# FACTORS THAT INFLUENCE THE RISK OF DEVELOPING MELANOMA AND AN INTERVENTION AIMED AT MODIFYING PREVENTABLE RISK FACTORS

# A Thesis

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Master of Science in Health Science

by

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#### **ABSTRACT**

**Problem:** Melanoma is a preventable and even treatable disease if caught in its early stages, yet prevalence is increasing on a global scale. To better understand the causes for the increase in prevalence, the current literature was examined for trends in disease awareness and attitudes and behaviors towards sun exposure and melanoma prevention. Behaviors were examined as either being primary prevention, such as preventing the development of the disease, or as being secondary prevention or aimed at early detection. Trends in knowledge, attitudes and behaviors were examined. **Methods:** The literature for review was found via the Weill Cornell Medical College online library through the PubMed database. All studies included were empirical research published after 2010 that examined trends in melanoma prevalence and prevention. **Results:** Based on the inclusion criteria, 19 empirical studies were included in the literature. There were 11 studies excluded because the studies were not empirical in nature, or the subject matter did not include trends in melanoma awareness and attitudes and behaviors aimed at prevention. Conclusions: Overall, subjects have adequate awareness of melanoma as a disease and are knowledgeable about means to prevent it. Yet, there is continued participation in risky behaviors based on positive attitudes towards sun exposure and preference for tanned skin. Current interventions are successful in educating subjects and increasing awareness, but have not exhibited success in changing attitudes and behaviors towards sun exposure in the population at risk.

# **BIOGRAPHICAL SKETCH**

Kate M. Horowitz is a native New Yorker, originally from Long Island, who now lives in Manhattan, New York. She attended Lehigh University in Bethlehem, Pennsylvania in 2010 and graduated with a Bachelor of Science in Biology in 2013. While at Lehigh University, she worked as a research assistant for biologist Dr. Murray Itzkowitz and helped on several projects. Additionally, she participated in a 2012 Child Psychiatry study at Stony Brook University. She is now attending Weill Cornell Graduate School of Medical Sciences in Manhattan, New York in order to gain a Master of Science degree in Physician Assistant Studies.

This thesis is dedicated to the memory of my grandfather, Arthur G. Cohen, who taught me "not to confuse activity with accomplishment".	)

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# TABLE OF CONTENTS

Biographical S	Sketch						iii
Dedication							iv
							V
Table of Cont	ents					•	vi
Review of the	e Literature						1
1.1 Introduction	on						1
1.2 Methods							4
1.3 Results							5
1.4 Discussion	1						5
1.5 Conclusio	n	•					12
D 1.D	•						1.4
	posai						14
			-	•	•	•	14
			-	•	•	•	16
	•		-	•	•	•	16
		-	-	•	•	•	16
	*		•	•	•		17
	2 1						17
2.3 Backgroun	_		-	•	•		18
2.3.1	Background .		•			•	18
2.3.2	Project Significance		•	•			19
			•			•	19
2.5 Research	Design and Methods		•	•			19
2.5.1	Design						19
2.5.2	Methods .						20
2.5.3	Statistical Analysis			•	•		21
2.5.4	Limitations .					•	22
2.5.5	Timeline .						22
2.5.6	Conclusion .						23
2.6 Summary			•	·	•	·	23
References							25
	Dedication Acknowledge Table of Cont Review of the 1.1 Introduction 1.2 Methods 1.3 Results 1.4 Discussion 1.5 Conclusion Research Prof 2.1 Abstract 2.2 Aims 2.2.1 2.2.2 2.2.3 2.2.4 2.3 Backgroun 2.3.1 2.3.2 2.4 Preliminan 2.5 Research 2.5.1 2.5.2 2.5.3 2.5.4 2.5.5 2.5.6 2.6 Summary	Dedication Acknowledgements Table of Contents  Review of the Literature  1.1 Introduction 1.2 Methods 1.3 Results 1.4 Discussion 1.5 Conclusion  Research Proposal  2.1 Abstract 2.2 Aims 2.2.1 Project Overview 2.2.2 Research Questions 2.2.3 Specific Aims 2.2.4 Hypothesis 2.3 Background and Significance 2.3.1 Background 2.3.2 Project Significance 2.4 Preliminary Studies 2.5 Research Design and Methods 2.5.1 Design 2.5.2 Methods 2.5.3 Statistical Analysis 2.5.4 Limitations 2.5.5 Timeline 2.5.6 Conclusion  2.6 Summary	Dedication Acknowledgements Table of Contents  Review of the Literature  1.1 Introduction 1.2 Methods 1.3 Results 1.4 Discussion 1.5 Conclusion  Research Proposal  2.1 Abstract 2.2 Aims 2.2.1 Project Overview 2.2.2 Research Questions 2.2.3 Specific Aims 2.2.4 Hypothesis  2.3 Background and Significance 2.3.1 Background 2.3.2 Project Significance 2.4 Preliminary Studies 2.5 Research Design and Methods 2.5.1 Design 2.5.2 Methods 2.5.3 Statistical Analysis 2.5.4 Limitations 2.5.5 Timeline 2.5.6 Conclusion  2.6 Summary	Dedication Acknowledgements Table of Contents  Review of the Literature  1.1 Introduction 1.2 Methods 1.3 Results 1.4 Discussion 1.5 Conclusion  Research Proposal  2.1 Abstract 2.2 Aims 2.2.1 Project Overview 2.2.2 Research Questions 2.2.3 Specific Aims 2.2.4 Hypothesis 2.3 Background and Significance 2.3.1 Background 2.3.2 Project Significance 2.4 Preliminary Studies 2.5 Research Design and Methods 2.5.1 Design 2.5.2 Methods 2.5.3 Statistical Analysis 2.5.4 Limitations 2.5.5 Timeline 2.5.6 Conclusion  2.6 Summary	Dedication Acknowledgements Table of Contents  Review of the Literature  1.1 Introduction 1.2 Methods 1.3 Results 1.4 Discussion 1.5 Conclusion  Research Proposal  2.1 Abstract 2.2 Aims  2.2.1 Project Overview 2.2.2 Research Questions 2.2.3 Specific Aims 2.2.4 Hypothesis 2.3 Background and Significance 2.3.1 Background 2.3.2 Project Significance 2.4 Preliminary Studies 2.5 Research Design and Methods 2.5.1 Design 2.5.2 Methods 2.5.3 Statistical Analysis 2.5.4 Limitations 2.5.5 Timeline 2.5.6 Conclusion  2.6 Summary	Dedication Acknowledgements Table of Contents  Review of the Literature  1.1 Introduction 1.2 Methods 1.3 Results 1.4 Discussion 1.5 Conclusion  Research Proposal 2.1 Abstract 2.2 Aims 2.2.1 Project Overview 2.2.2 Research Questions 2.2.3 Specific Aims 2.2.4 Hypothesis 2.3 Background and Significance 2.3.1 Background 2.3.2 Project Significance 2.4 Preliminary Studies 2.5 Research Design and Methods 2.5.1 Design 2.5.2 Methods 2.5.3 Statistical Analysis 2.5.4 Limitations 2.5.5 Timeline 2.5.6 Conclusion  2.6 Summary	Dedication Acknowledgements Table of Contents  Review of the Literature  1.1 Introduction 1.2 Methods 1.3 Results 1.4 Discussion 1.5 Conclusion  Research Proposal 2.1 Abstract 2.2 Aims 2.2.1 Project Overview 2.2.2 Research Questions 2.2.3 Specific Aims 2.2.4 Hypothesis 2.3 Background and Significance 2.3.1 Background 2.3.2 Project Significance 2.4 Preliminary Studies 2.5 Research Design and Methods 2.5.1 Design 2.5.2 Methods 2.5.3 Statistical Analysis 2.5.4 Limitations 2.5.5 Timeline 2.5.6 Conclusion  2.6 Summary

#### REVIEW OF THE LITERATURE

#### 1.1 INTRODUCTION

Melanoma is a form of skin cancer derived from melanocytes that most often manifests visibly on the skin. Melanoma is a cancer that is both preventable and treatable but only when it is discovered early, prior to metastasis, which happens at only 1 mm deep.<sup>1</sup> After metastasis, prognosis decreases from a treatable disease to a fatal disease. In its earliest stages, the ten-year survival rate is greater than 95%,<sup>2</sup> making early detection of utmost importance.

Melanoma is a neoplasm of melanocytes which most commonly occurs on the epidermis, but can also occur at various sites, including the mucosal epithelium and the retina.<sup>3</sup> Malignant melanoma first begins through radial growth and can then metastasize through the vertical growth phase. Early detection is crucial for melanoma because it is often treatable while in the radial phase.

Most melanomas are caused by exposure to ultraviolet (UV) radiation, such as sunlight or by artificial means such as tanning beds. Since melanoma is a cancer which is visible on the skin, diagnosis is based on physical exam followed by biopsy. But, most commonly, lesions are actually first identified by the patients or their family and friends at home, thus reinforcing a necessity for proper patient education. A nevus is evaluated as being a melanoma by its ABCD characteristics or asymmetry, borders, color and diameter. The characteristics of a melanoma lesion include a nevus that is asymmetrical, has irregular borders and is larger than 6 mm. Most often,

melanomas vary in color when compared to benign nevi. They can be blue, contain many different shades of the same color, contain a variety of colors or appear darker than most other nevi on the epidermis. Furthermore, lesions that evolve over time can also represent a melanoma.

Risk factors for melanoma include a patient's behavior, sun phototype and family history. Since UV exposure is the most significant risk factor for the development of melanoma, behaviors associated with sun or artificial UV exposure help increase the risk of melanoma.<sup>4</sup> In fact, short intermittent exposures resulting in sunburns are actually more significant for risk than daily exposures.<sup>5</sup> Use of artificial UV radiation through tanning beds is particularly dangerous. Tanning salon users were found to have a 75% increased risk of developing melanoma.<sup>6</sup> Childhood sunburns were found to be more dangerous in terms of malignant potential than those that occur during adulthood. Unfortunately, childhood sunburns remain quite common with as many as 73% of patients reporting sunburns during childhood. Additional risk factors include sun phototypes with lower Fitzpatrick scores, such as those with light skin, blue or green eyes, blonde or red hair, and those who report burning rather than tanning when exposed to the sun. Having multiple nevi also constitutes a higher risk for melanoma, as does mutations in the CDKN2A gene.<sup>8</sup> Family or personal history of melanoma is a fairly important risk factor. First degree relatives of patients with melanoma have double the risk of developing melanoma themselves. Moreover, survivors of any skin cancer are more likely to develop a first melanoma or a recurrence.1

Prevention of melanoma is accomplished in two ways: primary prevention and secondary prevention. Primary prevention focuses on limiting behaviors associated with causation. Patients are taught to limit exposure to sunlight and avoid artificial UV exposure through tanning salons. It is important to limit sun exposures but also practice sun protection. People can limit exposure by not going into the sun during its peak hours in the day (roughly 10:00 am-4:00 pm)<sup>3</sup> when the sun is highest in the sky and when UV radiation is thought to be at it is strongest. Seeking shade is also a viable option. Sun protection can be practiced through use of a broad spectrum sunscreen (covering both UVA and UVB rays) with sun protection factor (SPF) of fifteen or more on areas of exposed skin. While sunscreen is a method of protection, it is only successful when it is applied properly, such as 30 minutes before exposure and is reapplied every two hours or after exposure to water. This information varies per brand of sunscreen and directions are available on the bottle, which is an important resource that is often overlooked by consumers. Furthermore, hats, sunglasses and clothing which covers exposed skin are also ways to endorse primary prevention. There is limited evidence that there is a successful chemoprevention for melanoma. Possible use of non-steroidal anti-inflammatory drugs, or NSAIDs, is associated with melanoma prevention, but there is not enough evidence to support this at the present time. 10 so avoidance and protective behaviors are important means in the prevention of melanoma.

Secondary prevention is based on self skin exams and clinical skin exams which aim for the early detection of melanoma. Self skin exams are exams completed at home by patients themselves through the use of tools such as mirrors and flashlights

to better assess the skin.<sup>9</sup> Theoretically, patients should be taught by their physicians how to perform such exams and what should prompt evaluation by a physician. According to the Skin Cancer Foundation, it is recommended that self skin exams be completed on a monthly basis through the promotion of the campaign "if you can spot it, you can stop it". Clinical skin exams are completed by physicians or other providers which can identify dangerous nevi. There is no recommendation by the U.S. Preventive Services Task Force (USPTF) for routine clinical skin exams by primary care physicians at this time based on lack of supporting evidence. Despite this, clinical skin exams are a means of secondary prevention to detect melanoma in its early and treatable stage.

Though melanoma is preventable and treatable, its prevalence continues to increase. From 1975 to 2012 the rate of new cases of melanoma per 100,000 increased from 7.9 to 22. 9. Diagnosis rates are now increasing as much as 3% per year. Moreover, melanoma affects people of all ages and is a common cancer of young people (less than 29 years old) in particular. Being that melanoma is a preventable disease, implementing protective measures are necessary.

# 1.2 METHODS

Articles for the literature review were retrieved from the PubMed database via the Weill Cornell Medical College online library. Search terms included: "melanoma AND education", "melanoma AND prevention", "melanoma AND prevention AND education", and "sun protection AND sunbathing". From the studies located for

review, only empirical research studies published prior to 2010 were included. Any article that was not based on the prevention of melanoma was excluded.

#### 1.3 RESULTS

Out of the 30 articles meeting the inclusion criteria, 11 articles were excluded because they were not empirical in nature or the content of the study was not based on trends in melanoma awareness and prevention. Overall, 19 articles are included in the literature review, which examined trends in society's knowledge, behaviors and attitudes towards melanoma.

#### 1.4 DISCUSSION

# Articles that discuss the public's knowledge about melanoma

This portion of the literature review examines the extent of society's understanding of skin health, and perception of melanoma awareness. People can learn about skin cancer through several modes, whether it be through word of mouth, the media or from health care resources. As expected, certain sources of information are more accurate than others. In an Austrian cross-sectional study assessing patient knowledge by source, Haluza et al found that more people obtain their skin health information from media sources and friends than from physicians.<sup>4</sup> This finding can be very dangerous as health literacy obtained from media sources, such as TV and print media, can be easily misunderstood. Additionally, skin health information

obtained via friends or from word of mouth can be invalid or incorrect. As expected, it was found that the smaller subset of the population that was taught by health care professionals had a better core knowledge base about melanoma.<sup>4</sup> The information source utilized was also shown to vary by gender. Males were found to be more likely to utilize the Internet while females were more likely to reference materials found on skin care products<sup>4</sup> which corresponds to the finding that males are more likely to be less knowledgeable about melanoma than females.<sup>13</sup>

Not only does core knowledge vary by source, but it also differs by several variables including education level and socioeconomic class. Throughout the literature, it is well agreed upon that those with lower levels of education have less skin health literacy. In fact, 88% of Americans with less than a high school education were found to be unaware that melanoma is a form of skin cancer and are less likely to implement protective behaviors, such as the utilization of sunblock. In terms of socioeconomic class, lower classes are associated with later staged melanoma at diagnosis and therefore a worse prognosis. Without awareness of the disease itself, there is clearly no appreciation for risk factors and behaviors aimed at prevention.

# Articles that discuss behaviors aimed at primary prevention

Extensive research has been done to monitor trends of behaviors aimed towards primary prevention of melanoma. Unfortunately, the current literature shows that people are not routinely partaking in important preventative behaviors, but rather implement them sporadically, which does not minimize risk of melanoma. In a 2012 study based on questionnaires distributed in Northern Ireland, Gavin et al tracked the

most common sun protection methods in the population. It was found that people rarely avoid sun exposure, but rather use sunscreen or wear protective clothing.

Although sunscreen is an appropriate method for sun protection, it was found that most people do not apply it as recommended, leaving them more vulnerable to dangerous sun exposure. Although healthy behaviors are extremely valuable, the implementation of lifestyle changes can be a particularly challenging task. In a prospective cross-sectional study of high-risk children, Dunza et al was able to identify the critical time frame where at-risk children were the most vulnerable to change sun-related behaviors. It was shown that between eleven to fourteen years of age these children were most amenable to decreasing sun exposure and implementing protective behaviors. The pattern of sun exposure in the general public is particularly disturbing, as people are generally well educated on risk factors and methods of prevention, yet fail to implement these behaviors in their daily lives.

An interesting area of research is the study of the preventive behaviors employed by high-risk populations, such as melanoma survivors and people with a first-degree relative affected by the disease. Throughout the literature, it was shown that, despite risk factors for the development of melanoma, members of the high-risk population continue to partake in dangerous behaviors. Melanoma survivors have an increased risk of developing melanoma again, yet up to 49% of melanoma survivors reported at least one sunburn in the last year. In 2012, Shuk et al studied first degree relatives of melanoma patients. Through a series of interviews, they identified variables associated with the implementation of either risky or protective behaviors. It was found that protective behaviors (such as sunblock application and protective

clothing use) were not consistently employed. Rather, people were more likely to implement preventative behaviors only in certain environments such as the beach or pool.<sup>5</sup> Unfortunately, this lack of consistency can leave people exposed to endless hours in the sun without protection, which increases the risk for development or recurrence of melanoma. In a 2012 study by Manne et al, higher levels of education and aesthetic concerns about sun damage (such as photo-aging effects) were two characteristics resulting in more protective behaviors.<sup>16</sup> Overall, there is substantial data endorsing that, despite risk factors, this high-risk population continues to partake in dangerous behaviors.

# Articles that discuss behaviors aimed at secondary prevention: Self Skin Exams

In addition to the study of behaviors aimed at primary prevention, there is tremendous research on how often patients participate in the secondary prevention behavior of self skin exams. Several studies across Europe, Australia and the United states have shown that tumor depth was inversely related to self skin exams: people who did self skin exams had shallower and therefore less dangerous melanomas at diagnosis. Although self skin exams are highly recommended for survivors of melanoma, most of these patients do not do them as often as clinically recommended. Kasparian et al examined the frequency of self skin exams in high-risk patients. The subjects in this study were aware of their high-risk status through known CDKN2A gene mutations, which are associated with increased occurrence of melanoma. Unfortunately, not all members of this group performed self skin exams as often as clinically advised. Subjects who completed self skin exams more frequently were found to have higher levels of self-confidence in their ability to complete the exam

and better communication with their physicians.<sup>8</sup> Better physician-patient communication is of utmost importance. Patients who understood the proper method of conducting a self skin exam (such as using pictures as a reference) were actually more successful in detecting melanoma in its early stages.<sup>18</sup> Those that were informed to complete self skin exams by their physicians and felt that they were able to complete the exam properly were more likely to partake in the exams, and thus more likely to benefit from it.

# Articles that discuss behaviors aimed at secondary prevention: Clinical Skin Exams

A clinical skin exam, or full body skin examination by a health care practitioner, is another means of secondary prevention of melanoma. Throughout the literature, it is evident that people are not partaking in clinical skin exams as often as recommended. Lack of accessibility was identified as a barrier to obtaining a clinical skin exam. <sup>18</sup> For example, through examining the health care practices of patients with invasive melanoma one year prior to diagnosis, Swetter et al found that subjects that obtained medical care in one location were more likely to obtain recommended clinical skin exams than subjects who obtained their medical care from several different locations. <sup>18</sup> This finding was supported in a 2011 study by Coups et al, which examined the health care practices of first degree relatives of patients with melanoma. Coups et al concluded that this high-risk population was more likely to participate in clinical skin exams when they were easy to obtain. <sup>19</sup> Factors that were also associated with completion of clinical skin exams included a feeling of support by

family members and a perception that they would benefit from having the exam. <sup>19</sup>

Articles that discuss the public's attitude towards melanoma prevention

Overall the current literature suggests that the public does not partake in adequate UV protection, and is therefore increasing their risk factors for the development of cutaneous melanoma. The driving factors which perpetuate these risky behaviors are people's engrained attitudes regarding the appearance of their skin. In general, attitudes towards melanoma prevention are mediated more by skin tan preference than by health concerns.<sup>4</sup> In an online cross-sectional study of Austrian college women, it was found that the desire for tanned skin was stronger than the perception of the danger of the disease. <sup>20</sup> Moreover, high-risk women (women with fair skin phototypes and positive family histories for melanoma) were shown to be as likely to engage in sun tanning as women with few risk factors. <sup>20</sup> These high-risk women also reported significantly more sunburns.<sup>20</sup> Despite the potential threat melanoma poses, these women participated in dangerous behaviors mediated by their positive attitudes towards skin tan preference. This conclusion was supported in a cross sectional study by Kyle et al, which examined the knowledge, attitudes and behaviors of Scottish secondary school students. Up to 46% of subjects reported that their peers held positive attitudes towards sun tanning.<sup>21</sup> Moreover, females were found to be more knowledgeable about melanoma, but were also more likely to report increased self-confidence when tanned.<sup>21</sup> They were therefore more likely to suntan and have more sunburns than the males in the population. <sup>21</sup> Despite adequate awareness, the females in this population were influenced by their positive attitudes regarding tanned skin, and thus put themselves at increased risk for skin damage.

Furthermore, a 2014 population based study by Gefeller at al perpetuated this theory. Parents of children between the ages three and six years old were interviewed, and it was reported that parents with increased awareness of sun damage were also more likely to report that they found tanned skin aesthetically appealing. Furthermore, in a 2010 study based on self reported data from 8178 subjects from 12 different countries, Bränström et al identified that skin tan preference was the biggest indicator for intentional tanning. Positive attitudes towards sun exposure and skin tan preference shape the behavioral patterns of the general public; thus, it is not surprising that there is a large discrepancy between clinically recommended standards and the public's current skin care practices.

# Articles that discuss current interventions to prevent melanoma

Based on the association between skin attitudes and behaviors, several interventions have been created and examined within the current literature. Saridi et al examined the impact of an educational program on attitudes and behaviors of elementary school children to the sun. While the educational program increased the subjects' skin health knowledge, it did not alter their attitudes.<sup>24</sup> Unfortunately, attitudes regarding skin health were found to be the largest mediator for skin-related behaviors.<sup>23</sup>

In a different study, Robinson et al examined the success rate of various interventions that taught high-risk populations how to properly conduct self skin exams. PowerPoint presentations and Internet-based programs were identified as methods that were highly successful in teaching how to conduct a proper self skin exam.<sup>2</sup> This, in combination with the findings from the Kasparian et al study, shows

that patients are more likely to complete self skin exams when they feel confident in their abilities,<sup>8</sup> thus the implementation of PowerPoint and Internet teaching methods can feasibly increase the frequency of self skin exam completions.

Potential for behavioral change has been shown through interventions mediated by in-person interactions with physicians. Falk et al showed that physician-led interactions resulted in increases in protective behaviors, such as sunblock utilization. Unfortunately, this has been contradicted by other studies available in the literature. Rat et al demonstrated that physician-led interaction is simply not enough to evoke a change in behavior. There was even a large discrepancy between information recall which was based on physician style: increased recall was seen in groups with highly active physicians such as those that examined the patient, discussed risk at length and provided educational material. While there has been some success in behavioral change, there remains a discrepancy in the literature.

#### 1.5 CONCLUSION

Although melanoma is preventable and highly treatable in its early stages, the frequency of melanoma is unfortunately increasing. While oftentimes the first feasible method of prevention is to educate the public, the literature proves that the general public already has an awareness of the disease. Though the general public is knowledgeable about the correlation between sun exposure and development of melanoma, as a whole, they continue to partake in dangerous behaviors because they maintain strong and persistent attitudes regarding skin tan and aesthetic preferences.

There was some behavior change achieved through physician-led interactions.<sup>25</sup> Unfortunately, there was not only variability within the results, but not all people have access to medical care where such interventions could take place. Future research is needed to identify the most effective way to change attitudes toward tanned skin and therefore change behaviors regarding sun exposure in the general public as a whole.

An intervention aimed at altering attitudes towards melanoma, instead of educating the public about the disease, is needed. The discrepancy between sun exposure awareness and melanoma runs parallel with the awareness about tobacco use and the development of lung cancer. Overall, the general public was aware of the effects of smoking cigarettes, yet continued to partake in the behavior. The antitobacco "Truth" campaign, developed in 2000, targeted America's perception of tobacco use and has successfully decreased teenage smoking rates-to the lowest rate recorded in the last 40 years<sup>27</sup>- through changing attitudes and perceptions towards smoking. An anti-melanoma intervention that is modeled after the "Truth" antismoking campaign should be initiated, based on its success rate in changing the public's attitudes and behaviors towards smoking cigarettes and tobacco use.

#### RESEARCH PROPOSAL

#### 2.1 ABSTRACT

**Problem:** Melanoma, a preventable disease, is increasing in prevalence on a global scale. After review of the literature, it is apparent that the general public has adequate awareness about the disease, yet still values tanned skin and partakes in intentional sun exposure. There has been success in increasing melanoma awareness in the public, but this success is limited in terms of changing attitudes and behaviors towards sun exposure. Furthermore, an intervention, which has access to the entire population at risk, is needed. **Purpose**: The purpose of this study is to find out if an intervention modeled after the "Truth" campaign (which has shown to be successful in mediating attitudes and behaviors towards to tobacco and decreasing its use) can be translated to have success in melanoma prevention. **Research questions:** Can the SKIP intervention, modeled after the successful "Truth" anti-tobacco campaign, change attitudes and behaviors towards sun exposure? Methods: The study will be a randomized controlled study that will compare the efficacy of an intervention modeled after the "Truth" campaign and an educational intervention typically available in nonmedical settings. Attitudes and behaviors will be assessed by a questionnaire administered before the intervention and at one, three and six months after the intervention. Outcomes: The study will assess if a media campaign modeled after the "Truth" campaign will be successful in decreasing desire for sun exposure and unprotected sun exposure when compared to an educational

intervention. **Benefit:** If successful, this intervention can be a very valuable tool to ultimately reduce melanoma prevalence within the general public.

#### **2.2 AIMS**

#### 2.2.1 Project Overview

Melanoma is a preventable disease, yet prevalence of the disease is increasing on a global scale. Despite adequate awareness, people continue to maintain positive attitudes towards sun exposure and participate in risky behaviors proven to cause melanoma. Within the literature there has only been limited behavior modification success when interventions were mediated by in-person physician interactions.

Unfortunately, such interventions cannot translate to the entirety of the population at risk, being that physician interactions are unfortunately not available to all. This study includes utilization of the SKIP or "SKin Integrity Preservation" intervention, which aims to not only urge subjects to "skip" intentional sun exposure through changing attitudes and behaviors but also aims to be a means that is easily accessible to the public as a whole.

# 2.2.2 Research Questions

- 1. Can the SKIP intervention, modeled after the "Truth" anti-tobacco campaign, change positive attitudes towards sun exposure?
- 2. Can the SKIP intervention, modeled after the "Truth" anti-tobacco campaign, change attitudes towards skin tan preference?
- 3. Can the SKIP intervention, modeled after the "Truth" anti-tobacco campaign, increase behaviors aimed at preventing sun exposure and therefore melanoma?
- 4. Can the SKIP intervention, modeled after the "Truth" anti-tobacco campaign,

change sun-related behaviors in a non-medical setting?

# 2.2.3 Specific Aims

**AIM 1:** To decrease harmful pre-existing positive attitudes towards sun exposure and tanned skin.

**AIM 2:** To decrease intentional sun exposure and increase behaviors aimed at the primary prevention of melanoma.

**AIM 3:** To find a successful intervention that can be used in the future to decrease the prevalence of melanoma in the general public.

# 2.2.4 Hypothesis

**Null hypothesis:** The SKIP intervention, modeled after the anti-tobacco "Truth" campaign, will not alter attitudes and behaviors regarding sun exposure and will have similar efficacy to the non-physician mediated educational/teaching interventions already in use throughout the literature. Skin tan preference and preventative behaviors, such as utilization of sunscreen, protective clothing and shade seeking, will remain unchanged after the intervention.

Alternative hypothesis: The SKIP intervention, modeled after the anti-tobacco "Truth" campaign, will change attitudes towards tanned skin and behaviors regarding sun exposure. After the intervention, subjects will express increases in negative attitudes regarding sun exposure and will increase participation in preventative behaviors such as utilization of sunscreen, protective clothing and shade seeking.

#### 2.3 BACKGROUND AND SIGNIFICANCE

# 2.3.1 Background

Melanoma, a preventable form of skin cancer, is unfortunately increasing with new rates of new diagnosis climbing to 1.4% per year. 12 While exposure to unprotected ultraviolet radiation is the most important causative factor, many variables contribute to the increase in prevalence of this disease. Historically, a tanned complexion was not deemed desirable, but over the 20th and 21st centuries, the value of tanned skin within society increased immensely. Additionally, over the last two centuries, the common wardrobe has evolved to accept increased skin exposure, and therefore sun exposure. While intermittent sun exposure is in fact more contributory to the development of melanoma than chronic sun exposure,<sup>5</sup> intermittent sun exposure has increased over the last two centuries, as distant and global travel has become more accessible to the general public. Additionally, the strength of ultraviolet radiation has increased in recent years, secondary to environmental factors such as the depletion of the ozone layer. Of these many variables contributing to the increase in melanoma, attitudes towards skin tan preference, skin exposure and therefore sun exposure are modifiable risk factors. Unfortunately, the general public, and collegeaged women in particular, have been shown to be adequately aware of the disease and its risk factors, yet have been shown to maintain positive attitudes towards tanned skin and intentional sun exposure.<sup>20</sup> But, the discrepancy between knowledge and behaviors is not unique to melanoma and sun exposure. A similar predicament existed between lung cancer awareness and the continuation of tobacco use. A unique mediabased intervention, called the "Truth" campaign, targeted young adults with goals not

only to educate, but to change positive attitudes associated with tobacco use. Through catchy magazine and television advertisements, the "Truth" campaign has decreased teenage smoking rates from 23% to 7%.<sup>27</sup>

#### 2.3.2 Project Significance

The literature shows that, while awareness of melanoma is adequate, positive attitudes regarding sun exposure and tanned skin have counteracted protective behaviors, such as avoiding unprotected sun exposure. Young women have been shown throughout the literature to be aware of melanoma, yet hold positive attitudes towards sun exposure and tanned skin, and thus continue to participate in behaviors such as intentional sun tanning. The SKIP intervention, modeled after the successful anti-tobacco "Truth" campaign, will be initiated with a focus on altering attitudes and behaviors in young women.

#### 2.4 PRELIMINARY STUDIES

Not Applicable

#### 2.5 RESEARCH DESIGN AND METHODS

# **2.5.1** Design

The study will be a randomized controlled trial where the experimental group would be exposed to the SKIP intervention, modeled after the television advertisements from the "Truth" campaign. The control group would be exposed to an educational intervention, consisting of a PowerPoint presentation. Both groups will

receive surveys beforehand to assess attitudes and behaviors aimed at melanoma prevention. They will receive the same survey as follow-up one month after the intervention and then three and six months following the intervention. The surveys will include two sections: one addressing attitudes towards sun exposure and one addressing behaviors towards sun exposure. Attitudes, such as skin tan preference and concern for melanoma, and behaviors, such as participation in intentional sun exposure and utilization of SPF and protective clothing, will be assessed via multiplechoice questions. All answer choices will be based on a numerical scale based on how strongly the subject feels or how often the subject participates in the behavior. The subjects will be randomized into two groups (experimental and control) and will be blinded to what group they are in, while the researchers will not. A randomized controlled trial will be utilized in order to demonstrate the efficacy of the SKIP intervention based on comparing the results of the SKIP intervention with the results from the educational intervention. Three trials will be conducted once a month for three months and subjects will only be allowed to participate in one trial.

#### 2.5.2 Methods

The inclusion criteria includes female subjects aged 18-25 years old who are currently enrolled as full time students in two sister Universities (similar in student demographics, academics and location) in the Southeastern portion of the United States. Two universities in the Southeastern portion of the United States will be utilized to control for external variables secondary to a seasonal effect. Females 18-25 years old will be exclusively used as subjects, as the literature has identified young

women as being susceptible to both risky attitudes and behaviors towards sun exposure. Women from University A will be placed exclusively in the experimental group where they will watch a 15-minute video clip mimicking the "Truth" television commercials. Facts about melanoma will be displayed in vibrant colors which alternate with vignettes featuring pop culture references and catchy musical accompaniments. Women from University B will be placed exclusively in the control group where they will be exposed to a 15-minute PowerPoint presentation where facts about melanoma will be displayed.

Exclusion criteria include males, females outside the 18-25 year old age range, and students who are not at full time status in University A or University B.

The independent variable includes the type of intervention that the subjects take part in (either the experimental novel "Truth" like intervention verses educational/teaching intervention).

The dependent variable includes attitudes towards sun exposure, such as tanning and skin tan preference, as well as behaviors towards sun exposure, such as the use of SPF, protective clothing and seeking shade.

# 2.5.3 Statistical Analysis

Based on a a priori analysis, the sample size will be N=180 (three trials of 60 subject: 30 subjects per control group and 30 subjects per experimental group). Data will be derived from the pre-intervention and post-intervention surveys. Answers from the surveys will be transformed into a numerical score and compared between the pre-intervention and post-intervention scores from within the groups and between

the groups. Using the Statistical Package for the Social Sciences (SPSS), a Mann-Whitney U test, with a p-value  $\leq 0.05$ , will be conducted to see if there are significant changes in attitudes and behaviors towards sun exposure.

#### 2.5.4 Limitations

The limitations for this study include the honesty of subjects while answering survey questions and ability to locate subjects for follow-up. Further limitations include differences between the control and experimental groups such as the differences in cultures between University A and University B as well as random differences in characteristics of the subjects themselves such as personal or family history of skin cancer, prior melanoma awareness, race, origin of location and occupation. It is also important to note that while the "Truth" anti-tobacco campaign, which the SKIP intervention is modeled after, has had great success, it was also introduced at a time when anti-tobacco legislation, such as limiting the use of tobacco in indoor spaces, was also put into place.

#### 2.5.5 Timeline

The study will take 14 months to complete. Subjects will be recruited via phone and email in June 2016 while on "summer break" from the University.

Enrollment will take place before the start of the fall semester, July-August 2016. Data will be collected in three different trials, September 2016, October 2016 and November 2016. Follow-up surveys will be administered one month after the intervention (October 2016, November 2016 and December 2016), three months after the intervention (December 2016, January 2017 and February 2017) and six months

after the intervention (March 2017, April 2017 and May 2017). The conclusion of the study and the dissemination of findings will be completed by August 2017.

#### 2.5.6 Conclusion

College-aged women have been frequently studied in the current melanoma literature, and as a group, they have been identified as having adequate awareness of the disease, yet positive perceptions of tanned skin, and have been shown to participate in dangerous behaviors such as intentional sun tanning. This study will include 180 collegiate women (three trials of 60 subjects) to see if the SKIP intervention, modeled after the successful "Truth" anti-tobacco campaign, can have similar successes in changing attitudes and behaviors towards skin tan preference and therefore sun exposure. Since melanoma rates are globally increasing and current interventions have had minimal success or are not accessible to the entirety of the population at risk, this study will determine if a different type of intervention can decrease risky attitudes towards sun exposure and increase protective behaviors.

#### 2.6 SUMMARY

This study will show if an intervention that has proven to be successful in changing attitudes and behaviors towards tobacco use<sup>27</sup> can be successful in changing attitudes and behaviors towards sun exposure. If data suggests that this novel intervention significantly changes tan preference and intentional sun exposure, more trials will be conducted with broader demographics. If this novel intervention does

not have success, further research into the field should continue, in hopes to decrease the prevalence of this preventable disease.

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