¹⁸⁸ (Error! Reference source not found.).

KQ3. What Are the Harms of Counseling Interventions for Skin Cancer Prevention?

Two trials, both in adult participants (n=1573), reported potential harms of interventions (**Table 9**).

Number of Skin Procedures

The Check It Out trial (Weinstock et al., 2007) of counseling plus print materials and skin self-exam aids compared to minimal intervention (n=1356) assessed the number of participants reporting skin procedures (procedures not described) at 6- and 12-months followup. The proportion of participants reporting a procedure was significantly higher in the intervention group compared to the attention-control group at 6 months (p=0.0005): 55 participants (8.0%) in the intervention group compared to 24 participants (3.6%) in the control group. Between 6 and 12 months, the proportion reporting a procedure was similar between groups: 27 people (3.9%) in the intervention group versus 22 people (3.3%) in the control group (NS). As reported in KQ1, similarly few cases of atypical nevi, basal and squamous cell carcinomas, and melanoma were detected in both groups during the study period. ¹⁸⁷

Skin Cancer Worry

In the French study of PCP counseling with risk assessment and feedback compared to no intervention (n=217; Rat et al., 2014), a slightly higher proportion of adults in the intervention group versus control group reported worrying about developing melanoma, but this difference was not significant (28.9% vs. 18.4%, p=0.16). [185]

No included trials assessed vitamin D levels or paradoxically increased sun exposure accompanying sun protection behaviors. No studies with physical activity attention-controls suggested reduced physical activity in intervention participants. Of four trials reporting time spent in the sun at followup in intervention compared to control groups, no significant differences were observed. 173, 175, 176, 186

KQ4. What Is the Association Between Skin Self-Examination and Skin Cancer Outcomes?

We found no eligible RCTs, controlled trials or prospective cohort trials that evaluated the impact of skin self-exam on skin cancer or health outcomes. Although the Check It Out trial promoting skin self-exam (Weinstock et al., 2007) reported skin cancer outcomes, the impact was assessed according to intervention group, not according to practice of skin self-exam. The Skin Awareness trial in men over age 50 (Janda et al., 2011) reported skin cancer outcomes in a

followup paper, but was focused on the receipt of clinical skin exam and included 36.3 percent of the study population so was not included here. 196

KQ5. What Are the Harms of Skin Self-Examination?

We found no RCTs, controlled trials, or prospective cohort trials reporting the harms of performing skin-self exam that met our inclusion criteria.

Chapter 4 Discussion

Summary of Evidence

We included 21 trials that reported the impact of primary care-relevant behavioral interventions on skin cancer outcomes, sunburn, sun protection behaviors, and skin self-exam. The bulk of the evidence available was for the behavioral outcomes of sun protection behaviors and skin self-exam; evidence was much more limited for indoor tanning and for health outcomes. Most trials were of fair quality, and though there were several common intervention components across studies, measures were heterogeneous enough to preclude pooling of results. A summary of the evidence is located in Error! Reference source not found..

The evidence base has expanded substantially since the previous evidence review published in 2012: 14 of the 21 included studies are new since the previous evidence review. All nine studies reporting direct evidence for KQ1 are new since the previous review, as are all four studies of children aged 3–10, both studies of harms of interventions, and two of three studies of relatives of melanoma survivors. All studies assessing skin self-exam exclusively are new since the previous USPSTF evidence review on skin cancer screening.

Intermediate and Health Outcomes

All studies for KQ1 represent new evidence. Across nine fair- to good-quality pediatric and adult trials, the body of evidence suggests no consistent association between interventions and sunburn frequency in adults or children. In the single pediatric trial that suggested an intervention effect, it was for nonsevere sunburn only and not for more severe, blistering sunburns that are the hallmark risk factor for skin cancer later in life. One study in young adults suggested an intervention was associated with improvement in red or painful sunburns, but constitutes the only data for this age group. Baseline rates of sunburn were variable and low in some but not all populations (for example, in 4–10 year olds and their parents) so a floor effect may be possible in some studies.

The body of evidence for nevi or cancer outcomes is limited to two fair-quality studies. Based on one trial (n=867), an intervention promoting sun protection does not alter nevi counts in white children aged 3–10 over 3-year followup relative to controls. Based on another fair-quality trial among adults (n=1356), an intervention to promote skin self-exam is not associated with increased atypical nevi, non-melanoma skin cancer, or melanoma detection over 12 months compared to controls. No studies of sun protection-focused interventions among adults assessed skin cancer outcomes.

Studies were limited by short followup times (up to 3 years for children, up to 2 years for adults, 3–6 months in most studies), so it is possible that time frames were not sufficient to allow for observation of nevi or cancer events. However, sunburn outcomes would be observable within a relatively short study period, especially when outcome assessments occur at the end of summer, as most of these studies did.

Behavioral Outcomes

The current body of evidence builds on and supports the previous review's findings, adding evidence among children aged 3–10 from four new studies. Small to moderate effects of behavioral interventions on increased sun protection behaviors were observed in predominantly white or fair-skinned children aged 0–3, children aged 3–10, adolescents, young adults, and less consistently, adults compared to control populations. Though individual sun protection behaviors were inconsistently reported, sunscreen use was the most commonly improved behavior, followed by intentional sun exposure or outdoor tanning in adults and use of protective clothing in children. The clinical significance of these incremental increases in behaviors is unclear.

We found few consistent patterns according to age or population risk factors. Increased sun protection behaviors among intervention groups were observed relative to control groups in studies of all age groups, though overall, adult trial results were more mixed and fewer studies demonstrated an intervention effect. None of the trials among relatives of melanoma survivors (one in children and two in adults) found a significant effect on sun protection behavior, but the reasons for this are unclear. Family members of melanoma patients did not report higher levels of baseline sun protection behaviors relative to other included trials, except for sun avoidance in children in one study. Family members may be receiving skin cancer prevention information from multiple sources, or may require specific messaging. Study design limitations also may be a factor: two studies provided standard, non-tailored interventions to the control group and found increases in sun protection behavior in both groups. In the study of adult siblings of melanoma patients, the control group's "usual care" may have involved skin cancer screening, as melanoma patients were encouraged to invite their siblings to make screening appointments.

Intervention effects were not demonstrated for indoor tanning in young adults in two of three studies, but appearance-focused messages appeared to show an intervention effect in a single study of female university students who already were using indoor tanning. In the two studies finding no effect, baseline rates of indoor tanning were low; however, focusing solely on reducing indoor tanning may represent a missed opportunity for primary prevention.

Skin self-exam interventions were focused on adults, likely because skin cancer risk increases with increasing age. Relative to control conditions, interventions can increase rates of skin self-exam in young adults and adults. However, health benefits may be more likely if skin self-exam is repeated over time. No trial exceeded 12 months, and repeated measures were reported in only two trials with mixed results. One trial among men over age 50 (n=930) found that skin self-exam peaked at 6 months in the intervention group and returned to levels similar to the control group's at 12 months. The other study with repeated measures (n=1356) found sustained increases at 12 months.

Harms of Behavioral Interventions

Harms of behavioral interventions were rarely reported. Based on a single fair-quality trial, skin procedures may increase in the first six months after a skin self-exam-focused trial without a corresponding increase in cancer detection. Given the paucity of evidence for favorable association between skin self-exam and melanoma mortality or between skin self-exam

interventions (discussed in **Chapter 1**) and cancer detection (discussed in **KQ1**), increased biopsy resulting from skin self-exam remains a potential harm. However, there was insufficient evidence to draw firm conclusions.

No included trials reported evidence on paradoxically increased sun exposure accompanying sun protection behaviors, and no trials assessed vitamin D levels in participants. Skin cancer worry did not differ between groups at followup in one adult study focused on risk assessment and sun protection counseling, but baseline values for worry were not reported.

Observational Evidence on the Association Between Skin Cancer Prevention Behaviors and Health Outcomes

In the case of sparse data from trials on the direct link between interventions and health outcomes, assessment of observational evidence for associations between the behaviors that might result from interventions and health outcomes may help contextualize the findings. As a contextual question, we searched for new studies that would suggest different or more precise findings since those reported in the previous review and recommendation statement on UV exposure and skin cancer and other health outcomes, and between skin self-exam and skin cancer outcomes (described in **Chapter 1**).

UV Exposure and Health Outcomes

In its 2012 recommendation, the USPSTF found convincing evidence linking UV radiation exposure during childhood and youth to a moderately increased risk for melanoma later in life (range of OR 1.8-4.4); and for adults, adequate evidence linking recreational UV radiation exposure to an increase in melanoma risk (range of OR 1.3-5.0) based on case control and cohort studies of fair to good quality.^{2, 68} Our scan for more recent observational studies generally confirms this evidence. Overall, recent observational evidence provides even stronger evidence for the risks of indoor tanning use^{40, 69-79} and continued mixed evidence on the association between ambient sun exposure and melanoma development. 80-84 Followup data from a randomized trial included in the previous evidence review suggest a protective effect for sunscreen use and risk of invasive, but not in situ, melanoma development in adults. 85 One large population-based study, also confirming the previous evidence review's findings, found increased risk of both melanoma incidence and melanoma death with increasing quartile of UV exposure, but a beneficial association for increasing UV exposure quartile and reduced risk of several other cancers. 80, 84 Reduced physical activity and Vitamin D deficiency, potential harms of sun protection behavior, have not been detected in observational studies. Increased sunscreen use was associated with increased sunburns in cross-sectional studies, 96,97 suggesting a potential false reassurance pathway, but no included trials found evidence for this potential harm.

Reductions in UV exposure could prospectively reduce skin cancer risk. However, the best evidence would likely come from trials such as those included in this review, and no data beyond 3 years was available.

Skin Self-Exam and Health Outcomes

The 2009 USPSTF review on skin cancer screening found no new evidence on the effectiveness of either skin examination by a physician or skin self-exam in reducing the morbidity or mortality of skin cancer, but discussed one fair-quality case-control study. ^{4,5} A 20-year followup study of this same population published in 2016 found no beneficial association between skin self-exam and melanoma death. However, a more expansive measure of skin awareness did appear to be a significant independent predictor of melanoma death. As part of our systematic evidence review (KQs 4 and 5) we searched for trials or cohort studies examining the link between skin self-exam and health outcomes or harms and found no studies.

Intervention Considerations Across Age Groups

There were few patterns suggesting that specific intervention components, settings, or delivery inform intervention effectiveness. Interventions that found an effect on sun protection behaviors were typically, though not always, 12 months or longer, with more mail, phone, or virtual contact points with participants. Consistent with behavioral theory, this may suggest that higher intensity interventions or those that reinforce messages over time may improve intervention effectiveness. Interventions finding an effect were typically multi-component, with varying combinations of inperson counseling, phone counseling, virtual contact, print media, video, and sun protection aids or skin self-exam aids. The impact of physician counseling was difficult to assess. The two pediatric studies involving physician counseling also included other components such as print materials and sunscreen samples, and found improvements in sun protection behaviors relative to controls, but the two adult studies involving physician counseling—both single session interventions—found no intervention effect.

The two trials using solely electronic intervention delivery methods were effective for improving multiple behaviors compared to control conditions: one year of text messages and a self-administered online interactive education program improved sun protection, outdoor tanning, and skin self-exam. Similarly, the single study that focused on both parent and child sun protection behaviors also found an intervention effect for sun protection behaviors. If confirmed in other studies, family-focused and electronically-delivered interventions, perhaps combined with inperson counseling may represent promising approaches for future interventions.

In most trials of pediatric and adult populations, outcome assessments were timed to coincide with the end of summer or fall, which increases recall potential for recent summer behavior. However, most trials also found that sun protection and sunburn increased in both intervention and control groups between baseline and followup assessments. This likely highlights seasonal fluctuations in sun protection behaviors, and demonstrates the importance of including control groups. However, since many studies used minimal or non-tailored interventions for control groups, the effect of these comparison interventions, and therefore the precise impact of the main intervention, cannot adequately be assessed.

Applicability to U.S. Health Care

In general, study populations were likely applicable to white or fair-skinned U.S. primary health care populations. All six pediatric studies and eleven of 16 adult studies were conducted in the United States. Most participants were white, representing the population with the highest risk of melanoma. However, it is unknown whether these findings also apply to people of color, who have less favorable skin cancer mortality outcomes compared with fair-skinned populations. From the limited information reported, a fairly broad representation of socioeconomic status was present in the included study populations. Most pediatric studies' interventions were focused primarily on parents as the primary facilitator of their child's skin cancer prevention behavior. Although one study intervened directly with adolescents age 11-15, overall the findings may be most applicable to younger children.

All intervention components are theoretically implementable from or referable from primary care, though the ability of individual clinicians and practices to initiate intervention components likely varies widely. Single-session risk assessment and physician counseling may be the most easily translated into clinical practice, though no intervention effect was noted for this very low-dose intervention based on two non-U.S. studies. Components such as extended mailed interventions or text messaging campaigns may be more difficult to implement in clinical practice, though may be more easily implemented if non-physician team members are involved.

These findings should be interpreted in the context of prevalent cultural messaging about skin cancer prevention. Many people may be first exposed to sun protection messages, particularly around sunscreen use, in their daily lives rather than in a clinical encounter. Multi-component or multi-level strategies increasingly are considered best practice for cancer prevention interventions; ^{156, 197, 198} important target areas may include policy and community-level or occupational interventions, such as mass media campaigns, built environments to increase shaded areas, or free sunscreen dispensers at public beaches. ^{155, 156, 199, 200}

Limitations of Included Studies

We found few studies focused on adolescents, young adults or parents of children under age 3. Men over age 50, who as a group have the highest skin cancer risk, were the focus of only a single study. Evidence on health outcomes was limited.

In general, included trials were well-conducted, with adequate study designs that tested interventions developed with a theoretical basis and reporting some measure of practitioner training, intervention fidelity and/or adherence. All trials focused either on at-risk populations or included a tailoring component, allowing specific messaging for participants. Most studies reported seasonal considerations of intervention design, timing, and outcome assessment. However, several limitations should be considered. First, the widespread use of composite measures for behavioral outcome assessment represents a limitation with respect to efforts to assess links between interventions and clinical outcomes. While a composite measure may ease understanding of a series of behaviors that are likely practiced in concert (for example, sunglasses, sunscreen, and hat use) and small changes are likely encouraging, an incremental

change of a fraction of a point on a scale is more challenging to interpret clinically. Further, there was considerable heterogeneity in the types of scales used, the level of adaptation of existing measures, time frames assessed within items, and length of followup. Second, very few studies reported frequencies or absolute values that would allow assessment of behavior change over time or meta-analysis. Third, behavioral outcomes were assessed via self-report, introducing inherent response biases. Social desirability bias is possible; participants in either group might give a response they feel would be received favorably. Self-reported measures are also dependent on accurate participant recall, which can fluctuate even over very short time periods.

Included trials also had limitations with respect to reported health outcomes data. Given that skin cancer can take 10-20 years to develop, detecting improvements in skin cancer outcomes may have limited feasibility. Sunburn was assessed via heterogeneous self-reported measures and therefore was subject to bias. Direct observation of sunburn may be possible but is challenging to measure because of its impermanence and may require specialized equipment for true objective measurement. In the single study that looked at skin cancer outcomes, no confirmation with pathology reports was mentioned; further, the authors reported no attempt to identify skin cancer outcomes in people not reporting a skin procedure.

Limitations of Our Approach

We only included interventions that were conducted in or referable from primary care, and excluded both multilevel interventions in which the impact of a primary care component could not be assessed and populations of current survivors of skin cancer. We did not include interventions taking place in worksites, schools, or other community settings, since those are reviewed by the Community Preventive Services Task Force. Thus we are unable to assess the impact of primary care-relevant interventions relative to interventions in other contexts.

We limited our review to randomized trials and controlled trials. We were limited by the heterogeneity of the measures reported, and chose not to pool results. We were able to calculate standardized effect sizes for only a subset of studies. We limited our assessment of harms to those reported in included interventions. We excluded outcomes of attitudes, intentions, barriers, self-efficacy and other psychosocial measures that may mediate or moderate the impact of interventions; we acknowledge that these measures reflect attention to the theoretical mechanisms through which interventions can impact behavior. We did not analyze message framing (for example, gain or loss frame) or nuanced differences between messages beyond what was reported by trial authors.

Future Research Needs

Interventions focused on skin cancer prevention in young adults, who are most likely to practice indoor or outdoor tanning, are needed. Interventions that demonstrate increased sun protection practices in relatives of melanoma survivors, another population at increased risk of melanoma, represent a gap in the body of evidence. Studies of multilevel interventions with a primary care component, designed to allow assessment of the primary care component, also would strengthen

the body of evidence. In particular, studies that explore a primary care role in counseling frequent users of indoor tanning would provide valuable evidence given that indoor tanning behavior may have an addictive component. Studies of racially and ethnically diverse populations are needed, as are studies intervening with adolescents, young adults, and parents of preschool children.

The body of evidence would be strengthened by studies of sufficient power to observe longer-term health outcomes in trial cohorts, particularly those with interventions focused on promoting sun protection behavior, and by measures of maintenance of sun protection behaviors after trial completion. Ideally, measurement of sun exposure, sunburn, precursor lesions, and cancer should be objective and thoroughly reported. Studies with behavioral outcomes would be strengthened by use of standardized measures, frequency measures in addition to scales, and by complete and transparent reporting of unadjusted data. Investigations into the potential harms and benefits of skin self-exam, ideally using standardized measures, would further strengthen the body of evidence.

A summary of current ongoing studies is provided in **Appendix** C. Studies of mobile and electronic methods of intervention delivery increasingly are being conducted;²⁰¹ evidence on how these interventions, if successful, can be integrated and maintained in primary care settings also will provide relevant evidence.

Conclusion

The body of evidence on the impact of behavioral interventions has increased substantially since the previous review and generally reaffirms its findings, adding limited new evidence on intermediate and health outcomes and for behavioral outcomes in children aged 3–10. The current evidence base suggests that behavioral interventions can increase sun protection behavior in both pediatric and, less consistently, in adult populations; but the clinical significance of these increases is unclear. There is no consistent evidence that interventions are associated with improved sunburn frequency in children or adults. Interventions can increase skin self-exam in adults relative to control conditions, and may lead to increased skin procedures without detecting additional atypical nevi or skin cancers.

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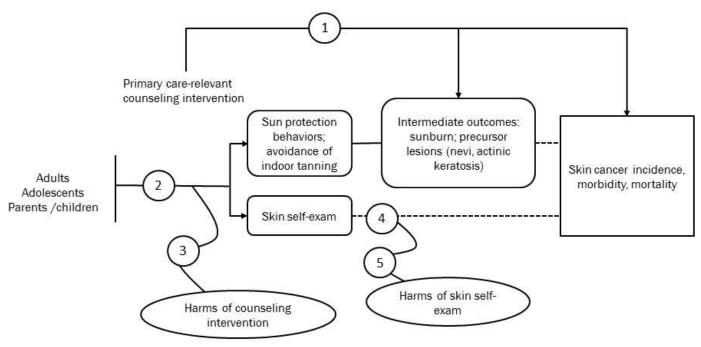
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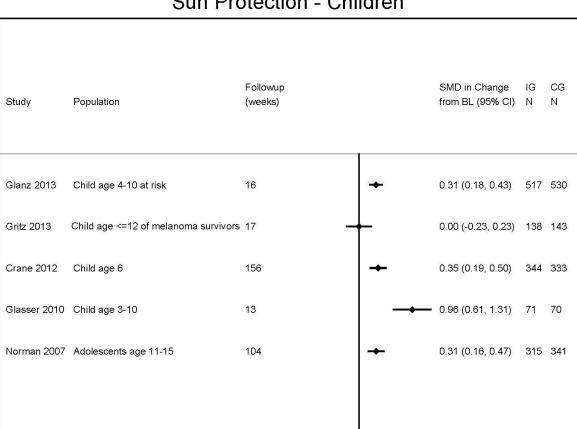
Figure 1. Analytic Framework and Key Questions



- Does counseling patients in skin cancer prevention improve a) intermediate outcomes (sunburn or precursor lesions) or b) skin cancer outcomes (melanoma, squamous cell, or basal cell carcinoma incidence, morbidity, or mortality)?
- Do primary care—relevant counseling interventions improve skin cancer prevention behaviors (e.g., reduced sun exposure, sunscreen use, use of protective clothing, avoidance of indoor tanning, and skin self-examination)?
- 3. What are the harms of counseling interventions for skin cancer prevention (e.g., increased time in the sun, reduced physical activity, vitamin D deficiency, and anxiety)?
- 4. What is the association between skin self-examination and skin cancer outcomes (melanoma, squamous cell, or basal cell carcinoma incidence, morbidity, or mortality)?*
- 5. What are the harms of skin self-examination?*

^{*}Key Questions (KQs) 4 and 5 will only be addressed systematically if there is sufficient evidence from KQs 1 to 3 that behavioral counseling increases skin self-examination behavior.

Figure 2. Standardized Mean Difference of Sun Protection Composite Scores in Children (KQ2)



Sun Protection - Children

(20 Dec 2016 - Cohen's d Standardized Mean Differences)

Abbreviations: SMD = standardized mean differences; BL = baseline; IG = intervention group; CG = control group

Note: Five of six trials are included in this forest plot. Studies differ in terms of study population, length of followup and composite scores. Crane 2006 was not included in forest plot because people were recruited at birth and therefore had no baseline data.

-1.31

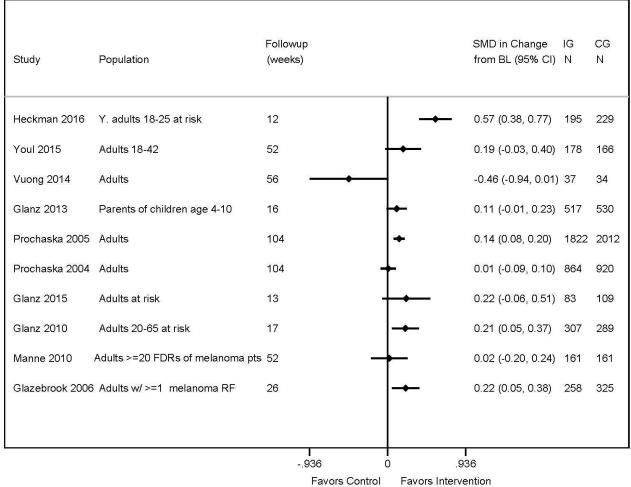
Favors Control

1.31

Favors Intervention

Figure 3. Standardized Mean Difference of Sun Protection Composite Scores in Adults (KQ2)

Sun Protection - Adults

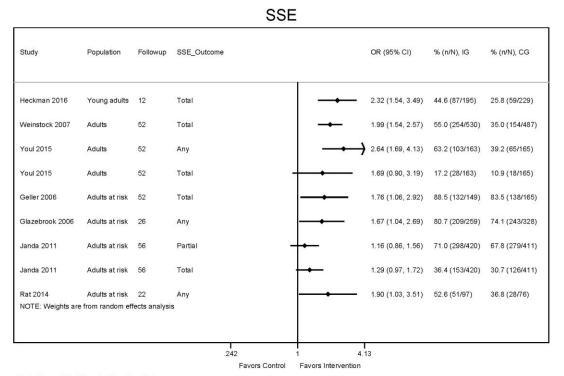


(20 Dec 2016 - Cohen's d Standardized Mean Differences)

Abbreviations: SMD = standardized mean differences; BL = baseline; IG = intervention group; CG = control group

Note: Ten of twelve trials reporting sun protection composite scores are included in this forest plot. Studies differ in terms of study population, length of followup and composite scores. One study was excluded from forest plot due to differences in outcomes reported.

Figure 4. Odds of Conducting Skin Self-Exam in Adults (KQ2)



(14 Dec 2016 - Odds Ratio)

Abbreviations: SSE = skin self-exam, OR = odds radio, IG = intervention group, CG = control group

Note: Seven of 11 studies are included in this forest plot. Studies differ in terms of study population, length of followup and type of skin self-exam (total, any, partial). Four studies were excluded from forest plot due to differences in outcomes reported.

Table 1. Description of Included Trials

Trial (k=21)	Country	Population	N Randomized	% Followup	Followup (months)	% Female	Age, Mean (SD) or Category,	Skin Cancer Risk Factors (%)	SES Indicators	Included for KQ(s)	
Children and			11411401111204	Топонтир	(monune)	1 Omaio	,0	1 401010 (70)	(70)	10. 114(0)	1011011
Crane 2006 ¹⁶⁸ Fair Kaiser Kids Sun Care	USA	Children age <1	728	75.3	36	49.7	0-6 mo	White: 81.9 (fair white skin: 43.7) Blonde/red hair: 20.3 Blue/grey eyes: 74.9	College degree or more: 42.4 Income ≥\$75K/yr: 16.1	2	X
Crane 2012 ¹⁷² Fair	USA	Children age 6	867ª	70.8	36	52.5	6 (NR)	White: 100.0 (fair white skin: 51.8) Blonde/red hair: 72.3 Blue eyes: 48.7 Painful burn/no tan: 12.1	College degree or more: 75.1 Income ≥\$100K/yr: 35.7	1, 2	
Glanz 2013 ¹⁷³ Good Project SCAPE (family)	USA	Children ages 4-10 at increased skin cancer risk	1301	80.5	4	49.0	7.1 (1.1)	White: 65.6 High skin cancer risk: 38.3 ^b Moderate skin cancer risk: 61.7 ^b	College degree or more: 40.2 Married or partnered: 88.7 Employed full-time: 42.7 Income ≥\$40K/yr: 73.0	1, 2	
Glasser 2010 ¹⁶⁹ Fair Sun Sense	USA	Children ages 3-10	197	71.6	3	48.2	3-4: 33.5 5-7: 34.0 8-10: 30.5	White: 44.7	NR	2	
Gritz 2013 ¹⁷⁰ Fair	USA	Children (age ≤12) of melanoma survivors	340	83.0	4	49.1	7.3 (3.9)	White: 98.2 Sun sensitivity: 2.29 (0.69) ^c Family history of skin cancer: 100.0	College degree or more: 78.2 Married: 91.5	1, 2	
Norman 2007 ^{171,190,191} Fair SunSmart	USA	Adolescents ages 11-15	819	80.1	24	53.5	12.7 (1.3)	White: 58.4 High skin sensitivity: 25.2 ^d Moderate skin sensitivity: 44.0 ^d	College degree or more: 66.4	2	X
Adults and yo								-			1
Geller 2006 ¹⁷⁴ Fair	USA	Adult (age ≥18) siblings of melanoma patients	494	63.6	12	53.4	18-50: 58.3 ≥51: 41.7	White: 100.0 (fair skin: 84.8) Family history of skin cancer: 100.0	At least some college: 76.8 Health insurance: 96.0 Has PCP: 86.0	2	X

Table 1. Description of Included Trials

	Country		N Randomized	% Followup	Followup (months)	% Female	Age, Mean (SD) or Category,	Skin Cancer Risk Factors (%)	SES Indicators (%)	Included for KQ(s)	In previous review
Glanz 2010 ¹⁷⁵ Fair Project SCAPE (adult)		Adults ages 20-65 at increased skin cancer risk	724	82.3	4	77.5	41.7 (11.0)	White: 80.2 High skin cancer risk: 36.6 ^b Moderate skin cancer risk: 63.4 ^b	College degree or more: 47.5 Income ≥\$40K/yr: 63.5		
Glanz 2013 ¹⁷³ Good Project SCAPE (family)		Parents of children ages 4-10	1301	80.5	4	>90.0	NR	White: 68.2	College degree or more: 40.2 Married or partnered: 88.7 Employed full-time: 42.7 Income ≥\$40K/yr: 73.0		
Glanz 2015 ¹⁷⁶ Fair PennSCAPE	USA	Adults (age range 18- 91) at increased skin cancer risk	206	93.2	3	73.4	55.2 (15.2)	White: 100.0 High skin cancer risk: 60.9b Moderate skin cancer risk: 39.1b NMSC personal history: 15.6 Family history of skin cancer: 43.2	College degree or more: 70.5 Married or partnered: 68.1 Employed: 57.8 Income >\$80K/yr: 60.7	·	
Glazebrook 2006 ¹⁷⁷ Fair Skinsafe	UK	Adults with ≥1 melanoma risk factor	589	77.9	6	80.3	38.3 (14.8)	NR°	College degree or more: 52.5 Professional/ nonmanual job: 41.3	2	X
Heckman 2016 ¹⁷⁸ Fair UV4.me	USA	Young adults ages 18-25 at increased skin cancer risk	965	65.2	3	66.1	21.8 (2.2)	White: 85.7 Fair skin: 86.3 High/moderate skin cancer risk: 100.0 ^b Family history of skin cancer: 35.2	College degree or more: 22.1 Employed full- time: 18.1 Receives public assistance: 18.8	1, 2	
Hillhouse 2008 ^{179,193,194} Fair	USA	University students ages 17-21 who use indoor tanning	430	95.8	6	100.0	18.6 (0.8)	Always burns, never tans: 7.4 ^f Usually burns, then tans: 23.5 ^f	Family SES "about average": 55.5	2	X

Table 1. Description of Included Trials

Trial (k=21)	Country	Population	N Randomized	% Followup	Followup (months)	% Female	Age, Mean (SD) or Category,	Skin Cancer Risk Factors (%)	SES Indicators (%)	Included for KQ(s)	
Janda 2011 ^{180,195} Fair Skin awareness study	Australia	Adult men ages 50-90	930	89.5	13	0.0	50-90: 100.0%	Fair/very fair skin: 62.3 Red/fair/blonde hair: 27.0 Blue/grey eyes: 46.6 High skin sensitivity: 6.19	College degree or more: 22.6 Employed full- time: 41.8 Income >\$80K/yr: 25.0 Rural: 49.0		
Mahler 2007 ¹⁸¹ Fair	USA	Adult university students ages 18-44	133	80.0	12	80.5	20.1 (3.4)	White: 45.0 Family history of skin cancer: 27.1	College students: 100.0	2	Х
Manne 2010 ¹⁸² Fair	USA	Adult (age ≥20) FDRs of melanoma patients	443	72.7	12	63.0	47.6 (13.2)	White: 98.2 Family history of skin cancer: 100.0	College degree or more: 62.1 Married: 70.4 Income ≥\$140K/yr: 16.2 Health insurance: 93.8	2	
Prochaska 2005 ¹⁸³ Fair	USA	Adults	5407	74.0	24	69.9	44.7 (12.7)	White: 96.7	Education, mean yrs: 14.5± 3.2	2	X
Prochaska 2004 ¹⁸⁴ Fair	USA	Adults	2460	68.9	24	75.0	42.5 (5.5)	White: 92.0	Education, mean yrs: 14.0±3.2 Married or partnered: 80.0	2	Х
Rat 2014 ¹⁸⁵ Fair Coparime	France	Adults at increased melanoma risk	217	79.7	5	76.0	43.2 (16.1)	High skin cancer risk: 100.0 ^h	College degree or more: NR ⁱ	1, 2, 3	
Vuong 2014 ^{186j} Fair	Australia	Adults age ≥18	108	70.0	13	59.0	<50: 59.0 ≥50: 41.0	High skin cancer risk: 76.0 ^b Moderate skin cancer risk: 18.0 ^b	College degree or more: 70.0 Married or partnered: 63.0	2	
Weinstock 2007 ¹⁸⁷ Fair Check It Out	USA	Adults age ≥18	1356	66.4	12	58.3	53.2 (14.8)	High skin cancer risk: 24.0 ^b Moderate skin cancer risk: 36.0 ^b	College degree or more: 38.0 Employed: 61.0	1, 2, 3	

Table 1. Description of Included Trials

Trial (k=21)	Country	Population	N Randomized	% Followup	Followup (months)		Age, Mean (SD) or Category, %	Skin Cancer Risk Factors (%)	SES Indicators (%)	Included for KQ(s)	•
Youl 2015 ^{188,192} Good Healthy Text	Australia	Adults ages 18-42	546	93.7	12	67.4	31.9 (6.2)	Fair or very fair skin: 65.8 Red hair: 4.0 Blue/gray eyes: 37.0 Tending to burn not tan: 26.0 Never tans: 15.0	College degree or more: 71.4 Married or partnered: 70.1 Employed full- time: 57.3 Private health insurance: 64.8	1, 2	

^a Crane 2012 randomized 867 participants but only reported results for white non-Hispanic participants (n=677). The authors report that results for white non-Hispanic participants were similar to results for all participants.

Abbreviations: k=number of studies; SD=standard deviation, SES=socioeconomic status, KQ=key question, NR=not reported, PCP=primary care provider, NMSC=nonmelanoma skin cancer, FDR=first-degree relative, yr=year.

^b As assessed by the brief skin cancer risk assessment tool (BRAT), which includes questions about family history, number of large moles, freckles, and sun sensitivity (skin color, natural hair color, ease of tanning, burning).

^c Mean (SD). Sun sensitivity index computed from questions on eye color, hair color, and skin; scores range from 1 (high sensitivity) to 4 (low sensitivity)

d Skin sensitivity determined by previously validated instrument with scores ranging 1-10 based on skin reaction to sun, untanned skin color, and hair color.

e In intervention practices, patients invited to participate in IG if they had ≥1 characteristic identified by research as a risk factor for melanoma (red hair, multiple moles, history of sunburn as a child, freckling, family history of melanoma, fair sun-sensitive skin). CG participants selected to match skin and demographic profile of IG participants.

f Study reports Fitzpatrick skin types: type I (always burns, never tans): 7.4%; type II (usually burns, then tans): 23.5%; type III (may burn, tans well): 40.8%; type IV (rarely burns, tans well): 25.8%; type V (very rarely burns, tans well, brown skin): 2.4%.

⁹ Defined as never tanning, only burning or freckling.

h Assessed via the Self-Assessment Melanoma Risk Score (SAMscore). Domains of SAMscore are skin type, freckles, moles, severe blistering sunburn in childhood, lived more than 1 year in high-sunshine country; personal history.

Study reports there were no significant differences between IG and CG for highest level of education attained.

^j The Vuong 2014 study was a controlled clinical trial (not randomized) of patients attending either an intervention clinic or a control clinic. All other included studies were randomized clinical trials or cluster randomized clinical trials.

Table 2. Summary of Outcomes Assessed, by Study

	N randomized	% White	Followup (months)	KQ1 Sunburn	KQ1 Nevi/ cancer	KQ2 Sun	KQ2 Sunscreen	KQ2 Indoor tanning	KQ2 SSE	KQ3 Harms
Children and adolescents					I.					l .
Crane 2006 ¹⁶⁸ (Kaiser Kids Sun Care)	728	81.9	36			Х	Х			
Crane 2012 ¹⁷²	867	100.0	36	X	X	X	X			
Glanz 2013 ¹⁷³ (Project SCAPE [family], children)	1301	65.6	4	Х		Х	Х		Х	
Glasser 2010 ¹⁶⁹ (Sun Sense)	197	44.7	3			X	X			
Gritz 2013 ¹⁷⁰	340	98.2	4	X		X	X			
Norman 2007 ^{171, 190, 191} (SunSmart)	819	58.4	24			Х	Х			
Adults and young adults	1		1		1	ı.	u.		Į.	
Geller 2006 ¹⁷⁴	494	100.0	12				X		Х	
Glanz 2010 ¹⁷⁵ (Project SCAPE [adult])	724	80.2	4	Х		Х	Х		Х	
Glanz 2013 ¹⁷³ (Project SCAPE [family], parents)	1301	68.2	4	Х		Х	Х		Х	
Glanz 2015 ¹⁷⁶ (PennSCAPE)	206	100.0	3	Х		Х	Х		Х	
Glazebrook 2006 ¹⁷⁷ (Skinsafe)	589	NR	6			X			Х	
Heckman 2016 ¹⁷⁸ (UV4.me)	965	85.7	3	X		X	X	X	X	
Hillhouse 2008 ^{179, 193, 194}	430	NR	6					Х		
Janda 2011 ^{180, 195} (Skin awareness study)	930	NR	13	•	•	•	•	-	Х	
Mahler 2007 ¹⁸¹	133	45.0	12			X				
Manne 2010 ¹⁸²	443	98.2	12			Х			Х	
Prochaska 2004 ¹⁸⁴	2460	96.7	24			X	X			
Prochaska 2005 ¹⁸³	5407	92.0	24			X	X	-		
Rat 2014 ¹⁸⁵ (Coparime)	217	NR	5	X		X		X	Χ	X
Vuong 2014 ^{186a}	108	NR	13			X				
Weinstock 2007 ¹⁸⁷ (Check It Out)	1356	NR	12		Х				Х	Х
Youl 2015 ^{188, 192} (Healthy Text)	546	NR	12	X		X			X	

[&]quot;X" indicates outcome was assessed; "." Indicates outcome was not assessed

Abbreviations: k=number of studies, KQ=key question.

^a The Vuong 2014 study was a controlled clinical trial (not randomized). All other included studies were randomized clinical trials or cluster randomized clinical trials.

Table 3. Description of Interventions, by Population

Trial	Study name	N randomized	Population	Intervention component (number of sessions/mailings)	Intervention length	Linked to primary care	Counseling	SSE or SPB aids	Tailored feedback	Comparison
Children a	and adolesce					00.10				
Crane 2006 ¹⁶⁸	Kaiser Kids Sun Care	728	Children age <1	PCP counseling (4); print materials for parents promoting child sun protection (4); sunscreen samples; hat	36 mo	X	X	X		Usual care
Crane 2012 ¹⁷²		867	Children age 6	Tailored mailings (14): newsletters for parents/ children promoting child sun protection	36 mo	X			X	Assessment only
Glanz 2013 ¹⁷³	Project SCAPE (family)	1301	Children ages 4-10 at increased skin cancer risk	Tailored mailings (3) for parents promoting children's and parents' sun protection	1 mo				X	Minimal intervention (standard mailing)
Glasser 2010 ¹⁶⁹	Sun Sense (Slip Slop Slap)	197	Children ages 3-10	In-person parent education (1); materials (children's video, print materials); sun protection aids (shirt, hat, sunscreen)	1 day	X	X	X		No intervention (plain T-shirt only)
Gritz 2013 ¹⁷⁰		340	Children (age ≤12) of melanoma survivors	Standard mailings (3) promoting sun protection; print materials, DVD; children's activities	5 mo					Minimal intervention (standard mailing)
Norman 2007 ¹⁷¹ , 190, 191	SunSmart	819	Adolescents ages 11-15	PCP counseling using tailored risk information (1); phone counseling (4); mailed materials promoting sun protection; sunscreen samples	18 mo	X	X	X	X	Attention control (physical activity)
	d young adul					1	1			
Geller 2006 ¹⁷⁴		494	Adult (age ≥18) siblings of melanoma patients	Health educator phone counseling (4); mailed print materials (3) promoting sun protection and SSE	5 mo		X		X	Usual care

Table 3. Description of Interventions, by Population

Trial	Study name	N randomized	Population	Intervention component (number of sessions/mailings)	Intervention length	Linked to primary care	Counseling	SSE or SPB aids	Tailored feedback	Comparison
Glanz 2010 ¹⁷⁵	Project SCAPE (adult)	724	Adults ages 20-65 at increased skin cancer risk	Tailored mailings (3) promoting sun protection and SSE; SSE aids	1 mo	X	3	X	X	Minimal intervention Mailed nontailored materials 1x
Glanz 2013 ¹⁷³	Project SCAPE (family)	1301	Children ages 4-10 at increased skin cancer risk	Tailored mailings (3) for parents promoting children's and parents' sun protection	1 mo				X	Minimal intervention (standard mailing)
Glanz 2015 ¹⁷⁶	PennSCAPE	206	Adults (age range 18-91) at increased skin cancer risk		1.5 mo	X		X	X	Minimal intervention (standard mailings)
Glazebrook 2006 ¹⁷⁷	Skinsafe	589	Adults with ≥1 melanoma risk factor	Interactive online program (1) with tailored feedback promoting sun protection and SSE	1 day	Х			X	Usual care
Heckman 2016 ¹⁷⁸	UV4.me	965	Young adults ages 18-25 at increased skin cancer risk	IG1: Tailored interactive web program (12 modules) IG2: Public website	NA				X	Assessment only
Hillhouse 2008 ^{179,} 193, 194		430	Female university students ages 17-21 who use indoor tanning	Standard print materials (1) promoting appearance-based alternatives to indoor tanning	1 day					Assessment only
Janda 2011 ^{180, 195}	Skin awareness study	930	Adult men ages 50-90	Standard mailing (1) promoting SSE (video, SSE aids; print materials); reminder postcards	1 mo			X		Minimal intervention SSE guide Print materials
Mahler 2007 ¹⁸¹		133	Adult university students ages 18-44	Facial photos of participant with simulated sun damage (1); appearance-focused video promoting sun protection (1)	1 day				X	Assessment only

Table 3. Description of Interventions, by Population

Trial	Study name	N randomized		Intervention component (number of sessions/mailings)	Intervention length	Linked to primary care	Counseling	SSE or SPB aids	Tailored feedback	Comparison
Manne 2010 ¹⁸²		443	Adult (age ≥20) FDRs of melanoma patients	Tailored mailings (3) promoting sun protection and SSE; phone counseling (1)	1.5 mo		X		X	Minimal intervention Mailed nontailored materials 3x Informational phone call 1x
Prochaska 2005 ¹⁸³		5407	Adults	Tailored mailings (3) promoting sun protection	12 mo	Х			Х	Assessment only
Prochaska 2004 ¹⁸⁴		2460	Adults	Tailored mailings (3) promoting sun protection	12 mo				Х	Assessment only
Rat 2014 ¹⁸⁵	Coparime	217	Adults at increased melanoma risk	PCP counseling using tailored feedback (1)	1 day	X	X		X	Assessment only
Vuong 2014 ¹⁸⁶		108	Adults age ≥18	PCP counseling using tailored feedback; print materials (1)	1 day	X	X		X	Assessment only
Weinstock 2007 ¹⁸⁷	Check It Out	1356	Adults age ≥18	Study team counseling (2); materials promoting SSE (print, video); SSE aids; tailored letter (1)	6 mo	X	X	X	X	Attention control (diet)
Youl 2015 ^{188, 192}	Healthy Text	546	Adults age 18-42	IG1: Tailored text messages promoting sun protection (21) IG2: Tailored text messages promoting SSE (21)	12 mo		004		X	Attention control (physical activity)

Abbreviations: SSE=skin self-exam, SPB=sun protection behavior, PCP=primary care provider, mo=months, CG1=control group 1, CG2=control group 2, 1x=one time, 3x=3 times, FDR=first-degree relative, IG1=intervention group 1, IG2=intervention group 2.

Table 4. Detailed Intervention Descriptions, by Population

Study	Population	Intervention description	Comparison group description	Theoretical basis
Children and		intol volution accompation	ucconputer:	THICOTOLICAL DAGIO
Crane 2006 ¹⁶⁸ Kaiser Kids Sun Care	Children age <1 (through parents)	In the single study focused on children age 0-3, the intervention was primary-care based. In intervention group clinics, the study placed prompts in each child's medical record to discuss sun protection at 2, 6, 18, and 36 months; providers were given materials and asked to provide them to parents at well-child visits. Materials included education materials and sunscreen samples; a child sun hat and sunglasses were also given. Exit interviews from a subsample of study participants suggested that the intervention components were delivered successfully approximately 40%-75% of the time; the lowest reported component was discussion of protective clothing (29%-44% of parents reporting PCP discussed).	Control group clinics practiced usual care, though all clinics received regular information about the study at departmental meetings. Parents in both groups were assessed via survey at baseline, 1, 2, and 3 years.	НВМ
Crane 2012 ¹⁷²	Children age 6 (through parents)	In this primary care-linked, home-based study, parents received 14 newsletters over 3 years. Newsletters were mailed each spring in 2-week intervals; most were aimed at parents, but mailings in years 2 and 3 included material for children. Early mailings contained review of skin cancer and its causes; later mailings included tailored information specific to each child, sun protection strategies for reducing risk, and suggestions for overcoming barriers. Newsletters contained interactive materials, and were written at a 6th grade or below reading level. Newsletters for children included age appropriate information and activities. All newsletters were pilot tested. Skin exams were conducted each summer, (setting not reported); parents also received a report with of the number of nevi counted.	Control group parents participated in data collection only; those that completing skin exams received a written report of the results.	PAPM
Glanz 2013 ¹⁷³ Project SCAPE (families)	Children ages 4-10 at increased skin cancer risk; parents of children ages 4-10	The Project SCAPE family trial, which built on the earlier adult trial (Glanz 2010 ¹⁷⁵), recruited children and their parents from a convenience sample of schools and recreation programs in Hawaii and Long Island. The intervention consisted of three packets mailed at 2-week intervals containing personalized risk feedback and recommendations, interactive skin cancer education materials, a family fun guide (containing games and stories about safe sun practices for parents and kids to complete together), suggestions for overcoming barriers, and reminders to engage in preventive practices. [Both child and parent outcomes are reported and included in this report.]	The comparison group received a single mailing containing a non-tailored, publicly available skin cancer prevention brochure for children, a tip sheet on sunscreen, hats, shade and shirts, and a bookmark encouraging child skin examination.	HBM, SCT
Glasser 2010 ¹⁶⁹ Sun Sense	Children ages 3-10	In the Sun Sense study, parent-child pairs were approached in the waiting room of a pediatric clinic waiting room. Intervention group parents received a 10-15 minute presentation from a public health graduate student; children were included when age-appropriate. The presentation discussed the prevalence of skin cancer, its relationship to sun exposure, and promoted 3 sun protection practices (shirt, sunscreen, hat). Families received a takehome package, including a video for children with "Slip Slop Slap" messaging, a shirt, a bucket hat, a large container of broad-spectrum sunscreen, and a brochure from the American Academy of Dermatology.	The comparison group received no intervention and participated in assessments only.	Health Behavior Framework (SCT, TPB, HBM, TTM, Social Influence Theory)

Table 4. Detailed Intervention Descriptions, by Population

Study	Population	Intervention description	Comparison group description	Theoretical basis
Gritz 2013 ¹⁷⁰	Children (age ≤12) of melanoma survivors	In this mailed-intervention study, parents in the intervention group (who were all melanoma patients) received three mailings sent over 5 months. Each mailing contained both print materials and either a 10 minute DVD (first mailing); magnet (second mailing); or a children's activity booklet (third mailing). The DVD showed melanoma survivors and their families discussing the importance of child sun protection, including overcoming barriers. The booklets contained testimonials from melanoma survivors, sun protection expectations and why/how they protect their children. The children's activity booklet contained puzzles, songs, and quizzes about sun protection.	Parents in the control group, also melanoma patients, received publicly available brochures in the same mailing schedule. Brochure topics were sun protection, physical activity and nutrition.	HBM, SCT
Norman 2007 ^{171,190,191} SunSmart	Adolescents ages 11-15	In the SunSmart study, adolescents were recruited through 45 primary care providers from 6 clinics in southern California. At baseline and 12 months, Adolescents in the intervention group participated in a 20-minute computer-based assessment before their primary care appointment, which generated a tailored feedback report on the adolescent's stage of change and self-efficacy provided to both the adolescent and their physician. The physician provided brief counseling (2-3 min) counseling based on the report. At 3, 6, 15, and 18 months the adolescent received phone assessments with a health counselor followed by mailings including tailored feedback from phone sessions, tip sheets, and sunscreen samples.	The control group was an attention control, with a similarly structured intervention focused on adoption and maintenance of physical activity and healthy eating behaviors.	ТТМ
Adults and yo Geller	Adult (age	In this study, siblings of recently-diagnosed melanoma patients were	Siblings in the control group	SCT, TPB, HBM,
2006 ¹⁷⁴	≥18) siblings of melanoma patients	recruited through melanoma patients seen at 4 multidisciplinary cancer management teaching hospitals in the Boston area. Intervention group participants were provided an initial motivational and goal-setting telephone interview session delivered by a health educator and tailored print materials targeting behaviors in relation to skin self-examination, physician screening, and sun protection. The telephone interview and subsequent print materials were tailored based on responses to a survey conducted at baseline.	received usual care; that is, the melanoma patient was encouraged to invite their sibling make an appointment to get screened. Siblings in the control group also participated in all assessments at baseline, 6, and 12 months.	PAPM, TTM
Glanz 2010 ¹⁷⁵ Project SCAPE (adults)	Adults ages 20-65 at increased skin cancer risk	The Project SCAPE adult trial recruited participants from the waiting rooms of outpatient primary care practices in Honolulu, Hawaii, and Long Island, New York. The intervention consisted of three packets mailed at 2-week intervals containing personalized risk feedback and recommendations, UV self-monitoring aids, skin self-examination instructions and practice tools, and skin cancer prevention and detection information.	The control group received a single mailing with a standard sun safety booklet, a sunscreen use tip sheet, and a bookmark encouraging skin self-examination.	НВМ, SCT

Table 4. Detailed Intervention Descriptions, by Population

Study	Population	Intervention description	Comparison group description	Theoretical basis
Glanz 2015 ¹⁷⁶ PennSCAPE	Adults (age range 18-91) at increased skin cancer risk	The PennSCAPE trial, which was an extension of the original Project SCAPE trial (Glanz 2010 ¹⁷⁵), recruited participants from the waiting room of a primary care practice in Pennsylvania. The intervention consisted of three separate mailings sent at 2-week intervals. The first mailing contained a personalized skin cancer profile based on participants' self-reported risk factors; the second mailing contained skin self-exam instructions, feedback on participants' self-reported SSE practices, a body map to track mole changes, and a bookmark with tailored sun protection reminders; the third mailing contained a booklet encouraging clinical skin exam and a tip sheet with personalized sunscreen recommendations.	The control group received three standard informational mailings about skin cancer, skin self-exam, and sun protection.	HBM, SCT
Glazebrook 2006 ¹⁷⁷ Skinsafe	Adults with ≥1 melanoma risk factor	In this single-session, primary care-based study conducted in the U.K., participants were recruited in primary care practices. Based on patient phenotype, doctors or nurses prescribed the Skinsafe computer program, which the patient then self-completed at a dedicated workstation in the practice waiting room. The interactive computer program included animation, photographs, and text to inform users about risk of sun exposure, skin risk factors, early signs of melanoma, ways to reduce risk, how to check skin for suspicious lesions, and provided individualized feedback about personal risk factors. The intervention was conducted in 1998.	The control group was selected to match the phenotypic characteristics of enrolled intervention group participants. They did not receive an intervention and participated in baseline and 6 months followup.	НВМ
Heckman 2016 ¹⁷⁸ UV4.me	Young adults ages 18-25 at increased skin cancer risk	In this web-based study, U.S. young adults age 18-25 were recruited online via web banner ads. Participants were randomized to 1 of 3 conditions: a tailored, interactive web program called UV4.me (IG1); a public website condition (IG2); or an assessment only control group (CG). IG1 participants received periodic reminders to access and complete the intervention modules The UV4.me intervention included 12 modules on topics such as indoor tanning, UV and health, skin cancer, sunscreen, and skin exams. Each module took about 10 minutes to review and included a goal-setting section. The public website group (IG2) received automated email reminders to visit the Skin Cancer Foundation website, which provided information on various skin cancer topics, such as prevention, true stories, news, and healthy lifestyles. On average, the 70.4% of IG1 participants who accessed the UV4.me website visited it more than 5 times, and the 84% of IG2 participants who accessed the Skin Cancer Foundation website visited it twice.	The assessment control group received no intervention and participated in assessments only.	Integrative Model for Behavioral Prediction
Hillhouse 2008 ^{179, 193,} 194	University students ages 17-21 who use indoor tanning	This single-session study of an appearance-focused intervention recruited female indoor tanners from two US universities. The intervention consisted of a professionally produced 24-page booklet with sections on the history of tanning, tanning norms, effects of UV radiation, effects of indoor tanning, indoor tanning guidelines, and appearance-enhancing alternatives to indoor tanning. Participants were asked to summarize and rate each section.	The control group received no intervention and participated in assessments only.	Jaccard behavioral alternative model, TPB, HBM

Table 4. Detailed Intervention Descriptions, by Population

Study	Population	Intervention description	Comparison group description	Theoretical basis
Janda 2011 ^{180, 195} Skin Awareness	Adult men ages 50-90	In this study of older men (50 years or older), the intervention group received a 12 minute DVD featuring a sport/TV personality which discussed what skin cancer is, risk factors for skin cancer, and explained that older men are at increased risk to develop skin cancer. Additionally the intervention group received written instructions on how to conduct a skin self-examination and a body chart diagram to record any suspicious found skin lesions, facilitate self-monitoring, and/or to aid recall when visiting a physician. The intervention group also received postcards to remind them to watch the DVD and examine their skin.	The control group received a generic self-skin examination guide and brochure, but no video, body chart, or reminder post cards.	Extended HBM
Mahler 2007 ¹⁸¹	Adult university students ages 18-44	This single-session study of an appearance-focused intervention included undergraduate students from a university in Southern California. Participants were randomized in a two-by-two factorial design, to receive either a brief video session, a UV facial photograph, both, or assessment only. The video sessions consisted of an 11-minute videotaped slideshow about photoaging of the skin due to UV exposure, effective practices for reducing photoaging, and general information about sunscreen. The UV facial photographs were taken with a modified instant camera that highlights nonuniform skin pigmentation resulting from chronic sun exposure and the resulting skin damage. Participants receiving the UV facial photographs also had natural-light instant photographs taken for comparison. Participants received course credit for their participation.	Participants were randomized in a two-by-two factorial design, to receive either a brief video session, a UV facial photograph, both, or assessment only.	НВМ, ТРВ, РМТ
Manne 2010 ¹⁸²	Adult (age ≥20) FDRs of melanoma patients	In this study of family members of patients with melanoma, the intervention group received mailed print materials and a phone call from a health educator targeting the participant's engagement with skin examination by a health care provider, skin self-examination, and sun protection habits. The print materials and phone call were specific to the study participant's age and gender, family history of melanoma, and previous knowledge of skin cancer.	The comparison group received generic print materials and a telephone call with general information on melanoma, melanoma risk, and skin examinations.	Preventive Health Model, TPM
Prochaska 2004 ¹⁸⁴	Adults	This study aimed to intervene on multiple risk behaviors simultaneously. Participants were recruited from a school-provided list of parents of 9th graders, and underwent a theory-based risk assessment for smoking, diet, and sun exposure. They were considered "at-risk" if they were in the precontemplation, contemplation, or preparation stage of change for at least one behavior. For each of their relevant behaviors, intervention group participants received mailed tailored feedback reports at 0, 6, and 12 months, as well as progress questionnaires to complete at 6 and 12 months.	Control group participants received no intervention and participated in assessments only.	TTM
Prochaska 2005 ¹⁸³	Adults	This study, which built on the earlier trial of multiple risk expert systems interventions (Prochaska 2004 ¹⁸⁴), recruited participants from a list of primary care patients provided by a large health insurance organization. To be eligible, participants needed to be at-risk for one of the following behaviors: smoking, high-fat diet, sun exposure, and relapse from regular mammography. For each of their relevant behaviors, intervention participants received mailed individualized computer reports at 0, 6 and 12 months, as well as progress questionnaire to complete at 6 and 12 months.	Control group participants received no intervention and participated in assessments only.	TTM

Table 4. Detailed Intervention Descriptions, by Population

Study	Population	Intervention description	Comparison group description	Theoretical basis
Rat 2014 ¹⁸⁵	Adults at increased melanoma risk	The Cohort of Patients at Risk for Melanoma (COPARIME) was a French cluster RCT that included a single risk assessment session with PCP counseling. Participants were recruited from primary care waiting rooms and completed the Self-Assessment Melanoma Risk Score (SAMScore). Intervention group participants received a total skin exam from their PCP, counseling on melanoma, and a brochure on prevention. Both intervention and control group were assessed by phone at 5 months.	Control group participants completed the SAMScore risk assessment survey in the waiting room but received no counseling or intervention.	No theoretical basis reported
Vuong 2014 ¹⁸⁶	Adults age ≥18	This single-session study took place in two general practices in Sydney, Australia. In the intervention practice, general practitioners were trained on a skin cancer risk assessment tool, advice to give patients about sun protection. Patients completed the paper-based skin cancer risk assessment tool in the waiting room before their appointment, self-scored it, and shared it with their physician. The physicians counseled patients based on their individual level of risk from the assessment and their sun protection behaviors. Intervention patients also received the SunSmart UV Alert pamphlet, which contained information about UV radiation, the UV index, and sun protection.	The control practice provided usual care, though control patients completed a skin cancer risk assessment after completing the baseline survey, and also completed the followup surveys at 1 and 13 months.	PMT
Weinstock 2007 ¹⁸⁷ Check It Out	Adults age ≥18	The Check-it-Out study recruited medium or high-risk adults from primary care practices in Rhode Island or Massachusetts. Participants with a scheduled visit to their PCP were invited to participate. The intervention consisted of two counseling sessions by a health educator (one in the clinic immediately before the patient's primary care appointment, one by phone) and educational materials and aids including: a booklet from the American Cancer Society, a 14-minute video on SSE, a magnet shaped as a hand mirror, a shower card with SSE instructions, a hand mirror, and a body diagram.	The attention control group received diet-focused materials, such as pamphlets, tips for diet improvement, a video, and a self-assessment tool.	TTM, HBM, SCT (SCT for control group only)
Youl 2015 ^{188,} 192 Healthy Text	Adults age 18-42	The Healthy Text study recruited a random sample of residents of Queensland, Australia from the electoral roll and government health insurance register. Participants were randomized to one of three groups: sun protection, skin self-exam, or attention control. Each group received one text message per week for 12 weeks, and then one text message per month for the following 9 months. The sun protection and SSE text messages contained tailored information (such as participant names and skin cancer risk factors), had a conversational tone, and focused on social support, self-efficacy, perceived environmental opportunity, goal setting, and outcome expectancies.	The attention control group received a similarly structured text messaging intervention focused on promoting physical activity.	SCT

Abbreviations: PCP=primary care provider, UV=ultraviolet, SSE=skin self-exam, RCT=randomized clinical trial, HBM=Health Belief Model; SCT=Social Cognitive Theory; PAPM=Precaution Adoption Process Model; TPB=Theory of Planned Behavior; TTM=Transtheoretical Model; PMT=Protection Motivation Theory, IG1=intervention group 1, IG2=intervention group 2, CG=control group.

Table 5. Association Between Counseling Interventions and Intermediate Outcomes or Skin Cancer Outcomes (KQ1): Children and Adolescents

Study	Population	Intervention (number of sessions/mailings)	Followup (months)	Outcome	Question/ instrument	Group	Followup N	Baseline	Followup	Between group difference
Crane	Children	Tailored mailings	36	Nevi	Number of nevi	IG	324	18.25 (17.32-19.22)		p=0.52
2012 ^{172a} Fair	age 6	(14): Newsletters for parents/	00	(small)	<2mm; geometric mean (95% CI)	CG	310	18.25 (17.32-19.22)		
		children promoting		Nevi	Presence of nevi	IG	324	1.29 (1.09-1.52)	3.26 (2.48-4.27)	p=0.09
		child sun protection		(large)	≥2 mm; odds (95% CI)	CG	310	1.29 (1.09-1.52)	3.95 (2.95-5.29)	
				Sunburn	Severe (blistering) sunburn, past	IG	324	0.01 (0.01-0.03)	0.02 (0.01-0.04)	p=0.15
					year; any vs none, Odds (95% CI)	CG	310	0.01 (0.01-0.03)	0.05 (0.03-0.09)	
					Nonsevere sunburn past year;	IG	324	0.82 (0.70-0.96)	1.26 (1.01-1.57)	p=0.02
					any vs none, Odds (95% CI)	CG	310	0.82 (0.70-0.96)	1.43 (1.14-1.79)	
Glanz 2013 ¹⁷³	Children ages 4-10 at	. , .	4	Sunburn	Red/painful sunburns past 12	IG	517	1.61 (0.04)	1.27 (0.04)	Effect size NR;
Good	increased skin cancer risk	promoting children's sun protection			mo (Scale 1=one to 5=5 or more) mean (SE) ^b	CG	530	1.68 (0.04)	1.37 (0.04)	p=0.67 ^b
Gritz 2013 ¹⁷⁰	Children (age ≤12) of		4	Sunburn	Rate of sunburns past 6 mo	IG	138	NR	NR	p=0.98 ^c
Fair	melanoma survivors	protection; print materials, DVD; children's activities			(baseline) or past 3 mo (followup)	CG	143	NR	NR	

^a Crane 2012 randomized 867 participants but only reported results for white non-Hispanic participants (n=677). The authors report that results for white non-Hispanic participants were similar to results for all participants.

Abbreviations: KQ=key question, CI=confidence interval, IG=intervention group, CG=control group, NR=not reported, SE=standard error, mo=months.

^b Adjusted for location and risk group.

^c Adjusted for demographics, sun sensitivity, and clinical characteristics. For the binary outcome of sunburn decreasing between baseline and followup, the authors report an odds ratio of 1.01 (95% CI NR).

Table 6. Association Between Counseling Interventions and Skin Cancer Prevention Behaviors (KQ2): Children and Adolescents^a

Study	Population	Intervention (number of sessions/mailings)	Followup (months)	Outcome	Question/instrument	Group	Followup N	Baseline	Followup	Between group difference
Crane 2006 ¹⁶⁸ Fair	Children age <1	PCP counseling (4); print materials for parents promoting child sun protection (4); sunscreen	36	Sun protection	Scale: Use of 7 sun protection strategies for child between 11 am and 3 pm (mean) (possible score 7-28) ^b	IG CG	276 269	NR NR	18.2 17.7	p=0.04 (overall effect) ^c
		samples; hat		Sunscreen	Always/frequently use 11am-3pm, N (%)	IG CG	276 269	NR NR	260.0 (94.2) 250.0 (93.1)	p=0.46 (overall effect)
Crane 2012 ^{172d} Fair	Children age 6	Tailored mailings (14): Newsletters for parents/children	36	Sun protection	5 sun protection strategies (1 never to 5 very often for each),	IG CG	344 333	15.6 (15.4- 15.8) 15.6 (15.4-	16.3 (16.1- 16.6) ^f 15.6 (15.3-	p<0.001 ^g
		promoting child sun protection		Sunscreen	mean (95% CI) ^e Use on days child is outside ≥15 min, current summer (1 never to 5 very often); mean (95% CI)	IG CG	344 333	15.8) 4.2 (4.1-4.3) 4.2 (4.1-4.3)	15.8) 4.3 (4.1-4.3) 4.2 (4.2-4.4)	p<0.001
Glasser 2010 ¹⁶⁹ Fair	Children age 3-10	In-person parent education (1); materials (children's video, print materials); sun protection aids (shirt,	3	Sun protection	Scale: 3 sun protection behaviors: 3 (low) to 12 (high), mean (SD) ^h Scale: 3 sun avoidance behaviors: 3 (low) to 12 (high), mean (SD) ^j	CG IG	71 70 71 70	7.4 (2.1) 7.5 (2.0) 8.3 (2.1) 9.0 (2.2)	9.4 (2.2) 7.5 (2.0) 9.3 (2.1) 9.0 (2.2)	p=0.0001 ⁱ p=0.07 ⁱ
		hat, sunscreen)		Sunscreen	Use most of the time, N (%) ^k	IG CG	71 70	29.0 (41.0) 32.0 (46.0)	50.0 (70.0) 35.0 (50.0)	p=0.0132 ⁱ
Glanz 2013 ¹⁷³ Good	Children age 4-10 at increased	Tailored mailings (3) for parents promoting family	4	Sun protection	Scale: 5 behaviors past 3 mo, 1 rarely/never to 4 always, mean (SE) ^{mn}	IG CG	517 530	2.2 (0.0) 2.2 (0.0)	2.5 (0.0) 2.3 (0.0)	Effect size 0.16; p<0.0001 ^{m o}
	skin cancer risk	sun protection		Time in sun	Hours spent in sun per day, <1 to 6 per day, 10am-4pm, weekends or weekday, mean (SE) ^{m p}	IG CG	517 530	3.41 (0.1) 3.5 (0.1)	2.98 (0.1) 3.1 (0.1)	Effect size NR; p=0.24 ^m
				Sunscreen	Use 10am-4pm, 1 (rarely) to 4 (always), mean (SE) ^m	IG CG	517 530	3.1 (0.0) 3.2 (0.0)	3.3 (0.0) 3.2 (0.0)	Effect size 0.13; p<0.0001 ^m
				SSE	SSE by parent, past 3 mo, adjusted % (SE) ^m	IG CG	517 530	60.0 (0.1) 57.0 (0.2)	87.0 (0.1) 81.0 (0.1)	p=0.06 ^m ; Effect size: NY: 0.22, Hawaii:(-0.02)

Table 6. Association Between Counseling Interventions and Skin Cancer Prevention Behaviors (KQ2): Children and Adolescents^a

Study	Population	Intervention (number of sessions/mailings)	Followup (months)	Outcome	Question/instrument	Group	Followup N	Baseline	Followup	Between group difference
Gritz 2013 ¹⁷⁰	Children (age ≤12)	Standard mailings (3) promoting sun	4	Sun protection	Scale: 14 behaviors past 3 mo; 1(fewer) to	IG	138	3.4 (0.1) ^r	3.7 (0.1) ^r	p=0.94
Fair	of	protection; print			5 (more), mean (SE)q	G	143	3.4 (0.1) ^r	3.7 (0.1) ^r	
	melanoma survivors	materials, DVD; children's activities		Sunscreen	Scale: sunscreen behaviors from 7 items,	IG	138	2.64 (0.1)	2.89 (0.1)	p=0.79
					past 3 mo; 1(fewer) to 5(more), mean (SE) ^s	CG	143	2.64 (0.1)	2.87 (0.1)	
Norman 2007 ^{171,}	Adolescen ts age 11-	PCP counseling using tailored risk	24	Sun protection	Scale: 7 behaviors past 6 mo; 1 (never)	IG	315	48.0 (47.1, 49.0) ^u	52.0 (50.9, 53.1) ^u	p=0.003 ^v
190, 191 Fair	15	information (1);phone counseling			to 5 (always), T score mean (95% CI) ^t	CG	341	47.9 (47.0, 48.9) ^u	48.7 (47.6, 50.0) ^u	
		(4); mailed materials promoting sun		Sunscreen	Always/often use sunscreen, past 6 mo,	IG	315	NR	52.9 (48.8, 57.0) ^u	p<0.05
		protection; sunscreen samples			% (95% CI)	CG	341	NR	45.9 (41.8, 49.8) ^u	

^a Results for individual sun protection behaviors (e.g., hat use, wearing sunglasses, avoiding mid-day sun, etc.) are not reported separately in this table. Statistically significant individual behaviors favoring the intervention group are noted in footnotes.

^b Behaviors in this scale: Shade-seeking, protective clothing, sunglasses, limiting sun exposure, hat use, and avoiding mid-day sun. No variance reported (SE/SD NR).

^c Statistically significant individual behaviors favoring IG at followup: Hat use and wearing sunglasses.

^d Crane 2012 randomized 867 participants, but only reported results for white non-Hispanic participants (n=677). The authors report that results for White non-Hispanic participants were similar to results for all participants.

e Behaviors in this scale: Clothing, hats, shade, sunscreen, midday sun avoidance,

^f Adjusted in linear mixed model analysis for within-child correlation over time.

⁹ Statistically significant individual behaviors favoring IG at followup: Avoiding mid-day sun, wearing protective clothing, hat use, and shade-seeking.

h Behaviors in this scale: Hat, shirt, sunscreen. Each item options 1 (rarely) to 4 (most of the time). Time frame asked is NR.

¹ Main effect, IG vs CG at followup, adjusted for race/ethnicity, age, pretest knowledge, attitudes, and behaviors. Analysis of covariance models were used to analyze effect of intervention on followup scores for sun protection and sun avoidance, corrected for baseline scores and for demographic differences between groups.

^jBehaviors in this scale: Considered sun when planning activities; adjusted activities for sun avoidance; limited time in the sun. Each item options 1 (rarely) to 4 (most of the time). Time frame asked is NR.

k Parent-reported: time frame NR.

¹Calculated p-value (p value for between group differences is NR in paper).

^m Adjusted for location and risk group.

ⁿ Behaviors in this scale: shirt with sleeves, sunglasses, shade-seeking, sunscreen, hat.

^o Statistically significant individual behaviors favoring IG at followup: Hat use, wearing a shirt, and wearing sunglasses.

P Parent report of children's time in sun.

^qBehaviors in this scale: Sunscreen (7 items); clothing (5 items); shade-seeking (1 item); avoiding midday sun (1 item).

This is not an error. Baseline and followup values were identical for IG and CG per the paper (B=0.000).

^s Behaviors in this scale include applying sunscreen 30 minutes before going outdoors; reapplying within 1 hour; reapplying after each hour outdoors.

Table 6. Association Between Counseling Interventions and Skin Cancer Prevention Behaviors (KQ2): Children and Adolescents^a

Abbreviations: KQ=key question, PCP=primary care provider, IG=intervention group, CG=control group, NR=not reported, CI=confidence interval, SD=standard deviation, SE=standard error, SSE=skin self-exam, NY=New York.

^tBehaviors in this scale: Shirt, shade-seeking, avoiding midday sun, limiting sun exposure, 3 sunscreen items (general, SPF 15 on face, SPF 15 on body). Cites Weinstock 2000 Sun Protection Behavior Scale.²⁰²

^u Data extrapolated from figure in paper.

Y Statistically significant individual behaviors favoring IG at followup: Avoiding mid-day sun, limiting sun exposure, all sunscreen items.

Table 7. Association Between Counseling Interventions and Intermediate Outcomes or Skin Cancer Outcomes (KQ1): Adults and Young Adults

		Intervention (number	Followup				Followup			Between group
Study	Population	of sessions/mailings)	(months)	Outcome	Question/instrument	Group		Baseline	Followup	difference
Glanz	Adults age	Tailored mailings (3)	4	Sunburn		IG	307	1.44 (0.07)	0.89 (0.07)	p=0.14 ^a
2010 ¹⁷⁵	20-65 at	promoting sun			past 12 mo; Scale of			,	, ,	•
Fair	increased skin				0=none to 3=3 or more	CG	289	1.37 (0.07)	0.96 (0.07)	
	cancer risk	SSE aids			sunburns; Mean (SE) ^a			, ,		
Glanz	Parents of	Tailored mailings (3)	4	Sunburn		IG	517	1.46 (0.04)	1.00 (0.04)	Effect size
2013 ¹⁷³	children age	for parents promoting			past 12 mo; Scale of					NR; p=0.97 ^b
Good	4-10	children's sun			1=one to 5=5 or more	CG	530	1.49 (0.04)	1.03 (0.04)	-
01	A -llt/	protection	0	0	sunburns; mean (SE)	10		, ,	, ,	- 0.00FC
Glanz 2015 ¹⁷⁶	Adults (age	Tailored mailings (3)	3	Sunburn		IG	83	1.54 (0.77)	1.47 (0.70)	p=0.065 ^c
Fair	range 18-91) at increased	on risk reduction, SSE, clinical skin			mo; (1=never; to 4=more than twice); Mean (SD)					
ган	skin cancer	exam, and sunscreen			than twice), Mean (SD)	CG	109	1.46 (0.87)	1.56 (0.92)	
	risk	exam, and sunscreen				00	103	1.40 (0.07)	1.50 (0.52)	
Heckman	Young adults	IG1: Tailored	3	Sunburn	Red/painful sunburn in	IG1	195	156 (54.5)	51 (26.3)	p=0.014
2016 ¹⁷⁸	age 18-25 at	interactive web			past mo, N (%)	IG2	205	172 (51.5)	78 (38.2)	
Fair	increased skin					CG	229	191 (56.3)	94 (41.2)	
	cancer risk	IG2: Public website								
Rat	Adults at	PCP counseling using	5	Sunburn		IG	97	NR	26 (26.8)	p=0.42 ^d
2014 ¹⁸⁵	increased	tailored feedback (1)			summer, N (%)					
Fair	melanoma					CG	76	NR	23 (30.3)	
Weinstock	risk Adults age	Study team	12	Nevi	Diagnosed severely	IG	688	NR	1 (0.15)	NR
2007 ¹⁸⁷	≥18	counseling (2);	12	INEVI	atypical nevi during 12-	CG	668	NR	1 (0.15)	INIX
Fair	210	materials promoting			mo study period, N (%)	CG	000	INIX	1 (0.13)	
i an		SSE (print, video);		Melanoma		IG	688	NR	0 (0)	NR
		SSE aids; tailored			during 12-mo study	CG	668	NR	1 (0.15)	
		letter (1)			period, N (%)				,	
				BCC	Diagnosed BCC during	IG	688	NR	7 (1.02)	NR
					12-mo study period, N	CG	668	NR	3 (0.45)	
					(%)					
				SCC	Diagnosed SCC during	IG	688	NR	3 (0.44)	NR
					12-mo study period, N (%)	CG	668	NR	4 (0.60)	
Youl	Adults age	IG1: Tailored text	12	Sunburn		IG1	173	151 (80.7)	121 (69.9)	IG1: OR 0.87
2015 ^{188, 192}	18-42	messages promoting	12	Sumbum	mo, N (%)	IG2	163	147 (83.5)	117 (71.8)	(95% CI 0.54,
Good	10 72	sun protection (21)			1110, 14 (70)	CG	165	152 (83.1)	120 (72.7)	1.40); p=0.962
0000		IG2: Tailored text					100	102 (00.1)	120 (12.11)	IG2: OR 0.95
		messages promoting								(95% CI 0.59,
		SSE (21)								1.55); p=0.800
					2 or more sunburns in	IG1	173	102 (54.5)	60 (34.7)	IG1: OR 0.82
					past 12 mo, N (%)	IG2	163	107 (60.8)	65 (39.9)	(95% CI 0.53,
										1.27); p=0.377

Table 7. Association Between Counseling Interventions and Intermediate Outcomes or Skin Cancer Outcomes (KQ1): Adults and Young Adults

		Intervention (number	Followup				Followup			Between group
Study	Population	of sessions/mailings)	(months)	Outcome	Question/instrument	Group	N	Baseline	Followup	difference
						CG	165	102 (55.7)	65 (39.4)	IG2: OR 1.20
										(95% CI 0.66,
										1.59); p=0.478

^a Adjusted for location, risk level, age, and gender.

Abbreviations: KQ=key question, SSE=skin self-exam, mo=month, SE=standard error, IG=intervention group, CG=control group, NR=not reported, SD=standard deviation, CG1=control group 1, CG2=control group 2, BCC=basal cell carcinoma, SCC=squamous cell carcinoma, IG1=intervention group 1, IG2=intervention group 2, OR=odds ratio.

^b Adjusted for location, risk level.

^c After adjusting for social norms, treatment effect was nonsignificant for sunburns (p=0.065). Without adjustment for social norms, treatment effect was significant for sunburn (p=0.03).

d Adjusted for age, sex, education level.

Table 8. Association Between Counseling Interventions and Skin Cancer Prevention Behaviors (KQ2): Adults and Young Adults^a

Study	Population	Intervention (number of sessions/ mailings)	Followup (months)	Outcome	Question/ instrument	Group	Followup N	Baseline	Followup	Between group difference									
Geller	Adult	Health	12	Sunscreen	,	IG	149	132 (55.9)	100 (67.4)	OR 0.96 (95%									
2006 ¹⁷⁴ Fair	(age ≥18) siblings of	educator phone			N (%)	CG	165	145 (56.6)	109 (66.1)	CI 0.67, 1.38); p value NR ^b									
	melanom	counseling (4);		Tanning	Tanned by end of last	IG	149	99 (41.7)	38 (25.7)	OR 0.72 (95%									
	a patients	mailed print materials (3)		(outdoor)	summer, N (%)	CG	165	96 (37.2)	59 (35.6)	CI 0.47, 1.09); p value NR ^b									
		promoting sun		SSE	Comprehensive mole	IG	149	143 (60.4)	132 (88.5)	OR 1.76 (95%									
		protection and SSE			examination, past 6 mo, N (%)	CG	165	166 (64.5)	138 (83.5)	CI 1.06, 2.91); p value NR ^b									
					Ask a family member to	IG	149	108 (45.5)	105 (70.8)	OR 0.97 (95%									
					check a mole, past 6 mo, N (%)	CG	165	113 (44.0)	114 (69.1)	CI 0.63, 1.50); p value NR ^b									
					Compare all moles, past	IG	149	135 (57.1)	134 (89.7)	OR 2.20 (95%									
														6 mo, N (%)	CG	165	158 (61.5)	137 (83.0)	CI 1.22, 3.98); p value NR ^b
											Use picture to assist	IG	149	35 (14.7)	65 (43.5)	OR 1.57 (95%			
					with mole examination, past 6 mo N (%)	CG	165	24 (9.5)	34 (20.5)	CI 0.89, 2.75); p value NR ^b									
Glanz	Adults age	Tailored	4	Sun	Scale: 6 behaviors past	IG	307	2.34 (0.03) ^d	2.57 (0.03) ^d	Effect size: 0.13,									
2010 ¹⁷⁵ Fair	20-65 at increased	mailings (3) promoting sun		protection	3 mo, 1 rarely/never to 4 always, mean (SE) ^c	CG	289	2.34 (0.03) ^d	2.46 (0.03) ^d	p=0.001 ^{d e}									
	skin	protection and		Sunscreen	, () ,		307	2.54 (0.06) ^f	2.78 (0.06) ^f	p=0.57 ^f									
	cancer risk	SSE; SSE aids			to 4 (always), mean (SE)	CG	289	2.63 (0.06) ^f	2.84 (0.06) ^f										
				Time in	<1 hour to 6 hours per	IG	307	2.55 (0.07) ^f	2.22 (0.07) ^f	p=0.35 ^f									
				sun	day, 10am-4pm, weekends or weekday, past 3 mo, mean (SE)	CG	289	2.60 (0.08) ^f	2.34 (0.08) ^f										
				SSE	Total body SSE, past 3	IG	307	39.0 (3.0) ^g	71.0 (3.0) ^g	p=0.004; Total									
					mo, adjusted % (SE)	CG	289	43.0 (3.0) ⁹	61.0 (3.0) ⁹	effect size=0.219; High-risk effect size=0.39									

Table 8. Association Between Counseling Interventions and Skin Cancer Prevention Behaviors (KQ2): Adults and Young Adults^a

Study	Population	Intervention (number of sessions/ mailings)	Followup (months)	Outcome	Question/ instrument	Group	Followup N	Baseline	Followup	Between group difference																
Glanz	Parents	Tailored	4	Sun	Scale: 5 behaviors past	IG	517	2.43 (0.02)	2.62 (0.02)	Effect size 0.07;																
2013 ¹⁷³ Good	of children	mailings (3) for parents		protection	3 mo, 1 rarely/never to 4 always, mean (SE) ^h	CG	530	2.39 (0.02)	2.53 (0.02)	p=0.02 ⁱ																
	age 4-10	promoting		Sunscreen			517	2.83 (0.04)	3.06 (0.04)	Effect size 0.06;																
		family sun			to 4 (always), mean (SE)	G	530	2.81 (0.04)	2.94 (0.04)	p=0.04																
		protection		Time in	Hours spent in sun per	G	517	2.80 (0.05)	2.46 (0.05)	Effect size NR;																
				sun	day, <1 to 6 per day, 10am-4pm, weekends or weekday, mean (SE)	CG	530	2.83 (0.05)	2.43 (0.05)	p=0.29																
				SSE	SSE (total/partial not	IG	517	54.0 (0.33)	79.0 (0.07)	Effect size 0.14;																
					specified), past 3 mo, adjusted % (SE)	CG	530	52.0 (0.60)	71.0 (0.08)	p=0.03 ^j																
Glanz	Adults	Tailored	3	Sun	Scale: 6 behaviors past	IG	83	2.53 (0.59)	2.78 (0.53)	p value NR,																
2015 ¹⁷⁶ Fair	(age range 18-91) at	mailings (3) on risk reduction,	on, am,	protection	3 mo, 1 rarely/never to 4 always, mean (SD) ^c	CG	109	2.64 (0.62)	2.76 (0.58)	NS ^k																
	increased	skin self-exam,		Sunscreen	Use 10am-4pm, 1	G	83	2.60 (1.04)	2.95 (0.92)	p value NR,																
	skin cancer risk	clinical skin exam, and	skin nd		ı		(rarely) to 4 (always), mean (SD)	G	109	2.90 (1.02)	3.15 (0.86)	NS ^k														
		sunscreen		Time in sun	Hours spent in sun per day, 1 to 6 per day, 10am-4pm, previous	IG	83	2.73 (1.72)	2.51 (1.64)	p=0.68 ^l																
								summer, weekends, mean (SD)	CG	109	2.67 (1.61)	2.50 (1.71)														
					Hours spent in sun per day, 1 to 6 per day,	IG	83	1.28 (1.26)	1.43 (1.43)	p=0.27 ¹																
					10am-4pm, previous summer, weekdays, mean (SD)	CG	109	1.64 (1.58)	1.57 (1.41)																	
				SSE	Scale: Recency of last	G	83	2.39 (1.26)	3.06 (1.15)	p=0.051 ^k																
		Interactive 6 online program (1) with tailored feedback promoting sun																	SS		SSE, 1 (never) to 4 (within the last mo), mean score (SD)	CG	109	2.62 (1.32)	2.98 (1.19)	
Glazebrook 2006 ¹⁷⁷	Adults with ≥1		Sun protection	Scale: 1 to 8 behaviors, past 6 mo, mean (SD) ^m	IG	258	4.60 (1.82)	5.36 (1.72) ⁿ	Effect size 0.18; Mean difference																	
Fair	melanoma risk factor				. ,	CG	325	4.66 (1.55)	5.06 (1.59) ⁿ	0.30 (95% CI 0.10, 0.51) ⁿ ; p=0.004 (ITT analysis) ^o																
		protection and		SSE	Check moles, past 6	G	259	159 (61.9)	209 (80.7) ⁿ	OR 1.67 (95% CI																
		SSE		mo, N (%)	CG	328	215 (65.7)	243 (74.1) ⁿ	1.04, 2.7) ⁿ ; p=0.035 (ITT analysis) ^o																	

Table 8. Association Between Counseling Interventions and Skin Cancer Prevention Behaviors (KQ2): Adults and Young Adults^a

Study	Population	Intervention (number of sessions/ mailings)	Followup (months)	Outcome	Question/ instrument	Group	Followup N	Baseline	Followup	Between group difference
Heckman	Young	IG1: Tailored	3	Sun	Scale: 5 UV exposure	IG1	195	1.44 (0.80)	0.89 (0.73)	IG1: Cohen D
2016 ¹⁷⁸ Fair	adults age 18-25 at increased	interactive web program (12 modules)	J	protection	behaviors, past mo,1 (never) to 5 (always), mean (SD) ^p	IG2	205	1.50 (0.79)	1.19 (0.70)	effect size IG1 vs CG: 0.43; treatment effect
	skin cancer risk	IG2: Public sk website			mean (OD)	CG	229	1.49 (0.80)	1.21 (0.73)	at followup vs CG: -0.30 (SE 0.07, p<0.001) IG2: Treatment effect at followup IG2 vs CG: -0.034, p=0.609 (multinomial logistic regression including time)
					Scale: 7 protection behaviors; 1 (never) to 5 (always), mean (SD) ^q	IG1	195	1.94 (0.81)	2.64 (0.89)	IG1: Cohen D effect size IG1 vs CG: 0.53;
						IG2	205	1.83 (0.81)	2.17 (0.84)	Treatment effect at followup: 0.429
						CG	229	1.95 (0.77)	2.17 (0.87)	(SE 0.090, p<0.001) (multinomial logistic regression including time) IG2: Treatment effect at followup IG2 vs CG: -0.024, SE 0.083, p=0.773 (multinomial logistic regression including time)
			Sunscreen		IG1	195	143 (49.8)	162 (83.1)	IG1: p<0.001	
					(%)	IG2	205	164 (48.5)	156 (76.1)	compared to CG
					CG	229	187 (55.0)	161 (70.3)	at baseline IG2: p=0.019 compared to CG at baseline	
						IG1	195	212 (74.1)	175 (90.7)	IG1: p=0.002

Table 8. Association Between Counseling Interventions and Skin Cancer Prevention Behaviors (KQ2): Adults and Young Adults^a

Study	Population	Intervention (number of sessions/ mailings)	Followup (months)	Outcome	Question/ instrument	Group	Followup N	Baseline	Followup	Between group difference
				Tanning	Did not engage in 1-4	IG2	205	254 (75.4)	163 (80.3)	IG2: p value
				(outdoor)	hours/week of intentional UV exposure in past mo, N (%)	CG	229	265 (78.2)	186 (81.6)	- NR; NS
				Indoor	IT in past mo, N (%)	IG1	195	26 (9.1)	8 (4.1)	IG1: p value NR;
				tanning		IG2	205	31 (9.3)	12 (5.9)	NS
						CG	229	30 (8.9)	17 (7.4)	IG2: p value NR; NS
				SSE	Total body SSE, past 3	IG1	195	36 (12.5)	87 (44.6)	IG1: p=0.003
					mo, N (%)	IG2	205	48 (14.3)	48 (23.4)	IG2: p value
						CG	229	43 (12.6)	59 (25.8)	NR; NS
Hillhouse 2008 ^{179,} 193, 194	Female university students	Standard print materials (1) promoting	6	Indoor tanning	IT sessions in past 3 mo, mean (SE)	IG	195	4.67 (0.60)	6.8 (0.93)	F statistic 12.42; p<0.001 ^r
Fair	age 17-21 who use indoor tanning	appearance- based alternatives to indoor tanning				CG	217	4.48 (0.55)	10.9 (0.93)	
Janda 2011 ^{180,}	Adult men age 50-90	Standard mailing (1)	13	SSE	Partial SSE, past 6 mo, N (%)	IG	420	222 (47.3)	298 (71.0)	OR 1.16 (95% CI 0.86, 1.56)
195 Fair		promoting SSE (video, SSE				CG	411	218 (47.4)	279 (67.8)	p<0.001 (group x time effect)
		aids; print materials);			Total SSE, past 6 mo, N (%) ^s	IG	420	53 (11.4)	153 (36.4)	OR 1.29 (95% CI 0.97, 1.72)
		reminder postcards				CG	411	48 (10.4)	126 (30.7)	p=0.85 (group x time effect)
Mahler 2007 ¹⁸¹ Fair	Adult university students age 18-44	Facial photos of participant with simulated sun damage (1); appearance- focused video promoting sun protection (1)	12	Sun protection	(see results in text)		NR	NR	NR	(see results in text)

Table 8. Association Between Counseling Interventions and Skin Cancer Prevention Behaviors (KQ2): Adults and Young Adults^a

Study	Population	Intervention (number of sessions/ mailings)	Followup (months)	Outcome	Question/ instrument	Group	Followup N	Baseline	Followup	Between group difference								
Manne	Adult (age	Tailored	12	Sun	Scale: 5 behaviors, last	IG	161	2.8 (0.66)	3.4 (0.79)	NS on								
2010 ¹⁸² Fair	≥20) FDRs of melanoma patients	mailings (3) promoting sun protection and SSE; phone counseling (1)		protection	6 mo, 1 (never) to 5 (always), mean (SD) ^t	CG	161	2.8 (0.65)	3.2 (0.73)	multivariable analysis including intentions, perceived barriers and benefits, and self-efficacy [unadjusted p=0.0475]								
				SSE	Number of times engaging in SSE in past	IG	193	0.42 (0.86)	8.8 (34.9)	p=0.10 for main effect adjusted								
					year or since previous assessment, mean (SD)	CG	161	0.34 (0.80)	6.2 (24.4)	for proband being diagnosed at a younger age								
Prochaska	Adults	Tailored	24	Sun	Scale: sun avoidance,	IG	864	12.65 (3.86)	13.99 (3.39)	NS (p>0.05) ^v								
2004 ¹⁸⁴ Fair		mailings (3) promoting		protection	no. of items and time frame NR, mean (SD) ^u	CG	920	12.60 (3.90)	13.35 (3.73)									
			sun protection									Sunscreen	Scale: sunscreen use,	IG	864	8.3 (4.00)	10.2 (3.94)	p<0.05
					no. of items and time frame NR, mean (SD) ^u	CG	917	8.2 (3.99)	9.2 (3.82)									
Prochaska	Adults	Tailored			24	24	24	24				Sun	Scale: sun avoidance,	IG	1822	12.7 (3.6)	13.7 (3.5)	p<0.005 ^w
2005 ¹⁸³ Fair		mailings (3) promoting			protection	no. of items and time frame NR, mean (SD) ^u	CG	2012	12.4 (3.7)	12.9 (3.6)]							
		sun protection		Sunscreen	Scale: sunscreen use,	IG	1822	8.6 (3.9)	10.0 (3.9)	p<0.0001								
					no. of items and time frame NR, mean (SD) ^u	CG	2012	8.5 (3.9)	9.2 (3.9)									
Rat 2014 ¹⁸⁵	Adults at	PCP	5	Sun	Took protective actions	IG	97	NR	65 (67.0)	p=0.06 ^x								
Fair	increased melanoma	counseling using tailored	ng p	5	-		protection	during most recent exposure, N (%)	CG	76	NR	42 (55.3)						
	risk using tailored feedback (1)		Tanning	Sunbathed in past year,	IG	97	NR	24 (24.7)	p=0.040 ^x									
			(outdoor)	N (%)	CG	76	NR	31 (40.8)										
			Indoor	Use of tanning beds, N	IG	97	NR	10 (10.3)	p=0.069 ^x									
			tanning	(%)	CG	76	NR	5 (6.6)										
				SSE	SSE (total/partial not	IG	97	NR	51 (52.6)	p=0.02 ^x								
					specified), past 12 mo, N (%)	CG	76	NR	28 (36.8)									

Table 8. Association Between Counseling Interventions and Skin Cancer Prevention Behaviors (KQ2): Adults and Young Adults^a

Study	Population	mailings)	Followup (months)	Outcome	Question/ instrument	Group	Followup N	Baseline	Followup	Between group difference
Vuong	Adults	PCP	13	Sun	Scale: 7 behaviors, usual	IG	37	16.70	16.64	Mean difference
2014 ¹⁸⁶	age ≥18	counseling		protection	practice, possible range 5			(0.57)	(0.35)	0.26 (95% CI
Fair		using tailored			(low) to 25 (high), mean	CG	34	14.90	16.39	-0.78, 1.29);
		feedback; print materials (1)		Time in	(SE) ^y Hours spent outdoors per	IG	37	(0.49)	(0.37)	p=0.63 Mean difference
		materials (1)		sun	day, mean (SE)			2.05 (0.24)	2.07 (0.22)	-0.34 hours
						CG	33	2.66 (0.28)	2.41 (0.23)	(95% CI -0.98, 0.3); p=0.29
Weinstock 2007 ¹⁸⁷	Adults age ≥18	Study team counseling (2);	12	SSE	Total body SSE, past 2 mo, N (%)	IG	530	124 (18.0)	254 (55.0)	Mean difference between groups
Fair		materials promoting SSE (print, video);				CG	487	114 (17.0)	154 (35.0)	at 12 mo: 19.3 (95% CI 13.0, 25.7); p<0.0001
		SSE aids; tailored letter			Number of areas examined (of 7 total),	IG	461	2.59	5.14	p<0.0001 difference
		(1)			past 2 mo, mean ^z	CG	440	2.46	3.83	between groups at 12 mo
Youl	Adults	IG1: Tailored	12	Sun	Scale: 6 behaviors,	IG1	178	2.50 (0.48)	2.63 (0.46)	IG1: p=0.032
2015 ^{188, 192}	age 18-42	text messages		protection	frequency 10am-3pm, 1	IG2	168	2.50 (0.55)	2.63 (0.50)	IG2:p=0.05
Good		promoting sun protection (21)			rarely/never to 4 always, mean (SD) ^{aa}	CG	166	2.46 (0.49)	2.50 (0.50)	
		IG2: Tailored text messages		Tanning (outdoor)	Attempted suntan in past 12 mo, N (%)	IG1	173	23 (12.3)	26 (15.0)	IG1: OR 0.95 (95% CI 0.52,
		promoting SSE (21)				IG2	163	39 (22.2)	30 (18.4)	1.71); p=0.421 IG2: OR 1.21
						CG	165	19 (10.4)	26 (15.8)	(95% CI 0.68, 2.15); p=0.030
				SSE	Any SSE, past 3 mo, N (%)	IG1	173	64 (34.2)	83 (48.0)	IG1: OR 1.42 (95% CI 0.92,
						IG2	163	65 (36.9)	103 (63.2)	2.19); p=0.742 IG2: OR 2.64
						CG	165	57 (31.1)	65 (39.2)	(95% CI 1.69, 4.13); p=0.001
				SSE	Total body SSE at time	IG1	173	20 (10.7)	24 (13.9)	IG1: OR 1.32
					at least CCE NI (0/)bb	IG2	163	30 (17.0)	28 (17.2)	(95% CI 0.69, 2.53); p=0.741
						CG	165	15 (8.2)	18 (10.9)	- IG2: OR 1.69 (95% CI 0.90, 3.2); p=0.153

^a Results for individual sun protection behaviors (e.g., hat use, wearing sunglasses, avoiding mid-day sun, etc.) are not reported separately in this table. Statistically significant individual behaviors favoring the intervention group are noted in footnotes.

b Difference in odds at follow-up for IG vs CG, adjusted for baseline, sibship, longitudinal data, skin color and intention to have dermatologist skin exam.

Table 8. Association Between Counseling Interventions and Skin Cancer Prevention Behaviors (KQ2): Adults and Young Adults^a

- ^c Behaviors in this scale: Shirt with sleeves, sunglasses, shade-seeking, sunscreen, avoiding midday sun, hat.
- ^d Adjusted for risk level, age, and gender.
- ^e Statistically significant individual behaviors favoring IG at followup: Hat use and wearing sunglasses.
- f Adjusted for location, risk level, age, and gender.
- ^g Adjusted for location, age, and gender.
- h Behaviors in this scale: shirt with sleeves, sunglasses, shade-seeking, sunscreen, hat.
- ¹ Statistically significant individual behaviors favoring IG at followup: Limiting sun exposure and shade-seeking.
- ^j Adjusted for location and risk level.
- ^k After adjusting for social norms, treatment effect was nonsignificant for overall SPB (p value NR, NS); sunscreen (p value NR, NS); sunglasses (p=0.066) and SSE (p=0.051). Without adjustment for social norms, treatment effect was significant for overall SPB (p=0.03); sunscreen (p=0.03); sunglasses (p=0.01) and SSE (p=0.02).
- ¹ Effect of treatment group difference scores, adjusted for age.
- ^m Behaviors in this scale: Shade-seeking, SPF 15+ sunscreen, hat, covering skin, sunburn, sunbathing, skin self-exam, skin exam by others at least every few months. Individual behavior scores NR.
- ⁿ Adjusted for baseline values and clustering.
- ° Results similar for as-treated analysis.
- P Behaviors in this scale: clothes that expose skin to the sun; unintentional tanning; indoor tanning; use of products to deepen tan; sunbathing.
- ^q Behaviors in this scale¹⁸⁹: SPF 15+ on face; SPF 15+ on body; shirt; long pants; hat; sunglasses; shade-seeking.
- For a subpopulation of 379 students, mean IT frequency increased in both IG and CG between fall and spring (significance NR). There were more significantly more IT abstainers in IG than CG in December and January (p<0.05).¹⁹⁴
- ^s Defined as checking each of 13 specific areas of the body.
- ^t Behaviors in this scale¹⁸⁹: Sunscreen, hat, shade-seeking, shirt, sunglasses. Individual item results not reported.
- ^u Authors cite Sun Protection Behavior Scale, sun avoidance inventory; 202-204 individual items not reported.
- ^v Both group and time alone showed significant increases in sun avoidance over time, interaction NS.
- w Statistically significant individual behaviors favoring IG at followup: Avoiding mid-day sun.
- ^x Adjusted for age, gender, education level.
- ^y Behaviors in this scale: Sunscreen, hat, shirt, sunglasses, limiting time in sun. Individual behaviors not reported.
- ^z No variance reported (SE/SD NR).
- ^{aa} Behaviors in this scale¹⁸⁹: Shirt, sunglasses, hat, sunscreen, shade-seeking, limiting midday sun. Individual behaviors not reported.
- bb For Youl 2015, Total SSE includes partner-assisted skin exam.

Abbreviations: KQ=key question, SPF=sun protection factor, IG=intervention group, CG=control group, OR=odds ratio, NR=not reported, SSE=skin self-exam, mo=month, SE=standard error, SD=standard deviation, UV=ultraviolet, CG1=control group 1, CG2=control group 2, IG1=intervention group 1, IG2=intervention group 2, IT=indoor tanning, NS=non-significant, PCP=primary care provider.

Table 9. Harms of Behavioral Counseling for Skin Cancer Prevention (KQ3)

Study	Population	Followup N	Intervention	Followup (months)	Harm	Outcome
Rat 2014 ¹⁸⁵ Fair	Adults at increased melanoma risk	173	PCP counseling using tailored feedback (1)	5	Worry	Greater proportion of patients in the IG worried about developing melanoma (28.9% vs. 18.4%; p=0.16)
Weinstock 2007 ¹⁸⁷ Fair	Adults age ≥18	901	Study team counseling (2); materials	12	Number of skin surgeries	At 6 months there was a significant between the number of skin surgeries in the IG compared to the CG (8.0% vs. 3.6%, p=0.0005).
			promoting SSE (print, video); SSE aids; tailored letter (1)			There was not a significant difference in the number of skin surgeries between the two groups at 12 months (3.9% vs 3.3%, p=0.5).

Abbreviations: KQ=key question, PCP=primary care provider, IG=intervention group, CG=control group SSE=skin self-exam.

Table 10. Summary of Evidence, by Population and Key Question

Key	No. of Studies (k),		Consistency	Reporting	Study	Body of Evidence	EPC Assessment of Strength	A a li a a la illita a
Question Children and	no. of obs. (n)	Outcome	/Precision	Bias	Quality	Limitations	of Evidence	Applicability
KQ1: Intermediate and health outcomes	k=3 RCTs n=2508 (All 3 trials identified in update all in populations ages 3-10 years)	One fair-quality trial among children age 6 (n=867) found a small intervention effect for the odds of nonsevere sunburn but no differences between groups in the odds of severe sunburn or number of nevi at 3-year followup. Two other trials among children (both mean age 7) found no differences between intervention and control groups in sunburn frequency at 4-month followup. No studies reported skin cancer outcomes.	Skin cancer/ nevi: NA Sunburn: Inconsistent, Imprecise	Suspected ^b	Good: 1 Fair: 2	Few studies overall; none in children <3 years or adolescents. Sunburn assessed by parent self-report; limited reporting of absolute values.	Skin cancer/ nevi: Insufficient Sunburn: Low	Likely applicable to US primary care for predominantly fair-skinned populations, though feasibility may vary
KQ2: Behavioral outcomes	k=6 RCTs n=4252 (4 trials identified in update, all in populations ages 3-10 years)	Five of 6 trials found statistically significantly greater improvements in parent-reported sun protection composite scores in intervention participants vs control participants at 3-months to 3-years followup. Effects were observed in all age groups. Standardized effect sizes ranged from 0 to 0.96 (0.16 to 0.50 in larger trials). In general, effects on individual sun protection behaviors, including sunscreen use, were consistent within each trial. No trials reported indoor tanning use.	Sun protection: Reasonably consistent, Imprecise Indoor tanning: NA Skin self- exam: NA	Suspected ^b	Good: 1 Fair: 5	Limited reporting of absolute values; clinical interpretation of composite scores difficult to assess; self- reported data; heterogeneous measures and time frames. Only one study each of children <3 years and adolescents.	Low	Likely applicable to US primary care for predominantly fair-skinned populations, though feasibility may vary
KQ3: Harms of intervention	No studies	NA	NA	NA	NA	NA	Insufficient	NA
KQ4: Association between SSE and outcomes	No studies	NA	NA	NA	NA	NA	Insufficient	NA
KQ5: Harms of SSE	No studies	NA	NA	NA	NA	NA	Insufficient	NA

Table 10. Summary of Evidence, by Population and Key Question

Key Question	No. of Studies (k), no. of obs. (n)	Summary of Findings by Outcome	Consistency /Precision	Reporting Bias	Study Quality	Body of Evidence Limitations	EPC Assessment of Strength of Evidence	Applicability
Adults and	young adults ^a							
KQ1: Intermediate and health outcomes	k=7 RCTs n=5315 (All 7 trials identified in update)	Of 6 trials, only one (n=965, 86% white, young adults mean age 22) reported a statistically significant difference in self-reported sunburns at 3-months follow-up in intervention compared to control participants. All other trials were conducted among adults with broader age ranges; none found an intervention effect. One US-based trial focused on skinself exam promotion (n=1356) reported minimal cases of melanoma, NMSC, and atypical nevi, and no differences between groups over 12-months follow-up.	Nevi/skin cancer: NA Sunburn: Inconsistent, Imprecise	Not detected	Overall: Good: 2 Fair: 5 Cancer/ nevi: Fair: 1 Sunburn: Good: 2, Fair: 4	Skin cancer/ nevi: Single study with 12- month followup, outcome assessment methods not clear Sunburn: Baseline rates low in some studies; heterogeneous self-reported measures	Skin cancer/ nevi: Insufficient Sunburn: Low	Sunburn findings are likely applicable. Cancer/nevi findings possibly applicable in SSE-focused intervention populations; unclear for interventions focused on sun protection behavior or indoor tanning.

Table 10. Summary of Evidence, by Population and Key Question

							EPC	
	N (0, 11 (1)					Body of	Assessment	
Key	No. of Studies (k),	, , ,	Consistency	Reporting	Study	Evidence	of Strength	Amuliaabilitu
Question KQ2:	no. of obs. (n) k=16	Outcome Most trials found greater	/Precision Sun	Bias Not	Quality Overall:	Limitations Same	of Evidence Sun protection:	Applicability Likely
Behavioral outcomes	15 RCTs, 1 CCT n=16,309 (10 trials identified	improvements in self-reported sun protection composite scores in	protection: Reasonably consistent,	detected	Good: 2 Fair: 14	limitations as listed in KQ2 (Children and	Low Indoor tanning: Low	applicable to US primary care for
	in update)	3 months to 2 years followup; 6 of 12	Imprecise		Sun	adolescents)	SSE:	predominantly
	in apaate)	reported statistically significant	Indoor		protection	adolescents	Moderate	fair-skinned
		between-group differences.	tanning:		Good: 2			populations;
		Sunscreen use (4 trials) and	Inconsistent/		Fair: 11			feasibility may
		intentional outdoor exposure (3	Imprecise		ladası			vary
		trials) were the most frequently reported improved behaviors. There	SSE: Reasonably		Indoor tanning:			
		was no evidence of effect	consistent/		Fair: 3			
		modification by age, risk factors, or	Imprecise					
		intervention components. 1 of 3 trials reporting indoor tanning, a study of			SSE: Good: 2			
		female young adult indoor tanners			Fair: 9			
		(n=430, mean age 19), found			i aii. o			
		relatively smaller increases in						
		number of indoor tanning sessions in						
		the past 3 months in the intervention vs control conditions at 6 month						
		followup. 9 of 11 trials showed						
		statistically significantly increased						
		reporting of total, partial, or any skin						
		self-exam (SSE) in the intervention vs controls groups. 3 of the above						
		trials were conducted in young						
		adults (n=1528). 2 of these reported						
		intervention effects: 1 for sun						
		protection behavior and SSE (k=965) and 1 for indoor tanning						
		(k=430).						
KQ3: Harms	k=2 RCTs	Skin procedures were more common	NA	Not	Fair: 2	Few studies;	Insufficient	May be
of	n=1573	in the intervention group in one trial		detected		outcome		applicable
intervention	(both trials identified in	of SSE promotion (n=1356) at 6 months follow-up but not 12 months.				measurement not well		
	update, both in	Cancer worry did not differ between				described		
	adult populations)	groups in one trial of counseling and						
		risk assessment (n =217).						
		None of the above trials involved						
		young adults.			<u> </u>			

Table 10. Summary of Evidence, by Population and Key Question

Key Question	No. of Studies (k), no. of obs. (n)	Summary of Findings by Outcome	Consistency /Precision	Reporting Bias	Study Quality	Body of Evidence Limitations	EPC Assessment of Strength of Evidence	Applicability
KQ4: Association between SSE and outcomes	No studies	NA	NA	NA	NA	NA	Insufficient	NA
KQ5: Harms of SSE	No studies	NA	NA	NA	NA	NA	Insufficient	NA

Abbreviations: KQ=key question, EPC=evidence-based practice center, RCT=randomized clinical trial, CCT=controlled clinical trial, SSE=skin self-exam, NA=not applicable.

^a One study (Glanz 2013) reported outcomes for both children and adults.
^b One trial (n=867) only reported results for white non-Hispanic participants (n=677).

Appendix A Table 1. Recommendations on Counseling for Skin Cancer Prevention From Other Groups

Organization	Country	Year	Recommendation
American Academy of Dermatology	U.S.	2016	Recommends clinicians provide sun protection counseling for all individuals. Encourages members of the public to regularly examine their skin for signs of skin cancer and to see a board-certified dermatologist if they notice any unusual spots on their skin, including anything changing, itching or bleeding. 2
Skin Cancer Foundation	U.S.	2016	Endorses the U.S. Surgeon General's recommendations to increase awareness about skin cancer prevention and the dangers of indoor tanning. ³ Recommends members of the public conduct monthly head-to-toe self-examinations of the skin to find any new or changing lesions that might be cancerous or precancerous. ⁴
American Cancer Society (ACS)	U.S.	2015	Recommends health care providers play a role in counseling patients about ways to protect themselves from skin cancer. ⁵ Recommends minimizing UV exposure by limiting time spent outdoors during peak UV exposure hours, wearing protective clothing, applying adequate sunscreen, and avoiding indoor tanning devices. ⁵ ACS also recommends individuals engage in monthly skin self-exams. ⁶
American Congress of Obstetricians and Gynecologists (ACOG)	U.S.	2015	Recommends clinicians talk to patients about sun exposure, sun-protective behaviors, and the harms of indoor tanning. ⁷
Michigan Quality Improvement Consortium	U.S.	2015	Recommends clinicians provide routine education and counseling to parents and children about skin cancer prevention ⁸
Community Preventive Services Task Force	U.S.	2014	Recommends education and policy approaches to encourage skin-protective behaviors in various settings, including child care centers, primary and middle schools, outdoor recreational sites, and outdoor occupational settings. ⁹
American Academy of Family Physicians (AAFP)	U.S.	2014	Endorses the USPSTF's previous recommendation that clinicians counsel children, adolescents, and young adults ages 10-24 who have fair skin about minimizing their exposure to UV radiation to reduce risk of skin cancer. Notes that the current evidence is insufficient to assess the balance of benefits and harms of patient skin self-exam. ¹⁰
U.S. Surgeon General	U.S.	2014	Recommends clinicians play a role in reducing UV exposure by providing counseling to patients, particularly adolescents and young adults with fair skin. ¹¹
Institute for Clinical Systems Improvement (ICSI)	U.S.	2013	Recommends that counseling patients to limit sun exposure is reasonable. 12 Endorses the USPSTF's previous recommendation statement that the current evidence is insufficient to assess the balance of benefits and harms of patient skin self-exam. 13
American Academy of Pediatrics (AAP)	U.S.	2011	Recommends pediatricians educate patients and parents about UV radiation exposure and protective behaviors, such as avoiding sunburns, wearing clothing and hats, limiting outdoor activities during periods of peak sun exposure, wearing sunglasses, and applying sunscreen. ¹⁴
Alberta Health Services	Canada	2013	Recommends counseling in health care settings, particularly for children, adolescents, and young adults, about minimizing exposure to UV radiation to reduce the risk of skin cancer. 15 Recommends regular skin-self exam to help individuals become familiar with their skin and notice any changes. 16
Royal Australian College of General Practitioners	Australia	2012	Recommends clinicians advise all individuals, particularly children, to adopt sun-protective measures such as minimizing sun exposure and using sunscreen. ¹⁷ Recommends individuals engage in skin self-exam annually (low-risk), every 3-6 months (medium risk), or every 3 months (high-risk). ¹⁸

Appendix A Table 1. Recommendations on Counseling for Skin Cancer Prevention From Other Groups

Organization	Country	Year	Recommendation
National Institute for Health and Care Excellence (NICE)	U.K.	2011	Recommends health care providers participate in prevention activities, such as one-to-one or group counseling, to raise awareness of the risks of UV exposure and the benefits of sunprotective behaviors. ¹⁹
International Agency for Research on Cancer (IARC), World Health Organization	International	2001	Recommends that health promotion interventions seek to increase appropriate use of sunscreen but cautions that sunscreen should not be used as a means of extending the duration of sun exposure. ²⁰

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One Light Br Dark Br Dark Br Very Carl SECTION 2: 11. Have yo last had 13. In the last had 14. If year, w Joseph Carl	wen. Skin Examinable EVER had yeer soal?** That is the meeth yeer skin checke of 27 meeths, ha skin cancer? ew many times? ore items - ADUL extine itled, pin temse And one of the cancer of the c	skin checked for and year when y of from head to to we you or a partn write number If for CHILD age 1 anse think about y the best respondict who E 1 to 10 E 1 to 10 E 1 to 10 and the best respondict who E 1 to 10 E 1 to	skin cancer to skin cancer canning; I to 10 years our CHLD with cancer cancer chill be with cancer ca	o to question 1. Monthly var your entire boo he is 1 to 10 ye dien. 239 255 worth?	g by, including you nars old and s survey <i>bloking</i> o age of this chi	and 30 m 31 m 2 h 3 h 3 h 4 h 0 6 h 0 6 h 0 2. in th and 30 m 2 h 0 6 h 0 6 h 0 7 4 h 0 6 h 0 7 For the 1 summer 5. H 0 7 6. H 0 9. H 0 9. H 0 10 Wh 10 10 Wh 10 11 Wh	A PM AN WEEKEN INTEREST OF THE PARTY OF T	ATS (Monday-Friday ATS (Monday-Friday ATS (Monday-Friday ATS (Safurday ATS (S		e outside par d	ay between	that
One Light Br Dank Bro Dank	wen. Skin Examinable EVER had yeer shal is the meeth yeer skin checks of 12 meeths, ha r skin cancer? ore Bams - ADUL settion bladed, pin nome that one of UDEST child who sackground labor of your sides! or old. sold. s	skin checked for and year when y of from head to b we you or a partn Write number If for CHILD age 1 asse think about y the best respon- kif who k: 1 to 10 to 1 to 10 years mation hild between the XDAY'S (Menday-	skin cancer I skin c	o to question 1. Monthly var your entire boo he is 1 to 10 ye dien. 239 255 worth?	g by, including you nars old and s survey <i>bloking</i> o age of this chi	and 30 m 31 m 2 h 3 h 3 h 4 h 0 6 h 0 6 h 0 2. In th and 30 m 2 h 0 6 h 0 6 h 0 7 4 h 0 6 h 0 7 6 h 0 7 6 h 0 7 7 6 h 0 7 7 7 8 h 1	A PM AN WEEKD INTEREST OF THE PARTY OF TH	erage, how many bear of the second of the se		e outside par d	ay between	that
One Light Bro Dark Bro Dark Bro Dark Bro Very Dar SECTION 2 - 11. Have ye prefers No	ven. ** ** ** ** ** ** ** ** **	and year when yed from head to to we you or a parin with a member. If for GHLD age 1 hase think about y the best response to 1 to 10 years mation hild between the SEARYS (Monday-	skin cancer i Skin c	o to question 1. Monthly var your entire boo he is 1 to 10 ye dien. 239 255 worth?	g by, including you nars old and s survey <i>bloking</i> o age of this chi	and 30 m 31 m 2 ho 3 ho 4 ho 6 ho 6 ho 6 ho 7 hu 8 ho 8 ho 8 ho 9 ho 9 hu 9 ho 9 hu 9 ho 9 hu	A PM AN WEEKD INTEREST OF THE PARTY OF TH	erage, how many bear of the second of the se		e outside par d	ay between	that
One Light Bro Dark Bro Dark Bro Dark Bro Very Dar SECTION 2: 11. Have ye preferable No	wen. ** ** ** ** ** ** ** ** **	and year when yet from head to be to	skin cancer I skin c	o to question 1. Monthly var your entire boo he is 1 to 10 ye dien. 239 205 worth?	g by, including you nars old and s survey <i>bloking</i> o age of this chi	and 30 m 21 n 22 n 30 n 31 m 2 n 30 n 4 n 6 n 6 n 6 n 6 n 7 and 30 m 2 n 7 4 n 8 n 8 n 8 n 8 n 8 n 8 n 8 n 8 n 8 n 8	I year, an WEEKD inside to 1 hour are inside or less insides or less insides to 1 hour are insides or less insides to 1 hour are inside to 1 hour are insides to 1 hour are insides to 1 hour are insides to 1 hour are inside to 1 hour are insides to 1 hour are insides to 1 hour are inside to 1 hour are insides to 1 hour are insides to 1 hour are inside to 1 hour are insides to 1 hour are insides to 1 hour are inside to 1 hour are insides to 1 hour are inside to 1 hour are insides to 1 hour are insides to 1 hour are inside to 1 hour are insides to 1 hour are inside t	ATS (Monday-Friday erage, how many be BO DATS (Saturday bow many times d cor. Binks about what day. r SUMSCREEN? r SUMSCREEN? r HAST? In the SHADE or AT SUMSCREEN? OUT WITH SHADE or TO SUMSCREEN.	All Control of the Co	e outside par d ? a a red QB pair 4 5 an year are est 0 0 0 0 0 0 0 0 0 0 0 0 0	ay between stel sumborn 5 m cut of cut ing cut of cut ing	n that
One Light Br Dank Bro Dank	wen. ** ** ** ** ** ** ** ** **	and year when yet from head to be to	skin cancer I Skin c	o to question 1. Monthly var your entire boo he is 1 to 10 ye dien. 239 205 worth?	g by, including you nars old and s survey <i>bloking</i> o age of this chi	and 30 m 21 n 22 n 30 n 31 m 2 n 30 n 4 n 6 n 6 n 6 n 6 n 7 and 30 m 2 n 7 4 n 8 n 8 n 8 n 8 n 8 n 8 n 8 n 8 n 8 n 8	A PM AN WEEKEN insides to 1 thour and a second a	ATS (Monday-Friday erage, how many be BO DATS (Saturday bow many times d cor. bink about what day. r SUNSCREEN? r SUNSCREEN? r HAT? In the SHADE or a SUNGLASSES? of time in the sun is sour mutanned skine?	NOTE OF THE PROPERTY OF THE PR	e outside par d ? a a red QB pair 4 5 an year are est 0 0 0 0 0 0 0 0 0 0 0 0 0	any behaveen Sax Size during CO O O O	n that

Figure. Core skin cancer prevention items for adults (A), adults reporting for children 10 years or younger (B), and adolescents aged 11 to 17 years (C).

Source: Glanz K, Yaroch AL, Dancel M, et al. Measures of sun exposure and sun protection practices for behavioral and epidemiologic research. *Arch Dermatol*. 2008;144(2):217-22.

Skin cancer counseling and skin self-exam search strategy

Databases searched:

MEDLINE

PubMed

Cochrane Central Register of Controlled Trials (CENTRAL)

Key

/ = subject heading

\$ = truncation

ti = word in title

ab = word in abstract

adj# = adjacent within x number of words

pt = publication type

fs = floating subheading

* = truncation

kw = kevword

Medline (via Ovid)

KQs 1-3, Trials & Harms

Database: Ovid MEDLINE(R) <1946 to March Week 4 2016>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <March 30, 2016>, Ovid MEDLINE(R) Daily Update <March 30, 2016> Search Strategy:

- 1 Skin Neoplasms/
- 2 Melanoma/
- 3 Hutchinson's Melanotic Freckle/
- 4 Hutchinson\$ Melanotic Freckle.ti,ab.
- 5 Melanoma, Amelanotic/
- 6 melanoma\$.ti,ab.
- 7 lentigo maligna.ti,ab.
- 8 Carcinoma, Basal Cell/
- 9 Carcinoma, Squamous Cell/
- 10 Neoplasms, Basal cell/
- 11 Neoplasms, Squamous cell/
- 12 skin cancer\$.ti,ab.
- 13 ((carcinoma\$ or neoplas\$) adj5 (skin or cutaneous)).ti,ab.
- 14 Nevus/
- 15 Nevus, Pigmented/
- 16 Dysplastic Nevus Syndrome/
- 17 (nevus or naevus or nevi or naevi).ti,ab.
- 18 ((naevoid or nevoid) adj3 syndrome\$).ti,ab.
- 19 Keratosis/
- 20 keratos#s.ti,ab.
- 21 Sunburn/
- 22 Sunburn\$.ti,ab.
- 23 Sunscreening Agents/
- 24 sunscreen\$.ti,ab.
- 25 Protective clothing/
- 26 protective cloth\$.ti,ab.
- 27 (((hat or hats) and (wear\$ or wore or brim\$)) or (use\$ adj3 hat) or (use\$ adj3 hats)).ti,ab.
- 28 Sunlight/
- 29 Ultraviolet Rays/
- 30 sunlamp\$.ti,ab.
- 31 tanning.ti,ab.
- 32 sunbed\$.ti,ab.
- 33 photoprotection.ti,ab.
- 34 sun protecti\$.ti,ab.
- 35 ((seek\$ or sun) and shade).ti,ab.
- 36 ((avoid\$ or minimiz\$ or minimis\$) and midday sun).ti,ab.

- 37 sun awareness.ti.ab.
- 38 sun safetv.ti.ab.
- 39 sun exposure.ti,ab.
- 40 (skin adj3 self adj3 (exam\$ or check\$)).ti,ab.
- 41 or/1-40
- 42 Health promotion/
- 43 Health Education/
- 44 Patient Education as Topic/
- 45 Preventive Health Services/
- 46 Consumer Health Information/
- 47 Counseling/
- 48 Directive Counseling/
- 49 Behavior Therapy/
- 50 Health Behavior/
- 51 Physician's Role/
- 52 Teaching Materials/
- 53 Parents/ed [Education]
- 54 health promotion.ti,ab.
- 55 (preventive health or health prevention).ti,ab.
- 56 consumer health.ti,ab.
- 57 health behavio\$.ti,ab.
- 58 counsel\$.ti,ab.
- 59 behav\$ therap\$.ti,ab.
- 60 advice.ti,ab.
- 61 advise.ti,ab.
- 62 educat\$.ti,ab.
- 63 provid\$ information.ti.ab.
- 64 behavio\$ intervention\$.ti.ab.
- 65 prevention intervention \$\.ti\, ab.
- 66 or/42-65
- 67 41 and 66
- 68 clinical trials as topic/ or controlled clinical trials as topic/ or randomized controlled trials as topic/ or metaanalysis as topic/
- 69 (clinical trial or controlled clinical trial or meta analysis or randomized controlled trial).pt.
- 70 Random\$.ti,ab.
- 71 control groups/ or double-blind method/ or single-blind method/
- 72 clinical trial\$.ti,ab.
- 73 controlled trial\$.ti,ab.
- 74 meta analy\$.ti,ab.
- 75 or/68-74
- 76 67 and 75
- 77 limit 76 to (english language and yr="2009 -Current")
- 78 remove duplicates from 77
- 79 Sunscreening Agents/
- 80 sunscreen\$.ti,ab.
- 81 Protective Clothing/
- 82 protective cloth\$.ti,ab.
- 83 (((hat or hats) and (wear\$ or wore or brim\$)) or (use\$ adj3 hat) or (use\$ adj3 hats)).ti,ab.
- 84 ((UV absorb\$ or ultraviolet absorb\$ or UV protect\$ or ultraviolet protect\$) and (laundry or detergent\$)).ti,ab.
- 85 sun protect\$.ti,ab.
- 86 photoprotect\$.ti,ab.
- 87 ((seek\$ or sun) and shade).ti,ab.
- 88 ((avoid\$ or minimiz\$ or minimis\$) and (sun exposure or midday sun)).ti,ab.
- 89 (avoid\$ and (sunlamp\$ or sunbed\$ or tanning bed\$ or tanning booth\$ or tanning salon\$ or tanning device\$ or indoor tanning or artificial light or artificial UV or artificial ultraviolet)).ti,ab.
- 90 or/79-89
- 91 adverse effects.fs.
- 92 harm\$.ti,ab.
- 93 adverse\$.ti,ab.
- 94 (increas\$ and ((time and sun) or sun exposure)).ti,ab.
- 95 ((reduce\$ or reduction) and physical activit\$).ti,ab.
- 96 Sedentary Lifestyle/

- 97 sedentary behavio\$.ti,ab.
- 98 depression/
- 99 Depressive Disorder/
- 100 mood disorders/
- 101 Anxiety/
- 102 (depression or depressed or depressive).ti,ab.
- 103 mood.ti.ab.
- 104 (anxiety or anxious).ti,ab.
- 105 vitamin D deficiency/
- 106 (vitamin D adj5 deficien\$).ti,ab.
- 107 Medical Overuse/
- 108 Unnecessary Procedures/
- 109 ((unnecessary or unneeded) adj3 (surg\$ or procedure\$ or biops\$)).ti,ab.
- 110 overdiagnos\$.ti,ab.
- 111 or/91-110
- 112 (67 or 90) and 111
- 113 clinical trials as topic/ or controlled clinical trials as topic/ or randomized controlled trials as topic/ or meta-analysis as topic/
- 114 (clinical trial or controlled clinical trial or meta analysis or randomized controlled trial).pt.
- 115 Random\$.ti,ab.
- 116 control groups/ or double-blind method/ or single-blind method/
- 117 clinical trial\$.ti,ab.
- 118 controlled trial\$.ti,ab.
- 119 meta analy\$.ti,ab.
- 120 cohort studies/ or longitudinal studies/ or follow-up studies/ or prospective studies/ or retrospective studies/
- 121 cohort.ti,ab.
- 122 longitudinal.ti,ab.
- 123 (follow up or followup).ti.ab.
- 124 113 or 114 or 115 or 116 or 117 or 118 or 119 or 120 or 121 or 122 or 123
- 125 112 and 124
- 126 limit 125 to (english language and yr="2009 -Current")
- 127 remove duplicates from 126
- 128 78 or 127

KQs 4-5, Skin Self-Exam

Database: Ovid MEDLINE(R) <1946 to March Week 4 2016>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <March 30, 2016>, Ovid MEDLINE(R) Daily Update <March 30, 2016> Search Strategy:

- 1 Skin Neoplasms/
- 2 Melanoma/
- 3 Hutchinson's Melanotic Freckle/
- 4 Hutchinson\$ Melanotic Freckle.ti,ab.
- 5 Melanoma, Amelanotic/
- 6 melanoma\$.ti,ab.
- 7 lentigo maligna.ti,ab.
- 8 Carcinoma, Basal Cell/
- 9 Carcinoma, Squamous Cell/
- 10 Neoplasms, Basal cell/
- 11 Neoplasms, Squamous cell/
- 12 skin cancer\$.ti,ab.
- 13 ((carcinoma\$ or neoplas\$) adj5 (skin or cutaneous)).ti,ab.
- 14 Nevus/
- 15 Nevus, Pigmented/
- 16 Dysplastic Nevus Syndrome/
- 17 (nevus or naevus or nevi or naevi).ti,ab.
- 18 ((naevoid or nevoid) adj3 syndrome\$).ti,ab.
- 19 Keratosis/
- 20 keratos#s.ti,ab.
- 21 or/1-20

- 22 Self examination/
- 23 (self adj3 (exam\$ or check\$)).ti,ab.
- 24 22 or 23
- 25 21 and 24
- 26 limit 25 to (english language and yr="2005 -Current")
- 27 remove duplicates from 26

CENTRAL

KQs 1-3, Trials & Harms

Issue 3 of 12, March 2016

- #1 melanoma:ti,ab,kw #2 "lentigo maligna":ti,ab,kw
- #3 (carcinoma* or neoplas*):ti,ab,kw near/5 (skin or cutaneous):ti,ab,kw
- #4 (skin next cancer*):ti,ab,kw
- #5 carcinoma:ti,ab,kw and (basal or squamous):ti,ab,kw
- #6 (nevus or naevus or nevi or naevi):ti,ab,kw
- #7 ((naevoid or nevoid) near/3 syndrome*):ti,ab,kw
- #8 keratos?s:ti,ab,kw
- #9 sunburn*:ti,ab,kw
- #10 suncreen*:ti,ab,kw
- #11 (protective next cloth*):ti,ab,kw
- #12 sunlight:ti,ab,kw
- #13 ((hat or hats) and (wear* or wore or brim*)):ti,ab,kw or (use* near/3 (hat or hats)):ti,ab,kw 36
- #14 sunlamp*:ti,ab,kw
- #15 tanning:ti,ab,kw
- #16 sunbed*:ti,ab,kw
- #17 photoprotection:ti,ab,kw
- #18 (seek* and shade):ti,ab,kw
- #19 sun:ti,ab,kw
- #20 (skin near/3 self near/3 (exam* or check*)):ti,ab,kw
- #21 {or #1-#20}
- #22 "health promotion":ti,ab,kw
- #23 "preventive health":ti,ab,kw
- #24 "consumer health":ti,ab,kw
- #25 counsel*:ti,ab,kw
- #26 (behavior* or behaviour*):ti,ab,kw next (therap* or intervention*):ti,ab,kw
- #27 health:ti,ab,kw next (behavior or behaviour):ti,ab,kw
- #28 (advice or advise):ti,ab,kw
- #29 educat*:ti,ab,kw
- #30 (provid* next information):ti,ab,kw
- #31 (prevention next intervention*):ti,ab,kw
- #32 {or #22-#31}
- #33 #21 and #32 Publication Year from 2009 to 2016, in Trials
- #34 sunscreen:ti.ab.kw
- #35 (protective next cloth*):ti,ab,kw
- #36 (hat or hats):ti,ab,kw
- #37 (UV or ultraviolet):ti,ab,kw and (laundry or detergent):ti,ab,kw
- #38 (sun next protect*):ti,ab,kw
- #39 photoprotect*:ti,ab,kw
- #40 (seek* or sun):ti,ab,kw and shade:ti,ab,kw
- #41 (avoid* or minimiz* or minimis*):ti,ab,kw and ("sun exposure" or "midday sun"):ti,ab,kw
- #42 avoid*:ti,ab,kw and (sunlamp* or sunbed* or tanning or "artificial light" or "artificial uv" or "artificial ultraviolet"):ti,ab,kw
- #43 {or #34-#42}
- #44 harm*:ti,ab,kw
- #45 (adverse next effect*):kw
- #46 adverse*:ti,ab
- #47 (increas* and time and sun):ti,ab,kw

#48	increas*:ti,ab,kw and (sun next exposure):ti,ab,kw
#49	(reduce* or reduction):ti,ab,kw and (physical next activit*):ti,ab,kw
#50	(sedentary next behavi*):ti,ab,kw
#51	(depression or depressed or depressive):ti,ab,kw
#52	mood:ti,ab,kw
#53	(anxiety or anxious):ti,ab,kw
#54	("vitamin D" near/5 deficien*):ti,ab,kw
#55	(unnecessary or unneeded):ti,ab,kw near/3 (surg* or procedure* or biops*):ti,ab,kw
#56	overdiagnos*:ti,ab,kw
#57	{or #44-#56}
#58	#43 and #57 Publication Year from 2009 to 2016, in Trials
#59	#33 or #58

KQs 4-5, Skin Self-Examination

Issue 3 of 12, March 2016

#1 #2 #3 #4 #5 #6 #7 #8 #9	melanoma:ti,ab,kw "lentigo maligna":ti,ab,kw (carcinoma* or neoplas*):ti,ab,kw near/5 (skin or cutaneous):ti,ab,kw (skin next cancer*):ti,ab,kw carcinoma:ti,ab,kw and (basal or squamous):ti,ab,kw (nevus or naevus or nevi or naevi):ti,ab,kw ((naevoid or nevoid) near/3 syndrome*):ti,ab,kw keratos?s:ti,ab,kw {or #1-#8} (self near/3 (exam* or check*)):ti,ab,kw
#10	(self near/3 (exam* or check*)):ti,ab,kw
#11	#9 and #10 Publication Year from 2005 to 2016, in Trials

PubMed, publisher-supplied KQs 1-3, Trials & Harms

Search	Query
<u>#58</u>	Search #38 OR #57
<u>#57</u>	Search #56 AND ("2009/01/01"[Date - Publication] : "3000"[Date - Publication])) AND English[Language]
<u>#56</u>	Search (#45 AND #55) AND publisher[sb]
<u>#55</u>	Search #46 OR #47 OR #48 OR #49 OR #50 OR #51 OR #52 OR #53 OR #54
<u>#54</u>	Search overdiagnos*[tiab]
<u>#53</u>	Search unnecessary procedure*[tiab] OR unneeded procedure*[tiab] OR unnecessary surg*[tiab] OR unneeded surg*[tiab] OR unneeded biops*[tiab]
<u>#52</u>	Search "vitamin d"[tiab] AND deficien*[tiab]
<u>#51</u>	Search anxiety[tiab] OR anxious[tiab]
<u>#50</u>	Search depression[tiab] OR depressed[tiab] OR depressive[tiab] OR mood[tiab]
<u>#49</u>	Search sedentary[tiab] AND behavio*[tiab]
<u>#48</u>	Search (reduce*([tiab] OR reduction[tiab]) AND ("physical activity"[tiab] OR "physical activities"[tiab])
<u>#47</u>	Search increas*[tiab] AND sun[tiab]
<u>#46</u>	Search adverse* [tiab] OR harm*[tiab]
#45	Search #11 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44

Search	Query
<u>#44</u>	Search (avoid*[tiab]) AND (tanning[tiab] OR sunlamp*[tiab] OR sunbed*[tiab] OR "artificial light"[tiab] OR "artificial uv"[tiab] OR "artificial ultraviolet"[tiab])
<u>#43</u>	Search (seek*[tiab] OR sun[tiab]) AND shade[tiab]
<u>#42</u>	Search (avoid*[tiab] OR minimiz*[tiab] OR minimis*[tiab]) AND (sun[tiab])
<u>#41</u>	Search sun protect*[tiab]
<u>#40</u>	Search (UV[tiab] OR ultraviolet[tiab]) AND (laundry[tiab] OR detergent*[tiab])
<u>#39</u>	Search hat[tiab] OR hats[tiab]
<u>#38</u>	Search #37 AND ("2009/01/01"[Date - Publication] : "3000"[Date - Publication])) AND English[Language]
<u>#37</u>	Search (#23 AND #35 AND #36) AND publisher[sb]
<u>#36</u>	Search random*[tiab] OR placebo*[tiab] OR trial[tiab] OR trials[tiab] OR metaanaly*[tiab] OR "meta analysis"[tiab] OR "meta analysis"[tiab] OR systematic[sb]
<u>#35</u>	Search #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34
<u>#34</u>	Search prevention intervention*[tiab]
<u>#33</u>	Search provid* information[tiab]
#32	Search educat*[tiab]
<u>#31</u>	Search advise[tiab]
<u>#30</u>	Search advice[tiab]
<u>#29</u>	Search health behavio*[tiab]
<u>#28</u>	Search behavio*[tiab] AND intervention*[tiab]
<u>#27</u>	Search counsel*[tiab]
<u>#26</u>	Search "consumer health"[tiab]
<u>#25</u>	Search "preventive health"[tiab]
<u>#24</u>	Search "health promotion"[tiab]
<u>#23</u>	Search #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22
<u>#22</u>	Search skin[tiab] AND self[tiab] AND (exam*[tiab] OR check*[tiab])
<u>#21</u>	Search "sun exposure"[tiab]
<u>#20</u>	Search "sun safety"[tiab]
<u>#19</u>	Search "sun awareness"[tiab]
<u>#18</u>	Search "sun protective"[tiab]
<u>#17</u>	Search "sun protection"[tiab]
<u>#16</u>	Search photoprotection[tiab]
<u>#15</u>	Search sunbed*[tiab]
<u>#14</u>	Search tanning[tiab]
<u>#13</u>	Search sunlamp*[tiab]

Search	Query
<u>#12</u>	Search sunlight[tiab]
<u>#11</u>	Search protective cloth*[tiab]
<u>#10</u>	Search sunscreen*[tiab]
<u>#9</u>	Search sunburn*[tiab]
<u>#8</u>	Search keratosis[tiab] OR keratoses[tiab]
<u>#7</u>	Search (naevoid[tiab] OR nevoid[tiab]) AND syndrome*[tiab]
<u>#6</u>	Search nevus[tiab] OR naevus[tiab] OR nevi[tiab] OR naevi[tiab]
<u>#5</u>	Search carcinoma[tiab] and (basal[tiab] or squamous[tiab])
<u>#4</u>	Search (carcinoma*[tiab] OR neoplas*[tiab]) AND (skin[tiab] OR cutaneous[tiab])
<u>#3</u>	Search "lentigo maligna"[tiab]
<u>#2</u>	Search "skin cancer"[tiab] OR "skin cancers"[tiab]
<u>#1</u>	Search melanoma*[tiab]

Skin Self-Examination

Search	Query
<u>#12</u>	Search #11 AND ("2005/01/01"[Date - Publication] : "3000"[Date - Publication]) AND English[Language]
<u>#11</u>	Search (#9 AND #10) AND publisher[sb]
<u>#10</u>	Search self[tiab] AND (exam*[tiab] OR check*[tiab])
<u>#9</u>	Search #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8
<u>#8</u>	Search keratosis[tiab] OR keratoses[tiab]
<u>#7</u>	Search (naevoid[tiab] OR nevoid[tiab]) AND syndrome*[tiab]
<u>#6</u>	Search nevus[tiab] OR naevus[tiab] OR nevi[tiab] OR naevi[tiab]
<u>#5</u>	Search carcinoma[tiab] and (basal[tiab] or squamous[tiab])
<u>#4</u>	Search (carcinoma[tiab] OR neoplas*[tiab] AND (skin[tiab] OR cutaneous[tiab])
<u>#3</u>	Search "lentigo maligna"[tiab]
<u>#2</u>	Search "skin cancer"[tiab] OR "skin cancers"[tiab]
<u>#1</u>	Search melanoma*[tiab]

Counseling to prevent skin cancer: search to identify existing systematic reviews

The search for existing synthesized literature and guidelines for literature published from 2011 through 2015 from: the Agency for Healthcare Research and Quality, Canadian Agency for Drugs and Technologies in Health, CDC Community Guide, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, Health Technology Assessment, DynaMed, Institute for Clinical Systems Improvement, Institute of Medicine, PubMed, NHS Health Technology Assessment Programme and the National Institute for Health and Clinical Excellence.

Cochrane Database of Systematic Reviews Issue 12 of 12, December 2015

#1 melanoma:ti,ab,kw
#2 carcinoma:ti,ab,kw
#3 "skin cancer":ti,ab,kw
#4 (sunscreen* or sunlamp* or sunbed*):ti,ab,kw
#5 ("sun exposure" or "sun protection" or "sun protective"):ti,ab,kw
#6 (#1 or #2 or #3 or #4 or #5) Publication Year from 2011 to 2015, in Cochrane Reviews (Reviews and Protocols)

Database of Abstracts of Reviews of Effects

((melanoma OR skin cancer OR (carcinoma AND skin) OR sunscreen* or sunlamp* or sunbed* or tanning OR sun exposure or sun protection or sun protective)) IN DARE FROM 2011 TO 2015

Health Technology Assessment (CRD HTA)

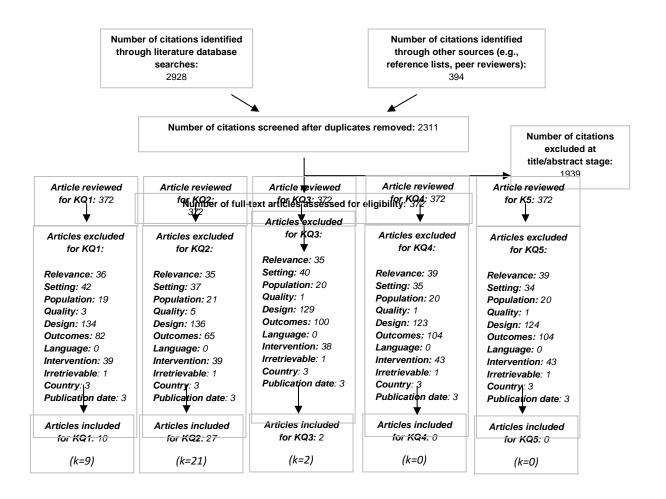
(melanoma OR skin cancer OR (carcinoma AND skin) OR sunscreen* or sunlamp* or sunbed* or tanning OR sun exposure or sun protection or sun protective) IN HTA FROM 2011 TO 2015

PubMed search strategy

Search	Query
<u>#13</u>	Search (((#12) AND systematic[sb]) AND English[Language]) AND ("2011"[Date - Publication] : "3000"[Date - Publication])
<u>#12</u>	Search (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11)
<u>#11</u>	Search ("skin cancer"[tiab] OR melanoma[tiab]) AND (inprocess[sb] OR pubmednotmedline[sb] OR publisher[sb])
<u>#10</u>	Search "Sunburn"[Mesh]
<u>#9</u>	Search ("Sunlight/adverse effects"[Mesh:NoExp] OR "Ultraviolet Rays/adverse effects"[Mesh])
<u>#8</u>	Search ("sun protection"[tiab] OR "sun protective"[tiab])
<u>#7</u>	Search (tanning[tiab] OR sunbed*[tiab] OR sunlamp*[tiab])
<u>#6</u>	Search ("Sunscreening Agents"[Mesh] OR sunscreen*[tiab])
<u>#5</u>	Search ("Carcinoma, Squamous Cell/epidemiology"[Mesh:noexp] OR "Carcinoma, Squamous Cell/etiology"[Mesh:noexp] OR "Carcinoma, Squamous Cell/genetics"[Mesh:noexp] OR "Carcinoma, Squamous Cell/prevention and control"[Mesh:noexp] OR "Neoplasms, Squamous Cell/epidemiology"[Mesh:noexp] OR "Neoplasms, Squamous Cell/etiology"[Mesh:noexp] OR "Neoplasms, Squamous Cell/prevention and control"[Mesh:noexp]) AND (skin[tiab] OR cutaneous[tiab] OR "skin neoplasms"[mesh:noexp])
<u>#4</u>	Search ("Neoplasms, Basal Cell/epidemiology"[Mesh:NoExp] OR "Neoplasms, Basal Cell/etiology"[Mesh:NoExp] OR "Neoplasms, Basal Cell/genetics"[Mesh:NoExp] OR "Neoplasms, Basal Cell/prevention and control"[Mesh:NoExp])

Search	Query
<u>#3</u>	Search ("Carcinoma, Basal Cell/epidemiology"[Mesh:NoExp] OR "Carcinoma, Basal Cell/etiology"[Mesh:NoExp] OR "Carcinoma, Basal Cell/genetics"[Mesh:NoExp] OR "Carcinoma, Basal Cell/prevention and control"[Mesh:NoExp])
<u>#2</u>	Search ("Melanoma/epidemiology"[Mesh:NoExp] OR "Melanoma/etiology"[Mesh:NoExp] OR "Melanoma/genetics"[Mesh:NoExp] OR "Melanoma/prevention and control"[Mesh:NoExp])
<u>#1</u>	Search ("Skin Neoplasms/epidemiology"[Mesh:NoExp] OR "Skin Neoplasms/etiology"[Mesh:NoExp] OR "Skin Neoplasms/genetics"[Mesh:NoExp] OR "Skin Neoplasms/prevention and control"[Mesh:NoExp])

Appendix B Figure 1. Literature Flow Diagram



Abbreviations: KQ = Key question

Appendix B Table 1. Inclusion and Exclusion Criteria

	Include	Exclude
Population	Persons of any age Parents/caregivers of children Children of melanoma survivors	Persons with prior history of skin cancer or who are otherwise under surveillance for skin cancer because of known increased risk (more than 25%)
Setting	Any setting linked with primary care health care delivery (e.g., home, clinic) Studies conducted in countries categorized as "Very High" on the Human Development Index (as defined by the United Nations Development Programme)	Settings not affiliated with primary care, such as community, worksite, child care, school, or recreational/tourism settings
Intervention	Stand-alone or multicomponent/multidimensional interventions aimed at improving sun protection behaviors or teaching skin self-examination Intervention must be initiated in, conducted in, or referable from primary care Interventions may include, but are not limited to: individual or group counseling, peer counseling, home visits, structured education, technology- or computer-based support, and distribution of written materials Interventions may be conducted by, but are not limited to: nurses/nurse practitioners, lay health workers, and physicians Health care system interventions (e.g., staff training)	Interventions not referable from primary care (occupational, recreational/tourism, policy-level interventions) Mass media campaigns Community interventions not affiliated with primary care Multicomponent interventions for which the effects of the primary care—relevant counseling component cannot be isolated
Comparison	Usual care, no intervention, waitlist, or minimal intervention	Another skin cancer counseling intervention
Outcomes	KQs 1, 4: Skin cancer outcomes: melanoma, basal cell, or squamous cell carcinoma incidence, morbidity, or mortality; intermediate outcomes: sunburn, nevi, and actinic keratosis KQ 2: Behavioral outcomes: sunscreen use; time spent in the sun; shade seeking; avoiding midday sun; avoiding indoor tanning; use of protective clothing, hats, or sunglasses; composite measures of sun protection behavior; skin self-examination behavior KQ 3: Any harm of behavioral counseling interventions, such as anxiety, increased time spent in the sun, reduced physical activity, or vitamin D deficiency KQ 5: Any harm of skin self-examination, including overdiagnosis and cosmetic or psychosocial harms	All KQs: Skin cancer metastasis or progression KQs 1, 2, 4: Outcomes with less than 3 months of followup after baseline assessment
Study design	KQs 1, 2: Randomized and controlled clinical trials KQs 3–5: Randomized and controlled clinical trials; prospective cohort studies	Case-control studies, cross-sectional designs, case series, case reports, narrative reviews, commentaries, editorials, and theses; qualitative studies; ecologic studies
Language	English	
Timing	2009 to present*	
Quality	Fair or good (according to design-specific	Poor (according to design-specific USPSTF

^{*} The USPSTF will continue to consider and use evidence that was included in its prior systematic reviews. For skin self-examination, the search period will begin with August 2005, the search date of the last USPSTF review on this topic.

Appendix B Table 2. Quality Assessment Criteria

Study Design	Quality criteria
Randomized	Valid random assignment?
controlled trials	Was allocation concealed?
USPSTF methods ²	Was eligibility criteria specified?
	Were groups similar at baseline?
	Were measurements equal, valid, and reliable?
	Was there intervention fidelity?
	Was there adequate adherence to the intervention?
	Were outcome assessors blinded?
	Was there acceptable followup?
	Were the statistical methods acceptable?
	Was the handling of missing data appropriate?
	Was there evidence of selective reporting of outcomes?
	Was the device calibration and/or maintenance reported?
Observational	 Was the cohort systematically selected to avoid bias?
studies (e.g.,	Was eligibility criteria specified?
prospective cohort	Were groups similar at baseline?
studies), adapted from the Newcastle-	Was the outcome of interest not present at baseline?
Ottawa Scale	Were measurements equal, valid, and reliable?
(NOS) ³	Were outcome assessors blinded?
(1100)	Was there acceptable followup?
	Were the statistical methods acceptable?
	Was the handling of missing data appropriate?

Abbreviations: USPSTF = U.S. Preventive Services Task Force

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Appendix C. Ongoing Studies

On December 14, 2016 we searched clinicaltrials.gov and WHO International Clinical Trials Registry platform for trials of behavioral counseling for sun protection and skin self-exam. We identified several relevant ongoing studies.

Study	Country	Population	Interventions	Relevant Outcomes	Anticipated Completion
A Randomized Controlled Trial of an Online Theory- based Intervention to Improve Adult Australians' Sun-protective Behaviours ²¹	Australia	Queensland residents aged 18 years and older	Online counseling lesson	Sun-protective behaviors	Currently recruiting
An Appearance-Based Intervention to Reduce Teen Skin Cancer Risk ²	USA	13 to 18 year- old females who have indoor tanned or have intention to indoor tan	Appearance- focused website intervention vs. control website	Indoor tanning behavior	Last updated on ClinicalTrials.gov in 2012; estimated final date of data collection May 2014
Melanoma prevention in Australian primary care patients ³	Australia	Adults with no history of melanoma (n = 273)	Risk assessment with tailored feedback vs. risk assessment and no tailored feedback	Sun protection behaviors 12 weeks after intervention	NR
Sun Protection, Tanning Behaviors and Attitudes in Adolescents ⁴	USA	Children and adolescents 12 to 14 years old (n = 293)	UV photography	Sun protection behaviors, indoor tanning 12 weeks after intervention	2018
Comparison of Two Strategies for Counseling Skin Examination and Sun Protection in First-degree Relatives of Patients With Melanoma (FADEMELA) ⁵	France	First degree relatives to patient with personal history of Stage 0 through IIB melanoma (estimated enrollment n = 1125)	Written advice from patient's PCP to FDRs of melanoma patients about sun protection	Sun protection behaviors one year after intervention	2018
The effect of personal ultraviolet radiation (UVR) devices and the SunSmart phone application on sun protection habits in the adult population in Queensland ⁶	Australia	Adults 18 to 35 with no history of skin cancer (n = 201)	UVR with and without Smart Phone Application (SunSmart)	Sun protection behaviors 12 weeks after intervention initaition	Data collection completed May 2016
Engaging Moms on Teen Indoor Tanning Through Social Media: Protocol of a Randomized Controlled Trial ⁷	USA	Mother-teen daughter dyads	Facebook- delivered health communication intervention	Indoor tanning 6 months after intervention	2019
Educational programmes for primary prevention of skin cancer ⁸ (Cochrane review)	Multiple countries	Children and adults excluding high-risk groups for the development of skin cancer (e.g. transplant	Studies that compare an educational program with the aim of preventing skin cancer with a placebo or no intervention.	The incidence of skin cancer following an educational program.	NR

Appendix C. Ongoing Studies

Study	Country	Population	Interventions	Relevant Outcomes	Anticipated Completion
		patients) or those with a history of skin			
		cancer.			

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Exclusion Codes E1. Not relevant E2. Not English E3. Not original research E4. Publication date (2009-present for KQ1-3; 2005-present for KQ4-5) E5. Ineligible COUNTRY E6. Ineligible SETTING E6a. Recreational/tourism E6b. Not primary care referable **E6c.** Occupational E6d. Childcare/school E6e. Other ineligible setting (community, etc.) E7. Ineligible POPULATION E7a. Melanoma patients E7b. NMSC patients E7c. Other patients under skin cancer surveillance because of known increased risks E8. Ineligible OUTCOMES E8a. Skin cancer metastasis or progression E8b. For KQs 1, 2, 4: Outcomes assessed <3 months after baseline assessment E8c. Protocol only/results-not-yet-reported **E8d**. Other ineligible outcomes E9. Ineligible INTERVENTION E9a. Mass media campaign E9b. Community interventions not affiliated with primary care E9c. Can't assess impact of primary care-referable component E10. Ineligible STUDY DESIGN E10a. No comparison group **E10b.** Comparison group is another skin cancer counseling intervention **E10c.** Other ineligible design **E11.** Irretrievable

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