

**Systematic development of a  
behavioural intervention to  
promote sun-protection  
behaviours amongst  
holidaymakers**

**Angela Margarete Martins Rodrigues**

**Thesis submitted in partial fulfilment for the  
qualification of Doctor of Philosophy**

**Institute of Health and Society, Faculty of Medical  
Sciences  
Newcastle University**

**June 2014**

## **Abstract**

Intermittent UV-exposure is a risk factor for melanoma. Recreational sun-exposure (e.g. holiday) is associated with melanoma incidence. Effective and affordable interventions to promote sun-protection behaviours (SPB) are needed. This PhD thesis describes the development of a behavioural change intervention to promote SPB amongst holidaymakers and a pilot of acceptability, feasibility, and fidelity of the intervention.

A systematic review was conducted to appraise efficacy of behavioural interventions to change SPB and experience of sunburn. Twenty-three randomised-controlled trials (RCT) were included and no evidence was found for the efficacy of interventions in reducing tanning, promoting protective clothing and seeking shade. Larger effects were observed for self-reported sun-exposure and number of sunburn experienced. Moderator analyses showed that effective interventions were more likely to stimulate social norms and provide appearance-based information about photoaging.

A qualitative study based on the theory domain framework was conducted to investigate perceptions of sun-related experiences and determinants of SPB. In a semi-structured interview, 17 holidaymakers showed a desire to tan attributing a high value to it during holidays. Most respondents knew how to perform SPB and identified key barriers to SPB.

Findings from systematic review and qualitative work informed the development and design of an evidence-based intervention. The prototype of the mobile phone based (app) intervention was initially tested using a user-centred design: 17 participants were satisfied with the prototype and expressed willingness to use it, with minor changes being introduced to optimise acceptability.

Novel outcome measures to assess sun protection behaviours were also explored. The two newly developed methods of outcome assessment (sunscreen use events classifier and mDNA damage caused by UV exposure) show robust evidence for the assessment of sun protection behaviours and skin damage during holidays. This work contributed to the development of a full protocol for the outcome assessment in a definitive trial.

Another systematic review was conducted to synthesize evidence on the question-behaviour effect (QBE) for health-related behaviours. Forty-one studies were included assessing a range of health behaviours. Findings showed a small QBE. Studies showed moderate heterogeneity, variable methodological quality and evidence for

publication bias. No dose-response relationship was found. Risk of bias within studies and publication bias indicate that the observed small effect size may be an over-estimate. Based on these findings, no changes would be introduced to the protocol of the definitive trial to tackle QBE.

A pilot study assessing the acceptability, feasibility and fidelity of the app use showed that the intervention was feasible and highly acceptable. Findings from the pilot study will inform a definitive RCT.

*To my late father, who always encouraged me through this journey, but unfortunately did not see it through completion.*

## Acknowledgements

There are many people who I would like to acknowledge for the support given throughout this journey of completing my PhD.

First and foremost, I'd like to express my gratitude to my PhD supervisors, Dr Vera Araujo-Soares and Professor Falko Sniehotta, who have always given me the opportunity to explore and develop my ideas and research questions. I am very lucky to have been supervised by Vera and Falko and I thank you for your incessant support and encouragement over the last four years. I am also very grateful to Professor Mark Birch-Machin, my co-supervisor, for all your guidance and friendly support on this project.

I thank all that have participated, helped and made this work possible, in particular to the participants of the empirical work of this thesis.

For providing input and expertise into different stages of this PhD, I'd like to thank Professor Patrick Olivier and his team, in their support for the digital technologies in this project. I'd also like to say a big thank you to Dr Jean Adams and Dr Tracy Finch, for their role as assessors and to Professor Martin White and Professor Sherry Pagoto for their role as examiners of this thesis.

I'd also like to acknowledge the Portuguese Science and technology Foundation for supporting me financially through the past four years. I'd also like to thank the Institute of Health and Society for their financial help through the last 3 months of my PhD.

For providing support and expertise into the randomisation procedure and for all the help with recruitment for the pilot study, I'd like to thank Dr Dorothy Newbury-Birch, Dr Deborah Stocken, Dr Stephanie O'Neil and Janice Armstrong.

More personally, I would like to thank many friends for their never-ending support. Cassandra Sampaio e Liliana Amorim, obrigada por estarem sempre disponíveis para me ouvir e por terem estado sempre ao meu lado ao longo deste percurso. Obrigada por nunca questionarem o nossa amizade, apesar da distância!

I would also like to express my gratitude to my friends and colleagues in Newcastle. In particular, Suzanne McDonald, Erin Graybill, Peter Tennant, Lucy Rehackova, Samuel Ginja, Nicki Hobbs, Leigh Daly Presseau, Sandra Machado and Dom Kwasnicka for supporting me through to my numerous crises, with coffee and never-ending kindness. Since "memory is deceptive because it is coloured by today's events" I would like to

thanks all of those that I've crossed my path over the last four years and have supported me somehow during this journey.

I'd also like to thank my colleagues from the Health Psychology Group for their help and expertise through different stages of this PhD. For all the support and kindness during my lab work, I couldn't be more thankful for all my colleagues at the Dermatological Sciences Lab: SJ, Asif, Anne, Jenny, Christine and Amy. For helping me with the initial lab work, I would like to also thank Coral Lapsley.

I would like to thank my parents for providing me with the foundation for all I did and their unwavering confidence in my ability. Um especial obrigada à minha mãe por ser a Mulher forte que é, e por me ter ensinado que a vida é uma contante aprendizagem.

I would also like to thanks my 'superstar' sister, who puts up with me and has always been an emotional pillar of strength. Obrigada por seres tu simplesmente, por estres sempre lá quando preciso e por seres a pessoa mais especial na minha vida! E por me lembrares constantemente que não posso deixar sempre tuda para última. And thanks for listening to my numerous crises over the phone!

Lastly, and most importantly, I thank Lloyd for all his support, patience and love. Thanks for making the writing up of this PhD enjoyable for me; and for always being there with a smile and a hug when they are needed the most.

# **Authors contribution list for the empirical chapters**

## **Chapter 2: Systematic review of sun protection interventions**

Angela Rodrigues (AR), Falko Sniehotta (FFS) and Vera Araujo-Soares (VAS) conceived the idea for the chapter together. AR screened, extracted the data, assessed the quality of included studies, performed the analysis and drafted the manuscript. VAS acted as second reviewer for 20% of screening and data extraction. FFS checked 20% of the quality assessment of included studies. All authors contributed to data interpretation and critically reviewed the manuscript.

## **Chapter 3: Qualitative study**

AR, FFS and VAS conceived the idea for the chapter together. AR collected the data by conducting semi-structured interviews, performed the qualitative analysis and drafted the manuscript. All authors contributed to data interpretation and critically reviewed the manuscript.

## **Chapter 4: User centred design**

AR, FFS and VAS conceived the idea for the chapter together. AR and VAS developed the designs and algorithms of the mISkin app and liaised with the application developers at Culture lab (Professor Patrick Olivier and his team), who implemented the specifications in an Android environment.

AR collected the data by conducting the user-centred study, performed the analysis and drafted the manuscript. The experts' consultations included Professor Patrick Olivier and his team of computer scientists, as well as Mark Birch-Machin (MBM), FFS, VAS and AR.

MBM, FFS, VAS and AR contributed to data interpretation and critically reviewed the manuscript.

## **Chapter 5: Measurement studies**

AR, MBM, FFS and VAS conceived the idea for the chapter together. AR collected all the data for the sensors and swabs data, and drafted the manuscript. The analysis and modelling for the sensors data were performed by Professor Patrick Olivier and his team of computer scientists at Culture lab.

AR conducted the laboratorial work (DNA extraction and Nanodrop) and the PCR analysis (various assays) of the mDNA in collaboration with a final-year Biomedical Science Student (Newcastle University) as part of the supervised Dissertation.

MBM, FFS, VAS and AR contributed to data interpretation and critically reviewed the manuscript.

### **Chapter 6: Question Behaviour Effect (QBE) Systematic Review**

AR and FFS conceived the idea for the paper together. AR and NH independently screened, extracted the data and assessed the quality of included studies. AR entered data into the statistical software and NH independently verified entries. AR performed the analysis and drafted the manuscript. All authors contributed to various discussions regarding this chapter, data interpretation and critically reviewed the manuscript.

### **Chapter 7: Internal pilot RCT**

AR, FFS, MBM and VAS conceived the idea for the chapter together. AR collected all the data described in this chapter, performed the quantitative (including all the lab work) and qualitative analyses and drafted the manuscript.

MBM, FFS, VAS and AR contributed to data interpretation and critically reviewed the manuscript.

## **Publications**

Two papers, based on the work in the thesis, have been published in peer-reviewed scientific journals:

**Rodrigues, A.**, Sniehotta, F., & Araujo-Soares, V. (2013). Are interventions to promote sun-protective behaviors in recreational and tourist settings effective? A systematic review with meta-analyses and moderator analyses. *Annals of Behavioral Medicine*. 45(2):224-38. doi: 10.1007/s12160-012-9444-8.

**Rodrigues, A.**, Hobbs, N., French, D., Glidewell, L., & Sniehotta, F. F. (In Press). The Question-Behavior Effect: Genuine effect or Spurious Phenomenon? A systematic review of randomized controlled trials with meta-analyses. *Health Psychology*.



A further six abstracts have been accepted as oral presentations at international and national conferences:

**Rodrigues, A.**, Sniehotta, F. F., Birch-Machin, M., & Araújo-Soares, V. *Acceptability and feasibility of a mobile-phone intervention to promote sun safe behaviors amongst holidaymakers: Findings from the internal pilot of the mISkin Randomized Trial.*

(Forthcoming, 2014): 35th Annual Meeting & Scientific Sessions of the Society of Behavioral Medicine, Philadelphia, PA, USA, 23-26<sup>th</sup> April 2014. (Awarded Meritorious Student Abstract)

**Rodrigues, A.**, Sniehotta, F. F., Birch-Machin, M., & Araújo-Soares, V. *A pilot study of a mobile-phone intervention to promote sun safe behaviours amongst holidaymakers: the mISkin app.* (2013): BPS Division of Health Psychology Annual Conference, Brighton, UK, 11-13th September 2013.

**Rodrigues, A.**, Sniehotta, F. F., Birch-Machin, M., & Araújo-Soares, V. *Systematic development of a behavioural intervention to promote sun safe behaviours.* (2013): UKCRC PHRCoE's conference Cardiff, UK, 9-10<sup>th</sup> July 2013.

**Rodrigues, A.**, Sniehotta, F. F., Birch-Machin, M., & Araújo-Soares, V. *Development and evaluation of mISkin, a mobile-phone intervention for sun-safe behaviours amongst holidaymakers.* (2012): UK Society for Behavioural Medicine 8th Annual Scientific Meeting, Manchester, UK, 10-11 December 2012.

**Rodrigues, A.**, Hobbs, N., French, D., Glidewell, L., & Sniehotta, F. F. *Does answering questions about a health-related behaviour change that behaviour? A systematic review with meta-analysis.* 26th European Health Psychology Conference, Prague, Czech Republic. 21st to 25th August 2012.

**Rodrigues, A.**, Araújo-Soares, V., & Sniehotta, F. F. (2011, September). *Interventions promoting sun-protective behaviours: An analysis of effective behaviour change techniques and modes of delivery.* Presented at the 25<sup>th</sup> European Health Psychology Conference, Creta, Greece. 21<sup>st</sup> to 24<sup>th</sup> September 2011.

# Table of Contents

Abstract .....	ii
Acknowledgements.....	v
Authors contribution list for the empirical chapters .....	vii
Publications .....	viii
Chapter 1 Introduction .....	1
1.1 Skin cancer: an overview.....	2
1.1.1 Incidence and mortality trends .....	2
1.1.2 Causes .....	3
1.1.3 Melanoma and social economic status.....	4
1.1.4 Economic burden of Skin Cancer.....	5
1.2 Sun-Protection behaviours: prevalence and measurement.....	6
1.2.1 Prevalence of sun-protection behaviours .....	7
1.2.2 Measurement of sun-protection behaviours .....	8
1.3 Predictors of Sun Protection Behaviours: the role of behaviour change theory..	11
1.4 Interventions to prevent skin cancer and promote sun protection behaviours ....	12
1.4.1 Policies and Guidelines on Sun Protection Behaviours .....	14
1.4.2 Prevention initiatives .....	15
1.4.3 Interventions to Promote Sun Protection Behaviours: evidence from a systematic review .....	16
1.4.4 Interventions in Recreational Settings: key setting for skin cancer prevention .....	17
1.5 Aims and objectives of the Research.....	19
1.6 Overview of the Thesis .....	20
Chapter 2 The efficacy of interventions to promote sun-protection behaviours in recreational settings: A systematic review with meta-analyses and moderator analyses .....	22
2.1 Abstract .....	22
2.2 Introduction .....	22
2.3 Methods .....	24
2.3.1 Study inclusion criteria.....	24

2.3.2 Search Strategy .....	24
2.3.3 Methodological Quality.....	25
2.3.4 Data Abstraction and Analysis .....	25
2.4 Results .....	27
2.4.1 Description of included studies .....	27
2.4.2 Meta-Analyses of efficacy by outcome .....	48
2.4.3 Structured Narrative Moderator Analysis.....	57
2.5 Discussion.....	61
Chapter 3 ‘A tan is worth a thousand words’: a qualitative study about sun-protection practices in holidaymakers.....	65
3.1 Abstract.....	65
3.2 Introduction .....	65
3.3 Materials and Methods .....	67
3.3.1 Participants.....	67
3.3.2 Materials and procedure .....	68
3.3.3 Analysis .....	69
3.4 Results .....	69
3.4.1 Current sun protection behaviours .....	69
3.4.2 Key themes emerging from interviews .....	72
3.4.3 Are people aware of the reasons why to be SunSmart?.....	73
3.4.4 Do people know how to be SunSmart? .....	73
3.4.5 What are the reasons given to justify sun-exposure?.....	76
3.4.6 What are the main barriers and facilitators mentioned for sun protection? ..	78
3.5 Discussion.....	84
Chapter 4 Systematic development and user-centred design of the mISkin mobile-phone intervention .....	88
4.1 Abstract.....	88
4.2 Introduction .....	88
4.3 Development process of the mISkin intervention.....	92
4.3.1 Identifying active ingredients and behaviour change theory evidence .....	93
4.3.2 Intervention design.....	96

4.3.3 Evaluation of the mISkin app prototype: user-centred study.....	100
4.3.4 Refinement of the mISkin intervention.....	106
4.4 Discussion.....	106
Chapter 5 Development of novel objective measures of sun protection behaviours ..	110
5.1 Abstract.....	110
5.2 Introduction .....	111
5.3 Study 1: Patterns of sunscreen application.....	112
5.3.1 Introduction.....	112
5.3.2 Sample .....	112
5.3.3 Materials.....	113
5.3.4 Procedures .....	113
5.3.5 Results.....	114
5.3.6 Conclusion.....	114
5.4 Study 2: Assessing mDNA damage caused by UV exposure .....	115
5.4.1 Introduction.....	115
5.4.2 Sample .....	116
5.4.3 Materials and procedures.....	117
5.4.4 Results.....	119
5.4.5 Conclusion.....	126
5.5 General discussion.....	127
Chapter 6 The Question-behaviour Effect: Genuine effect or Spurious Phenomenon?	
A systematic review of randomized controlled trials with meta-analyses.....	130
6.1 Abstract.....	130
6.2 Introduction .....	130
6.3 Methods .....	132
6.3.1 Inclusion criteria.....	132
6.3.2 Search Strategy .....	133
6.3.3 Study Selection and Data Extraction.....	133
6.3.4 Assessment of Risk of Bias and Critical Appraisal .....	133
6.3.5 Analytic strategy .....	134
6.4 Results .....	135

6.4.1 Description of included studies .....	135
6.4.2 Does answering questions change behaviour? .....	148
6.4.3 Possible moderators of the QBE .....	150
6.5 Discussion.....	152
Chapter 7 An internal pilot study of a definitive randomised controlled trial of the mISkin Smartphone intervention to prevent excess sun exposure amongst holidaymakers..	157
7.1 Abstract.....	157
7.2 Introduction .....	157
7.3 Aims .....	160
7.4 Methods .....	160
7.4.1 Study design .....	160
7.4.2 Participants .....	161
7.4.3 Interventions description .....	161
7.4.4 Outcomes and methods of assessment .....	164
7.4.5 Sample size .....	166
7.4.6 Randomisation.....	168
7.4.7 Blinding.....	168
7.4.8 Statistical methods.....	168
7.5 Results .....	168
7.5.1 Participants.....	168
7.5.2 Primary outcomes for the internal pilot: Acceptability .....	170
7.5.3 Primary outcomes for the internal pilot: Feasibility .....	179
7.5.4 Primary outcome for the definitive RCT: Epidermal mDNA skin damage ..	184
7.5.5 Secondary outcomes .....	184
7.6 Discussion.....	191
Chapter 8 General Discussion .....	196
8.1 Introduction .....	196
8.2 Interventions development, design and reporting .....	197
8.3 Outcome measurement .....	200
8.4 Trial methodology.....	202
8.5 Implications for practice.....	203

8.6 Implications for future research .....	204
8.7 Overall conclusions .....	205
Appendices.....	206

## List of figures

Figure 1-1: The Behaviour Change Wheel (Michie <i>et al.</i> , 2011).....	13
Figure 2-1: Flow Diagram (adapted from PRISMA, 2009).....	28
Figure 2-2: Funnel plot of interventions assessing sun-protective behaviours (composite score).....	47
Figure 2-3: Funnel plot of interventions assessing sunscreen use .....	48
Figure 2-4: Forest plot of standardized mean differences (SMD), 95% confidence intervals, for sun-protective behaviours (composite) change in subgroups after intervention.....	49
Figure 2-5: Forest plot of standardized mean differences (SMD), 95% confidence intervals, for sunscreen use change in interventions vs. control group after intervention (continuous measures). .....	52
Figure 2-6: Forest plot of standardized mean differences (SMD), 95% confidence intervals, for sunscreen use change in interventions vs. control group after intervention (dichotomous measures). .....	52
Figure 2-7: Forest plot of standardized mean differences (SMD), 95% confidence intervals, for shade use change in interventions vs. control group after intervention. ..	53
Figure 2-8: Forest plot of standardized mean differences (SMD), 95% confidence intervals, for sun-exposure change in interventions vs. control group after intervention. .....	54
Figure 2-9: Forest plot of standardized mean differences (SMD), 95% confidence intervals, for sunburn in interventions vs. control group (continuous measures).....	55
Figure 2-10: Forest plot of standardized mean differences (SMD), 95% confidence intervals, for sunburn in interventions vs. control group (dichotomous measures).....	56
Figure 4-1: Development process stages for the mISkin intervention.....	93
Figure 4-2: Share of smartphone operating systems in the UK (Oct 2012), adapted from comScore MobiLens® (2012 ). .....	96
Figure 4-3: The mISkin app workflow.....	100
Figure 5-1: Example of the Classification Results. ....	114
Figure 5-2: The principle of the amplification plot and CT values to determine mDNA damage as seen on results from the real-time PCR assays.....	119
Figure 5-3: Log amplification plot of the 83bp qPCR standardising assay to confirm Nanodrop concentrations.....	121

Figure 5-4: Log amplification plot of the 500bp assay to determine non-specific mDNA strand breaks (general mDNA damage).....	123
Figure 5-5: Log amplification plot of the 500bp assay to determine non-specific mDNA strand breaks (general mDNA damage). X-axis is Cycle Number; maximum number of 30 cycles. Y-axis is representative of fluorescence emission intensity. ....	126
Figure 5-6: Causal modelling for the outcome assessment used in the mISkin project. ....	129
Figure 6-1: Trial selection flow diagram (adapted from PRISMA (Moher et al., 2009a)) .....	136
Figure 6-2: Forest plot of standardized mean differences (SMD) and 95% confidence intervals for health-related behaviours in measurement vs. no measurement conditions. ....	149
Figure 6-3: Funnel plot of trials reporting health-related behaviour outcomes. ....	150
Figure 7-1: Participants randomised in the internal pilot of the mISkin trial.....	161
Figure 7-2: Main screen of the mISkin application.....	163
Figure 7-3: Flow diagram (adapted from CONSORT (Moher et al., 2001)).....	169

## List of Tables

Table 1-1: UPF Ratings and Protection Categories.....	6
Table 2-1: Characteristics of Included studies.....	30
Table 2-2: Quality assessment of Randomized Controlled Trials (RCTs) and Controlled Before-After Studies (CBAs) .....	46
Table 2-3: Effects size for Sun-Protective Clothing and use of Hat and Sunglasses. ...	50
Table 2-4: Studies ordered by effect size on sun-protective behaviours and clusters of behaviour change techniques used .....	59
Table 2-5: Studies ordered by effect size on sun-protective behaviours and modes of delivery used. ....	60
Table 3-1: Summary of participants' characteristics and sunscreen use, ranked by sunscreen quantity (mg.) .....	71
Table 4-1: Included behaviour change techniques within the intervention development phase with explicit evidence-based and theoretical reasoning. ....	94
Table 4-2: Description of the mISkin app main features/behaviour change techniques and rationale for inclusion. ....	98
Table 4-3: Feedback on the mISkin app provided by participants in the user-centred study.....	104
Table 5-1: Distribution of test subjects during pilot study different phases. ....	116
Table 5-2: The concentration of the stage one skin swab samples, obtained using the Nanodrop spectrophotometer. ....	120

Table 5-3: The concentration of the stage two skin swab samples, obtained from the Nanodrop spectrophotometer. ....	121
Table 5-4: Individual CT values for the 83bp assay.....	122
Table 5-5: The individual CT values for each triplicate sample.....	123
Table 5-6: Main changes introduced to the skin swabs protocol. ....	124
Table 5-7: Showing the average CT values from all human and cultured samples converted into actual number of DNA copies. ....	125
Table 6-1: Characteristics of included studies.....	137
Table 6-2: Standardized mean differences (Cohen's d) for question-behaviour effect by moderator variables. ....	151
Table 7-1: Demographics of Study Participants by Group (N=42).....	170
Table 7-2: Feedback on the mISkin app provided by participants in the internal pilot study (N=12).....	174
Table 7-3: Descriptive statistics about the mISkin app usage.....	181
Table 7-4: Main problems and changes introduced to the trial protocol.....	183
Table 7-5: Means and standard deviations of primary and secondary outcomes by allocation (N=42) at baseline and post-holiday.....	187
Table 7-6: Bivariate correlations on behavioural measures of sun protection before and after holiday. ....	188
Table 7-7: Means (SDs) and psychometric properties of psychological variables by allocation (N=42) at baseline and post-holiday.....	190



# Chapter 1 Introduction

Over the past few decades, the incidence rates of skin cancer have been increasing worldwide in Caucasian populations (Lens and Dawes, 2004).

Skin cancer results from a complex interaction of endogenous non-modifiable risk factors (i.e. skin phenotype, propensity to develop nevi, freckles, and family history of skin cancer) and exposure to ultraviolet radiation (UV). In particular, intermittent sun-exposure (e.g. summer holidays in sunny settings) has been shown to increase melanoma risk considerably (Gandini *et al.*, 2005). Epidemiologic studies suggest that implementation of sun-protection behaviours (SPB) would decrease the amount of intermittent sun-exposure and would have an important impact on the reduction of skin cancer incidence (Armstrong and Kricger, 2001).

Effective interventions should be able to reduce sun-exposure by encouraging people to seek shade, avoid sun-exposure during peak radiation hours, wear protective. A previous systematic review (Saraiya *et al.*, 2004) concluded that there was evidence for the effectiveness of interventions in changing sun-protection behaviours amongst adults, but considerable gaps in the evidence were identified. The authors of the systematic review did not provide quantified effect sizes and quality assessment of trials were not used to scrutinise the included studies. Therefore the review found inconclusive evidence for effectiveness of interventions in preventing sunburn and interventions targeting children. In addition, the majority of interventions that had been incorporated had several shortcomings: a) measurement procedures (e.g. lack of objective measures); b) study designs (e.g. mainly uncontrolled before-after); c) poor intervention description and reporting; d) lack of systematic development building on established knowledge; and e) poor description of theory base. This is in line with recent findings about behaviour change interventions limitations (Dombrowski *et al.*, 2007).

With all of these aspects taken in to consideration, the purpose of this work is to systematically develop an intervention to promote sun-protection behaviours amongst holidaymakers.

According to Cancer research UK (Cancer Research UK, 2013a), 40% of the British population experiences severe and painful sunburn during their holidays. Moreover, the British population are believed to receive around 30% of their annual UV exposure during their two-week summer vacations (World Health Organisation, 2002). Therefore, effective interventions in tourism settings are required to reduce intermittent sun-exposure and, consequently, prevent skin cancer.

## **1.1 Skin cancer: an overview**

Skin cancer refers to the three conditions: malignant melanoma, squamous cell carcinoma (SCC) and basal cell carcinoma (BCC). The latter two are widely referred to as non-melanoma skin cancer (NMSC).

Malignant melanoma is a lethal and aggressive form of cancer (American Cancer Society, 2011). Early diagnosis and treatment is associated with a favourable prognosis. Later diagnosis and treatment implies a more advanced phase of the disease and reduces drastically the chances of recovery, increasing the potential for metastases and death (Cancer Research UK, 2013b).

In the initial phase, NMSC has a good prognosis, high survival rates and a very low risk of metastasis (Marks, 1995; Cancer Research UK, 2013b). However, when diagnosis occurs in an advanced stage, treatment is more invasive, painful and causes disfigurement (Cancer Research UK, 2013b).

### **1.1.1 Incidence and mortality trends**

Skin cancer incidence rates have been rising for the past 30 years and are the most common form of all cancers in Caucasian populations (Lens and Dawes, 2004). NMSC is much more frequent than malignant melanoma. However, malignant melanoma is much more dangerous and is responsible for the majority of deaths from skin cancer (Cancer Research UK, 2013b).

In 2010, cutaneous melanoma was the 5<sup>th</sup> most common form of cancer in the USA (U.S. Cancer Statistics Working Group, 2013). The American Cancer Society estimates that in 2014, about 72,100 new melanomas will be diagnosed in the USA alone and over 9,710 are expected to die from melanoma (American Cancer Society, 2011). Skin cancer in general, has a higher rate of diagnosis among older people, but melanoma is one of the more frequent cancers in young people (American Cancer Society, 2011; Cancer Research UK, 2013b). Statistics related to NMSC are not accurate because these types of cancer, in general, are unreported to cancer registries (American Cancer Society, 2011). This same source states that more than 3.5 million BCC and SCC are diagnosed each year and it is thought that 2,000 result in death.

In 2010, in the UK, malignant melanoma was responsible for 2,209 deaths and was the 5th most common cancer in that year (Cancer Research UK, 2013). In the same year, about 99,549 new non-melanoma skin cancers (NMSC) and 12,818 new melanoma cases were registered in the UK (Cancer Research UK, 2013b). The age-standardised melanoma incidence rate for 2010 was 17.1 per 100,000 population in UK. In addition,

Møller and colleagues (2007) estimated that the incidence of malignant melanoma of the skin in England would increase by 88% in men and 66% in women by 2020.

Australia and New Zealand lead the world incidence rates for melanoma, having the highest rates of between 30-40 per 100,000 population (Ferlay *et al.*, 2010).

Incidence rates for skin cancer are higher in Northern European countries than those in Southern countries and are higher among fair-skinned people (Ferlay *et al.*, 2010; Cancer Research UK, 2013b). The rise in melanoma incidence is relative to the increase in recreational and intermittent sun-exposure. Affluence seems to have an important yet indirect effect on this trend, since it facilitates accessibility to holidays abroad in sunny destinations where people are intensively and intermittently exposed to the sun (de Vries *et al.*, 2003b; Agredano *et al.*, 2006b; Cancer Research UK, 2013b).

### **1.1.2 Causes**

Research in this area suggests that skin cancer results from an interaction between behavioural risk factors, constitutional predisposition factors and environmental factors (Marks, 1995; Armstrong and Kricger, 2001).

*Modifiable behavioural risk factors* include sun-exposure and consequent history of sunburn. These modifiable behavioural factors are considered the major etiologic factors for melanoma (Armstrong and Kricger, 1994; Kricger *et al.*, 1994; Kricger *et al.*, 2007). Behavioural risks factors and intermittent sun exposure (intensive exposure over short periods of time) in particular, has been shown to increase the risk of melanoma skin cancer. A recent systematic review of observational studies supports the hypothesis that intermittent sun-exposure is a major risk factor for melanoma (Gandini *et al.*, 2005). Non-melanoma skin cancers are also positively associated with UV exposure, more precisely SCC, which has been found to be associated with chronic exposure to UV light (Kricger *et al.*, 1994), whereas BCC has been linked to an intermittent pattern of sun-exposure (Kricger *et al.*, 1995).

*Endogenous risks factors* (hence not modifiable) include skin phenotype, propensity to develop nevi, number of nevi, freckles, tendency to sunburn and family history of skin cancer. The total number of nevi /moles (either benign or atypical nevus) is the most important risk for the development of melanoma (Desmond and Soong, 2003).

Phenotypic characteristics such as fair skin, fair or red hair and blue eyes are important predictors of nevus occurrence, freckles and sunburn and consequently skin cancer (Desmond and Soong, 2003). Studies have shown that the CDKN2A (p16INK4) gene on chromosome 6 is associated with family susceptibility to skin cancer (Kamb *et al.*,

1994). A study by Davies and colleagues (2002) has investigated the signalling pathways between genes and human cancer. The authors found that there is a high frequency of BRAF (gene) mutations in melanoma, more precisely, BRAF was faulty in more than half of all malignant melanomas (Davies et al., 2002).

*Environmental factors* also contribute to the rise of skin cancer incidence rates. It is evident that the increase is related to the ongoing ozone layer depletion, which has a direct impact on the amount of UV radiation that reaches the Earth's surface (Marks, 2000). Additionally, estimates demonstrate that for a 1% decrease in ozone levels there will be a rise of approximately 1-2% in melanoma mortality (de Gruijl et al., 2003).

### **1.1.3 Melanoma and social economic status**

The incidence of cancers seems to vary according to socioeconomic group in various countries (Bentham and Aase, 1996; de Vries *et al.*, 2003a) including the UK (Quinn and Britain, 2001). Unlike other forms of cancer (e.g. cervical and lung cancers), the incidence of malignant melanoma is higher amongst the least deprived groups (Shack *et al.*, 2008).

A study conducted by Shack and colleagues (2008) investigated socio-economic differences in malignant melanoma cancer incidence among 36,142 patients diagnosed in England during 1998–2003. Data was obtained from all eight English cancer registries. Socioeconomic group classification was based on patients' postcode of residence at diagnosis, using the income domain of the Index of Multiple Deprivation 2004. The incidence of malignant melanoma was higher for the least deprived patients, but there was no evidence of a cohort effect for this association. Comparable associations with deprivation have also been reported in Scotland, Wales and Northern Ireland (ISD Scotland; Donnelly DW *et al.*, 2009; Welsh Cancer Intelligence and Surveillance Unit, 2011), but also in other countries such as Norway (Bentham and Aase, 1996) and US (Clarke *et al.*, 2010). Available data from Wales seems to suggest that this trend can be track back to the early 90's (Welsh Cancer Intelligence and Surveillance Unit, 2011).

When considering the incidence of melanoma by socioeconomic status on men and women, this trend was similar across gender and in different regions on England (Melanoma in men: Rate Ratio= 0.49 95% CI: 0.47–0.52, Melanoma in women: Rate Ratio= 0.48 95% CI: 0.46–0.51) (Shack *et al.*, 2008). However, the deprivation gap between the most and least deprived is larger for men in the North East of England.

Similar results have also been described by Wallingford and colleagues (2013), with the exception that the later observed slightly different patterns among young people in

the north of England. More precisely, among the young white female population in the north, the second most affluent group had the highest incidence rates of all (6.48 per 100 000), followed closely by the second most deprived group (5.69 per 100 000) (Wallingford *et al.*, 2013).

The observed differences in the incidence of malignant melanoma seem to be explained by the existing association between socioeconomic status and risk factors. Malignant melanoma is also significantly associated with UV exposure, especially intermittent and excessive exposure that occurs through holidays abroad (Bentham and Aase, 1996) and sunbed use (Boniol *et al.*, 2012; Bataille, 2013). In England, sunbed use is particularly prevalent among young people, as data shows that 6% of all 11–17 year olds have used sunbeds on at least one occasion. . Within the country young women in the north are the most prevalent users of all (up to 50%) (Thomson *et al.*, 2010). Recent evidence shows that exposure to sunbeds before the age of 35 was increased the risk of malignant melanoma by 75% (Boniol *et al.*, 2012; Bataille, 2013). A report published in 2009 by Walsh and colleagues, shows that the distribution of sunbed locations varies by level of area deprivation, with higher rates in more deprived areas. Notably, concentrations of high sunbed outlet rates per 100,000 population can be seen in the urban areas of North West and North East England (Walsh *et al.*, 2009).

These patterns could possibly impact on the gradient of association between melanoma incidence and deprivation, resulting in a possible shift of this relationship in future decades, with a higher incidence rate in the more deprived.

The recent banning of sunbed use in those under 18 years of age in the UK (Sunbeds Regulation, Act 2010) could possibly impact on the amount of harmful exposure to artificial UV in the future. However, this regulation will only affect commercial outlets, so private use remains unregulated and its effects may continue to be seen (Wallingford *et al.*, 2013). However, the lag time between exposure and melanoma is long so it may take longer to fully assess their impact.

#### **1.1.4 Economic burden of Skin Cancer**

With the incremental increase in skin cancer incidence rates, there is a higher demand on health care services and subsequent costs. There is a lack of evidence concerning the economic burden of skin cancer to health systems.

US Medicare expenditure for NMSC is estimated at \$426 million per year (Chen *et al.*, 2001) and \$495 million per year for malignant melanoma (Fader *et al.*, 1998). Estimates for 2010 predicted that costs of melanoma will exceed \$5 billion (Fader *et al.*, 1998).

In 2002, the total cost of skin cancer in the UK was estimated at more than £190 million (MORRIS, 2005). According to these authors, the costs borne by the National Health Service (NHS) were approximately £71 million, with malignant melanoma accounting for 19% of total NHS costs, making it more costly than other skin cancer. Additionally, deaths associated with skin cancer led to an estimated loss of £90 million to NHS.

This evidence shows the importance of skin cancer preventive efforts to reduce associated costs of skin cancer for health care services.

## 1.2 Sun-Protection behaviours: prevalence and measurement

According to WHO (World Health Organisation, 2002), four out of five cases of skin cancer could be prevented by sun-protection behaviours, which include: staying in the shade; avoiding the midday sun; appropriate clothing; using sunscreen.

Amongst sun-protection behaviours, avoidance of the sun seems to be the best way to reduce UV exposure (Cancer Research UK, 2011b; World Health Organisation, 2011b). This is based on the fact that shade alone can reduce UV exposure by 50-95%, depending on the type of shade provider: a beach umbrella provides the least protection and dense foliage the best protection (Lautenschlager *et al.*, 2007).

Another way of sun protection is the use of protective clothing. There is sufficient evidence suggesting that clothes (textiles) are a reliable source of photoprotection, blocking UV and providing protection from sunlight risks (Lautenschlager *et al.*, 2007). The degree to which a fabric protects the skin from UV rays is expressed in the ultraviolet protection factor (UPF) and it is comparable to the sun protection factor of sunscreen (SPF) (Saravanan, 2007; Gies and McLennan, 2012). A specific labelling system to describe level protection for textiles has been developed (Table 1-1) (Saravanan, 2007). Some of the materials that provide the best protection are: polyester, lycra, nylon, denim and unbleached or naturally coloured cotton (Gies and McLennan, 2012). Wool and silk are also moderately effective (Gies and McLennan, 2012).

**Table 1-1: UPF Ratings and Protection Categories**

UPF Rating	Protection Category	% UV radiation Blocked
UPF 15 - 24	Good	93.3 - 95.9
UPF 25 - 39	Very Good	96.0 - 97.4
UPF 40 - 50+	Excellent	97.5 - 99+

The evidence for broad-spectrum sunscreen effectiveness in preventing skin cancer remains unsatisfactory (Lautenschlager *et al.*, 2007) and skin cancer prevention programmes should preferentially advocate other behavioural measures (e.g. protective clothes, avoiding sun-exposure) to be used in conjunction sunscreen. Evidence suggests that broad-spectrum sunscreens SPF 15+ are effective in: 1) preventing SCC; 2) reducing solar keratoses (important in melanoma and BCC aetiology); and in, 3) decreasing nevus development (precursor of melanoma development) (Green and Williams, 2007).

There seems to be some contradiction concerning sunscreen use amongst UK policy drivers. Currently, there is a discrepancy between the National Institute for Health and Care Excellence (NICE) recommendation for sunscreen with a SPF15 and the British Association of Dermatologists (BAD), Cancer Research UK and the British Skin Foundation recommendation for a SPF30 (The British Skin Foundation, 2011). This is highlighted by a statement on January 28th 2011 by the BAD (pp.4), "it is unfortunate that the advice from NICE now contradicts the advice from the leading skin cancer charities and professional bodies involved in skin cancer prevention campaigns" and "so there will be continued public confusion and disparity of messaging on a crucial subject"(The British Skin Foundation, 2011). Nevertheless, there is a general agreement on the need of sunscreen use, as well as on the need to use other sun-protection behaviours.

### **1.2.1 Prevalence of sun-protection behaviours**

In 2005, 28,235 Americans participated in the 2005 National Health Interview Survey (NHIS) which included questions regarding sun-protection behaviours, sunbed use and experience of sunburn (Coups *et al.*, 2008). Study results show that the use of protective clothing was very low amongst all ages and more than half of the participants did not frequently use SPF15+ sunscreen. Most participants reported avoidance of sun-exposure when outdoors and higher frequency of sunbathing were reported by young people (35.4%). When asked about their last year of experience participants reported a low sunburn rate (11.2%), as well as low sunbed usage. However, the frequency of sunbed usage was considerably higher in the age group 18 to 29 years (20.2%).

In the UK, a study conducted in the North West of England with 288 subjects (Ling *et al.*, 2003), revealed that 35% of women and 8% of men reported regular use of sunscreen and, of those who used it, 40% use a SPF $\leq$ 10 and 30% use a SPF between 11-15.

Results from a survey conducted in March 2008 by Cancer Research UK and the Office for National Statistics (ONS) with a sample of 1087 individuals about preferred methods of sun-protection and skin cancer routine screening shows that: 83.9% used sunscreen, 41.0% stayed in the shade, 39.9% used covering-up strategies, 15.1% limited the time spent in the sun, 7.5% avoided sunbeds, and 4.5% checked for moles (Cancer Research UK, 2011b).

### **1.2.2 Measurement of sun-protection behaviours**

A previous systematic review (Saraiya *et al.*, 2004) identified measurement as a critical issue in existing literature regarding skin cancer prevention efforts evaluation. The lack of a gold standard measure for sun-protection measurement may be the reason.

Self-report is practical, quick and easy to administer, and the most simple and inexpensive method of measuring. Self-report can also help capture the respondents' own views of a behaviour, providing access to phenomenological data. This will also help collecting information on social, situational and behavioural factors, including revealing patterns. For these reasons, self-report questionnaires are the conventional procedure to collect data about sun-protection practices, but limitations of these methods have been identified. Recently, there is evidence that answering questionnaires can affect people's health-related behaviours (French and Sutton, 2010). This reactivity phenomenon has been described as the 'question-behaviour effect' (QBE) and has been reported for different types of health behaviours such as physical activity, blood donation and cervical screening (Godin *et al.*, 2008; Sandberg and Conner, 2009; Spence *et al.*, 2009).

To overcome validity problems normally associated with self-report measures, some attempts have been undertaken to improve sun-protection behaviours measurement.

Joint efforts from researchers in the US and Australia have been in place to undertake a series of research efforts to develop a valid self-report measure of sun-protection behaviours. A study conducted by O'Riordan and colleagues (2006) with 88 beachgoers examined criterion validity of self-reported sun-protection practices using an objective measure: sunscreen swabbing. All measures were taken before entering the beach and when leaving the beach. Authors also included an observational measure of protective clothes used while on the beach. Data collection was undertaken over 3 days and participants were unaware of observation procedures. Even though self-reported sun exposure, use of sunscreen and protective clothes seem to have good criterion validity when compared to direct observation and sunscreen use swabbing, some limitations were identified. Moderate to good agreement ( $k= 0.49-0.77$ ) was obtained between self-report and the swabbing



procedure, but agreement between self-report and visual inspection of sunburn was small to fair. In addition, some problems were also identified with the swabbing technique. There were no significant differences in the absorbance readings of swabs from individuals who had applied sunscreen at baseline only, follow-up only, or baseline and follow-up. However, the swabbing technique also detected the presence of sunscreen when participants reported not applying sunscreen. All of the outcome assessments were based on a single day and on-site assessment.

Another study conducted by O’Riordan and colleagues (O’Riordan *et al.*, 2008a) examined the feasibility of conducting a study assessing the validity of self-reported sun-related behaviours using a multimethod approach in a swimming pool setting. The study enrolled 27 pool-goers and used the following measures: survey, diary, direct observation, dosimeter (measures personal UV exposure doses) and sunscreen swabbing. Participants were enrolled before swimming lessons. After providing consent, they completed a survey, sunscreen swabs were taken and direct observations were conducted (participants were unaware of this). Participants were also asked to wear a dosimeter until 4pm during the day and to complete a diary over the following 4 days. On the fourth day, participants were asked to wear another dosimeter until 4pm that day also. On the same day, sunscreen swabs were taken and observations conducted. For sun-protection behaviours in general, comparing data from the diary, survey and direct observation revealed moderate to substantial agreement in these measures. For sun-exposure, data from dosimeters compared with the survey and diary showed fair to moderate agreement. Finally, when comparing data from different measures on sunscreen use, validation issues emerged: a) sunscreen swab and diary measures showed only fair agreement ( $k = 0.36$ ); b) survey and diary measures showed fair agreement ( $rs: 0.72-0.81$ ); and c) survey and sunscreen swab measures showed poor agreement ( $k = 0.16$ ). These results demonstrate that sunscreen use measurement needs to be improved in future research. However, this study was not powered enough ( $N=27$ ) to investigate these differences.

Another study by the same team (O’Riordan *et al.*, 2009) investigated concurrent validity of self-reported measures (survey and diary) and direct observation of the use of protective clothing (i.e. hat use, shirt with sleeves and sunglasses) in 564 pool-goers. Participants were enrolled during 4 days. On the first day, participants completed a ‘*Sun Habits Survey*’ and were asked to fulfil a diary during the next 4 days. Direct observations were conducted by research staff on two of these days. Results showed that levels of agreement between the three approaches were slight to moderate for parents (0.15-0.60), children (0.10-0.52) and lifeguards (0.10-0.55). However, the diary method appears to be somewhat more valid than the survey.

Recognising the limitations self-reports but also its practicality, Glanz and colleagues (2008) initiated a collaborative effort in the USA to develop a set of core items to measure sun-protection practices across different populations (children, adolescents and adults). The validity of this questionnaire survey was tested with 515 pool-goers (Glanz *et al.*, 2010a) by comparing it to dosimeter data (measures personal UV exposure doses) for each participant and diary (self-monitoring of behaviour) records. Results show moderate agreement between self-reported measures and dosimeter values ( $r = .28$  to  $.57$ ). Subsequently, this questionnaire has also been used in trials assessing the effect of behavioural interventions to prevent skin cancer on sun protection outcomes (Glanz *et al.*, 2010b; Pagoto *et al.*, 2010).

Although results from these studies provided relevant evidence for sun-related behaviours measurement, limitations need to be highlighted. Firstly, the different approaches used to assess sunscreen application showed poor to fair agreement, demonstrating that more research is needed to improve sunscreen measurement. Secondly, the dosimeter data used does not take into account whether or not clothes were covering the device and thus, influencing values found. Thirdly, observation procedures are known to be prone to observer bias (Waddington, 2004), possibly influencing results in sun-protection behaviour. Fourthly, self-report measures have been criticized for recall bias and social desirability bias. This is especially important for studies testing the validity of a self-report measure (questionnaire) against another self-reported measure (self-monitoring diary). Future research needs to actively design studies that tackle these limitations and include larger samples to allow for accurate hypothesis testing.

In line with this, clinical and objective measures have been suggested to measure sun-exposure (indirectly) by associated skin damage (Krishnan *et al.*, 2004; Harbottle and Birch-Machin, 2006; Birch-Machin and Swalwell, 2010). A recent study (Harbottle *et al.*, 2010) tested an innovative test for skin damage using skin epithelial swabs. This involves a simple technique (skin swab) that tests for mitochondrial DNA (mDNA) damage caused by UV exposure. Results show a significant increase in skin damage (in the epidermis) with increased sun-exposure. These findings demonstrate the effectiveness of skin epithelial swab in assessing mDNA damage caused by UV exposure. Future research should involve investigating whether this method can be used to assess mDNA damage caused by UV exposure in a sample of holidaymakers.

### **1.3 Predictors of Sun Protection Behaviours: the role of behaviour change theory**

Theories in the field of behaviour change provide useful insight for the explanation of variables influencing adoption of sun-protection behaviours. Different behaviour change models such as the health belief model (Rosenstock *et al.*, 1988), protection motivation theory (Rogers, 1975), social cognitive theory (Bandura, 2001), and the theory of planned behaviour –TPB –(Ajzen and Madden, 1986; Ajzen, 1991) hypothesise a diversity of cognitions influencing behaviour change in general. More recent approaches emphasise the importance of post-intentional constructs such as implementation intentions (Gollwitzer and Sheeran, 2006; Webb and Sheeran, 2007) and planning (Sniehotta *et al.*, 2005; Sniehotta *et al.*, 2006) for behaviour change and its importance in translating intention into behaviour.

Some studies investigating the influence of cognitive variables have been successfully used in predicting sun-protection behaviours. Bränström, Ullén and Brandberg (Branstrom *et al.*, 2004) explored the explanatory power of TPB variables and other social cognitive variables (e.g. perceived risk) in understanding sun-related behaviours. The results show that positive attitudes towards a tanned appearance and sunbathing as well as descriptive norms (related to sun-exposure) were strongly associated with sun-exposure, intentional tanning, sunbed use and spending holidays abroad in sunny locations. In addition, perceived risk of sunbathing was related to the use of different sun-protection behaviours and intention to decrease sun-exposure. Perceived behavioural control (PBC) was also a significant predictor of sun-protection behaviours.

The TPB framework has also been used to predict sunscreen intentions and use (Hillhouse *et al.*, 1997; Myers and Horswill, 2006), sunbathing and sunbed intentions to use and actual behaviour (Hillhouse *et al.*, 1997). A study by Hillhouse and colleagues (Hillhouse *et al.*, 1997) with college students showed that attitudes towards behaviour, subjective norms and PBC explained the following variance in intentions: 37% for sunscreen use; 59% for sunbathing; and 63% for sunbed use (all self-report measures). The variance explained by intentions in behaviours was: 49% for sunscreen use; 70% for sunbathing; and 71% for sunbed use.

The study by Myers and Horswill (Myers and Horswill, 2006), using TPB variables and self-efficacy to predict sun-protection behaviours, found that the model strongly predicted intention and self-reported sunscreen use, explaining 32% and 45% of variance respectively.

In addition, Jackson and Aiken (Jackson and Aiken, 2000) used a comprehensive model for the prediction of sunbathing and sun-protection intentions in young women

by combining a range of psychosocial variables (beliefs, self-efficacy, attitudes, and norms). Results from this study showed that intentions to sun-protection were best predicted (shown as effect sizes) by perceived susceptibility ( $d=.52$ ), self-efficacy ( $d=.25$ ), and norms ( $d=.23$ ). Sunbathing behaviour was predicted by advantages of sunbathing ( $d=.55$ ), perceived susceptibility ( $d=-.55$ ), and norms for sunbathing ( $d=.42$ ).

Planning constructs have also been applied to the prediction of sun-related behaviours (Jones *et al.*, 2001; de Vries *et al.*, 2006). The De Vries and colleagues study (de Vries *et al.*, 2006) analysed the impact of action plans in sunscreen use by adolescents. Results showed that action plans added 5% additional variance explained and in conjunction with intentions were the best predictors of sunscreen use.

In a similar way, Jones and colleagues (Jones *et al.*, 2001) explored the predictive power of an integrated model with the TPB, the Health Belief Model and a measure of planning. Authors found that intention was the strongest predictor of behaviour and planning mediated, in part, the effects of intention on sunscreen use. Together, intention and planning explained 58% of variance in sunscreen use.

A study conducted by Araujo-Soares and colleagues (2013b) with 177 adolescents explored the predictive utility of the theory of planned behaviour (direct and belief-based), descriptive norms, prototype perceptions and planning on springtime sunscreen use. All participants completed measures at T1 and then sunscreen use was reported 2 months later. Findings show that gender, intention and prototype evaluation were predictive of sunscreen use. Belief-based measures of attitude, subjective norm and perceived behavioural control were the best predictors of intention.

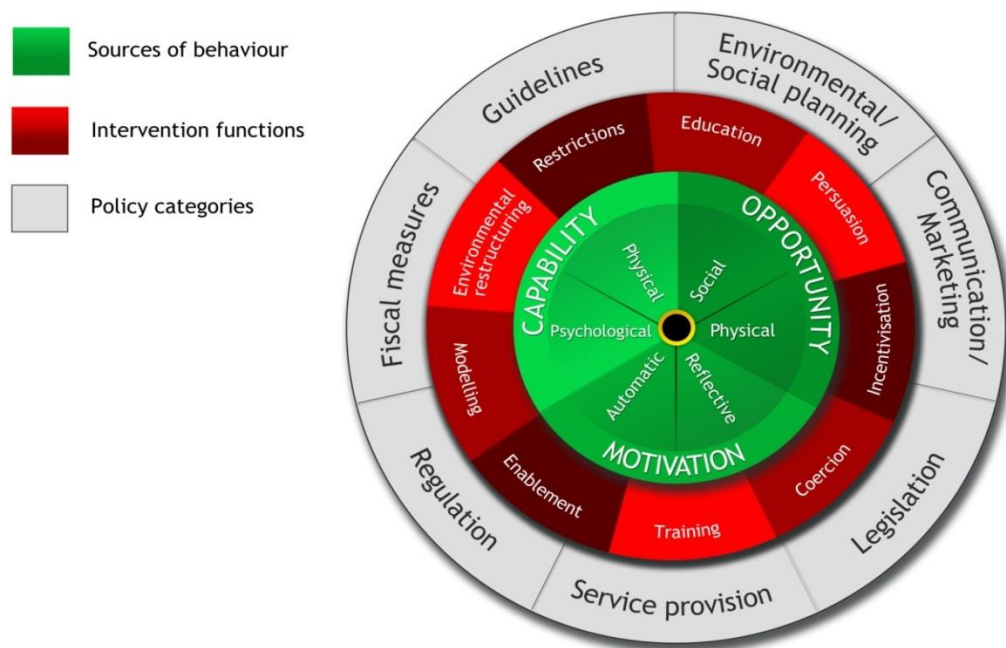
## **1.4 Interventions to prevent skin cancer and promote sun protection behaviours**

Considering the strong behavioural aetiology in skin cancer, several preventive strategies have been developed to change sun-protection behaviours in populations.

The majority of interventions for skin cancer prevention involve a multiplicity of target audiences (e.g. families, patients, clinicians), and, for this reason, there is no clear-cut way of classifying these interventions. Glanz and colleagues (2004) created a typology of four categories to describe interventions aimed at promoting sun-protection behaviours: a) individual-directed strategies; b) environmental and policy interventions; c) media campaigns; and d) community-wide multi-component interventions.

In order to design effective interventions, a recent framework has been developed to characterise interventions and policies to change behaviours: the 'behaviour change wheel' (BCW) (Michie et al., 2011). This framework has 3 layers (Figure 1-1): behaviour system, intervention functions and policy categories. The behaviour system entails three essential conditions: capability, opportunity, and motivation. This forms the centre of the 'behaviour change wheel' (BCW) surrounded by nine intervention functions (i.e. education, environmental restructuring, incentivisation, persuasion, restrictions, training, modelling, enablement and coercion) aimed at change in one or more of the behaviour system conditions (enhancing capability, opportunity and/or motivation); around this are placed seven categories of policy that could enable those interventions to occur (i.e. service provision, legislation, communication/marketing, environmental/social planning, guidelines, fiscal measures and regulation) (Michie et al., 2011). In this framework, the importance of policies was recognised and classified as an essential element for intervention development. Policies enable the development of interventions and behaviours can only be influenced through interventions.

**Figure 1-1: The Behaviour Change Wheel (Michie et al., 2011).**



Given this fact, policies and guidelines are of great interest for the design of a behaviour change intervention to prevent skin cancer. The next section will briefly describe main policies and guidelines within this area.

### **1.4.1 Policies and Guidelines on Sun Protection Behaviours**

Several guideline documents have been published in previous decades to guide skin cancer prevention.

In the UK, the first guideline for skin cancer prevention was published in 1992 in the White Paper Health of the Nation. The target set was to reduce the annual increase in the incidence of skin cancer by 2005. However, this target was not achieved since incidence rates increased until 2005 and are still increasing to this day (Cancer Research UK, 2011b).

The subsequent White Papers (1999, 2004) did not include any target setting for skin cancer prevention. However, the 1999 White Paper – “*Saving Lives: Our healthier nation*” – provided some guidelines for messages in educational campaigns (e.g. provide evidence of consequences related to over sun-exposure).

Nowadays, target setting is not mandatory and is being done at a local level through the Joint Strategic Needs Assessment and Local Area Agreements (i.e. improvement targets set by local authorities and agreed by the central government). This fact might explain the low levels of adoption of skin cancer prevention activities by Primary Care Trusts and Local Authorities observed in a recent assessment by the Chartered Institute of Environmental Health (CIEH). A survey conducted in 2004 by this institution (Chartered Institute of Environmental Health, 2004) found that only 12% of surveyed Local Authorities adopted policy recommendations and developed a strategy to prevent skin cancer.

Guidance is also being provided for practical implementation of skin cancer prevention strategies. In 1998, the Health Education Authority (HEA) developed guidance to facilitate the incorporation of skin cancer prevention in the strategic plan of Local Authorities (Health Education Authority, Skin cancer prevention: policy guidelines for local authorities.). In addition, in 2005, CIEH published practical guidance entitled ‘Saving Our Skins Toolkit’ (The Chartered Institute of Environmental Health, 2005) which aimed to support Local Authorities and Health Departments in the development and diffusion of skin cancer prevention messages. More recently, 12 NHS Cancer Networks are committed to the development of actions to prevent skin cancer through the National Cancer Action Team’s, National Awareness and Early Diagnosis Initiative (Department of Health, 2007). Recent guidance published by the National Institute for Health and Clinical Excellence (2011) established recommendations for the development of strategies to prevent skin cancer by raising awareness and increasing knowledge of the risks of UV exposure, modifying attitudes and prompting behaviour change.

In the USA, target setting was established by *Healthy People* goals and objectives (Healthypeople.gov, 2010), which provided national targets and priorities to improve the health of Americans. *Healthy People 2020* set the following objectives:

1. Increase the proportion of adolescents who use sun-protection measures to 11% (i.e. seek shade between 10 am and 4pm, use sun-protective clothing, use sunscreen with a sun-protection factor (SPF) of 15 and avoid sunbeds);
2. Increase the proportion of adults who follow sun-protection practices to 80%;
3. Decrease rates for melanoma deaths to 2.4 per 100,000 people.

Skin cancer prevention strategies are also briefly referred to in this document, establishing a target to increase the proportion of schools that undertake skin cancer prevention strategies to 80%.

The Center for Disease Control and Prevention (CDC) is also an important policy driver in the USA. This organisation provides practical guidance for preventive efforts in the area of skin cancer.

Finally, the World Health Organisation (WHO) also has a key role as a policy driver, providing specific guidance for skin cancer prevention. In 1992, WHO developed the INTERSUN programme “to reduce the global burden of diseases resulting from exposure to UV radiation” (webpage) (World Health Organisation, 2011a). More precisely, the INTERSUN programme aims to:

*“provide information, practical advice and sound scientific predictions on the health impact and environmental effects of UV exposure; encourage countries to take action to reduce UV-induced health risks; and provide guidance to national authorities and other agencies about effective sun awareness programmes.”*  
(World Health Organisation, 2011a).

#### **1.4.2 Prevention initiatives**

Recognising the importance of skin cancer prevention, Australia has a clear and strong strategy for the promotion of sun-protection. In 1980, the Anti-Cancer Council of Victoria (ACCV) launched a large-scale campaign branded ‘Slip! Slop! Slap!’ to promote individuals to reduce their sun exposure (Montague *et al.*, 2001), which was a limited public education program. The main feature of the campaign was an animated seagull called Sid advising the population to slip on a shirt, slop on some sunscreen, and slap on a hat (Montague *et al.*, 2001). The initial messages of this campaign were not systematically structured or developed. Interestingly, Montague, Borland and Sinclair (Montague *et al.*, 2001) described this process as “Initially, these efforts were

based on individual behaviour change models and/or on the intuition of the advertising designers” (pp. 294). In 1998, a new broad-based, multifaceted skin cancer prevention program was launched, the SunSmart program.

With the increased recognition that supportive environments are a key component for individual change, campaigns started to focus more on promoting the development of sun safe environments (Montague *et al.*, 2001).

The injection of resources into the SunSmart program in 1988 enabled the small scale program to become a much larger and broader campaign that could argue strongly for structural change to support individual behaviour change. In the late 1980s, the program, which design was based on social-cognitive theories of behaviour change (Prochaska *et al.*, 1985; Rosenstock *et al.*, 1988; Bandura, 1991), was characterised as a population-wide approach.

The mass media campaign became more intensive with time and in the late 1990s the campaign incorporated more negative messages (Montague *et al.*, 2001). Though the SunSmart campaign has considerable achievements, evidence suggests that some populations (i.e. adolescents) still present low levels of compliance with sun-protection recommendations (Livingston *et al.*, 2001; Dobbinson *et al.*, 2008). For this reason, further campaigns are needed to promote sun-protection practices amongst Australian adolescents.

In the UK, the SunSmart campaign was launched in 2003 and it represents the national campaign for skin cancer prevention conducted by Cancer Research UK (Cancer Research UK, 2011b). The SunSmart campaign has the following main goals: to stop the annual increase of incidence and mortality rates for skin cancers and to change sun-related knowledge, attitudes and behaviour. The SunSmart UK skin cancer prevention strategy is highly involved in cancer-related research and can be defined as an evidence-based campaign that is driven from qualitative and quantitative research (Cancer Reserach UK, 2009). Since this campaign was launched in 2003, it has focused on a different target audience each year, e.g. schools (2004, 2005), men and outdoor workers (2006, 2012), holidaymakers (2007) and adolescents/young adults (2008, 2009, 2010, 2011, 2012). As these numbers suggest, holidaymakers are not currently the primary focus of the SunSmart campaign.

### **1.4.3 Interventions to Promote Sun Protection Behaviours: evidence from a systematic review**

A systematic review of interventions to prevent skin cancer (Saraiya *et al.*, 2004) concluded that there was significant evidence for the effectiveness of interventions in



primary schools to improve children's covering-up behaviours and for the effectiveness of interventions in recreational/tourism settings to promote covering-up behaviours in adults.

The section devoted to interventions delivered in recreational settings included 11 trials of which no meta-analyses were performed. Saraiya and colleagues (Saraiya *et al.*, 2004) concluded that there was evidence of effectiveness of interventions on: 1) adult's sun-protection behaviours, such as wearing sun-protective clothing; and 2) increasing children's sunscreen use.

The most effective interventions involved a family-based approach at the holiday/recreational site (e.g. 'Pool Cool Program', (Glanz *et al.*, 2002)), took place in diverse geographical settings, (e.g. Australia, U.S. and England) and included strategies such as: providing information to children and adults (e.g. leaflets or booklets); activities aiming at changing knowledge, attitudes, beliefs, and intentions; activities to influence behaviour (e.g. modelling); and environmental policies (e.g. provision of shade) (Saraiya *et al.*, 2004). However, the review did not provide evidence related to specific intervention techniques and did not identify specific theoretical mechanisms of behaviour change associated with effectiveness.

Several problems with the evidence base were identified by this review, these included: a) measurement strategies (e.g. lack of objective measures); b) study designs (e.g. mainly uncontrolled before-after designs); c) intervention descriptions (e.g. poor/insufficient reporting); d) insufficient measurement of mediating factors and behavioural/health outcomes; and e) poor description of theory base.

#### **1.4.4 Interventions in Recreational Settings: key setting for skin cancer prevention**

Recreational settings are an emergent ideal place for skin cancer prevention and several factors contribute to this. Firstly, there has been an increase in the proportion of people travelling to sunny and warmer destinations for holidays. In the UK, National Statistics data (National Statistics, 2010) shows that UK residents made approximately 69.0 million visits abroad in 2008. These numbers more than doubled when comparing to data from 1994 where 30 million UK residents travelled abroad (National Statistics, 2010). Spain (13.8 million) and France (10.9 million) dominated the list of preferred destinations, followed by USA, Ireland, Italy, Germany and Portugal (National Statistics, 2010).

Secondly, the number of individuals engaging in risk behaviours during their holidays is increasing. As stated before, sunburn is a common experience during holidays (World

Health Organisation, 2002; Cancer Research UK, 2013a) and sun-related behaviours, like intentional seeking sun-exposure are increasingly high (Manning and Quigley, 2002; Diffey and Norridge, 2009). A study carried out at Belfast Airport in 1999 (Manning and Quigley, 2002), with 476 Irish individuals travelling to Mediterranean holiday destinations, found that 9 out of 10 participants intended to acquire a suntan, 60% intended to use sunscreen with a SPF15+ and 25% of respondents reported multiple cases of sunburn on previous holidays. Furthermore, 64% planned to sunbath between 11 am and 3 pm and for at least 4 hours a day during their holidays. A study conducted by Silva and colleagues (Silva *et al.*, 2009) found that holidays abroad in warmer countries than the UK are associated with an increase in the number of body nevus (melanoma precursor).

Thirdly, a previous systematic review about interventions to prevent skin cancer (Saraiya *et al.*, 2004) has identified interventions in recreational settings as being effective in promoting sun-protection behaviours. Different kinds of interventions in recreational settings have been tested, most of them using educational, environmental, media and appearance-based strategies to influence behaviours. Implementation settings were varied and included swimming pools (Glanz *et al.*, 2002), beaches (Weinstock *et al.*, 2002) and ski resorts (Walkosz *et al.*, 2007).

In the UK, studies evaluating effectiveness of sun-protection interventions in recreational settings are sparse. The SunSmart campaign (implemented by the Cancer Research UK website) is the major intervention being rolled out in the UK at the moment.

Considering the time of day or location barriers in interventions targeting holidaymakers, mHealth interventions (e.g. mobile-phones, PDAs) are potentially an effective option for skin cancer prevention. To date, there is no effective, affordable, scalable and geographically flexible mobile intervention available to promote sun-protection behaviours for people making holidays in high UV destinations.

## 1.5 Aims and objectives of the Research

Overall, this PhD thesis aims to systematically develop and pilot an evidence-based mobile-phone intervention to promote sun-protection behaviours amongst holidaymakers.

To achieve this aim, the study has seven objectives:

- To conduct a systematic review with narrative synthesis, meta-analysis and moderator analysis to identify active features associated with efficacy of behavioural interventions aimed at promoting sun-protection in touristic settings;
- To investigate perceptions of sun-related experiences and the relevant Theoretical Domain behavioural determinants of sun-protection behaviours;
- To develop a draft intervention following a systematic methodology with full replicable reporting of the process;
- To explore potential holidaymakers views on a mobile-phone intervention and examine their reactions to the intervention using a user-centred approach to refine the initial intervention draft;
- To explore new approaches of assessing sun exposure and sun protection during holidays and investigate the proof of concept of novel outcome measures;
- To synthesize the evidence for the question-behaviour effect (QBE) on health-related behaviours, in order to possibly inform the research protocol of a randomised controlled trial;
- To develop a protocol for a definitive randomised controlled and, subsequently, conduct an internal pilot study to assess the feasibility and acceptability of the newly developed intervention and trial procedures.

## 1.6 Overview of the Thesis

The purpose of this chapter has been to introduce the rationale for this area of study and to outline aims and objectives of this research.

**Chapter 2** describes the methods and main findings of a systematic review with meta-analysis and moderator analysis assessing the efficacy of 23 skin cancer prevention interventions designed to promote sun-protection behaviours in recreational/tourist settings.

**Chapter 3** outlines the main methods employed in the qualitative study and highlights the findings emerging from the semi-structured interviews conducted with 17 potential holidaymakers about their perceptions on sun-related experiences.

**Chapter 4** provides a detailed description of the systematic process of developing the behavioural change intervention to promote sun protection amongst holidaymakers. More precisely, it describes how evidence and theory were used to inform this process and presents the main findings from the user-engagement study.

**Chapter 5** tackles identified needs of using reliable and valid forms of assessing patterns of sun protection behaviours, as well as the use of more robust measures of sun exposure, outlining the optimisation process and the validity of novel objective methods to assess sunscreen use and skin damage after UV exposure. Finally, it also highlights the decision process of a full protocol for outcome assessment of sun protection over holiday.

Despite the suggestion of novel methods of measuring sun protection in Chapter 5, it would be risky to not include any form of self-report as part of the outcome assessment procedure for an RCT in this area. For this reason, the literature was appraised to identify the potential effects of answering questionnaires on health-related behaviours and, more precisely, on sun protection. **Chapter 6** describes the methods employed in a systematic review assessing the question-behaviour effect on health-related behaviours in 41 studies (no studies on sun protection). This chapter also explores potential moderators of the question-behaviour effect on a series of subgroup analyses.

Based on the information and evidence collected in previous chapters, **Chapter 7** presents the protocol for the definitive randomised controlled trial evaluating the efficacy of the behavioural intervention to improve sun protection practices. For a parsimonious use of the available resources for this trial, an internal pilot was deemed appropriate. This chapter describes the main findings from the internal pilot study

(N=42) of the behavioural intervention developed, exploring acceptability, feasibility and satisfaction with the intervention and trial procedures.

Finally, **Chapter 8** provides a synthesis of the findings from this research, and the strengths and limitations of the approach taken are acknowledged. The thesis concludes by identifying recommendations for policy, practice and future research.

# **Chapter 2 The efficacy of interventions to promote sun-protection behaviours in recreational settings: A systematic review with meta-analyses and moderator analyses**

## **2.1 Abstract <sup>1</sup>**

Intermittent sun exposure and sunburn are risk factors for skin cancer that mostly occur in recreational/tourist settings. This chapter assesses the efficacy of skin cancer prevention interventions designed to promote sun-protection behaviours in recreational/tourist settings.

Systematic review with meta-analyses of controlled trials with outcome measures of sun-protection behaviours and/or sunburn published until January 2011.

Twenty-three studies were included. No evidence for the efficacy of current interventions in reducing tanning or promoting protective clothing and seeking shade was found. Meta-analyses show a small heterogeneous effect for interventions on sun-protection behaviour indices. Larger but heterogeneous effects were observed for self-reported sun exposure and sunburns. Modest methodological quality suggests risk of bias. Effective interventions were more likely to stimulate social norms supporting sun-protection behaviours and provide appearance-based information about photoaging illustrated with UV photographs.

There is weak and inconclusive evidence for the efficacy of interventions in promoting sun-protection behaviours.

## **2.2 Introduction**

The incidence of skin cancer in Caucasian populations has been increasing worldwide over recent decades (Lens and Dawes, 2004). In 2007, melanoma incidence rate was 18.7 per 100,000 persons, making melanoma the 8<sup>th</sup> most common form of cancer in the USA with a mortality rate of 2.7 per 100,000 persons (U.S. Cancer Statistics Working Group, 2010). In 2009, 68,720 new cases of melanoma were diagnosed in the USA resulting in an estimated 8 650 mortalities (American Cancer Society, 2011). In addition, more than 2.2 million people in the US develop non-melanoma skin cancer every year (American Cancer Society, 2011).

Skin cancer results from a complex interaction of endogenous non-modifiable risk factors (i.e. skin phenotype, propensity to develop nevi, freckles, and family history of skin cancer) with exposure to ultraviolet radiation (UV). In particular, intermittent and

---

<sup>1</sup> This chapter and its appendices have been published as a journal article in *Annals of Behavioral Medicine* (Rodrigues *et al.*, 2013).

intensive sun exposure is a major risk factor for melanoma skin cancer (Gandini *et al.*, 2005). Moreover, there is evidence linking squamous cell carcinoma to chronic UV exposure (Kricker *et al.*, 1994) and basal cell carcinoma to a more intermittent pattern of sun-exposure (Kricker *et al.*, 1995). Effective interventions to reduce intermittent sun-exposure would considerably reduce skin cancer incidence (Armstrong and Kricker, 2001). To date, it is not known what the most effective strategies are to control levels of intermittent sun-exposure by encouraging people to avoid sun-exposure during peak radiation hours and seek shade, wear protective clothing, hats and sunglasses and apply sunscreen. Tourism and recreational settings are the main sources of intermittent UV exposure and intentional seeking of sun-exposure. Intentional sun-exposure has become increasingly prevalent (Manning and Quigley, 2002; Diffey and Norridge, 2009) and recreational sun-exposure is associated with melanoma prevalence (Agredano *et al.*, 2006a). For example, 40% of the British population experiences severe and painful sunburn during their holidays (Cancer Research UK, 2011a) and the UK population receives around 30% of their annual UV exposure in the two-week period of summer vacation (World Health Organisation, 2002). Likewise, Americans double their annual UV dose during 3-week holiday in the Caribbean, Pacific Islands or at holiday destinations near the equator (Godar *et al.*, 2001).

The most recent systematic review in the field reviewed the evidence for interventions promoting sun-protection behaviours in both controlled and uncontrolled trials until June 2000 (Saraiya *et al.*, 2004). From 11 included reports of evaluations of interventions in recreational/tourism settings, authors concluded that there was evidence for the efficacy in increasing protective clothing amongst adults as well as for sunscreen use and sun-protection behaviours in youths. The distinction between adult and youth samples is important. Intervention content and context often differ and the vast majority of trials focus on evaluating interventions for either of these groups. The authors found that there was limited evidence to conclude on the efficacy of interventions in preventing sunburn for youths or adults (Saraiya *et al.*, 2004). No meta-analyses were performed and the small number of studies included in this review did not allow for subgroup analyses exploring possible intervention features accounting for differences in efficacy.

This is the first systematic review with meta-analyses of controlled trials of skin cancer prevention interventions in recreational/tourism settings. The review provides an up-to-date test of the efficacy of interventions in promoting sun-protection behaviours, reducing UV exposure and consequent sunburn experience amongst adults and youths. An exploratory integrative narrative moderator analysis of behaviour change

techniques and intervention delivery features is conducted to identify possible moderators of efficacy. Moreover, the methodological quality of the evidence base is critically evaluated and an agenda for future research is outlined.

## **2.3 Methods**

This review is based on a comprehensive protocol (see Appendix A).

### **2.3.1 Study inclusion criteria**

#### Types of studies

Published randomized controlled trials (RCTs), cluster randomized controlled trials (CRTs) and non-randomized controlled before-after studies (CBAs) comparing either two or more types of interventions with each other or one or more intervention with no intervention or standard practice (control group) were included in this review.

#### Types of participants

The review considered studies including both adults and children within recreational or tourism settings (e.g. beaches, swimming pools, skiing resorts). Studies were also included if the intervention under investigation explicitly aimed at preparing participants for intermittent exposure at recreational or tourism sites (e.g. recruitment at airports, through travel agencies).

#### Types of interventions

Any intervention aimed at promoting sun-protection behaviours and/or preventing sun-exposure and sunburn (avoidance of sun-exposure during peak radiation hours and seeking of shade, protective clothing, hats and sunglasses and application of sunscreen) was eligible for inclusion.

#### Types of outcomes

Studies reporting observed, objectively recorded or self-reported outcome measures of sun-protection behaviours (i.e. use of protective clothing, minimizing sun-exposure/shade seeking, sunscreen use) and experience of sunburn were included in this review.

### **2.3.2 Search Strategy**

A comprehensive database search was conducted in Ovid (MEDLINE, EMBASE, PsycINFO, ERIC), Cochrane Library (CENTRAL), and CINAHL using keywords and index terms. The search strategy was developed in consultation with an experienced librarian and encompasses three main categories of keywords and index terms: 1)



Health condition and sun-related effects on human skin (e.g. Melanoma, Skin Neoplasm, Sunburn, Skin Aging, Suntan); 2) Type of interventions, as well as main behavioural and social cognitive outcomes (e.g. Health Promotion, Health Behaviour, Public Health, Attitude, Knowledge); 3) Recreational settings (e.g. Recreation, Tourism, Holiday, Bathing Beaches, Swimming Pools) (see Table 1 in Appendix A for full strategy). No language restrictions were established. Hand searches of reference lists of relevant published studies were conducted.

### **2.3.3 Methodological Quality**

Methodological quality was appraised using standard criteria by the Review Body for Interventional Procedures of the UK National Institute of Clinical Excellence ([www.nice.org.uk](http://www.nice.org.uk)) covering the quality of random allocation concealment, description of withdrawals and dropouts, intention-to-treat-analysis, and blinding of participants, intervention providers and outcome assessors (Avenell *et al.*, 2004). In addition, relevant quality appraisal criteria from the Cochrane Effective Practice and Organization of Care Group (Cochrane Effective Practice and Organisation of Care Review Group (EPOC), 2002) were used to assess CBAs was coded by one reviewer (AR). Twenty percent of papers were independently second coded by a second reviewer (FFS) resulting in high agreement ( $\kappa= 0.88$ ) with only one disagreement each on random allocation concealment, intention to treat analysis and blinding of providers (in all cases uncertain vs. not implemented).

Risk of bias across studies was analysed narratively.

### **2.3.4 Data Abstraction and Analysis**

Titles and abstracts for all studies identified through the searches were screened for eligibility against the inclusion criteria. Full texts for all potentially eligible studies were obtained and assessed for inclusion. Excluded studies and reasons for exclusion were documented. Two researchers independently screened the first 20% of references (AR and VAS). Inter-rater reliability using Cohen's kappa coefficient showed a full agreement between both researchers ( $\kappa= 1.00$ ). Data extraction was also performed independently by two researchers for 20% of included studies (AR and VAS). Data extraction form was pre-specified in the protocol and piloted beforehand. The data extraction form included information about study design and setting, participants' characteristics, outcome assessment details and intervention ingredients. Content of interventions were further characterized using a reliable taxonomy of behaviour change techniques (Michie *et al.*, 2010). This taxonomy was extended to include environmental intervention techniques, as well as other specific skin cancer prevention relevant techniques. Information about the reported theory used to inform

the development of the intervention was extracted. Methods of delivery were coded in terms of format (i.e. individual or group/community,), content (i.e. oral communication, written material, videos, photos, interactive activities, environmental resources), provider (i.e. professionals delivering the intervention materials) and setting (i.e. location) of the intervention (Davidson *et al.*, 2003). These ratings were independently coded by two reviewers (AR & VAS); discrepancies were resolved in discussion with a third coder (FFS). To optimize the power and coherence of findings in the moderator analyses, some behaviour change techniques and features of modes of delivery were grouped into coherent clusters.

Studies reporting sufficient data to calculate odds ratios (ORs) or standardized mean differences (SMDs) with 95% confidence interval (CI) were considered for meta-analysis. A separate meta-analysis was computed for each outcome reported by two or more studies (sun-protection behaviours (composite score), sunscreen use, shade use, sun-exposure, sunburn and protective clothing use). Results from comparable studies were pooled together using RevMan (version 5.0) (*Review Manager (RevMan)*, 2011) to compute weighted odds ratios and weighted standardized mean differences. Heterogeneity across studies was assessed using chi-square tests with the significance set at  $p < 0.1$  and  $I^2$  test statistic for quantification of the effect of heterogeneity (Higgins and Green S, 2011). According to Cochrane guidelines (Higgins and Green S, 2011),  $I^2$  values of 40% or less denoted low heterogeneity and values of 50% or higher denoted notable heterogeneity.

Due to the heterogeneous nature of the mostly complex interventions in this review, effect sizes for all outcomes were calculated using random effects model (inverse-variance approach). All outcomes were analysed comparing intervention vs. control groups. When studies tested more than one intervention, the comparison was based on the most intensive intervention. Meta-analyses were performed for the full sample, with subgroup analyses for youths (mean participant age <16 years) and adult samples separately to allow comparisons with a previous review by Saraiya and colleagues (2004). In order to include CRTs in meta-analyses, standard statistical adjustments were made for design effects (Higgins and Green S, 2011). Sensitivity analyses were conducted using alternative ICC estimates of 0.01 and 0.03. Neither of these variations changed key findings of meta-analyses. Possible publication bias was assessed by plotting the inverse of the standard errors of effect estimates using 'funnel plots' to explore symmetry. These were assessed visually to see if the effect decreased with increasing sample size and results show no evidence of considerable asymmetry was found. Absence of publication bias was further confirmed by Egger's regression test.

Cochrane Collaboration (Higgins and Green S, 2011) suggests that non-randomized trials should not be meta-analysed. Hence, non-randomized studies and studies not providing sufficient information for inclusion in meta-analyses were synthesized narratively. The PRISMA statement for reporting systematic reviews (Moher *et al.*, 2009b) was implemented in this review.

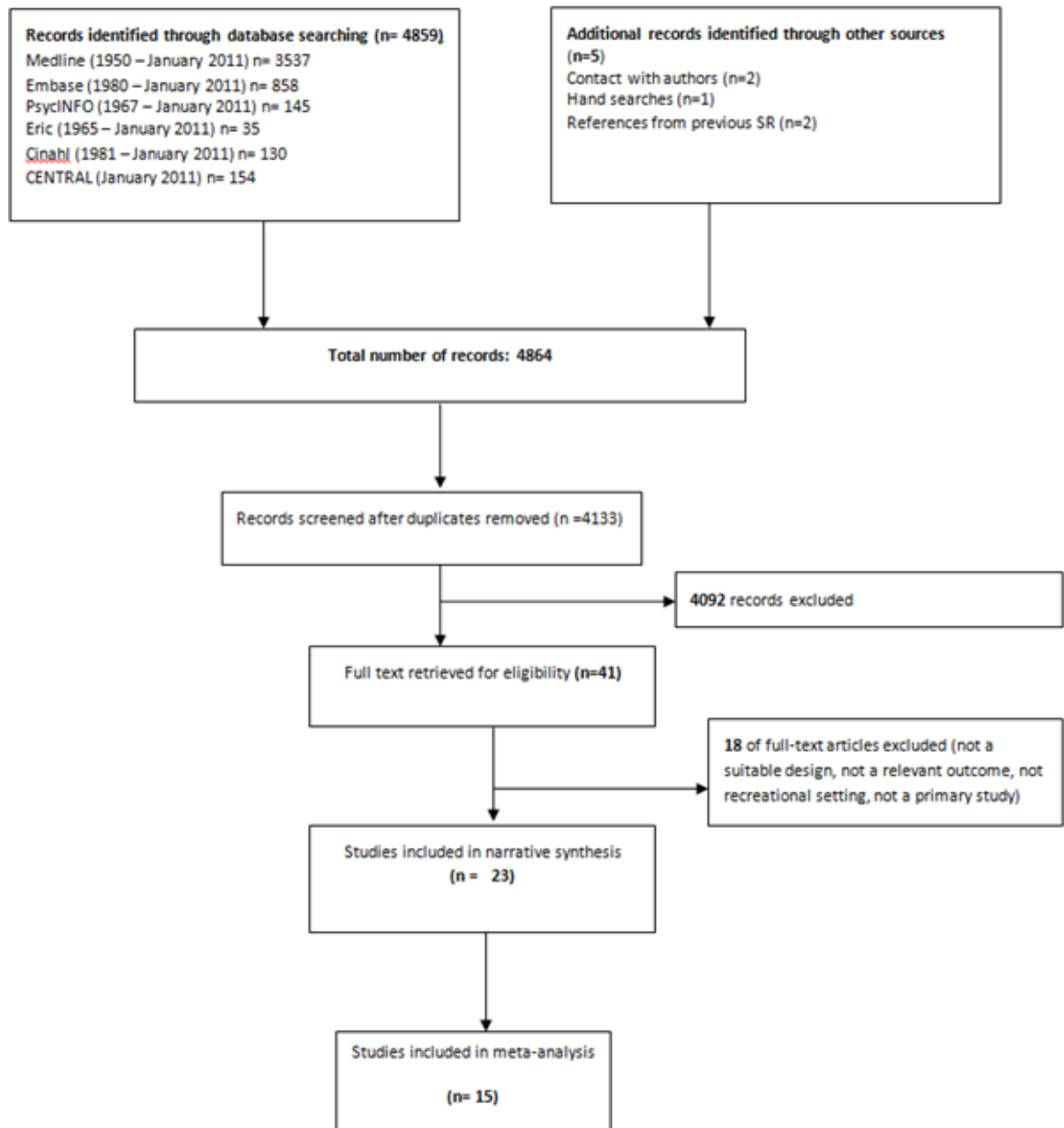
## **2.4 Results**

Twenty-two articles reporting 23 studies met the inclusion criteria from an initial 4868 retrieved records (see Figure 2-1). For 41 records, full texts were retrieved for detailed analysis and 18 were excluded. Main reasons for exclusion were study design (e.g. uncontrolled studies), study setting (not recreational or tourism setting) and relevant outcomes not measured.

### **2.4.1 Description of included studies**

The details of the studies included are summarized in Table 2-1. Sixteen included studies were CRTs (Dey *et al.*, 1995; Mayer *et al.*, 1997; Winett *et al.*, 1997; Dietrich *et al.*, 1998; Segan *et al.*, 1999; Glanz *et al.*, 2000; Geller *et al.*, 2001; Glanz *et al.*, 2001; Glanz *et al.*, 2002; Buller *et al.*, 2005; Nicol *et al.*, 2007; Olson *et al.*, 2007; Walkosz *et al.*, 2007; Walkosz *et al.*, 2008; Pagoto *et al.*, 2010), four were RCTs (Weinstock *et al.*, 2002; Mahler *et al.*, 2003b; Dupuy *et al.*, 2005; Mahler *et al.*, 2006) and three CBAs (Mayer *et al.*, 2001; Pagoto *et al.*, 2003; Roberts and Black, 2009).

Figure 2-1: Flow Diagram (adapted from PRISMA, 2009)



## Participants

The review represents a total of 30,794 participants (mean sample size =1534.4; Range: 27 to 12,385). The mean average age of participants was 25.9 (SD=13.1), ranging from 6.6 (Glanz *et al.*, 2002) to 39.3 (Nicol *et al.*, 2007). Thirteen studies (Dey *et al.*, 1995; Segan *et al.*, 1999; Geller *et al.*, 2001; Weinstock *et al.*, 2002; Mahler *et al.*, 2003b; Pagoto *et al.*, 2003; Buller *et al.*, 2005; Dupuy *et al.*, 2005; Mahler *et al.*, 2006; Nicol *et al.*, 2007; Walkosz *et al.*, 2008; Roberts and Black, 2009; Pagoto *et al.*, 2010) involved adults and included more female than male participants (52.5% to 100% female). Studies included predominantly Caucasian participants (57.2% to

100%), with only two studies (Glanz *et al.*, 2000; Glanz *et al.*, 2001) including mainly other ethnic backgrounds (i.e. Hawaiian and Asian).

Eight studies (Mayer *et al.*, 1997; Winett *et al.*, 1997; Dietrich *et al.*, 1998; Glanz *et al.*, 2000; Glanz *et al.*, 2001; Mayer *et al.*, 2001; Olson *et al.*, 2007; Walkosz *et al.*, 2007) targeted youths aged from  $\leq 1$  to 13/14y and included similar proportions of boys and girls (47.1% to 55% girls). Two studies included both adults and youths (Glanz *et al.*, 2001; Glanz *et al.*, 2002). Five studies enrolled and measured outcomes in outdoor staff (Winett *et al.*, 1997; Geller *et al.*, 2001; Glanz *et al.*, 2001; Buller *et al.*, 2005). One study was conducted with ski outdoor staff (Buller *et al.*, 2005), 1 study involved group leaders of a 'Summer Fun program' (Glanz *et al.*, 2001) and the other 3 involved aquatics staff (e.g. lifeguards). Two studies included more women (Geller *et al.*, 2001; Glanz *et al.*, 2001) and one study included more male outdoor staff (Buller *et al.*, 2005). Winett and colleagues' study 1 and 2 (1997) did not provide demographic information.

**Table 2-1: Characteristics of Included studies**

Study ID/ Location/Design	Participants/Setting	Intervention	Outcomes
Roberts, 2009  USA  CBA	<p><u>Setting/context</u>: 2 private Midwestern universities</p> <p><u>Period of study</u>: Not stated</p> <p><u>Inclusion criteria</u>: students at included universities and who were travelling to sunnier environments (&lt; 35° latitude) for spring break.</p> <p><u>Exclusion criteria</u>: not stated</p> <p><u>Gender</u>: 73% female</p> <p><u>Mean Age (SD)</u>:                      A (<i>Community intervention</i>): 21.2y (4.7)                      B (<i>Combination intervention</i>): 20.4y (2.7)                      C (<i>Control</i>): 20.4y (4.0);</p> <p><u>Skin type</u>: Not stated</p> <p><u>Baseline comparability</u>: Not stated</p>	<p><u>Content</u>:</p> <p>A – “Definitely a 15” a community health campaign, including posters, informational booths and brief educational messages about sun exposure and skin cancer were advertised in the student newspaper (n= 31);</p> <p>B – community health campaign + 45-minute weekly sessions based on Cognitive-Behavioural Intervention for 3 weeks in small groups (n=30);</p> <p>C – No intervention (n=27).</p> <p><u>Duration</u>: 3 weeks intervention</p> <p><u>Delivered by</u>:</p> <p>A – Different media channels                      B - Different media channels +a clinical psychologist</p> <p><u>Theoretical basis</u>: Social Learning Theory and Transtheoretical model</p> <p><u>% Dropout</u>:</p> <p>A – 3.2%                      B – 6.7%                      C – 11.1%</p> <p><u>BCT coding</u>: 1, 2A, 3, 21, 22, 41, 43</p>	<p><u>Outcomes</u>:</p> <ol style="list-style-type: none"> <li>1) SPB – hours of sun-exposure, use of protective clothes and sunscreen use by self-report retrospectively and diaries.</li> <li>2) Skin colour - examiners rated skin colour and level of tan</li> <li>3) Stage of Change</li> <li>4) Attitudes and Beliefs</li> <li>5) Knowledge</li> </ol> <p><u>Follow up</u>:</p> <p>1 week following spring break (2 weeks after intervention)</p>
Pagoto, 2010  USA  CRT	<p><u>Setting/context</u>: 2 public beaches in eastern Massachusetts</p> <p><u>Period of study</u>: June-July 2006</p> <p><u>Inclusion criteria</u>:</p> <p><b>Participants</b>: Female, ≥18y, non-English speaking, sixth-grade reading level and provided at least 2 types of contact details.</p> <p><u>Exclusion criteria</u>:</p>	<p><u>Content</u>:</p> <p>I –Sunless intervention: 1) explanation of sunless tanners, application instructions and application demonstration; 2) pamphlet about skin cancer; 3) UV-filtered photo (n= 125);</p> <p>C– No intervention (n=125).</p> <p><u>Duration</u>: not stated</p> <p><u>Delivered by</u>: research assistants</p> <p><u>Theoretical basis</u>: not stated</p>	<p><u>Outcomes</u>:</p> <ol style="list-style-type: none"> <li>1) Sunbathing – how much time they spent in the sun with the intention of getting a tan (0= never; 7= every day)</li> <li>2) Sunburn – number of sunburn (0= not at all; 5= ≥5)</li> <li>3) Sunscreen Use – how often applied sunscreen (0= never; 4= always)</li> <li>4) Other SPB – how often use other</li> </ol>

Study ID/ Location/Design	Participants/Setting	Intervention	Outcomes
	<p><b>Participants:</b> Male, ≤18y, English speaking.  <b>Gender:</b> 100% female  <b>Mean Age (SD)</b>            I:33.6y (13.3)            C: 28.8y (10.9)  <b>Skin type:</b> 45.2% level 4  <b>Baseline comparability:</b>            Significant differences in age.</p>	<p><b>% Dropout:</b> not stated  <b>BCT coding:</b> 1, 2, 21, 22, 28, 27, NT1, NT3, 41</p>	<p>protection. Composite mean calculated.            5) Sunless Tanning Use – how many times they used sunless tanning products.   <b>Follow up:</b> after 2 months and 1 year</p>
<p><sup>2</sup>Walkosz, 2008<sup>3</sup>             USA and Canada             CRT</p>	<p><b>Setting/context:</b> guests at 26 ski resorts  <b>Period of study:</b> 2001-2002  <b>Inclusion criteria:</b>  <b>Ski areas</b> – National Ski areas Association (NSAA) members and have at least two aerial chairlifts.  <b>Participants</b> – guests at ski areas; and &gt;18y.  <b>Exclusion criteria:</b>  <b>Participants</b> – employees, non-English speakers and previously interviewed.  <b>Gender:</b> 72.4% male  <b>Age:</b> 68.3% were 45y or less  <b>Skin type:</b> Not stated  <b>Baseline comparability:</b> there were significant differences between pre-test and post-test on ethnicity, education, age, location, expertise and weather.</p>	<p><b>Content:</b>            I – “Go Sun Smart” campaign. Guest materials included posters and brochures for ski and snowboard schools, signage at the base of chairlifts and on chairlift poles, electronic signs and grooming reports, brochures, and table tents and posters in lodges; and an employee-training program. All messages mentioned: wear sunscreen, sunglasses, and a hat (n= not stated).            C – No intervention (n= not stated).   <b>Duration:</b> January to April 2002  <b>Delivered by:</b> resort managers  <b>Theoretical basis:</b> Diffusion of innovations theory  <b>% Dropout:</b>            Guests samples were cross-sectional one and changed from baseline to follow-up            Baseline – n=2991            Follow up – n=3535  <b>BCT coding:</b> 1, 2, 20, 21, 26, 28, 30, NT1, 41, 43</p>	<p><b>Outcomes:</b>            1) SPB – sunscreen use and use of different protective clothes. Two summed composite scores: a) sunscreen and lip balm (range=0-2) and b) sunscreen; lip balm; goggles gloves; face cover; neck cover; and head cover (range=0–7).            2) Sunburn.   <b>Follow up:</b>            January to March 2002</p>

2 Statistical results were provided by Andersen and colleagues' paper (2009). This paper reports the results of the cross-over design of the control group after two years of original study.

3 Authors did not report results for primary outcomes. Therefore, results from the 2009 paper were used for analysis.

Study ID/ Location/Design	Participants/Setting	Intervention	Outcomes
<p>Nicol, 2007</p> <p>France</p> <p>CRT</p>	<p><u>Setting/context</u>: 3 beach resorts in France</p> <p><u>Period of study</u>: Summer 2003</p> <p><u>Inclusion criteria</u>: Caucasian adult between 18 and 65 years per family and arrive to resort on a Saturday for a week holiday</p> <p><u>Exclusion criteria</u>: Participants belonging to the same family</p> <p><u>Gender</u>: 36.3% male, 63.7% female</p> <p><u>Mean Age (SD)</u> : 39.3y (range: 18–79y)</p> <p><u>Skin type</u>: Not stated</p> <p><u>Baseline comparability</u>: no significant differences between groups</p>	<p><u>Content</u>:</p> <p>A - free sunscreen provided at any time (n=118)</p> <p>B - free sunscreen with new labelling (n=118)</p> <p>C – No sunscreen provided (n=128)</p> <p><u>Duration</u>: 1-week at each resort</p> <p><u>Delivered by</u>: research staff</p> <p><u>Theoretical basis</u>: not stated</p> <p><u>% Dropout</u>: 7.1%</p> <p><u>BCT coding</u>: NT1, 20, 21, 41</p>	<p><u>Outcomes</u>:</p> <p>1) Sunscreen use – “Weighed quantity” of SCs applied and , “declared quantity” of SCs applied was collected by the daily self-questionnaire (measure unit was “coffee-spoon of SC”)</p> <p>2) Sunburn &amp; Sun-exposure – daily chronologic tables self-completed every evening, recording sun exposure by units of 30 min</p> <p><u>Follow up</u>: Diary record for every day, during intervention</p>
<p>Olson, 2007</p> <p>USA</p> <p>CRT</p>	<p><u>Setting/context</u>: 10 U.S. communities</p> <p><u>Period of study</u>: 2000-2003</p> <p><u>Inclusion criteria</u>:</p> <p><b>Communities</b> – from New Hampshire and Vermont; had a middle school with grades 6 through 8 within 1 building; at least 1 primary care practice serving the community; and a freshwater beach or town swimming pool.</p> <p><b>Participants</b> – children entering 6 to 8 who were at community beaches and swimming pools.</p> <p><u>Gender</u>: 57.1% female</p> <p><u>Age</u>: not sated; 98.1% were at 6th grade at baseline</p> <p><u>Skin type</u>: 40.4% “rarely burns, always tan”</p> <p><u>Baseline comparability</u>: Differences in weather conditions across years.</p>	<p><u>Content</u>:</p> <p>I – Program materials and training for adult role models emphasized 2 roles: protecting themselves and being an effective role model and educator for the teens. Teen materials emphasized being protected while having outdoor fun. Community environmental cues in each setting were used to increase awareness of sun protection. We reinforced the intervention messages by using branded program materials: a unique, bright logo and the slogan, “Be SunSafe.” (n= 357).</p> <p>C – No intervention (n= 437).</p> <p><u>Duration</u>: 3 academic years (2000-2003)</p> <p><u>Delivered by</u>: Research staff, teachers, coaches, lifeguards and clinicians</p> <p><u>Theoretical basis</u>: Social Cognitive Theory and Protection Motivation Theory</p> <p><u>% Dropout</u>:</p> <p>Cross-sectional samples of early adolescents</p>	<p><u>Outcomes</u>:</p> <p>1) Observed SPB – The total percent of body surface protected by different clothing types and/or sunscreen</p> <p>2) Self-report of sunscreen use</p> <p><u>Follow up</u>: 2002 and 2003</p>



Study ID/ Location/Design	Participants/Setting	Intervention	Outcomes
		Baseline: n=794 1y follow up: n=637 2y follow up: n=492 <u>BCT coding</u> : 1, 2, 2a, 3, 4, 20, 21, 24, 26, 28a, 29, 30, 32, NT2, 41, 43, 46	
Walkosz, 2007  USA and Canada  CRT	<u>Setting/context</u> : parents of children enrolled in ski schools at 24 ski resorts <u>Period of study</u> : 2001-2002 <u>Inclusion criteria</u> : <b>Ski areas</b> – National Ski areas Association (NSAA) members; have at least two aerial chairlifts; and be located at Western North America <b>Participants</b> –children in ski schools. <u>Exclusion criteria</u> : not stated. <u>Children gender</u> : I: 47.3% female C: 52.6% female <u>Children age (mean)</u> : I: 6.6y C:7.2y <u>Skin type</u> : Not stated <u>Baseline comparability</u> : Not stated	<u>Content</u> : I – “Go Sun Smart” campaign. Guest materials included posters and brochures for ski and snowboard schools, signage at the base of chairlifts and on chairlift poles, electronic signs and grooming reports, brochures, and table tents and posters in lodges; and an employee-training program. All messages mentioned: wear sunscreen, sunglasses, and a hat (n= 186 children). C – No intervention (n= 171 children). <u>Duration</u> : December 2001 to April 2002 <u>Delivered by</u> : resort managers <u>Theoretical basis</u> : Diffusion of innovations theory <u>% Dropout</u> : Cross-sectional sample of children and baseline values not stated <u>BCT coding</u> : 1, 2, 20, 21, 26, 28, 30, NT1, 41, 43	<u>Outcomes</u> : Parental report about: 1) Sunscreen use - whether children were wearing sunscreen 2) Other SPB – whether children were wearing sunscreen lip balm, sunglasses or goggles, and a hat or helmet. 3) Sunburn – Sunburn experience while skiing, snowboarding or playing outside at a ski resort.  <u>Follow up</u> : 3-day period in mid-January to early April 2002
Mahler, 2006  USA  RCT	<u>Setting/context</u> : 4 beach areas in California <u>Period of study</u> : late June of 2002 or 2003 <u>Inclusion criteria</u> : <b>Beaches</b> – not stated <b>Participants</b> – beachgoers who appeared to be >18y and wasn't the sole adults with small children. <u>Exclusion criteria</u> : not residents of San	<u>Content</u> : A–Photoaging information via laminated card (n=62) B – UV photo (n=61) C – Photoaging information brochure plus UV photo (n= 61) D – Control (n= 60) <u>Duration</u> : time necessary to read brochure or see UV photo	<u>Outcomes</u> : 1) Sun protection index – Estimate number of hours spent at the beach and sunbathed and frequencies of sunscreen use on face and body when sunbathing 2) Skin colour change – objective assessment of skin colour change using spectrophotometry 3) Sun protection intention 4) Cognitions: perceived susceptibility to

Study ID/ Location/Design	Participants/Setting	Intervention	Outcomes
	<p>Diego County and not available for follow-up.</p> <p><u>Gender</u>: 59% female</p> <p><u>Mean Age (SD)</u>: 35.7y (11.1y)</p> <p><u>Skin type</u>:</p> <p>Burns moderately, then develop light tan – 31.7%</p> <p>Burns moderately, then develop moderate tan – 23.5%</p> <p><u>Baseline comparability</u>: no significant differences</p>	<p><u>Delivered by</u>: research staff</p> <p><u>Theoretical basis</u>: not stated</p> <p><u>% Dropout</u>: 10%</p> <p><u>BCT coding</u>: 1, 2, 21, 32, 41</p>	<p>photoaging, perceived rewards of sunbathing/tanning and perceived costs of sun-protection use</p> <p><u>Follow up</u>: 2-months</p>
<p>Buller, 2005</p> <p>USA and Canada</p> <p>CRT</p>	<p><u>Setting/context</u>: employees in ski schools at 26 ski resorts</p> <p><u>Period of study</u>: 2001-2002</p> <p><u>Inclusion criteria</u>:</p> <p><b>Ski areas</b> – not stated</p> <p><b>Participants</b> – employees at ski areas.</p> <p><u>Exclusion criteria</u>: not stated.</p> <p><u>Gender</u>: 36% female at baseline</p> <p><u>Mean Age</u>: 34y (range=18-87y)</p> <p><u>Skin type</u>: Not stated</p> <p><u>Baseline comparability</u>: Not stated</p>	<p><u>Content</u>:</p> <p>I – “Go Sun Smart” campaign. Guest materials included posters and brochures for ski and snowboard schools, signage at the base of chairlifts and on chairlift poles, electronic signs and grooming reports, brochures, and table tents and posters in lodges; and an employee-training program. All messages mentioned: wear sunscreen, sunglasses, and a hat (n= not stated).</p> <p>C – No intervention (n= not stated).</p> <p><u>Duration</u>: January to April 2002</p> <p><u>Delivered by</u>: resort managers and employees’ supervisors</p> <p><u>Theoretical basis</u>: Diffusion of innovations theory, Self-persuasion Theory and Social Cognitive Theory</p> <p><u>% Dropout</u>:</p> <p>Cross-sectional sample of employees</p> <p>Baseline: n=7289</p> <p>Follow up: n=3801</p> <p><u>BCT coding</u>: 1, 2, 20, 21, 26, 28, 30, NT1, 41, 43</p>	<p><u>Outcomes</u>:</p> <p>1) Sunburn - yes/no and a continuous measure of the number of sunburn.</p> <p>2) SPB – Frequency of different behaviours: using sunscreen and sunscreen lip balm; wearing protective clothing, hats, and sunglasses/goggles; having sunscreen, sunglasses, and a hat at all times while at work; minimizing time in the sun; and seeking shade</p> <p>3) Attitudes toward Sun protection</p> <p>4) Self-efficacy expectations – confidence in practicing sun safety the next time working outdoors.</p> <p><u>Follow up</u>: March to April 2002</p>

Study ID/ Location/Design	Participants/Setting	Intervention	Outcomes
Dupuy, 2005  France  RCT	<p><u>Setting/context</u>: 4 French beach resorts  <u>Period of study</u>: July and August 2001  <u>Inclusion criteria</u>:  <b>Resorts</b> – not stated  <b>Participants</b> – adults arriving to the resort  <u>Exclusion criteria</u>: History of skin cancer, recent history of severe sunburn, contraindication to sun exposure, known contact dermatitis to sunscreen, pregnancy or breastfeeding and participation of another member of the family in the study.  <u>Gender</u>: 80% female  <u>Mean Age (range)</u>:            A: 40y (18-66)            B: 39y (18-78)            C: 39y (18-66)  <u>Skin type</u>: % dark complexion            A: 50%            B: 48%            C: 49%  <u>Baseline comparability</u>: no significant differences</p>	<p><u>Content</u>:            A– SPF 40 labelled as “high protection” (n=119).            B – SPF 40 labelled as “basic protection” (n=117).            C – SPF 12 labelled as “basic protection” (n= 123).            All groups received free sunscreen.  <u>Duration</u>: 1 week  <u>Delivered by</u>: research staff  <u>Theoretical basis</u>: not stated  <u>% Dropout</u>: 6.8%  <u>BCT coding</u>: NT1, 41</p>	<p><u>Outcomes</u>:            1) Sunbathing –            Duration of sunbathing by self-report, mean cumulative exposure by subject            2) Sunburn - yes/no            3) Sunscreen use – Weighting all the sunscreen tubes at the end of the study</p> <p><u>Follow up</u>:            End of last day of week intervention</p>
Mahler, 2003  USA  RCT	<p><u>Setting/context</u>: 2 beach areas in California  <u>Period of study</u>: July to August 2000  <u>Inclusion criteria</u>:  <b>Beaches</b> – not stated  <b>Participants</b> – seated beachgoers who appeared to be &gt;18y and wasn't the sole adults with small children.  <u>Exclusion criteria</u>: not stated.  <u>Gender</u>: 66% female</p>	<p><u>Content</u>:            A–Photoaging information brochure (ACS Brochure) (n=22)            B – UV photo (n=19)            C – Photoaging information brochure plus UV photo (n= 18)            D – Control (n= 17)  <u>Duration</u>: time necessary to read brochure or see UV photo  <u>Delivered by</u>: research staff</p>	<p><u>Outcomes</u>:            1) Intentional Sun exposure – Estimate number of hours spent at the beach and sunbathed            2) Incidental sun exposure – Estimate the average number of hours in the sun            3) Sunscreen use frequency – Frequencies of sunscreen use on face and body when sunbathing            4) Sunscreen samples used – Yes/No</p>

Study ID/ Location/Design	Participants/Setting	Intervention	Outcomes
	<p><u>Mean Age (SD):</u> 35.3y (9.9y)</p> <p><u>Skin type:</u> Burn easily, then develop light tan – 27.6% Burns moderately, then develop light tan – 31.6%</p> <p><u>Baseline comparability:</u> no significant differences</p>	<p><u>Theoretical basis:</u> not stated</p> <p><u>% Dropout:</u> 17%</p> <p><u>BCT coding:</u> 1, 2, NT1, 20, 21, 32, 41</p>	<p>5) Intention to sunscreen use 6) Intention to other SPB</p> <p><u>Follow up:</u> 1-month</p>
<p>Pagoto, 2003</p> <p>USA</p> <p>CBA</p>	<p><u>Setting/context:</u> lakefront beach (control and intervention separated by 1mile)</p> <p><u>Period of study:</u> Summer 2000</p> <p><u>Inclusion criteria:</u> <b>Beach</b> – public assess; sand-covered beach populated by Caucasian beachgoers. <b>Participants</b> –beachgoers &gt;18y and English speakers. <u>Exclusion criteria:</u> not stated. Gender: % female I: 55 C: 75 <u>Mean age (SD) :</u> I: 27.96y (6.2y) C: 24.49y (3.2y) <u>Skin type:</u> % type III: I=36; C=49 % type IV: I=25; C=27 <u>Baseline comparability:</u> Group comparisons show significant differences in age, sun exposure levels and gender</p>	<p><u>Content:</u> I: Multi-component intervention involving six components: 1) sun protection recommendations consistent with sensitivity level; 2) pamphlet of safe sun recommendations; 3) UV photos; 4) commitment cards; 5) free sunscreens and instructed on proper application of sunscreen; and 6) research assistants modelled proper sun protection by repeatedly applying sunscreens and wearing protective clothing, hats and sunglasses (n= 53) C: no intervention (n= 47) <u>Duration:</u> not stated <u>Delivered by:</u> research staff <u>Theoretical basis:</u> Transtheoretical model <u>% Dropout:</u> 61% <u>BCT coding:</u> 2, 2a, 21, 22, 24, 25,28a, 41</p>	<p><u>Outcomes:</u> 1) SPB – A composite score of items that included (a) frequency of sunscreen use (SPF 15 or higher), (b) frequency of protective clothing use during sun exposure, and (c) the number of body parts protected from sun. Composite scores ranged from 1 to 7 with higher scores indicating increasing degree of sun protection. 2) Sun exposure - average number of days per week and the average number of hours per week spent (a) sunbathing and (b) engaging in outdoor activities over the past 2 months. Composite scores were calculated. 3) Stage of change – Staging algorithm</p> <p><u>Follow up:</u> 2-months</p>
<p>Weinstock, 2002</p> <p>USA</p>	<p><u>Setting/context:</u> 7 salt water beaches in Rhode Island</p> <p><u>Period of study:</u> Summer 1995</p> <p><u>Inclusion criteria:</u></p>	<p><u>Content:</u> I: Components – 1) educational pamphlet, personalized sun sensitivity assessment and feedback (written</p>	<p><u>Outcomes:</u> 1) SPB – Sun Protection Behaviour Scale (SPBS) 2) Stage of change - Stage of change for</p>

Study ID/ Location/Design	Participants/Setting	Intervention	Outcomes
RCT	<p><b>Beach</b> – not stated.</p> <p><b>Participants</b> – Beachgoers.</p> <p><u>Exclusion criteria</u>: not stated.</p> <p><u>Gender</u>: 60 % female</p> <p><u>Mean age (SD)</u> : 33y (12y)</p> <p><u>Skin type</u>: 55% moderate sensitivity type</p> <p><u>Baseline comparability</u>: The only significant difference between groups was in stage of change.</p>	<p>and verbal), SPF 15 sunscreen, and instant sun damage imaging photographs that reveal damage to the skin that is not visible in normal light. 2) Follow-up interventions included two three- to-four page expert system feedback reports matched to the individual's stage of change (n= 1143)</p> <p>C: no intervention (n= 1181)</p> <p><u>Duration</u>: 12 months</p> <p><u>Delivered by</u>: research staff</p> <p><u>Theoretical basis</u>: Transtheoretical model</p> <p><u>% Dropout</u>: 37.7%</p> <p><u>BCT coding</u>: 1, 2, 4, 19b, 27,41</p>	<p>sun protection: two algorithms were used to measure stage of change. Each algorithm consisted of a short series of questions designed to assess intentions and behaviours for reducing sun exposure.</p> <p><u>Follow up</u>: Follow up at 2, 12, 24 months</p>
Glanz, 2002  USA  CRT	<p><u>Setting/context</u>: 28 swimming pools</p> <p><u>Period of study</u>: Summer 1999</p> <p><u>Inclusion criteria</u>:</p> <p><b>Pools</b> – size and provision of swimming lessons.</p> <p><b>Participants</b> – parents of children aged 5 to 10 years, who were taking swimming lessons.</p> <p><u>Exclusion criteria</u>: not stated.</p> <p><u>Gender</u>:</p> <p>Parents: 80.3 % female Children: 47.1% female</p> <p><u>Mean age (SD)</u> :</p> <p>Parents: 39.2y (7.7y) Children: 6.6y (1.5y)</p> <p><u>Skin type</u>: not stated</p> <p><u>Baseline comparability</u>: Differences between groups in gender, more male parents responded in the IP arm.</p>	<p><u>Content</u>:</p> <p>I: The Pool Cool intervention included orientation and training and leader's guide for pool staff and educational and environmental components for the children and their parents (n= 558)</p> <p>C: Injury prevention (IP) arm received a parallel program that included lessons and activities on bicycle and rollerblading safety, fire safety, traffic and walking safety, poisoning and choking prevention, and playground safety (n= 446)</p> <p><u>Duration</u>: 8–10 lessons over 2 or 4 weeks</p> <p><u>Delivered by</u>: research staff and swimming pool staff</p> <p><u>Theoretical basis</u>: Social cognitive theory</p> <p><u>% Dropout</u>: 15.5%</p> <p><u>BCT coding</u>: 1, 2, 21, 22, 24, 26, NT1, 41, 43, 46</p>	<p><u>Outcomes</u>:</p> <p>1) SPB – Sun Protection Habits score, measuring five protective behaviours (using sunscreen, wearing a shirt, wearing a hat, seeking shade, and wearing sunglasses).</p> <p>2) Sunburn – measurement procedures not stated</p> <p>3) Knowledge - The Knowledge index was created by scoring answers to 8 questions as 0 (incorrect) or 1 (correct) and adding up the scores to calculate a summary Knowledge score.</p> <p><u>Follow up</u>: 8 weeks later</p>
Geller, 2001	<p><u>Setting/context</u>: 28 swimming pools</p> <p><u>Period of study</u>: Summer 1999</p>	<p><u>Content</u>:</p> <p>I: The Pool Cool intervention included</p>	<p><u>Outcomes</u>:</p> <p>1) SPB – Sun protection behaviours,</p>

Study ID/ Location/Design	Participants/Setting	Intervention	Outcomes
USA  CRT	<p><u>Inclusion criteria:</u>  <b>Pools</b> – size and provision of swimming lessons.  <b>Participants</b> – staff attending the orientation sessions at baseline survey and staff who were at the pool site at the end of summer at post-test survey  <u>Exclusion criteria:</u> not stated.  <u>Gender:</u> 68.7% female  <u>Mean age (SD):</u>  I: 21.0y (0.76y)  C: 20.8y (0.96y)  <u>Skin type:</u> % moderate to high risk - 68.1  <u>Baseline comparability:</u> Differences between groups in skin type and use of sun protection (Both higher in control group)</p>	<p>orientation and training and leader’s guide for pool staff and educational and environmental components for the children and their parents (n= 142)  C: Injury prevention (IP) arm received a parallel program that included lessons and activities on bicycle and rollerblading safety, fire safety, traffic and walking safety, poisoning and choking prevention, and playground safety (n= 78)  <u>Duration:</u> not stated  <u>Delivered by:</u> research staff and swimming pool staff  <u>Theoretical basis:</u> Social cognitive theory  <u>% Dropout:</u> ≈10%  <u>BCT coding:</u> 1, 21, 22, 26, 41, 43</p>	<p>including sunscreen, shade, hats, shirts, and sunglasses. The average score for all five behaviours comprised the sun protection habits index.  2) Sunburn – Sunburn was defined as “how many times last summer did you get a sunburn?” with responses being none, 1, 2, 3, 4, or 5 or more.  3) Knowledge - 8 knowledge questions were asked and a mean summary score was tabulated, ranging from a low of 0 to a high of 8.  4) Attitudes &amp; Social norms - items were added together and mean scores were computed   <u>Follow up:</u> 8 weeks later</p>
Glanz, 2001  USA  CRT	<p><u>Setting/context:</u> 14 recreational sites that provided “Summer Fun programs  <u>Period of study:</u> Summer 1996  <u>Inclusion criteria:</u>  <b>Sites</b> – not stated  <b>Participants</b> – all group leaders that led groups of children through various daily activities.  <u>Exclusion criteria:</u> not stated.  <u>Gender:</u> 60.9% female  <u>Mean age (SD):</u> 20.9y (7.7y)  <u>Skin type:</u> not stated  <u>Baseline comparability:</u> Differences between groups in gender and age.</p>	<p><u>Content:</u>  A: Educational – Materials for SunSmart included a leader’s guide containing activities and information, educational materials for the children and their parents, and incentives (n= 63)  B: Educational + environmental supports: large sunscreen dispensers, sun safety posters, and portable shade tents; in addition, there were consultations with SunSmart staff about sun safe policies (n= 83)  C: no intervention (n= 30)  <u>Duration:</u> 6-weeks intervention  <u>Delivered by:</u> research staff and sites staff  <u>Theoretical basis:</u> Social cognitive theory; Transtheoretical Model; Social Marketing Process</p>	<p><u>Outcomes:</u>  1) SPB – Composite of 5 behaviours (wearing a shirt with sleeves, wearing sunglasses, seeking shade, using sunscreen, and wearing a hat).  2) Knowledge - The knowledge index was created by adding up all the correct answers to calculate a summary knowledge score.  3) Attitudes  4) Social norms – The sun protection norms index was created by adding responses to 3 statements about whether most staff use sunscreen, wear hats, and cover up when outdoors  5) Skin cancer risk factors</p>

Study ID/ Location/Design	Participants/Setting	Intervention	Outcomes
		% Dropout: ≈38.6% BCT coding: 13, 19, 24, 28, 41, 43, 46	Follow up: 8 weeks later and 3 months after intervention ended
Mayer, 2001  USA  CBA	<u>Setting/context</u> : 2 zoological sites <u>Period of study</u> : January 1999 and July-August 1999 <u>Inclusion criteria</u> : <b>Sites</b> – sell similar items in their gift shops. <b>Participants</b> – zoo visitors who appeared 12 years or younger as they exited the zoo and park sites. <u>Exclusion criteria</u> : not stated. <u>Gender</u> : not provided <u>Mean age (SD)</u> : not provided <u>Skin type</u> : not stated <u>Baseline comparability</u> : not stated.	<u>Content</u> : I: Educational and environmental changes strategies, involving interactive activities with children and signage in recreational sites C: no intervention <u>Duration</u> : 10 weeks in Winter and 8 weeks in Summer study <u>Delivered by</u> : research staff and zoo staff <u>Theoretical basis</u> : not stated <u>% Dropout</u> : Cross-sectional sample of children <b>Winter study</b> Baseline: n=3093 Follow up: n=5628 <b>Summer study</b> Baseline: n=3954 Follow up: n=4570  BCT coding: 21, 41, 43	<u>Outcomes</u> : 1) Hat use – Direct unobtrusive observations of hat use by children; Observations were conducted from 2:00 to 4:00 PM in the winter study and from 3:00 to 5:00 PM in the summer study.  <u>Follow up</u> : Observations took place on a portion (range 32–45%) of baseline and intervention phase days of both the winter and the summer study.
Glanz, 2000  USA  CRT	<u>Setting/context</u> : 14 recreational sites that provided “Summer Fun programs <u>Period of study</u> : Summer 1996 <u>Inclusion criteria</u> : <b>Sites</b> – not stated. <b>Participants</b> – Children 6 to 8 years of age. <u>Exclusion criteria</u> : not stated. <u>Children Gender % girls</u> : A – 52/ B – 44/ C - 52 <u>Children Mean age</u> : A – 7y B – 7y	<u>Content</u> : A: Educational – training for recreation leaders, on-site activities for children and take-home interactive educational activities (n=207) B: Educational + environmental supports: large sunscreen dispensers, sun safety posters, and portable shade tents; in addition, there were consultations with SunSmart staff about sun safe policies (n=268) C: no intervention (n=281) <u>Duration</u> : 6 weeks <u>Delivered by</u> : research staff and recreational staff	<u>Outcomes</u> : 1) Children SPB – Composite measure, assessed by five sun-protection behaviours: wearing a shirt with sleeves, wearing sunglasses, seeking shade, wearing a hat, and using sunscreen.  <u>Follow up</u> : 6 weeks later and 3 months after intervention ended

Study ID/ Location/Design	Participants/Setting	Intervention	Outcomes
	<p>C – 7y</p> <p><u>Skin type</u>: not stated</p> <p><u>Baseline comparability</u>: Significant differences between parents in age and between children in skin cancer risk index.</p>	<p><u>Theoretical basis</u>: Social Cognitive Theory; Transtheoretical Model; Social Marketing Process</p> <p><u>% Dropout</u>: 25.6%</p> <p><u>BCT coding</u>: 13, 19, 24, 28, 41, 43, 46</p>	
<p>Segan, 1999</p> <p>Australia</p> <p>CRT</p>	<p><u>Setting/context</u>: flights departing from Melbourne airport</p> <p><u>Period of study</u>: November 1993</p> <p><u>Inclusion criteria</u>:</p> <p><b>Flights</b> – flights to the southern or northern coast of Queensland</p> <p><b>Participants</b> – Victorian adults, who looked under 50 and were holidaying in Queensland</p> <p><u>Exclusion criteria</u>: under 17y, overseas visitors and adults not holidaying in Queensland.</p> <p><u>Gender</u>: 64 % female</p> <p><u>Mean age</u>:</p> <p>I: 32.2</p> <p>C: 33.4</p> <p><u>Skin type</u>: not stated</p> <p><u>Baseline comparability</u>:</p> <p>Tourists in the intervention group were more likely to report that they would try to get a dark tan on their holiday, and were less likely to have packed a hat.</p>	<p><u>Content</u>:</p> <p>I: Full-colour six-page brochure entitled 'The SunSmart Holiday Guide: How to enjoy your holiday in the sun without getting burnt' (n=168)</p> <p>C: no intervention (n=205)</p> <p><u>Duration</u>: Time needed to read the brochure</p> <p><u>Delivered by</u>: Research staff</p> <p><u>Theoretical basis</u>: Precede-proceed Model and Social Cognitive theory</p> <p><u>% Dropout</u>: 16.37</p> <p><u>BCT coding</u>: 1, NT1, 5b, 20, 21, 28</p>	<p><u>Outcomes</u>:</p> <p>1) SPB – Frequency of occurrence of five different sun-related behaviours (wearing a hat, using sunscreen, using shade, wearing covering clothing, and wearing less clothing so as to expose skin). A composite outdoor sun-protection measure was computed.</p> <p>2) Sun-exposure – suntan acquired (none, light, moderate, dark) and how many days respondents were outside for more than two hours between 10am and 2pm.</p> <p>3) Sunburn – An 8-point composite sunburn measure was computed. This summed the number of times burnt (range 0 no burn, to 3 burnt 3(+) times), extent (strip 0, in-between area 1, large area 2) and severity (red not tender 0, red and tender 1, blistered 2) of the worst burn.</p> <p><u>Follow up</u>: when participants returned from holiday</p>
<sup>4</sup> Dietrich, 1998	<p><u>Setting/context</u>: 10 towns in New Hampshire</p> <p><u>Period of study</u>: 1995-1996</p>	<p><u>Content</u>:</p> <p>I: intervention components promoted the same message: avoid</p>	<p><u>Outcomes</u>:</p> <p>1) Children SPB – The caregivers of children then were interviewed regarding all forms of sun protection in use by the</p>

<sup>4</sup> Results from this study were completed by another report of the same study (Dietrich et al., 2000).



Study ID/ Location/Design	Participants/Setting	Intervention	Outcomes
USA  CRT	<p><u>Inclusion criteria:</u>  <b>Towns</b> – populations of 4000 to 15 000 that included at least: 500 children 2 to 9 years of age; 20% of households with 1990 incomes below the federal poverty level; one elementary school; one nearby primary care practice; one nearby Head Start program; and a freshwater beach.  <b>Participants</b> – Children 2 to 9 years of age visiting town freshwater beaches between 10 AM and 3 PM  <u>Gender:</u> I: 45% / C: 51%  <u>Age children ≥5y</u> – I: 61% / C: 64%  <u>Skin type Burns easily:</u> 54%  <u>Baseline comparability:</u> No significant difference between intervention and control towns.</p>	<p>the sun between 11 AM and 3 PM, cover up using hats and protective clothing, use sun block with a sun protection factor (SPF ≥15), and encourage sun protection among family and friends (n= 5 towns)  C: no intervention (n= 5 towns)  <u>Duration:</u> Spring and early summer 1996  <u>Delivered by:</u> project staff, clinicians, teachers and lifeguards  <u>Theoretical basis:</u> not stated  <u>% Dropout:</u>  Cross-sectional sample  Baseline:  I: n=456 / C: n=409  Follow up 1:  I: n=561 / C: n=504  Follow up 2:  I: n=746 / C: n=744   <u>BCT coding:</u> 20, 21, 22, 24, 26, 27, NT1, 41, 43</p>	<p>children with them at the time of interview.   <u>Follow up:</u> during summer 1996 and Summer 1997</p>
Mayer, 1997  USA  CRT	<p><u>Setting/context:</u> 48 aquatic classes  <u>Period of study:</u> Summer, 1995  <u>Inclusion criteria:</u>  <b>Classes</b> – all available aquatics classes of children in our target age range of 6–9 years.  <b>Participants</b> – all children attending selected classes  <u>Exclusion criteria:</u> Only one child per family  <u>Gender:</u> % female  I: 47.6  C: 51.8</p>	<p><u>Content:</u>  I: Intervention content was based around four topic areas: sunscreen, protective clothing, shade, and peak sunlight hours. A 5-min SUNWISE lesson was incorporated at the beginning. Parents received a manual containing information about skin cancer prevention and Project SUNWISE and instructions/materials for the child and family home-based activities (n=84)  C: no intervention (n= 85)  <u>Duration:</u> 6-weeks intervention  <u>Delivered by:</u> Aquatics staff and research assistants</p>	<p><u>Outcomes:</u>  1) Children Skin colour – measured objectively using a portable colorimeter  2) Children SPB -  Phone interviews to parents about specific use of sunscreen and protective clothing. Composite score.   <u>Follow up:</u>  For colorimeter: last aquatic lesson; For parents' measures: 7 to 30 days after the last mailed material</p>

Study ID/ Location/Design	Participants/Setting	Intervention	Outcomes
	<p><u>Mean Age:</u> 7y  <u>Skin type:</u> % sometimes burns            I: 38.6            C: 42.7  <u>Baseline comparability:</u>            No statistically significant differences between the groups</p>	<p><u>Theoretical basis:</u> Social cognitive theory  <u>% Dropout:</u> 10.1  <u>BCT coding:</u> 1, 13, 21, 22, 41</p>	
<p>Winett, 1997_a  USA  CRT</p>	<p><u>Setting/context:</u> 23 swimming pools  <u>Period of study:</u> Summer 1993  <u>Inclusion criteria:</u>  <b>Pools</b> – served at least 50-75 patrons on warm summer days; had a pool manager and at least two lifeguards.  <b>Participants</b> – every guest (children, adolescents and adults) and lifeguard at pools  <u>Exclusion criteria:</u> not stated  <u>Gender:</u> not stated  <u>Mean Age:</u> not stated  <u>Skin type:</u> not stated  <u>Baseline comparability:</u> not stated</p>	<p><u>Content:</u>            A: Components that constituted the program Safe Sun were: 1) 2 informational posters; 2) 1 poster also in a prominent location provided feedback for patron groups on the percent practicing Safe Sun; 3) Lotteries were conducted at each pool; 4) Lifeguards were given a Safe Sun hat and two Safe Sun shirts and asked to wear the hat and shirt when on and off duty at the pool. (n= 12 pools)            B: “Education Only” condition received only the informational posters. (n= 11 pools)  <u>Duration:</u> From early July to mid-august 1993  <u>Delivered by:</u> Research staff  <u>Theoretical basis:</u> Not stated  <u>% Dropout:</u>            Cross-sectional sample of patrons, but numbers not provided.            41,000 separate observations of children and adolescents, adults and lifeguards.   <u>BCT coding:</u> 1, 5c, 13, 19a, , 41</p>	<p><u>Outcomes:</u>            1) SPB - Behaviours included wearing a shirt, hat or sunglasses or being completely in the shade. % of patrons and lifeguards at each pool each day engaging in specific protective behaviours.   <u>Follow up:</u> Multiple observations until mid-august</p>
<p>Winett, 1997_b  USA</p>	<p><u>Setting/context:</u> 4 swimming pools  <u>Period of study:</u> Summer 1994  <u>Inclusion criteria:</u>  <b>Pools</b> – served at least 50-75 patrons on warm summer days;</p>	<p><u>Content:</u>            A: Full intervention from week 2 and added shade strategy after 6 weeks (n= 1 pool)            B: Full intervention from week 2 (n= 1 pool)</p>	<p><u>Outcomes:</u>            1) SPB - Behaviours included wearing a shirt, hat or sunglasses or being completely in the shade. % of patrons and lifeguards at each pool each day engaging in specific protective behaviours.</p>

Study ID/ Location/Design	Participants/Setting	Intervention	Outcomes
CRT	<p>had a pool manager and at least two lifeguards.</p> <p><b>Participants</b> – every guest (children, adolescents and adults) and lifeguard at pools</p> <p><u>Exclusion criteria</u>: not stated</p> <p><u>Gender</u>: not stated</p> <p><u>Mean Age</u>: not stated</p> <p><u>Skin type</u>: not stated</p> <p><u>Baseline comparability</u>: not stated</p>	<p>C: Full intervention from week 4 and shade strategy after 2 weeks (n= 1 pool)</p> <p>D: “Education Only” condition (n= 1 pool)</p> <p><u>Duration</u>: 8-weeks</p> <p><u>Delivered by</u>: Research staff</p> <p><u>Theoretical basis</u>: Not stated</p> <p><u>% Dropout</u>: Sample size not stated</p> <p><u>BCT coding</u>: 1, 5c, 13, 19a, 22, 41, 43</p>	<p><u>Follow up</u>: Multiple observations until week 8</p>
<p>Dey, 1995</p> <p>UK</p> <p>CRT</p>	<p><u>Setting/context</u>: holidaymakers travelling from a UK airport</p> <p><u>Period of study</u>: Summer 1993</p> <p><u>Inclusion criteria</u>:</p> <p><b>Flights</b> – all flights from Air UK Leisure from Manchester airport</p> <p><b>Participants</b> – all passengers at those flights</p> <p><u>Exclusion criteria</u>: passengers not departing from Manchester airport</p> <p><u>Gender</u>: % female</p> <p>I: 52.1</p> <p>C: 52.9</p> <p><u>Median Age</u></p> <p>I: 32y (range: 0-97y)</p> <p>C: 33y (range: 1-88y)</p> <p><u>Skin type</u>: % white skin</p> <p>I: 49.6</p> <p>C: 50.0</p> <p><u>Baseline comparability</u>: No significant differences between groups.</p>	<p><u>Content</u>:</p> <p>I: Leaflet “If You Worship The Sun, Don't Sacrifice Your Skin” was placed in seat pockets on flights (n= 6276)</p> <p>C: no intervention (n= 6109)</p> <p><u>Duration</u>: time necessary to read leaflet</p> <p><u>Delivered by</u>: cabin crew</p> <p><u>Theoretical basis</u>: not stated</p> <p><u>% Dropout</u>: 0%</p> <p><u>BCT coding</u>: 1</p>	<p><u>Outcomes</u>:</p> <p>1) Sunburn – elicited with question: "Did you suffer from any sunburn during your recent holiday?"</p> <p><u>Follow up</u>: in returning flights (same participants)</p>

CBA – controlled before and after study; CRT – cluster randomized trial; RCT – randomized control trial; BCT- behavior change techniques; SPB – sun-protective behavior.

## Settings

Seven studies were conducted at beaches (Weinstock *et al.*, 2002; Mahler *et al.*, 2003b; Pagoto *et al.*, 2003; Dupuy *et al.*, 2005; Mahler *et al.*, 2006; Nicol *et al.*, 2007; Pagoto *et al.*, 2010). Other settings were swimming pools (Mayer *et al.*, 1997; Winett *et al.*, 1997; Geller *et al.*, 2001; Glanz *et al.*, 2002), ski resorts (Buller *et al.*, 2005; Walkosz *et al.*, 2007; Walkosz *et al.*, 2008), recreational community settings (Dietrich *et al.*, 1998; Olson *et al.*, 2007), zoos (Mayer *et al.*, 2001) and 2 studies (Glanz *et al.*, 2000; Glanz *et al.*, 2001) enrolled participants in diverse recreational sites (e.g. community parks and YMCAs). Three studies recruited future holidaymakers at airports (Dey *et al.*, 1995; Segan *et al.*, 1999) and amongst college students travelling to destinations < 35° latitude for spring break (Roberts and Black, 2009). Studies were conducted in USA (n=16), jointly in the USA and Canada (n=3), France (n=2), Australia (n=1) and the UK (n=1).

## Outcome Measures

Most included studies reported an overall composite measure of sun-protection behaviours summarizing a range of self-reported sun-protection behaviours as the primary outcome (n=14). Behaviours reported separately were sunscreen use (n=5) and use of protective clothing (n=3). Seven studies assessed self-reported sun-exposure and three studies measured skin colour. Eight studies reported incidence of sunburn as an outcome. With the exception of two studies (Mayer *et al.*, 1997; Mahler *et al.*, 2006) that used spectrophotometry to assess changes in skin colour, the majority of studies used self-reports and/or direct observation methods to assess sun-protection behaviours. Observational methods varied from covert recording of hat use (Mayer *et al.*, 2001) to body surface protection indices based on observation of different types of protection (Dietrich *et al.*, 1998; Glanz *et al.*, 2001; Buller *et al.*, 2005; Dupuy *et al.*, 2005).

## Interventions

Most studies examined the efficacy of multi-component interventions (Mayer *et al.*, 1997; Winett *et al.*, 1997; Glanz *et al.*, 2000; Geller *et al.*, 2001; Glanz *et al.*, 2001; Mayer *et al.*, 2001; Glanz *et al.*, 2002; Weinstock *et al.*, 2002; Mahler *et al.*, 2003b; Pagoto *et al.*, 2003; Buller *et al.*, 2005; Mahler *et al.*, 2006; Walkosz *et al.*, 2007; Walkosz *et al.*, 2008; Roberts and Black, 2009; Pagoto *et al.*, 2010) involving a mix of educational and environmental components. Other interventions were described as community-based (Dietrich *et al.*, 1998; Olson *et al.*, 2007), environmental/ policy changes (Dupuy *et al.*, 2005; Nicol *et al.*, 2007) and educational/informational strategies (Dey *et al.*, 1995; Segan *et al.*, 1999).

Fourteen studies reported a theoretical basis to their interventions, including Social Cognitive Theory (Mayer et al., 1997; Segan et al., 1999; Glanz et al., 2000; Geller et al., 2001; Glanz et al., 2001; Glanz et al., 2002; Buller et al., 2005; Walkosz et al., 2007; Walkosz et al., 2008; Roberts and Black, 2009), 'Transtheoretical' Model (Glanz et al., 2000; Glanz et al., 2001; Weinstock et al., 2002; Pagoto et al., 2003; Roberts and Black, 2009), Diffusion of Innovations Theory (Buller et al., 2005; Walkosz et al., 2007; Walkosz et al., 2008); Self-persuasion Theory (Buller et al., 2005; Walkosz et al., 2007; Walkosz et al., 2008); Protection Motivation Theory (Olson et al., 2007), and the Precede-proceed Model (Segan et al., 1999).

The duration of interventions varied considerably. Some community-based interventions were delivered for up to 3 years (Olson et al., 2007) and others only took the time needed to read a leaflet (Dey et al., 1995; Segan et al., 1999). In addition, most studies evaluated effects of interventions using short-term follow-ups (n=17), ranging from 1 week to 6 months. In addition, 2 studies reported long-term follow-ups, ranging from 12 (Pagoto et al., 2010) to 24 months (Weinstock et al., 2002).

#### Methodological quality of trials

As seen in Table 2-2, sixteen studies (Dey *et al.*, 1995; Mayer *et al.*, 1997; Winett *et al.*, 1997; Dietrich *et al.*, 1998; Segan *et al.*, 1999; Glanz *et al.*, 2000; Geller *et al.*, 2001; Glanz *et al.*, 2001; Glanz *et al.*, 2002; Weinstock *et al.*, 2002; Mahler *et al.*, 2003b; Buller *et al.*, 2005; Mahler *et al.*, 2006; Nicol *et al.*, 2007; Olson *et al.*, 2007; Walkosz *et al.*, 2007; Walkosz *et al.*, 2008; Pagoto *et al.*, 2010) stated random allocation of participants to conditions without providing details about procedures. Four studies stated random allocation based on a computer-generated random number sequence, but the detailed procedures were not described. Only one trial was considered as having made a good attempt at concealment of randomization (Dupuy *et al.*, 2005). One trial (Mahler *et al.*, 2006) was classified as not having a concealed random allocation. Four studies stated numbers and reasons for participant dropout (Dey *et al.*, 1995; Glanz *et al.*, 2002; Pagoto *et al.*, 2003; Mahler *et al.*, 2006). Fifteen studies only stated the numbers of withdrawals and 2 studies stated study withdrawals but did not provide numbers and reasons for attrition (Winett *et al.*, 1997). Ten studies in this review reported analysis based on intention-to-treat (ITT) principles (Winett *et al.*, 1997; Dietrich *et al.*, 1998; Glanz *et al.*, 2000; Glanz *et al.*, 2001; Buller *et al.*, 2005; Dupuy *et al.*, 2005; Nicol *et al.*, 2007; Olson *et al.*, 2007; Walkosz *et al.*, 2008; Pagoto *et al.*, 2010). Two studies (Dupuy *et al.*, 2005; Nicol *et al.*, 2007) reported effective blinding procedures for participants and intervention providers.

**Table 2-2: Quality assessment of Randomized Controlled Trials (RCTs) and Controlled Before-After Studies (CBAs)**

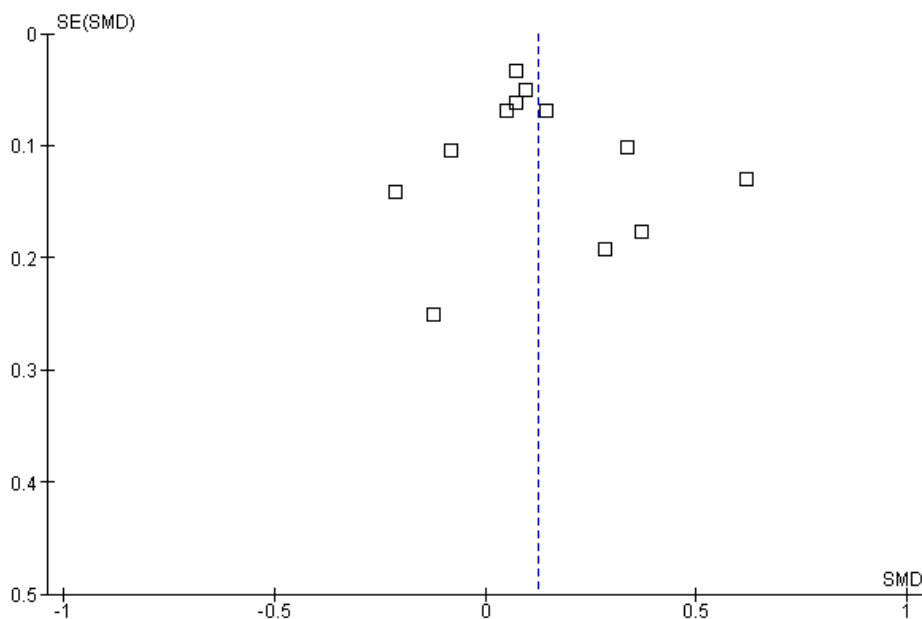
<b>Study ID</b>	<b>Quality of random allocation concealment</b>	<b>Description of withdrawals and dropouts</b>	<b>Intention-to-treat?</b>	<b>Participants blinded to treatment status?</b>	<b>Intervention providers blinded to treatment status?</b>	<b>Outcome assessors blinded to allocation?</b>	<b>Primary outcome measure reliable?</b>	<b>Characteristics for CBAs using second site as control</b>	<b>CBAs' protection against contamination</b>
<b>RCTs</b>									
Dupuy, 2005	A	B(I)	A	A(I)	A(I)	A(II)	B	--	--
Nicol, 2007	B(I)	B(I)	A	A(I)	A(I)	A(I)	A	--	--
Walkosz, 2007	B(I)	B(I)	C	B(I)	B(I)	A(II)	B	--	--
Buller, 2005	B(I)	B(I)	A	B(I)	B(I)	B(I)	B	--	--
Pagoto, 2010	B(I)	B(I)	A	B(I)	B(I)	B(I)	A	--	--
Glanz, 2002	B(I)	A	C	B(I)	B(I)	B(I)	C	--	--
Dey, 1995	B(I)	A	C	B(I)	B(I)	B(I)	B	--	--
Dietrich, 1998	B(II)	B(I)	A	B(I)	B(I)	A(II)	A	--	--
Geller, 2001	B(I)	B(II)	B	B(I)	B(I)	B(I)	C	--	--
Glanz, 2000	B(I)	B(I)	A	B(I)	B(I)	B(I)	B	--	--
Glanz, 2001	B(I)	B(I)	A	B(I)	B(I)	B(I)	C	--	--
Mahler, 2006	C	A	C	B(I)	B(I)	B(I)	A		
Mahler, 2003	B(I)	B(I)	C	B(I)	B(I)	B(I)	A	--	--
Mayer, 1997	B(I)	B(I)	C	B(I)	B(I)	B(I)	A	--	--
Olson, 2007	B(I)	B(II)	A	B(I)	B(I)	B(I)	A	--	--
Segan, 1999	B(I)	B(I)	C	B(I)	B(I)	B(I)	C	--	--
Walkosz, 2008	B(I)	B(I)	A	B(I)	B(I)	B(I)	B	--	--
Weinstock, 2002	B(I)	B(I)	C	B(I)	C	B(I)	B	--	--
Winett, 1997_a	B(I)	C	A	B(I)	B(I)	B(I)	A	--	--
<b>CBAs</b>									
Pagoto, 2003	--	A	--	B(I)	B(I)	B(I)	B	A	A
Mayer, 2001	--	B(I)	--	B(I)	B(I)	B(I)	A	B	A
Roberts, 2009	--	B(I)	--	B(I)	B(I)	B(I)	B	A	B
Winett, 1997_b	--	C	--	B(I)	B(I)	B(I)	A	B	B

The coding encompasses the following meaning: A – Done; B – Unclear; C – not done. For randomization, B(I) means that no description of procedures provided and B(II) real chance of disclosure of concealment. In withdrawals, B(I) means that only numbers were provided and B(II) that withdrawals were mentioned, but no numbers provided. In all items related to blinding, A(I) means that blinding procedures are likely to be effective, A(II) no description of blinding procedures was provided and B(I) no mention of blinding.

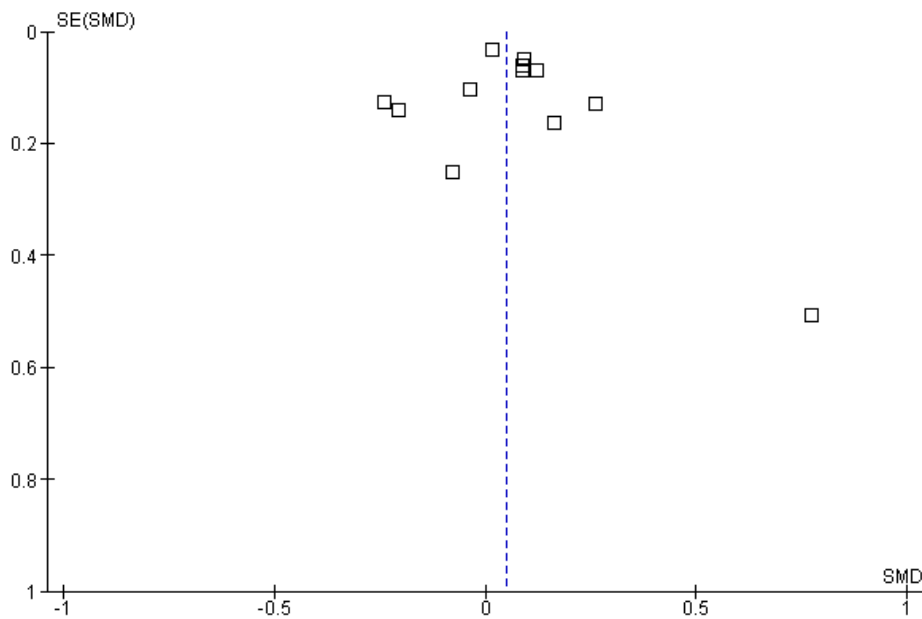
Four studies (Dietrich *et al.*, 1998; Dupuy *et al.*, 2005; Nicol *et al.*, 2007; Walkosz *et al.*, 2007) stated that outcome assessors were blinded to participants' allocation, but no details were given about specific procedures. For CBA trials, two out of four studies (Pagoto *et al.*, 2003; Roberts and Black, 2009) provided a detailed description on the characteristics of intervention and control settings and clarified that the two sites were similar. Two studies reported appropriate protection against contamination between conditions (Mayer *et al.*, 2001; Pagoto *et al.*, 2003). The majority of studies (n=13) did not provide information about the reliability of outcome measures.

Visual inspection of funnel plots did not suggest the presence of publication bias (Please see Figure 2-2 and Figure 2-3). This conclusion is further supported by Egger's regression test for sun-protection behaviour composite score (p=0.42) and sunscreen use (p=0.85).

**Figure 2-2: Funnel plot of interventions assessing sun-protective behaviours (composite score)**



**Figure 2-3: Funnel plot of interventions assessing sunscreen use**



## 2.4.2 Meta-Analyses of efficacy by outcome

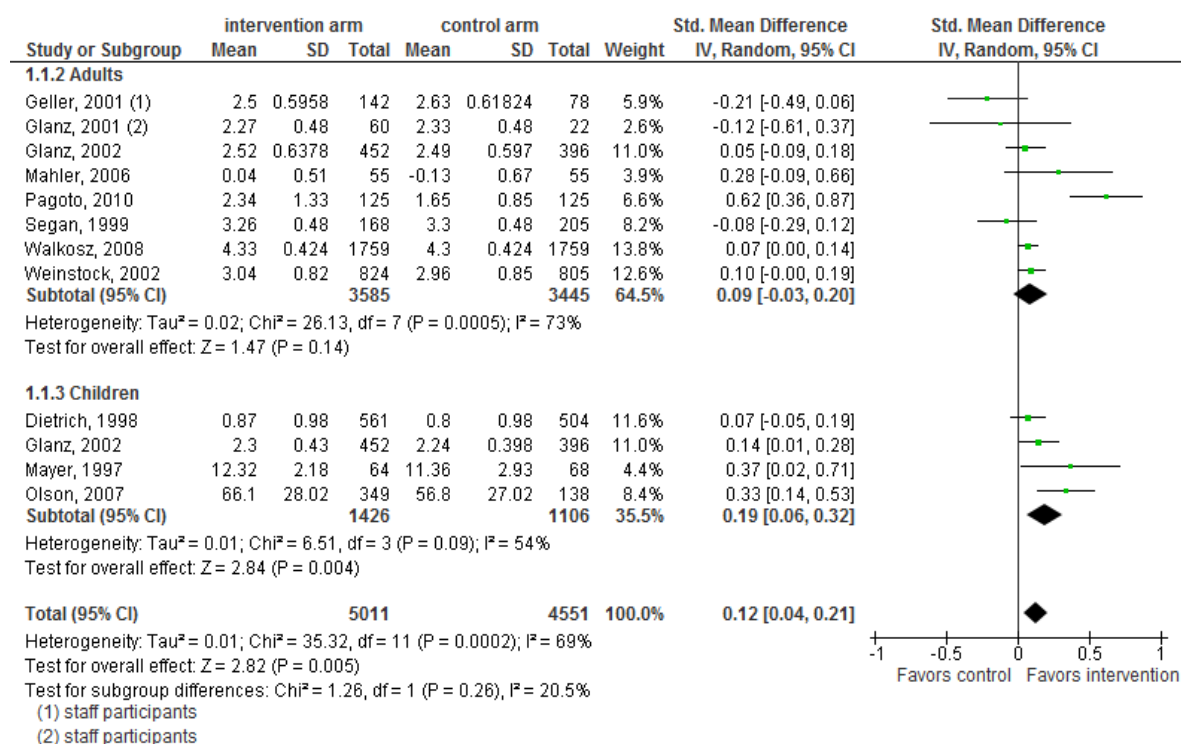
### Sun-protection behaviour indices

Figure 2-4 shows the forest plot of the comparison of intervention and control arms in increasing sun-protection behaviours measured using a composite score. Results show that interventions had a significant effect on sun-protection behaviours with a standardized mean difference (SMD) of 0.12 (95% CI=0.04; 0.21) with high heterogeneity of  $I^2 = 69\%$  and a  $\chi^2 = 35.32$  (df=11,  $p < 0.001$ ).

While differences between adults and younger participants were not significant, meta-analysis by type of participants shows that interventions targeting children had a significant effect on sun-protection behaviours (SMD= 0.19; 95% CI=0.06; 0.32) with moderate heterogeneity of  $I^2 = 54\%$  and a  $\chi^2 = 6.51$  (df=3,  $p = 0.09$ ). For adults, the comparison was not significant (SMD= 0.09; 95% CI=-0.03; 0.20) and heterogeneity was high with a  $I^2 = 73\%$  and a  $\chi^2 = 26.13$  (df=7,  $p < 0.001$ ).



**Figure 2-4: Forest plot of standardized mean differences (SMD), 95% confidence intervals, for sun-protective behaviours (composite) change in subgroups after intervention.**



Evidence from CBA studies and RCTs not meeting the inclusion criteria for the meta-analysis reinforces the findings of the meta-analyses and suggest that interventions were slightly less effective for adults. While Pagoto and colleagues' (2003) found a significant medium-size effect of a multi-component intervention on adults' sun-protection behaviours (SMD=0.68; 95% CI= 0.28, 1.09), Robert and Black (2009) found no significant effect (SMD=0.55; 95% CI=-0.01, 1.10) of a community health campaign delivered with or without weekly 'Cognitive-Behavioural Intervention' sessions. While both of these CBA studies used rather small sample sizes, Buller et al.'s (2005) large scale CRT found that the 'Go Sun Smart' campaign in ski resort had no effect on sun-protection behaviours. Conversely, three CRTs found environmental and educational interventions effective in promoting sun-protection behaviours amongst children (Winett *et al.*, 1997; Glanz *et al.*, 2000) and adolescents (Olson *et al.*, 2007). Notably, Winett et al (1997) found that the same 'Safe Sun' program was effective for children, but not for adults. The '*Sunless intervention*' (Pagoto *et al.*, 2010) promoting sunless tanning products to reduce the motivation for sun-exposure for tanning was the most effective intervention for adults.

In addition to the small, heterogeneous effect size estimate, there is a notable risk of bias. Eight trials (Dey *et al.*, 1995; Mayer *et al.*, 1997; Segan *et al.*, 1999; Geller *et al.*, 2001; Glanz *et al.*, 2002; Weinstock *et al.*, 2002; Mahler *et al.*, 2003b; Walkosz *et al.*, 2007)

targeting sun-protection behaviours were not analysed based on intention-to-treat analysis (ITT) principles. Only two studies used effective blinding procedures for participants (Dupuy *et al.*, 2005; Nicol *et al.*, 2007) and two trials did not provide any information about withdrawals or drop outs (Winett *et al.*, 1997; Glanz *et al.*, 2000). The meta-analysis is highly influenced by Mayer's large-effect RCT in children (1997). Sun-protection behaviours of children were assessed through parental telephone interviews. This method has a high likelihood of social desirability and recall bias. Two studies using observational outcome measures (Winett *et al.*, 1997; Olson *et al.*, 2007) did not employ blinding procedures. Similar limitations applied to several studies included in the narrative synthesis. Based on these considerations, the evidence can be described as inconclusive.

### Protective clothing

Table 2-3 shows a summary of the meta-analyses for protective clothing outcomes. No evidence for the efficacy of interventions aiming at increasing protective clothing was found (see Table 2-3).

**Table 2-3: Effects size for Sun-Protective Clothing and use of Hat and Sunglasses.**

Effect sizes	Protective clothing	Hat	Shirt	Trousers	Sunglasses
Dichotomous outcomes (OR, 95%CI)					
Adult	--	--	--	--	--
Children	--	0.74 [0.36, 1.52] k=1 (Walkosz <i>et al.</i> , 2007)	--	--	1.36 [0.72, 2.55] k=1 (Walkosz <i>et al.</i> , 2007)
Continuous outcomes (SMD, 95%CI)					
Adult	-0.12 [-0.33, 0.08] k=1 (Segan <i>et al.</i> , 1999)	-0.03 [-0.15, 0.10] k=4 (Segan <i>et al.</i> , 1999; Geller <i>et al.</i> , 2001; Glanz <i>et al.</i> , 2002; Weinstock <i>et al.</i> , 2002)	0.02 [-0.10, 0.15] k=2 (Dietrich <i>et al.</i> , 1998; Glanz <i>et al.</i> , 2002)	--	-0.13 [-0.37, 0.10] k=2 (Geller <i>et al.</i> , 2001; Glanz <i>et al.</i> , 2002)
Children	0.05 [-0.07, 0.17] k=1 (Dietrich <i>et al.</i> , 1998)	0.08 [-0.01, 0.16] k=3 (Mayer <i>et al.</i> , 1997; Dietrich <i>et al.</i> , 1998; Glanz <i>et al.</i> , 2002)	0.02 [-0.07, 0.11] k=2 (Geller <i>et al.</i> , 2001; Glanz <i>et al.</i> , 2002)	0.05 [-0.03, 0.13] k=1 (Dietrich <i>et al.</i> , 1998)	0.04 [-0.10, 0.17] k=1 (Glanz <i>et al.</i> , 2002)

Two CBAs provided information on the effect of interventions targeting protective clothing. Roberts and Black (2009) found a medium effect of a community health campaign on protective clothing (SMD=0.67; 95% CI= 0.11, 1.23). Mayer and colleagues (2001) found a negative significant effect of a an intervention consisting of interactive activities and environmental cues favouring controls on objectively recorded hat wearing in the winter (OR=0.83; 95% CI= 0.72, 0.96) and a similar non-significant tendency during summer (OR=0.89; 95% CI= 0.77, 1.01).

### Sunscreen Use

Figure 2-5 presents the forest plot of effects of interventions on sunscreen use as continuous measure of frequency or regularity of use. Overall, results show that interventions did not have a significant effect on sunscreen use (SMD= 0.05; 95% CI=-0.01; 0.12) with low heterogeneity ( $I^2 = 47%$ ,  $\chi^2 = 20.80$ ,  $df=11$ ,  $p=0.04$ ).

Though no significant differences were observed between groups, the effect estimate was significant for youths but not for adults. The meta-analysis shows that there is no evidence for the efficacy of interventions in increasing adults' sunscreen use (SMD= 0.02; 95% CI=- 0.06; 0.11) with moderate heterogeneity ( $I^2 = 49%$ ,  $\chi^2 = 15.58$ ,  $df=8$ ,  $p=0.05$ ). Congruent with these findings, Dupuy's trial (2005) of varying sunscreen labels (SMD=0.17; 95% CI= - 0.09, 0.42) and Roberts and Black study (2009) did not show an effect on adults' sunscreen use (SMD=0.50; 95% CI=-0.05, 1.06).

For studies targeting children, meta-analysis shows a significant, homogeneous effect in increasing sunscreen use (SMD=0.11; 95% CI=-0.02, 0.19).

**Figure 2-5: Forest plot of standardized mean differences (SMD), 95% confidence intervals, for sunscreen use change in interventions vs. control group after intervention (continuous measures).**

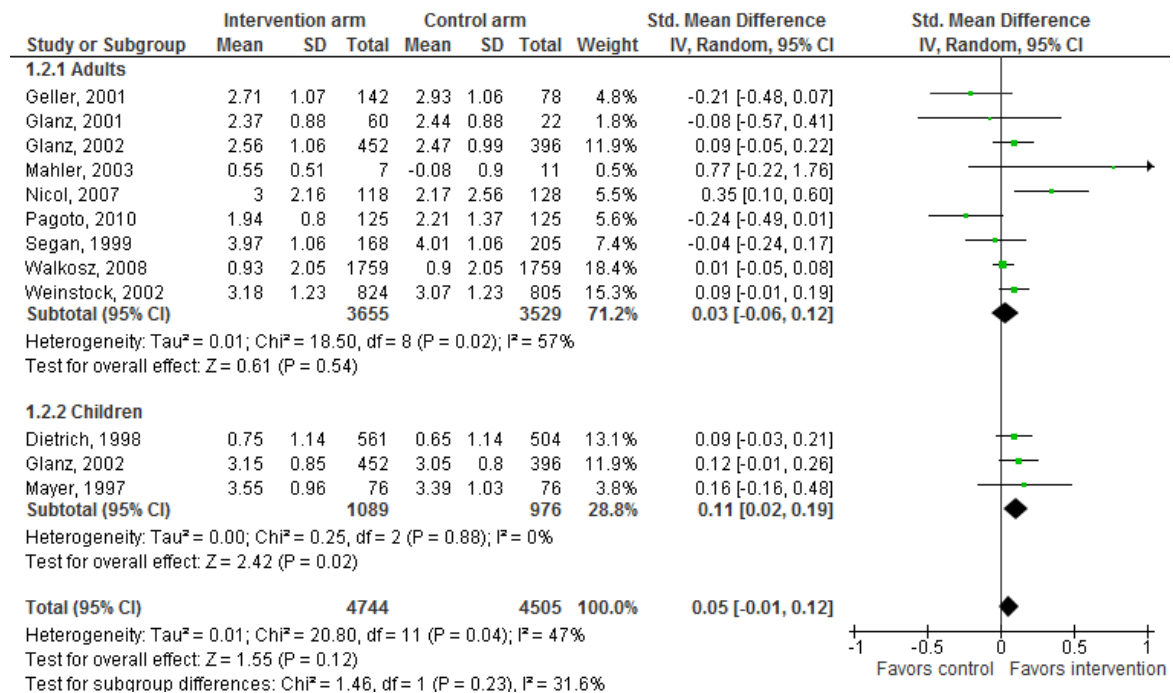
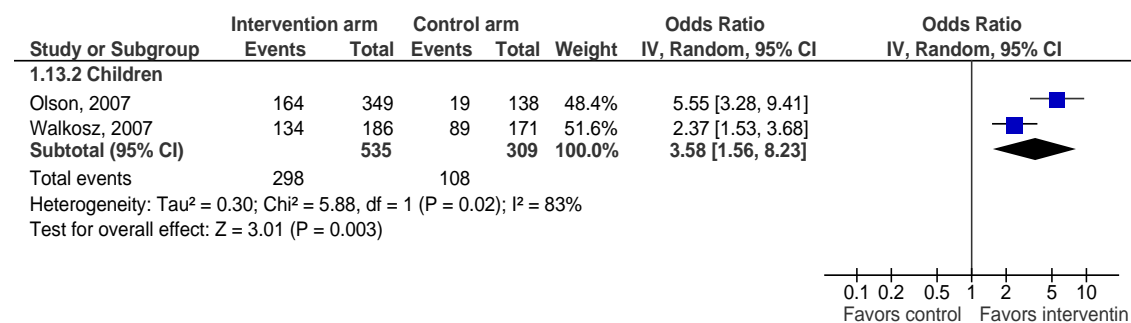


Figure 2-6 suggests that, for studies measuring sunscreen use as a dichotomous variable in children, the odds of participants using sunscreen in the intervention group compared with control group were considerably higher (OR= 3.58; 95% CI=1.56; 8.23) with very high heterogeneity of  $I^2=83%$  and a  $\chi^2=5.88$  (df=1,  $p=0.02$ ). However, both included studies have a very high risk of bias. In Olson’s CRT (2007), outcome assessment was highly prone to social desirability (assessors with branded clothing asked adolescents about their sunscreen practices at the beach). Walkosz’s CRT (2007) conducted outcome assessments based on parents’ interviews, without reporting information about reliability or validity.

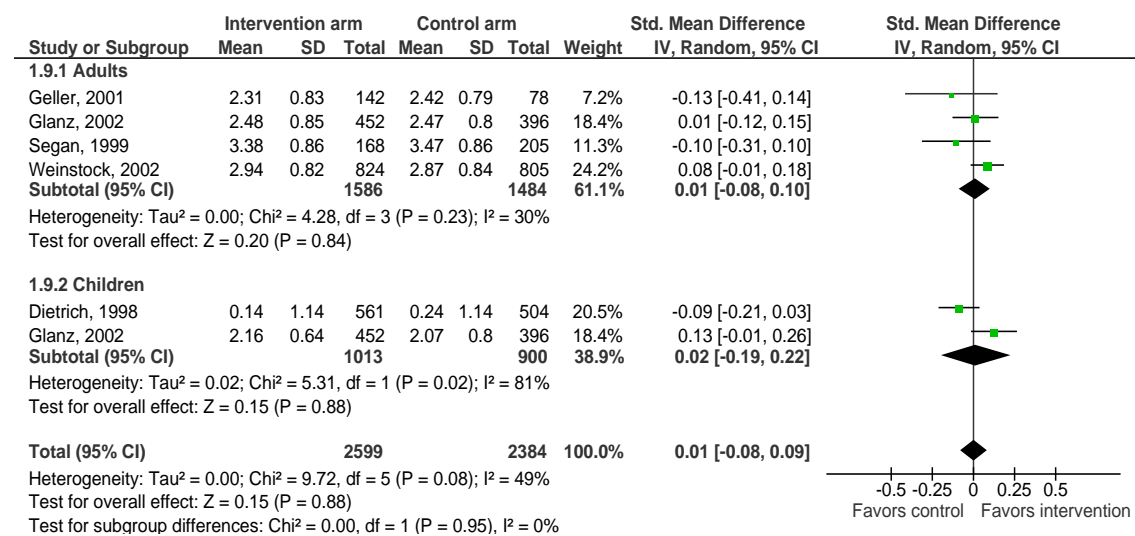
**Figure 2-6: Forest plot of standardized mean differences (SMD), 95% confidence intervals, for sunscreen use change in interventions vs. control group after intervention (dichotomous measures).**



## Protection by shade

No evidence for the efficacy of interventions in increasing the use of shade in either adults or children was found (Figure 2-7). Heterogeneity values were low for studies involving adults ( $I^2 = 30\%$ ,  $\chi^2 = 4.28$ ,  $df=3$ ,  $p=0.23$ ) but substantial for studies with children ( $I^2 = 81\%$ ,  $\chi^2 = 5.31$ ,  $df=1$ ,  $p=0.02$ ).

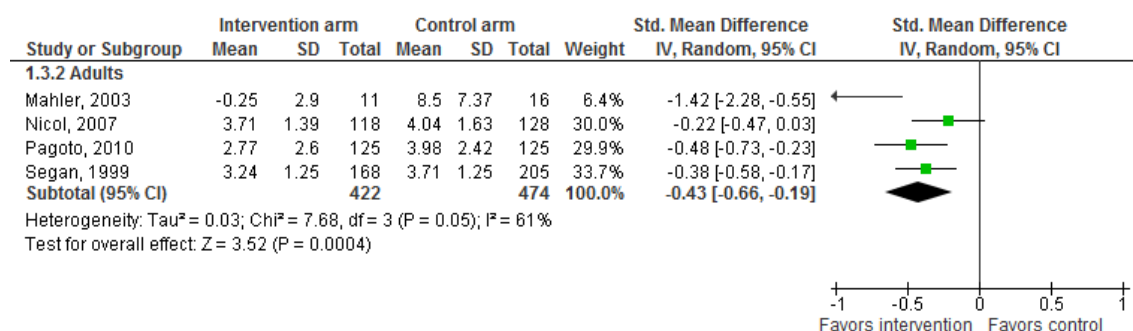
**Figure 2-7: Forest plot of standardized mean differences (SMD), 95% confidence intervals, for shade use change in interventions vs. control group after intervention.**



## Sun-exposure

Meta-analytic results (Figure 2-8) show that interventions resulted in a significant decrease in self-reported sun-exposure amongst adults, with a moderate effect size (SMD= -0.43; 95% CI=-0.66; -0.19). Heterogeneity was high, with a  $I^2$  of 61% and a  $\chi^2$  of 7.68 ( $df=3$ ,  $p=0.05$ ) mostly caused by a very small study evaluating the effects of photoageing information with UV photos (Mahler *et al.*, 2003b) had a very large effect in decreasing self-reported sun-exposure.

**Figure 2-8: Forest plot of standardized mean differences (SMD), 95% confidence intervals, for sun-exposure change in interventions vs. control group after intervention.**



Two CBA studies (Pagoto *et al.*, 2003; Roberts and Black, 2009) found that participants allocated to multi-component interventions for sun-protection behaviours showed a non-significant trend to spend more rather than less time exposed to the sun compared to controls (SMD= 0.11; 95% CI= -0.44, 0.65; SMD=0.28; 95% CI= -0.11, 0.68, respectively). Dupuy and colleagues (2005) did not find effects of sunscreen labelling on sun-exposure (SMD= -0.18; 95% CI= -0.43, 0.08).

Overall, there is mixed evidence for the efficacy of interventions promoting reduced sun-exposure. Mahler’s study (2003b) is an outlier, which has a very small sample and did not conduct an ITT or employ appropriate blinding procedures. In all studies outcome assessment relied on self-reported sun-exposure. Sun exposure was not measured as outcome in youth’s trials.

### Skin colour

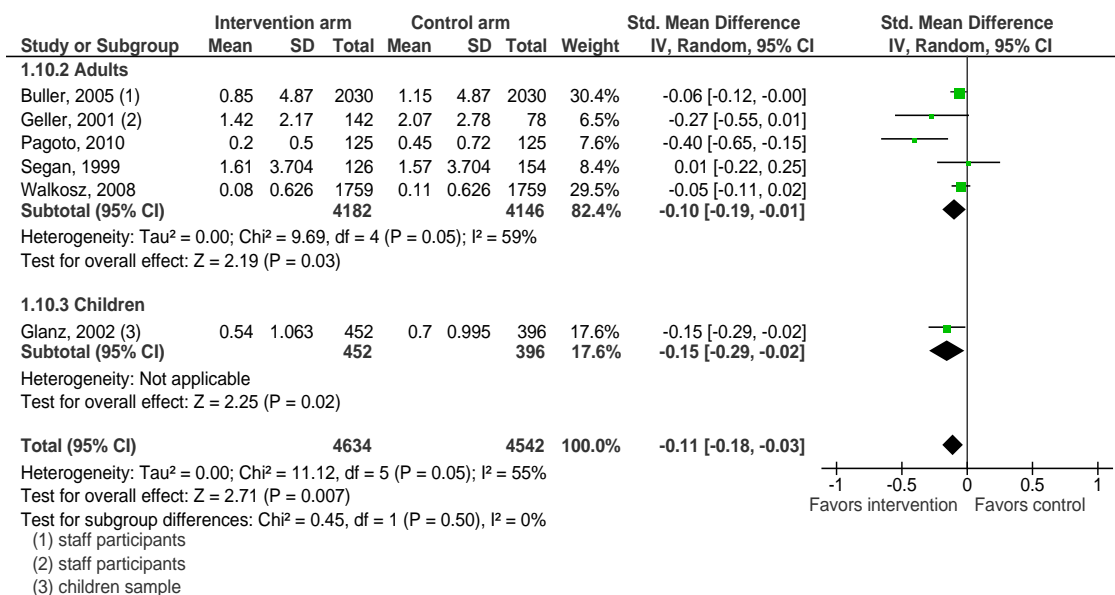
Skin colour was measured as outcomes in three studies (Mayer *et al.*, 1997; Mahler *et al.*, 2006; Roberts and Black, 2009) as a proxy for sun-exposure. The tanning of the skin is the result of increased melanin production caused by UV-related DNA damage to the skin. Skin colour change was the primary outcome for the study by Mahler and colleagues (Mahler *et al.*, 2006) by using skin reflectance spectrophotometry for reading of skin tanning. The results from this study show no effect of the intervention.

Likewise, Mayer and colleagues (1997) assessed skin colour in children using colorimeter and did not find a significant effect of the intervention. A colorimeter measure of the green-to-red axis detects changes in skin redness and enables erythema quantification. For changes in tanning, the black-to-white axis and blue-to-yellow axis was used (Creech and Mayer, 1997). Roberts and Black (2009) used an observational method to assess skin colour pre and post intervention in adults and did not find a significant effect of intervention.

## Sunburn

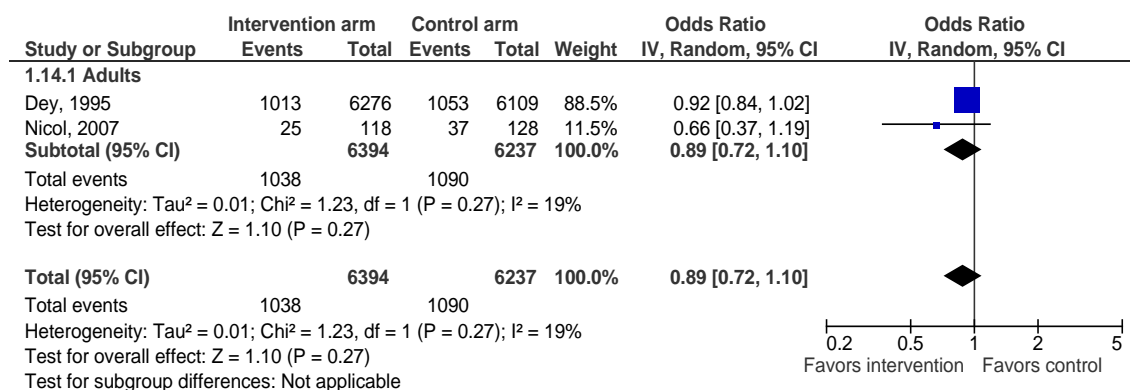
Figure 2-9 presents the forest plots of the comparisons of intervention and control conditions on self-reported sunburn. Results show intervention groups had a small, significant decrease in reported sunburn (SMD=-0.11; 95% CI=-0.18; -0.03). Only one study included children (Glanz et al., 2002) and suggested a slightly higher effect size in decreasing reported sunburn (SMD=-0.15; 95% CI=-0.29; -0.02), compared with adult studies (SMD=-0.10; 95% CI=-0.19; -0.01). Heterogeneity values in the adults' subgroup were substantial, with a  $I^2 = 59%$  and a  $\chi^2 = 9.69$  (df=4, p=0.05).

**Figure 2-9: Forest plot of standardized mean differences (SMD), 95% confidence intervals, for sunburn in interventions vs. control group (continuous measures).**



As shown in Figure 2-10, effects of interventions on dichotomous measures of sunburn experience were not significant (OR=0.89; 95% CI=0.72; 1.10). Heterogeneity values were low, with an  $I^2$  of 19% and a  $\chi^2$  of 1.23 (df=1, p=0.27).

**Figure 2-10: Forest plot of standardized mean differences (SMD), 95% confidence intervals, for sunburn in interventions vs. control group (dichotomous measures).**



Walkosz and colleagues (2007) stated in their methods section that effects of the intervention on sunburn would be analysed, but did not report these findings. Varying the labels of sunscreen bottles was not found to affect sunburn (OR=0.95; 95% CI= 0.46, 1.98) (Dupuy et al., 2005). The CBA study by Roberts and Black (2009) did not find an effect of the intervention in preventing sunburn (SMD=-0.29; 95% CI=-0.76; 0.33).

These findings suggest that evidence for efficacy of interventions in preventing sunburn is inconclusive for adults. Interventions targeting children found no evidence of efficacy in preventing sunburn. In most studies, sunburn assessment ranged from asking about frequency of occurrence to asking whether or not participants experienced any sunburn during the intervention period.

### Long- term effects

Only two studies provided information about long-term intervention effects (Weinstock et al., 2002; Pagoto et al., 2010). One trial (Weinstock et al., 2002) showed a significant long-term effect of a multicomponent intervention in promoting sun-protection behaviours in adults (SMD: 0.18; 95% CI= 0.09, 0.28), sunscreen use (SMD: 0.17; 95% CI= 0.07, 0.27), seeking shade (SMD: 0.14; 95% CI= 0.04, 0.24) and no effect for hat use (SMD: 0.03; 95% CI= -0.07, 0.14). Pagoto and colleagues' trial (2010) also found significant long-term effects of a sunless tanning intervention in decreasing sun-exposure (SMD: -0.43; 95% CI= -0.68, -0.18) but not for sun-protection behaviours (composite) (SMD: 0.17; 95% CI= -0.08, 0.42), sunscreen use (SMD: 0.12; 95% CI= -0.13, 0.37) or sunburn experience (SMD: -0.01; 95% CI= -0.26, 0.23).



### 2.4.3 Structured Narrative Moderator Analysis

Due to the considerable heterogeneity of interventions and their effects in this review, features of intervention content and modes of intervention delivery were explored to investigate possible impact on efficacy.

Table 2-4 and Table 2-5 list the included studies in order of their effect size on sun-protection behaviours (composite index or most similar other outcome measure). The studies were then mapped against the behaviour change techniques and methods of delivery identified by two independent coders from published reports<sup>56</sup>. Similar approaches have been successfully used in identifying potential directions for practice and research in systematic reviews on other behaviours (Dombrowski *et al.*, 2007; Michie *et al.*, 2009a).

Almost all interventions utilized behaviour change techniques aimed at providing resources (e.g., making sunscreen or shade available), providing information on the consequences of performing sun-protection behaviours (e.g. sunburn prevention, risk of skin cancer) and providing information on how to perform relevant sun-protection behaviours (e.g., accurate sunscreen application). Table 2-4 suggests that interventions highlighting supportive social norms for sun-protection behaviours (e.g. providing information about others' behaviour and social norms) and providing appearance-based information about skin photoageing illustrated with UV photographs of skin damage appear to be more effective than interventions not using these techniques.

Table 2 5 shows that interventions using written information (not exclusively) appear more effective than the median effect size, while interventions using interactive sessions seem to be less effective than the median. In this review, 'interactive sessions' were mostly insufficiently described in included reports and exclusively used in interventions targeting children and adolescents. For all other features of intervention delivery, no clear associations with efficacy were observed. There is no evidence to date favouring individual, group or community levels of intervention delivery. While some of the most effective interventions in this review used individual feedback through UV photographs, this feature was also utilized

---

<sup>5</sup> For a total of 17 out of the 23 trials included in the review it was possible to compute an effect size for an sun protection behavior (SPB) outcome – either an index of SPBs (the most common outcome of studies in this review), or, for studies not reporting an overall SPB index, on the reported outcome most similar to the SPB index (e.g. sunscreen use).

<sup>6</sup> Definition of clustering of behaviour change techniques: Provide info on why to perform behaviour (Provide information on consequences of behaviour in genera and to the individual, Provide knowledge about target behaviour);Environmental resources (Enhancing/restricting access/availability of target environmental resources, Providing environmental cues); Provide info on how to perform behaviour (Sensorial experience of performing the behaviour or set of behaviours, Provide information on where and when to perform the behaviour, Provide instruction on how to perform the behaviour, Model/Demonstrate the behaviour); Prompting/cueing (Prompt practice, Use of follow up prompts, Teach to use prompts/ cues); Social influences (Provide information about others' approval, Facilitate social comparison); Self-regulation strategies (Goal setting (behaviour), Environmental restructuring, Agree behavioural contract );Policy changes (Implementation of policies related to the target behaviour). Prompt identification as role model, Appearance-based fear appeals and feedback are single techniques as clustering was not appropriate. Bold vertical line represents median split of effect size.

in three trials with null findings, suggesting that more research is needed to understand the contribution this technique may have on the efficacy of complex interventions.

**Table 2-4: Studies ordered by effect size on sun-protective behaviours and clusters of behaviour change techniques used**

Behaviour change Techniques	Cohen's d	Sample size	Provide info on why to perform behaviour	Environmental resources	Provide info on how to perform behaviour	Prompting/ cueing	Social influences	Self-regulation strategies	Prompt identification as role model	Appearance-based fear appeals with information about photoageing	Policy changes	Feedback
Study ID												
Mahler 2003	1.08 [0.49, 1.67]	27	X	X	X					X		
Olson 2007	0.94 [0.42, 1.47]	487	X	X	X	X	X	X	X	X	X	
Pagoto 2003 <sup>6</sup>	0.68 [0.28, 1.09]	100	X	X	X		X	X				
Pagoto 2010	0.62 [0.36, 0.87]	250	X	X	X	X	X					
Roberts 2009 <sup>6</sup>	0.55 [-0.01, 1.10]	52	X	X	X	X	X					
Walkosz 2007	0.48 [0.04, 0.91]	357	X	X	X	X	X		X			
Mayer 1997	0.37 [0.05, 0.69]	152	X	X	X			X				
Nicol 2007	0.35 [0.10, 0.60]	246	X	X	X							
Mahler 2006	0.28 [-0.09, 0.66]	110	X	X	X					X		
Dupuy 2005	0.17 [-0.09, 0.42]	236	X	X								
Weinstock 2002	0.10 [-0.00, 0.19]	1629	X	X		X	X					X
Walkosz 2008	0.07 [0.00, 0.14]	3518	X	X	X	X	X		X			
Dietrich 1998	0.06 [-0.06, 0.18]	1065	X	X	X	X		X				
Glanz 2002	0.05 [-0.09, 0.18]	848	X	X	X	X		X			X	
Segan 1999	-0.01 [-0.24, 0.23]	280	X		X		X	X				
Mayer 2001 <sup>7</sup>	-0.08 [-0.18, 0.02]	5528		X	X	X						
Geller 2001	-0.21 [-0.49, 0.06]	220	X	X	X	X						

<sup>7</sup> Controlled before-and-after design.

**Table 2-5: Studies ordered by effect size on sun-protective behaviours and modes of delivery used.**

Modes of delivery Study ID	Cohen's d	Sample size	Content: Written info	Content: oral communication	Content: UV photo/light	Content: Interactive activities	Format: Individual	Format: group/community	Setting: beach or swimming pools	Setting: 'Pre exposure sites'
Mahler 2003	1.08 [0.49, 1.67]	27	X		X		X		X	
Olson 2007	0.94 [0.42, 1.47]	487	X	X				X		X
Pagoto 2003 <sup>5</sup>	0.68 [0.28, 1.09]	100	X	X	X		X		X	
Pagoto 2010	0.62 [0.36, 0.87]	250	X	X	X		X		X	
Roberts 2009 <sup>5</sup>	0.55 [-0.01, 1.10]	52	X	X	X			X		X
Walkosz 2007	0.48 [0.04, 0.91]	357	X	X		X		X		
Mayer 1997	0.37 [0.05, 0.69]	152	X	X		X		X	X	
Nicol 2007	0.35 [0.10, 0.60]	246	X				X		X	
Mahler 2006	0.28 [-0.09, 0.66]	110	X		X		X		X	
Dupuy 2005	0.17 [-0.09, 0.42]	236	X				X		X	
Weinstock 2002	0.10 [-0.00, 0.19]	1629	X	X	X		X		X	
Walkosz 2008	0.07 [0.00, 0.14]	3518	X	X		X		X		
Dietrich 1998	0.06 [-0.06, 0.18]	1065				X	X			X
Glanz 2002	0.05 [-0.09, 0.18]	848			X	X		X	X	
Segan 1999	-0.01 [-0.24, 0.23]	280		X			X			X
Mayer 2001 <sup>5</sup>	-0.08 [-0.18, 0.02]	5528		X			X	X		
Geller 2001	-0.21 [-0.49, 0.06]	220			X	X		X	X	

<sup>5</sup> Controlled before-and-after design.

## 2.5 Discussion

This is the first systematic review of interventions aimed at reducing skin cancer risk by controlling exposure to ultraviolet radiation delivered to people in recreational and tourist settings, using Cochrane methodology (Higgins and Green S, 2011) and meta-analyses. Overall, evidence for the efficacy of current behavioural interventions for skin cancer prevention is limited. No evidence was found for the efficacy of current interventions in reducing objectively measured tanning or promoting protective clothing and seeking shade, key targets of most public health guidelines on skin cancer prevention (World Health Organisation, 2011a). Meta-analyses show a small significant but heterogeneous effect for interventions on composite scores of sun-protection behaviours. Subgroup analyses suggest no significant differences between youths and adults; however, effects on sun-protection behaviour and sunscreen use are significant only for youths. The most encouraging effects were found for self-reported sun exposure and sunburn, two measures with a considerable risk of recall bias.

This review raised concerns about the risk of bias in the included trials. Few studies provided standard information about randomization and blinding procedures and at least nine studies did not perform intention-to-treat analyses. Consequently, even the few instances where meta-analyses suggest significant effects of interventions need to be interpreted with some caution. Moreover, outcome measurement in the majority of trials is based on retrospective self-reports, often without information about reliability and validity of the outcome measures. Questionnaires differ from study to study making it difficult to directly compare effects between studies. Where observational measures were used, they often involved considerable risk of social desirability bias through insufficient blinding of assessors and participants (e.g., study personnel in branded clothing approached adolescents on the beach to ask questions on sunscreen use and record clothing (Olson *et al.*, 2007)). Despite these limitations, it is important to highlight some constraints that are inherent to research in this type of context. Most recreational settings pose unique challenges to achieve low risk of bias in RCTs (e.g. random selection of participants, cluster randomization, protection against contamination between settings, blinding, follow up of a mobile population) and these considerations should be taken into account when discussing the risk of bias of the included trials.

The availability of affordable and scalable handheld diaries, portable global positioning systems (GPS), UV dosimeters, small scale accelerometers built into sunscreen bottles (Armstrong *et al.*, 2009), as well as skin swabs to measure sunscreen application and mitochondrial DNA damage (Harbottle and Birch-Machin, 2006; Harbottle *et al.*, 2010)

provides a range of new options with the potential to improve the reliability and specificity of outcome measurement and the quality of trials conducted in recreational environments.

Most studies did not provide sufficient information about intervention procedures and components and, therefore, it was difficult to determine exactly what interventions consisted of. Insufficient reporting of interventions reduces the possibility to replicate and implement findings. Although some studies stated the theoretical framework for interventions' design, authors did not specify how theory was used to inform intervention development and its specific components. Clear and complete reporting is a key condition for replicable and cumulative science (Dombrowski *et al.*, 2007). No evidence was found for an improvement on the quality of studies, reporting in published articles or, indeed, the efficacy of interventions since 2000, as reviewed by Saraiya and colleagues. If attempts to tackle skin cancer through behavioural interventions are to be taken seriously, methodology and reporting will need to improve. Better reporting will make it easier at the stage of evidence synthesis to conclude what is effective in promoting sun-protection behaviour and what is not, thereby gathering the evidence to develop more effective interventions in the future (Davidson *et al.*, 2003; WIDER, 2007; Michie *et al.*, 2010; Schulz *et al.*, 2011).

In order to highlight possible directions for future research and practice, *structured narrative moderator analyses* was conducted to explore intervention features associated with more effective trials. While this methodology is explorative in nature, it provides an important step in synthesizing the evidence from trials of highly heterogeneous complex interventions with multiple interacting components. These analyses suggest that interventions using behaviour change techniques facilitating social norms for sun-protection behaviour (e.g. providing information about others' behaviour and social norms) and using appearance-based information about photoaging illustrated with UV photographs (e.g., pictures of cases of skin damage) appeared to be more likely to result in larger than median effect sizes. This is in concordance with evidence that appearance-based strategies are effective in promoting sun-protection behaviours (Dodd and Forshaw, 2010). Hollands and colleagues' review (2010) on the effect of visual feedback (e.g. UV photos) on health behaviour includes a section on the effect of UV photos on sun-safe behaviours in different settings. Of the 4 trials included in the Holland's review, two are included in this review (38, 40). The other two trials were conducted with college students outside of recreational/tourist settings (Gibbons *et al.*, 2005; Mahler, 2007). Only Gibbons' trial was effective in reducing sunbed use, a measure broadly related but outside the scope of this review. Two of the studies included in the present review used a 2 (information about photoageing or not) x 2 (individualized UV photos or not) factorial design (Mahler *et al.*, 2003b; Mahler *et al.*, 2006). Both studies found a significant

interaction effect, suggesting that the combination of photoageing information and UV photos has a stronger effect on sun-protection behaviour than the sum of the individual components. For the present review, a pre-specified protocol only including the most intensive arms into the meta-analyses was implemented. This specific evidence from the two Mahler trials reinforces the findings that the joint delivery of a comprehensive information package and UV photographs appears to be effective, and this is in line with the findings of the trial by Olson and colleagues.

Furthermore, interventions using written information seemed to be more effective and interventions using interactive sessions less effective than the median effect size in this review. The nature of this narrative analysis is exploratory rather than conclusive, but it suggests avenues for future research and practice.

One limitation to this review is the exclusive focus on published trials. While standard tests (e.g., funnel plot inspection; Egger's regression test) do not show evidence of possible publication bias, it is possible that the effect size estimates would shift with the inclusion of unpublished materials. Moreover, more sophisticated analyses of the effect of methodological quality on effect sizes would be desirable, but the level of reporting and the limited number of high quality trials included in this review did not allow for such analyses.

This review did not appraise the efficacy of interventions conducted in Australia; even though these would be expected to be retrieved through the search strategy conducted. A possible explanation is the fact that Australian sun protection interventions are at a different stage of programme evaluation, where the primary focus is currently on widespread implementation and not ascertaining efficacy. The Slip!Slap!Slop programme is a successful population-based campaign that has been implemented since early 1980s (Montague *et al.*, 2001). The programme is part of a National initiative delivered primarily through Cancer Councils across Australia.

In conclusion, even though this review found that there is limited evidence how best to promote sun-protection behaviours amongst people in recreational and tourist settings, it provides information about possible avenues for skin cancer prevention interventions. While meta-analyses suggests that interventions promoting sun-protection behaviours reduce adults' self-reported sun-exposure, no corresponding effects on other sun-protection behaviours, objective and observed measures of skin colour or reported sunburn were found. For children and adolescents, results were more promising, indicating mostly small to medium effects on overall sun-protection behaviours, sunscreen application and sunburn. Methodological and measurement issues introduce sources of possible bias and more

research is needed to better understand how best to protect the public from intermittent intensive UV exposure at recreational and touristic sites.



## **Chapter 3 ‘A tan is worth a thousand words’: a qualitative study about sun-protection practices in holidaymakers**

### **3.1 Abstract**

Public health interventions that aim to limit direct UV exposure are increasingly important for skin cancer prevention. Epidemiologic studies suggest that implementation of sun-protection behaviours would decrease the amount of intermittent sun-exposure. More knowledge regarding perceptions, beliefs and attitudes of holidaymakers towards sun protection is needed. This qualitative study aimed to investigate perceptions of sun-related experiences and the relevant behavioural domain determinants of sun-protection behaviours.

Semi-structured interviews based on the Theoretical Domains Framework with a convenience sample of 17 respondents aged 21-62 years old were conducted. Data were analysed using thematic analysis.

Respondents showed a desire to tan and attributed a high value to acquiring a tanned appearance during holidays. The harming effects of sun exposure were universally recognised. Most respondents knew how to perform sun-protection behaviour, but several key barriers to sun protection were identified: the impact of these behaviours on the holiday experiences, the fear of social consequences, inconvenience of sun protection and lack of environmental resources. Some self-regulatory strategies were identified by participants as facilitators of sun protection.

The importance attributed to a tanned appearance seemed a strong motivation for overexposure amongst the holidaymakers interviewed. Suggested public health messages included highlighting the harmful effects of sunlight on appearance and strategies that demonstrate effective ways of performing sun protection practices (e.g. applying sunscreen properly).

### **3.2 Introduction**

Epidemiologic studies suggest that implementation of sun-protection behaviours decreases the amount of intermittent sun-exposure and thereby a reduction in the incidence of skin cancer (Armstrong and Krickler, 2001). Tourism settings are of particular interest for skin cancer prevention interventions since intermittent UV exposure has been shown to be an important risk factor for melanoma (Gandini *et al.*, 2005). Despite public health interventions aiming to limit direct UV exposure are increasingly important for skin cancer prevention, a systematic review of interventions to promote sun-protection behaviours in recreational

settings found weak evidence of current interventions in promoting sun-protection behaviours (Chapter 2).

To date, there is no effective, affordable, scalable and geographically flexible mobile intervention available to promote sun-protection behaviours for people on holiday in high UV destinations. The Medical Research Council (MRC) guidance for developing and evaluating complex interventions (Craig *et al.*, 2008) suggests a stepwise approach to intervention development including: a) identifying the evidence base; b) identifying/developing theory; and c) modelling process and outcomes (Craig *et al.*, 2008; Craig *et al.*, 2010). The systematic review (Chapter 2) identified the limits of past research but also identified possible avenues for future research.

More knowledge regarding perceptions, beliefs and attitudes of holidaymakers is needed. A previous study based in England explored the common reasons behind sunbed use amongst young females. The aim of the study was to uncover the motivations, views and experiences of 69 female sunbed users aged 15-18 (Lake *et al.*, 2013). Results from this study showed that having a natural 'healthy' tan is the most powerful influence concerning people's sun exposure.

A study conducted in Australia explored adolescents aged 15 and 16 years attitudes towards sun-protection (Potente *et al.*, 2011). The study involved 51 adolescents and the findings revealed the complexity of the factors that influence sun-protection. The negative perceived impact of sun protection on peers and group dynamics, social norms, negative stereotypes about regular sunscreen users, lifestyle, environment, and fashion seem to be key factors influencing adolescents' use of sun-protection.

In another study, qualitative methods were used to assess whether images showing the detrimental damage of excessive UV exposure on the skin had an impact on forty-seven women's judgments about using sun-protection (Williams *et al.*, 2012). Promisingly, women noted how clear the UV-aged images showed the impact of sun exposure on ageing. The initial shock of the visible damaged skin was an immediate reaction amongst women and resulted from a combination of seeing a notable difference between the generated and original picture and also the observation that the generated image was unattractive (Williams *et al.*, 2012). All women expressed determination to change their lifestyles and increase their use of sun protection. However, no follow up assessment was conducted to determine whether this changed actual sun protection behaviour.

A study with 26 Glaswegian holidaymakers (Garside *et al.*, 2010) also explored the social processes in the desire to obtain a tanned appearance and how having a tan is seen as a 'symbolic artefact' brought back from holiday that usually implies a good holiday. The study also showed that participants have a good level of knowledge about negative consequences of sun exposure, but do not follow preventive advice about sun protection.

The aim of this chapter is to investigate these topics by drawing on previous evidence and theory about potential predictive behavioural domains. The 'Theoretical Domains Framework' (TDF) (Michie *et al.*, 2005; Francis *et al.*, 2009b) is a specific approach designed to identify theoretical domains relevant that can be perceived as barriers or facilitators to behaviour change. The TDF is the result of an expert consensus approach designed to identify theoretical domains relevant for behaviour change (Michie *et al.*, 2005). The development of this framework was based on the identification of overlapping theoretical constructs from distinct theories, simplifying these into construct domains and finalising with validation studies. The 12 theoretical domains included in this framework provide reliable evidence for the selection of theories to explore behaviour change (Michie *et al.*, 2005). This framework constitutes a step forward in simplifying psychological theory within the area of behaviour change and in helping the process of evidence-based practice. This framework is also a major contribution to the process of designing more effective interventions, as specific theoretical domains can be targeted to identify themes and potential mechanisms for behaviour change. This approach has been successfully applied to the development of interventions for healthcare services, such as diagnosis and disease management (Foy *et al.*, 2007; Hrisos *et al.*, 2008).

Based on the TDF, a qualitative research process was conducted using semi-structured interviews, to investigate perceptions of sun-related experiences and identify relevant behavioural domains determining sun-protection behaviours. The interviews will focus primarily on sun protection practices while on holiday.

### **3.3 Materials and Methods**

#### **3.3.1 Participants**

To be eligible to this study, participants had to be more than 18 years old and have spent sunny holidays abroad in the past (Please see advertisement leaflet in Appendix B).

A total of 23 participants replied to the advertisement, but 6 individuals withdraw from the study (no reasons provided). The final sample included 17 adults aged 21-62 years old (20-34y: n=9; 35-49y: n=5; 50-65y: n=3) who replied to advertisements within Newcastle University and the community in the area of Newcastle upon Tyne (e.g. supermarkets notice

board, nurseries notice board, sports groups/associations). In total, 13 women (76%) and 4 men participated in this study. Data saturation was assessed according to standard criteria (Francis *et al.*, 2009a).

### **3.3.2 Materials and procedure**

The study was reviewed and approved by the Newcastle University Faculty of Medical Sciences Ethics Committee (Reference No: 00427\_2/2013) prior to commencement.

Eligible individuals were assessed for inclusion by the researcher (AR) and were required to provide informed consent before participation (Appendix C and D).

Semi-structured interviews were conducted based on a topic guide informed by the “Theoretical Domains Framework” (TDF) (Appendix E). The topic guides elicit specific information about their experiences over holidays. Most participants based this on their experience of beach holidays, only two participants referred to the struggles of sun protection during ‘city breaks’ holidays.

At the beginning of the interview participants were asked if they had heard about the specific recommendations for sun protection. If they had, they were prompted to describe their understanding of it; if not, participants were shown the relevant guidelines for sun protection (SunSmart) by showing a laminated card with the World Health Organisation (2011a) recommendations for sun protection:

- **Seek shade** when UV rays are the most intense (between 10am to 4pm),
- **Wear protective clothing** ( hat with a wide brim, sunglasses, and tightly woven, loose fitting clothes),
- **Use sunscreen.** Apply a broad-spectrum sunscreen of SPF 15+ liberally and re-apply every two hours, or after working, swimming, playing or exercising outdoors.

Data was collected between May and June 2012 and interviews were conducted in an office at Newcastle University to maintain privacy and confidentiality. All interviews were conducted by a female researcher (AR) with experience in interviewing. Special attention was given to assure participants that personalised data collected through interviews would be kept anonymous. In line with good practice, all recordings will be kept for six years, making them available for re-analysis if necessary (Newcastle University Ethics Committee, 2006).

Interviews lasted between 30-50 minutes and were audio-recorded with respondent’s consent. The recordings were anonymously transcribed verbatim before analysis.

Participants completed a standard self-reported questionnaire to assess skin sensitivity (Appendix E) based on Fitzpatrick's skin types (Fitzpatrick, 1988). This also included questions about their estimated sun exposure without sun protection based on their self-reported skin type.

In addition, participants were asked to apply sunscreen to their forearm. Instructions given specified that the application should only include the areas between their wrist and elbow. The sunscreen bottle was weighed before and after each application (measurement in grams). In order to estimate sunscreen use, arm surface was calculated using a combination of wrist (w) and elbow (e) circumferences ( $r = \frac{w + e}{2}$ ) along with forearm length (H) measurement (all in centimetres) ( $\text{arm surface} = (2 \times \pi \times r \times H) + (2 \times \pi \times (r \times r))$ ). A ratio was calculated between sunscreen use (converted to milligrams) and arm surface ( $\text{cm}^2$ ).

### **3.3.3 Analysis**

Transcribed interviews were subjected to thematic analysis in accordance with Braun and Clarke (2006) and within the TDF constraints. More specifically, interviews were initially coded using the 'Theory Domain Framework' guidelines and further analyses were used to identify overriding themes within and across the domains using an inductive approach. One researcher (AR) analysed the transcriptions by classifying utterances into theoretical domains. Utterances were discussed and agreed with the other members of the team during a data analysis clinic. A theme was considered 'relevant' if it was frequently mentioned in responses, indicating that it might be important for the process of change. Quotes have been used to exemplify the themes throughout this paper. Each quote is illustrated with a code that represents participants' gender, age and skin type (i.e. male, 28, skin type III).

Interview transcripts were also analysed in separate sub-groups according to participants' intention to tan and to use sun-protection.

## **3.4 Results**

### **3.4.1 Current sun protection behaviours**

#### *Sunscreen use*

Sunscreen was the method of sun-protection most commonly reported by participants. The majority stated that they put it on before leaving the house but without taking special care to apply it within any particular timeframe (i.e. 30min before exposure). Participants tended to apply sunscreen on their most sensitive body parts (e.g. face, shoulders and back) and rub it on thoroughly until no white marks are visible.

Most participants recognised that they might not use enough sunscreen. This was supported by the objective measurement of sunscreen use conducted during the interviews (Table 3-1). Results show that the majority of the sample used less than the recommended sunscreen quantity (i.e. 2mg/cm<sup>2</sup>).

**Table 3-1: Summary of participants' characteristics and sunscreen use, ranked by sunscreen quantity (mg.)**

Participants ID	Age	Gender	Skin type <sup>9</sup>	Self-reported safe sun exposure (min)	Recommended sun-exposure UVB MED (mj/cm) <sup>10</sup>	Sun exposure Estimation <sup>11</sup>	Sunscreen use (mg)/arm surface (cm <sup>2</sup> ) <sup>12,13</sup>	Intention to tan	Intention to use sun protection
Participant 6	46	Female	4	60	40–60	Optimistic	0.02	Yes	Ambivalent <sup>14</sup>
Participant 9	24	Female	5	Few hours	60–90	Optimistic	0.02	Yes	Ambivalent <sup>6</sup>
Participant 12	43	Male	2	20	25–40	Conservative	0.02	No	Yes
Participant 16	49	Female	2	20	25–40	Conservative	0.02	No	Yes
Participant 14	21	Female	3	Few hours	30–50	Optimistic	0.02	No	Yes
Participant 1	32	Female	3	Few hours	30–50	Optimistic	0.03	No	Yes
Participant 8	29	Male	3	120	30–50	Optimistic	0.03	No	Yes
Participant 15	28	Male	4	20	40–60	Conservative	0.03	Yes	Yes
Participant 3	30	Female	1	5	15–30	Conservative	0.04	No	Yes
Participant 13	55	Female	2	30	25–40	Realistic	0.04	No	Yes
Participant 5	35	Female	2	30	25–40	Realistic	0.04	Yes	Yes
Participant 4	50	Female	3	30-60	30–50	Realistic	0.04	Yes	Yes
Participant 17	26	Female	3	Few hours	30–50	Optimistic	0.04	Yes	Yes
Participant 11	23	Female	1	30-60	15–30	Optimistic	0.05	No	Yes
Participant 10	45	Male	2	30	25–40	Realistic	0.05	Yes	Yes
Participant 2	62	Female	2	10	25–40	Conservative	0.07	No	Yes
Participant 7	27	Female	2	20	25–40	Conservative	0.11	Yes	Yes

<sup>9</sup> Type I: always burns easily, never tans; Type II: Usually burns easily, tans with difficulty; Type III: Burns moderately, tans gradually; Type IV: Rarely burns, always tans well; Type V: Very rarely burns, tans very easily; Type VI: Never burns, deeply pigmented;

<sup>10</sup> Personal minimal erythemal dose (MED) is an objective measure of sun sensitivity and it specifies the dose of ultraviolet B (UV-B) light required to produce visible redness of the skin (Fitzpatrick, 1988).

<sup>11</sup> The sun exposure estimation classification was based on the discrepancy between the self-reported optimal sun-exposure and the guidelines for optimal sun-exposure. If the first was higher, then participants' estimation was classified as optimistic. If the second was higher, the participants' estimation was classified as conservative regarding their estimation. If both estimations were similar, then the estimation was considered realistic.

<sup>12</sup> The amount used to test products for their SPF efficacy is 2 mg/cm<sup>2</sup> and recommendations about sunscreen application quantities are based on this figure (The British Association of Dermatologists, 2013).

<sup>13</sup> Median: 0.04

<sup>14</sup> Participants stated that sun protection is not a goal for their holidays, but also mentioned some preparatory behaviour, such as buying sunscreen and packing it.

In addition, the majority of interviewees mentioned that they use a higher sunscreen SPF at the beginning of the holiday and then switch to one with a lower SPF. The most commonly reported scenario is starting with a sunscreen with an SPF of 30 and then dropping to SPF 15. Self-reported SPF usage ranged from 10 to 50+, although some also mentioned using tanning oils as sun-protection.

In general, re-applying sunscreen seems to be prompted by feeling that the skin is hot or starting to burn and most participants recognise they should be doing it more often than every two hours but fail to do so.

#### *Cover up strategies*

Some participants mentioned the use of cover-up strategies for sun-protection. Most people reported that they use hat and sunglasses as a method of protection. Using hats seems to be the covering-up method less enjoyed as it is linked to aesthetic and comfort concerns.

The use of clothes to cover up tended to be related to feeling too hot and wanting an extra layer of protection.

#### *Seeking shade*

Seeking shade was the least used method for sun protection, with some mentioning that they like being exposed to the sun. The major problem was avoiding sun exposure between 10am and 4pm, as participants were more likely to seek shade only between 12 and 2pm. Also, some said that seeking shade was not compatible with their holiday routines (e.g. being 'out and about'; sightseeing). As methods of seeking shade, some participants used umbrellas or trees to avoid direct exposure to sunrays.

### **3.4.2 Key themes emerging from interviews**

Major themes and sub-themes were identified during the analysis. The major themes were driven by constructs included in the TDF and were identified by parsimoniously clustering utterances.

In addition, findings regarding sub-group analyses according to participants' intention to tan and to use sun-protection are presented. Eight interviewees showed an intention to tan over their holidays, whilst nine said that getting a tan was not a goal for their holidays. Regarding their intention to use sun protection, two participants showed ambivalent intentions and fifteen had a clear intention to use sun protection.



### 3.4.3 Are people aware of the reasons why to be SunSmart?

The majority of respondents mentioned the intention to avoid sunburn as a strong reason to use sun protection:

*'I get sunburnt if I haven't [put some protection on]' (female, 23y, skin type I).*

*'Well I wouldn't get burnt for one' (female, 32y, skin type III).*

There was widespread acknowledgement that not using sun protection can lead to damage of the skin and, subsequently, skin cancer:

*'Well there's always the risk of skin cancers and sun related skin cancers which hopefully this helps protect you against' (female, 27y, skin type II).*

Ageing was also mentioned as an adverse effect of unprotected sun-exposure:

*'It also causes long term skin damage from a point of view just the structure and texture of the skin, tends to get more wrinkles, ageing of the skin' (female, 62y, skin type II).*

The importance of sunlight to the synthesis of vitamin D was also mentioned as a reason to engage in more sun exposure:

*'Obviously the vitamin D aspect which ... we're not getting enough of that in this country at the moment' (male, 43y, skin type II).*

*'[adverse effects] Cause I know that a certain proportion in the UK quite a lot of course, are deficient in vitamin D and so I know that I probably, to some degree I need to get more sun' (male, 28y, skin type IV).*

Participants with ambivalent intention to use sun protection were less likely to mention vitamin D as a positive outcome.

### 3.4.4 Do people know how to be SunSmart?

Sunscreen was the most commonly reported method of sun-protection and was considered the first line of protection for the majority of interviewees. There was mixed knowledge about the specific guidelines for sunscreen application. More precisely, there was some uncertainty about how much sunscreen to put on, as participants considered the recommendation of 'apply sunscreen liberally' to be very vague.

*'It's the use of the word 'liberally'. Probably I'd imagine most people, including myself, don't use enough in the first place' (female, 23y, skin type I).*

*'Again it's something I don't quite know whether you're supposed to put it on so you can see the whiteness and let it sink in or you're supposed to rub it in so that it's gone.'* (female, 27y, skin type II).

There seems to be a fairly good idea of when and where to apply sunscreen and to do it 30 minutes before sun-exposure, taking special care with exposed areas prone to sunburn.

*'After we've been for breakfast I would put in on straight away erm before we were even down by the pool or the beach (...) I do reapply it every couple of hours. Maybe not every 2 hours but maybes every 3 or 4. But yeah, after swimming and every 3 or 4 hours as well (...) I use sun block on my feet and I take extra care erm on my shoulders because the burn. My knees burn which is a really bizarre place to burn and my nose and my forehead'* (female, 26y, skin type III).

The area where more confusion was noted related to when to reapply sunscreen. Some people were unsure, but others seem to understand it should be done when contact with water occurs or every two hours. One of the main reasons given to reapply sunscreen was when feeling their skin was starting to burn.

*'If I put any more on it's because I would be aware that I was getting hot and then maybe a little red'* (male, 28y, skin type IV).

About the specific guideline for sunscreen SPF, participants seem to roughly know that it should be >15SPF. Some participants mention that they would use the lowest SPF possible so that they could still get a tan.

*'I mean to be honest the [SPF] 2 and the [SPF] 4 I would use to get the colour right as opposed to the protection'* (female, 46y, skin type IV).

Most people state that they are confident about putting on sunscreen and think the procedure is easy and straightforward. But a few participants mention that this is actually a difficult task. The majority of respondents indicated that spray is easier to put on than sunscreen lotions or creams.

*'It's ehm it's not really an issue [applying sunscreen], it's part of me'* (male, 46y, skin type II).

*'I find it difficult. It's just such a chore in all honesty. Yeah I'm not very good at it and it takes me a while'* (female, 26y, skin type III).

*'I find the spray ones better to apply. (...) I would say it is quite straightforward to apply the sunscreen' (female, 32y, skin type III).*

Another method of sun-protection also mentioned was covering-up, such as using a t-shirt or a hat. Respondents knew about the existence of clothes with a sun-protection factor. Cotton was mentioned as the textile offering more protection, as well clothes densely woven, reasonably loose fitting and long sleeves. Some participants stated that they've never thought about specific types of protective clothes, as just tend to use their normal clothes.

*'I sort of wear all the tight woven clothes and broad brimmed hat' (male, 43y, skin type II).*

Some were unsure about what would be an ideal hat that would provide the best protection from the sun. The majority stated that a wide-brimmed hat would offer the best protection as it protects the face and the neck.

*'Something that protects your face and the back of your neck' (male, 43y, skin type II).*

Sunglasses were also mentioned as a method for sun-protection. Most respondents knew about sunglasses with UVA/UVB filters for the best protection, but some people were still a bit unsure about what to look for in sunglasses.

*'Erm I usually look to see if they've got some kind of protection in erm and obviously the style' (female, 55y, skin type II).*

Another method for sun-protection mentioned was to avoid sun-exposure during peak hours by either staying indoors or seeking shade structures such as trees and umbrellas. Participants were unsure about how to choose from different types of shade structures. Indoors or big shaded areas were mentioned as the best way to protect from the sun. Shade provided from trees was also mentioned as a good method of sun-protection.

*'Erm better than being indoors I would probably choose something that tends to be with a tree or an umbrella or something like that' (female, 26y, skin type III).*

*'I sort of assumed any shade the same' (female, 35y, skin type II).*

In general, knowledge of peak hours was fairly reasonable with the majority of interviewees saying peak hours were around 11am-3pm. Some respondents were

confident that they would find shade if needed. Again, the main reason given for seeking shade was when feeling too hot in the midday sun.

*'If I need to find shade I'll find shade, you know' (female, 46y, skin type IV).*

*'The main reason I'm choosing shade is because I'm feeling hot' (male, 28y, skin type IV).*

The majority of participants were not aware of the importance of the UV index as an important resource to prevent overexposure to the sun's rays. Most thought that temperature was an accurate measure of the sun's intensity.

*'I don't really know what they are [UV levels] to be honest. So it doesn't really make a difference' (female, 21y, skin type III).*

*'I kind of associate hot temperatures with high [UV] levels' (female, 49y, skin type II).*

### **3.4.5 What are the reasons given to justify sun-exposure?**

#### **Desire for a tan**

The desire to have a tan during the holiday period was a reason for not using as much sun protection as recommended by the WHO guidelines. This desire seemed to be more likely among people with an intention to tan.

This intention was related to appearance-based concerns:

*'I do like having a slight tan because I generally look quite pale and ill the rest of the time' (male, 28y, skin type IV).*

Others justified that having a tan is part of their social identity:

*'I come from that sort of background where I worry about not getting a tan. How on earth would I come back off holiday [without one]' (female, 46y, skin type IV).*

Another reason given for not using as much sun protection as recommended was attributed to cultural identity. This seemed to be more likely among people with an intention to tan:

*'I like to be sat in the sun, it's very British thing' (male, 45y, skin type II).*

Participants stated that having a tan is a symbol of being on holiday:

*'Erm as wrong as it is the point of going on holiday is to get a nice tan' (female, 46y, skin type IV).*

*'If I came home from holiday without a tan I'd be gutted' (female, 24y, skin type V).*

Some also mention that not having a tan after holiday as an opportunity cost:

*'If you go on holiday and you don't come back with a tan, you've kind of got sort of some opportunity cost - like you had the opportunity and you didn't take it, which is really silly'. (female, 26y, skin type III)*

*'It's that you've paid quite a lot really to go away on holiday and you want a nice tan' (female, 27y, skin type II).*

Some participants also stated that their main goal for the holiday is to get the right balance between getting a tan and using sun-protection. Avoiding sunburn seemed to be the way used by holidaymakers to judge the success of their holidays.

*'I'm wanting a balance of kind of sun. Some tanning erm but not, you know, unhealthy' (male, 28y, skin type IV).*

*'Erm I usually go for the lowest 'cause it's like vanity of trying to tan but also making a token gesture of trying not to be in pain' (male, 29y, skin type III).*

### Psychological well-being

Some respondents also mention the benefits for the mental health as a reason to enjoy sun exposure:

*'Obviously you feel better. Obviously mental health problems, mental health issues' (male, 43y, skin type II).*

*'Well emotionally really as I said I feel better in the sun than I do out of the sun' (female, 46y, skin type IV).*

The fact that feeling the sun on the skin is associated with sensorial pleasure was also mentioned as a barrier for sun protection.

This seemed to be more likely among people with an intention to tan:

*'You've went outside into the sun and dried off and the sun's lying there and it was so nice to just lie there after swimming and you're so relax and feeling the sun' (male, 28y, skin type IV).*

*'Also I quite like to get some sun on my face, so I feel I've been on holiday if I've had a little bit of sun on my face' (female, 35y, skin type II).*

### **3.4.6 What are the main barriers and facilitators mentioned for sun protection?**

#### Characteristics of sun protection methods

##### *Inconvenience of sun protection use*

Sunscreen use was seen as a behaviour that involves conscious effort and time:

*'It's just the faff of putting it on, it takes time so that's mainly it. It's just the hassle of doing it' (male, 43y, skin type II).*

Participants also mentioned that specific characteristics of sunscreen made it more difficult to use:

*'It's not the nicest thing to put on – it's quite oily; and doing it at the beach, where's sand everywhere, it just sticks' (male, 28y, skin type IV).*

Another aspect commonly stated was the inconvenience of reapplying sunscreen regularly and after swimming:

*'I think it's a bit of a bind really to be honest, you know, all the time having to reapply and thinking about doing it' (female, 55y skin type II).*

Some respondents also reported sunscreen use as something not enjoyable:

*'It's just such a chore in all honesty' (female, 26y, skin type III).*

*'Not something I like doing' (male, 43y, skin type II).*

## *Comfort*

A reason commonly given to seek shade was to avoid heat, rather than UV rays:

*'The main reason I'm choosing shade is because I'm feeling hot' (female, 46y, skin type IV).*

Sunglasses were used to protect eyes from sunlight and not so much as protection from UV rays.

*'It's something like I wear sunglasses anyway but just not for the reasons of actual protection from the sun' (male, 29y, skin type III).*

## *Fashion concerns*

Covering up strategies seem to be highly influenced by fashion concerns:

*'I would again just really based on style and then probably just t-shirts or thin shirts or thin shorts and yeah' (male, 29y, skin type III).*

*'I don't do that because then I think well I would get tan lines or won't get a tan'. (female, 24y, skin type V).*

This was even more obvious for hat and sunglasses:

*'No, it would probably just be the style of it that I choose [hat]' (female, 21y, skin type III).*

*'Oh no - just the ones that look good from (specific brands) or somewhere else [sunglasses]' (female, 46y, skin type IV).*

## Characteristics of the holidays

### *Interference with the holiday experience*

Some participants mentioned that sun-safe behaviours would interfere with their holiday experience:

*'I would be missing the point of going on holiday' (male, 45y, skin type II).*

This was even more salient about seeking shade between 10am and 4pm:

*'You don't go on a beach holiday to just sit under an umbrella; you go sort of to be in the sun' (male, 29y, skin type III).*

Others also stated that putting on sunscreen made them being less spontaneous on holiday:

*'You're so relaxed and feeling the sun and there would always have the sensation of well I can't lie here for too long [without putting more on]' (male, 28y, skin type IV).*

### Social influences

#### *Fear of being left out*

The fear of being excluded from the group dynamic and desire of being included in social activities was also described as a barrier to use sun protection. This was especially important for seeking shade behaviour:

*'If you're on holiday with somebody you wouldn't want to be everyone in the sun and then me sat by myself not talking to anybody. You wouldn't really want to have to spend the entire holiday by yourself, which will be happening' (female, 27y, skin type II).*

#### *Fear of peer judgement*

Some respondents mentioned the fear of mockery as a barrier to use sun protection, mostly because it can be perceived as being an overly cautious person:

*'They just like to bake in the sun and they always sort of mock me 'cause I'm trying to find the shade' (male, 43y, skin type II).*

Participants with ambivalent intention to use sun protection were less prone to fear social costs associated with sun protection practices.

#### *Family and friends reinforcement*

Most participants mentioned individuals that reinforce their use of sun protection. Partners and family were described as key influence on sun safe behaviours:

*'We go in a group so there's always, you know, we sort of remind each other type thing so' (female, 35y, skin type II).*

*'She has [partner] certainly got me into wearing sun cream if I'm not wearing' (male, 28y, skin type IV).*



Sun protection behaviours were also described as learnt and influenced by parental practices:

*'I think the way I protect must be come through the way my mum and dad protect my skin' (female, 26y, skin type III).*

*'They [parents] wouldn't let you out unless you had a hat on and sunglasses and lots and lots and lots of sun tan lotion on and the clothes' (female, 27y, skin type II).*

Friends were also seen as a positive influence on sun-protection behaviour:

*'I said since I have made friends here I have become more aware of the harmful effects of the sun' (female, 32y, skin type III).*

#### *Social cues*

Some participants also mentioned that being next to someone that uses sun-protection would remind them to put it on and to use it more often:

*'I guess if other people are putting sun cream on, that would remind me. If someone's doing that, -'Oh, yeah, I was supposed to...'* (female, 23y, skin type I).

#### *Sunscreen users as 'a cautious person'*

The stereotype of being cautious person instead of someone 'cool' was also mentioned by participants as a characteristics of a sunscreen user.

*'I probably don't think I'm the coolest of people so I don't mind spending that extra time putting sun cream on so I don't get burnt. I see that as an investment' (female, 23y, skin type I).*

#### *Change in personal roles and identity*

Becoming a parent or a grandparent was mentioned as a life change that made respondents use more sun protection:

*'With the children it has changed a bit; so I would – before I had the children I would spend quite a long time in the sun' (female, 32y, skin type III).*

*'I'm about to become a grandma I worry more generally about lifestyle behaviours that can have an effect on me not being around for my grandchildren' (female, 46y, skin type IV).*

Another change in life, like getting older, was also mentioned as key for use of protection as opposed to a younger age:

*'If you asked me 25 years ago I would have said something different' (female, 49y, skin type I).*

### Sun protection resources

#### *Availability of resources*

Lack of shade facilities at the resort site was described as a major barrier for using sun-protection:

*'I think the only problem is, as I've mentioned before, is trying to find shade if you're on, sort of on the beach'(male, 43y, skin type II).*

*'Well just if you were on holiday where there's no shade that would be a problem'(male, 28y, skin type IV).*

Also, the belief that making sunscreen available everywhere would increase its use:

*'Just having it available, having the sunscreen, you know, you don't want to carry around a big bottle like that, you know what I mean' (female, 50y, skin type III).*

Costs associated with sun-protection were also raised as a barrier for being SunSmart:

*'Erm I guess if sun cream was cheaper [it would help using more] erm because it is really expensive and therefore especially, especially because then it doesn't really last' (male, 28y, skin type III).*

### Self-regulatory strategies in sun protection practices

#### *Forgetfulness*

A reason often mentioned for not engaging in sun protection seems to be 'forgetting':

*'Then sometimes I just forget and I'll just be there and I won't have anything' (male 28y, skin type III).*

*'I probably put it on in the morning and forget for the rest of the day' (female, 21y, skin type III).*

### *Coping and facilitation planning*

Among strategies used to help sunscreen application, some participants mention associating or placing different sun-protection behaviours together.

*'If I'm putting sun cream on, I'd usually take a hat with me so I associate them together. (female, 23y, skin type I).*

Another strategy mentioned was packing sun protection before going on holiday and to take them before leaving the house:

*'And the sunscreen, yeah and pack them and we usually make sure that we pack enough erm' (female, 23y, skin type I).*

*'Erm consciously thinking about like before I'd leave the house sunscreen' (male, 29y, skin type III).*

Some participants also mentioned that having more places selling sunscreen on holiday will help them to be SunSmart.

*'I guess if more places sold sun cream it would make it easier' (female, 23y, skin type I).*

Planning activities beforehand (either before going on holiday or on site) was also suggested as a strategy to use more sun-protection:

*'I think you need to plan a bit your day; especially if you are going to make sure you don't spend too many hours in the sun' (female, 32y, skin type III).*

The use of sun protection methods was also described as part of the daily routine by some participants, which make them more likely to use it:

*'When I'm leaving the house I apply the sun cream then because it's... like, you know, daily routine more like, you know, sort of brushing your teeth almost like, you know, and get ready so yeah' (male, 29y, skin type III).*

The existence of cues in the environment was also mentioned as a strategy that would make participants to use more sun protection:

*'We've been places that have signs up (...) There's little signs up everywhere reminding you to sort of things like that' (female, 35y, skin type II).*

Overall, participants with ambivalent intention to use sun protection are less likely to mention/use self-regulatory strategies.

### **3.5 Discussion**

This study produced significant insights about experiences and perceptions of holidaymakers about sun-protection behaviours, using a theoretical framework to identify key barriers and facilitators. Importantly, this study highlights holidaymakers' motives, providing important implications that might impact on future public health messages and policies for skin cancer prevention.

The desire for a tanned appearance and the cultural and social value attributed to a tan was reported by a large portion of respondents. Having a tan was perceived as being healthy, more attractive, as a symbol of being on holiday and spending an enjoyable time abroad. These appearance-based beliefs have been found in previous studies to be strong motivators for not using sun-protection. For example, there have been few qualitative studies that have explored the desire for a tan, Lake and colleagues (2013) also found that the value given to a tanned appearance was reported by sunbed users. A similar finding was also reported by Potente and colleagues (2011) in their ethnographic study with Australian adolescents. A systematic review of qualitative studies (Garside *et al.*, 2010) also concluded that the perceived benefits of having a tan can outweigh the perceived benefits of sun protection practices. Appearance-based beliefs have been intensively explored as predictors of sun protection use in several studies (e.g. (Jackson and Aiken, 2000; Cafri *et al.*, 2009).

Our results suggest that holidaymakers possess a widespread recognition of the health risks of excessive UV exposure, such as burning, premature skin ageing and increased risk of skin cancer. These findings suggest that public health messages may be more effective if the emphasis shifts from the damaging effects of excessive sun-exposure to appearance-based motives.

In line with this, special attention should be given to holidaymakers' who have a clear intention to avoid sunburn while still trying to get a tan. This type of behaviour can be described as an intention to perform a behaviour (e.g. sun exposure) until it incites potential negative consequences (e.g. sunburn) whilst still getting the positive effects of this action (e.g. getting a tan). This phenomenon has been reported previously (Clarke *et al.*, 1997) and supports the hypothesis of a 'non-risk reduction strategy' whereby people engage in risky sun behaviour but also make sure to protect themselves 'just enough' to prevent sunburn.

Whilst some holidaymakers perceived sun protection as relatively easy to perform, gaps in the knowledge about specific guidelines for sun protection seem to exist (e.g. how much to put on, when to put it on, peak hours, UV levels, types of shade). Participants in this study also perceived sun protection as a chore that removes spontaneity and a carefree lifestyle when on holiday. Similar findings have been reported in a study with Australian adolescents, whom described sun protection as a 'big deal' (Potente *et al.*, 2011). Portuguese students have also described using sunscreen as being an unpleasant experience (Araujo-Soares *et al.*, 2013b).

Several barriers and facilitators were identified for sun protection in this study. Results showed the influence of significant others for sun protection, more specifically the desire to fit in with the group and the fear of peer judgement. This finding is consistent with previous literature (Abroms *et al.*, 2003; Potente *et al.*, 2011). Another interesting finding was the importance of environmental resources for sun protection. Overexposure to the sun was sometimes influenced by the lack of resources in the environment (shade availability) or by situational constraints (e.g. concurrent activities like sightseeing) (Garside *et al.*, 2010).

This study also highlights the role of self-regulatory strategies in facilitating the use of sun protection, such as planning and cues for action. Previous research has found that facilitation planning (e.g., to buy and carry sunscreen, set reminders, ask others to remind) is associated with sunscreen use in a sample of adolescents (Araujo-Soares *et al.*, 2013b).

Another interesting finding of the study was the differences found between participants with and without intention to tan. On one hand, participants with a clear intention to tan were more likely to focus on the positive attributes of getting a tan, justify their actions as being part of a specific group or culture and describe sun exposure as a positive experience. On the other hand, participants with ambivalent intentions to use sun protection appeared to be less prone to fear of the social consequences of their behaviour and less likely to use self-regulatory strategies for sun protection. Holidaymakers without intention to use sun protection were also more likely to use less sunscreen (as measured during the interview process). This specific type of participant is similar to one of the subtypes described in other studies (Pagoto *et al.*, 2004; O'Riordan *et al.*, 2008b). In these, four categories of beachgoers were identified: 1) low-risk sun worshipper (mostly skin types III and IV); 2) high-risk 'sunburners' (mostly skin types I and II); 3) moderate- to high-risk tan seekers (mostly skin types II and III); and 4) low-risk sun indifferent. The results from our study also show the existence of a clear subtype of tan seekers (5 out of 17) that are at a moderate-to high-risk. Both

studies (Pagoto *et al.*, 2004; O'Riordan *et al.*, 2008b) found that the largest subtype includes holidaymakers with a clear intention to tan, despite having a sensitive skin type that is prone to sunburn. Special attention should be given to this group as they have a strong desire to get a tan that seems to offset their concerns about personal risk.

Another interesting finding is the high proportion of individuals who overestimate their safe sun exposure assessment according to their skin type. Other studies have reported this phenomenon known as optimistic bias (Clarke *et al.*, 1997; Bränström *et al.*, 2006). This can be described as a tendency to judge own susceptibility to a disease as lower than the susceptibility of others, which will lead to less intention to change behaviour (Bränström *et al.*, 2006).

This study has clear implications for future strategies in the area of skin cancer prevention with holidaymakers. Firstly, our results suggest that future public health messages should address the importance attributed to a tanned appearance, instead of focusing on the damaging effects of sunlight. For example, the study conducted by Pagoto and colleagues (2010) examines the impact of an intervention that promotes sunless tanning as a substitute for sunbathing, showing a short-term effect on sun-exposure, sunburn, and use of protective clothing. Systematic reviews in this area have shown that appearance-focused interventions might be able to promote safer UV exposure and sun protection (Dodd and Forshaw, 2010; Williams *et al.*, 2013). Moreover, specific strategies such as seeing appearance-based information about photoaging illustrated with UV photographs (i.e., pictures of cases of skin damage) might be helpful in changing behaviour (Williams *et al.*, 2013; Chapter 2), since this highlights the immediate effects rather than only giving long term risks (e.g. cancer).

Secondly, strategies to promote sun protection should also focus on how to perform the behaviours (e.g. how to apply sunscreen properly). For example, perhaps future public measures should emphasis the specific quantity of a proper sunscreen application translating it to real-life quantifiable examples (e.g. for a full body application use the equivalent of a full shot glass of sunscreen). A previous systematic review showed that providing resources (e.g., making sunscreen or shade available); providing information on the consequences of performing sun protection (e.g. sunburn prevention, decreasing risk of skin cancer); and providing information on how to perform relevant sun-protection behaviours (e.g., accurate sunscreen application) was present in almost all studies analysed (Chapter 2). However, it seemed obvious in this study that those interviewed were very much aware of the negative effects of overexposure and might be less receptive to change behaviour based on this knowledge.

Thirdly, by providing evidence on how peer/group influences sun protection behaviours, this study corroborates previous research that urges for the need to facilitate social norms for sun protection (e.g. providing information about others' behaviour) (Potente *et al.*, 2011; Chapter 2).

Finally, this research also provides an important insight about the influence of self-regulatory strategies for sun protection and the importance of tackling forgetfulness associated with these behaviours. Therefore, public health messages could frame sun protection as a behaviour that fits the holidaymakers' routine/lifestyle and can easily become a habitual behaviour. The importance of self-regulatory strategies for behaviour change is supported by other studies (Knittle *et al.*, 2010), and more precisely in promoting sunscreen use (Araujo-Soares *et al.*, 2013b).

Some limitations of this study need to be acknowledged. Participants were British holidaymakers aged 21-62, with the majority having a skin type of II or III. Therefore, the findings need to be generalised with caution. The fact that the results of this study are based on a convenience sample might be biased and not representative of all British holidaymakers. Nevertheless, the perceptions of participants involved do not differ significantly from what have been found in previous studies (Garside *et al.*, 2010), but future studies should compare how different holidaymakers are within the UK and/or abroad (e.g. Northern European countries). Even though there was no mention in this sample, it would be also important to assess the influence of certain lifestyle habits (e.g. drinking) on sun protection during holidays. Due to the limited size of the sample, there was no scope for subgroup analyses. Future studies should explore differences regarding age, gender, or socio-economic status. For thematic analyses, having a second rater for the coding and to evaluate the emergent themes would improve the reliability and strengthen the methodology of this study.

Evidence suggests that some holidaymakers prepare for their trips by using sunbeds and getting a 'base tan'. However, this aspect of holidaymakers practices was not captured in this study and should be explored in future studies as it might help to understand the specific pattern of sunny holidays lifestyle and strengthen any preventive messages targeting this population. Finally, the self-reported skin type assessment might have been biased for some participants. The tendency was to think that they possessed a more resistant skin type than the one the interviewer observed.

To conclude, our results suggest that public health messages should shift from the traditional focus on the harming effects of sunlight to the importance attributed to a tanned appearance, promoting specific strategies that support people in engaging both in sun protection and getting a tan at the same time.

## **Chapter 4 Systematic development and user-centred design of the mISkin mobile-phone intervention**

### **4.1 Abstract**

Tourism settings are of particular interest for skin cancer prevention. Intermittent UV-exposure is a risk factor for melanoma. To date, no effective, affordable and geographically flexible interventions to promote sun-protective behaviours are available. This chapter aims to: a) describe in detail the development process of a prototype of an evidence-based mobile-phone intervention (mISkin) aimed at supporting holidaymakers in reducing excessive UV-exposure; and b) describe the prototype evaluation and intervention refinement, using user-centred design.

The development of the mobile-phone intervention followed the MRC framework guidelines to develop and evaluate complex interventions, and this was informed by a) a systematic review of RCTs identifying behaviour change techniques (BCTs) and delivery methods associated with effectiveness of sun safe interventions; b) theoretical considerations for the inclusion of behaviour change techniques and main components of the intervention; and c) a user-centred study based on prototypes and scenarios to optimise acceptability, using semi-structured interviews.

The evidence- and theory-based information was successful in identifying acceptable BCT's and modes of delivery. All 17 participants in the user-centred study were satisfied with the mISkin prototype and expressed willingness to use it. Feedback from participants on prototypes and scenarios was used to introduce changes in order to optimise acceptability (e.g. customisable prompts, videos).

The mISkin app was designed to protect holidaymakers from excess UV-exposure and was based on current evidence and user-centred design principles. Based on users' feedback the app has been refined and a fully functional version will be tested in a feasibility study.

### **4.2 Introduction**

Skin cancer incidence within Caucasian populations has been increasing worldwide (Lens and Dawes, 2004). Exposure to ultraviolet radiation (UV) and history of sunburn – modifiable behavioural factors – are considered the major etiologic factors for melanoma (Armstrong and Kricger, 1994; Kricger *et al.*, 1994; Kricger *et al.*, 2007). Epidemiologic studies suggest that sun safe habits, such wearing protective clothes, avoiding sun exposure during midday and sunscreen use, would decrease the amount of intermittent sun-exposure and have an important impact on reducing skin cancer incidence (Armstrong and Kricger, 2001).



Skin cancer is the most common form of all types of cancer diagnosed in the UK (Cancer Research UK, 2013b). In the UK, the age-standardised melanoma incidence rate for 2010 was 17.1 per 100,000 population. In the same year, malignant melanoma was the fifth most common cancer (Cancer Research UK, 2013c).

The number of individuals engaging in risk behaviours during their holidays is increasing. As stated previously, sunburn is a common experience over holiday (World Health Organisation, 2002; Cancer Research UK, 2013a) and sun-related behaviours, such as intentional seeking sun-exposure are increasingly high (Manning and Quigley, 2002; Diffey and Norridge, 2009).

In the UK, studies evaluating effectiveness of sun-protective interventions in recreational settings are sparse. Currently, the SunSmart campaign (implemented by the Cancer Research UK website) is the major intervention being rolled out.

According to the Medical Research Council (MRC) guidance for developing and evaluating complex interventions (Craig *et al.*, 2008; Craig *et al.*, 2010), the first step in this process is the development of the complex intervention itself. The development process is complex and entails three essential elements: a) identifying the evidence base; b) identifying/developing theory; and c) modelling process and outcomes. The MRC framework also emphasises that the development of a complex intervention should be informed by users, in order to have an intervention 'fit-for-trial' and to improve evidence-based practice in this area.

A recent systematic review and subsequent moderator analyses (Rodrigues *et al.*, 2013) showed that almost all interventions reviewed utilised behaviour change techniques aimed at providing resources (e.g., making sunscreen or shade available), providing information on the consequences of performing sun-protection behaviours (e.g. sunburn prevention, reducing risk of skin cancer) and providing information on how to perform relevant protective behaviours (e.g., accurate sunscreen application). The analysis also showed that interventions highlighting supportive social norms for sun-protective behaviours (e.g. providing information about others' behaviour and social norms) and providing appearance-based information about skin photo-ageing, illustrated with UV photographs of skin damage, appear to be more effective than interventions that do not use these techniques. Modes of delivery were also explored in these analysis and the main findings indicated that the most effective interventions in this review used individual feedback through UV photographs. The review raised several concerns about the evidence base, including: a) the risk of bias in most included trials is high; b) poor outcome measurement procedures; c) most studies did not provide sufficient information about intervention procedures and components; and

d) the lack of a theoretical framework for the interventions' design. One suggestion from this review was the use of new technologies in future interventions, since affordable and scalable handheld diaries, global positioning systems (GPS), UV dosimeters and small scale accelerometers built into sunscreen bottles are a reality nowadays.

Considering the time of day or location barriers in interventions targeting holidaymakers, interventions that use mobile computing and communication technologies (e.g. mobile-phones, PDAs) are potentially an effective option for skin cancer prevention.

Several systematic reviews have explored the effects of mobile technologies on changing health-related behaviour. Fry and colleagues (2009) reviewed the effectiveness of periodic prompts for health promotion. Nineteen studies were included and of those 11 studies provided evidence for the effectiveness of prompts. The main conclusion of this review is the need for future research to explore prompt frequency. Weekly prompts were significantly more effective than infrequent prompts, but doubts remain whether more frequent prompts (i.e. daily) might be beneficial for behaviour change. Authors also argue for the potential of tailored periodic prompts, suggesting that this strategy should be investigated in future well-design studies. Cole-Lewis and colleagues (2010) reviewed 12 studies to assess the effectiveness of text messaging to change health behaviours. From these, 8 studies showed evidence for the effectiveness of text messaging to support weight loss and smoking cessation. Authors highlighted the need for future well-designed interventions to be based on a theoretical rationale that guides the development of components and content. Future studies should also investigate the effects of text messaging factors (e.g. dose and duration) and the long-term effects of this type of intervention. Heron and Smyth (2010) synthesised and appraised 27 ecological momentary interventions aimed at improving health behaviours. Ecological momentary interventions encompass strategies that are delivered to people during their everyday lives (i.e., in real time) and in their natural settings (i.e., real world). Findings suggested that EMI interventions are effective in supporting smoking cessation and weight loss in overweight women. From these findings, authors suggested that more qualitative methods are needed in this area to gather participants' perspectives and feedback on the intervention, especially during the acceptability and feasibility phase of intervention development. Also, future studies should focus on using real-time momentary data for outcome assessment, as well as data about intervention use and compliance (e.g. frequency, time, and duration). More importantly, authors urged for the importance of tailoring intervention to specific individuals' characteristics and needs. Another review conducted by Free and

colleagues (2013) aimed at summarising the evidence for the effectiveness of interventions based on mobile technologies and their impact on health-related behaviour change. The review included 26 trials and found mixed evidence for the benefits of mobile-based intervention in changing health behaviour. More precisely, text messaging was effective in supporting smoking cessation. For diet and physical activity, interventions showed either small or no effects whatsoever. This review concludes that more powered high quality trials are needed in this area of research. Finally, some doubts persist regarding the effects of different peripherals (e.g. camera, sensors) and specific behaviour change techniques.

Two RCTs have previously explored the impact of text reminders on sun-protective behaviours (Armstrong *et al.*, 2009; Gold *et al.*, 2011). Armstrong and colleagues (2009) conducted a study to evaluate the effectiveness of a text messaging intervention prompting sunscreen use in Canada. Participants that were allocated to the intervention condition were prompted over a period of 6 weeks. The reminders had two components: a daily local weather forecast and a text reminder related to sunscreen use. The sunscreen cap was fitted with an electric monitor that recorded every time the sunscreen bottle was opened. Text message reminders were found to significantly increase the daily adherence rate to sunscreen application (intervention group: adherence rate 56.1%, control group = 30%) after adjusting for weather conditions (Armstrong *et al.*, 2009). Even though this study is the first to use electronic monitors to assess daily sunscreen application, no information was retrieved regarding quantity of sunscreen usage, since this would support findings from the electronic monitors. In addition, participants suggested that the prompts used should be customised to their personal preferences. Finally, the fact that the study was conducted over autumn (with only 17 sunny days) might play a role in explaining adherence rates, as sun protection is usually a practice associated with summer.

In another study (Gold *et al.*, 2011) younger Australian adults (16-29 years old) were recruited via mobile advertising offers. The study tested the effectiveness of SMS to increase knowledge and promote beneficial behaviour change related to sun safety amongst younger adults over a 4-month period. A total of eight text messages were sent fortnightly over summer during a pre-specified broadcast period. The messages were humorous, short, used informal language and were aimed at increasing knowledge, reinforcing protective behaviours, changing attitudes and increasing perceived behavioural control. The results showed no significant differences in the frequency of seeking shade, tanning preferences or wearing protective clothing (Gold *et al.*, 2011).

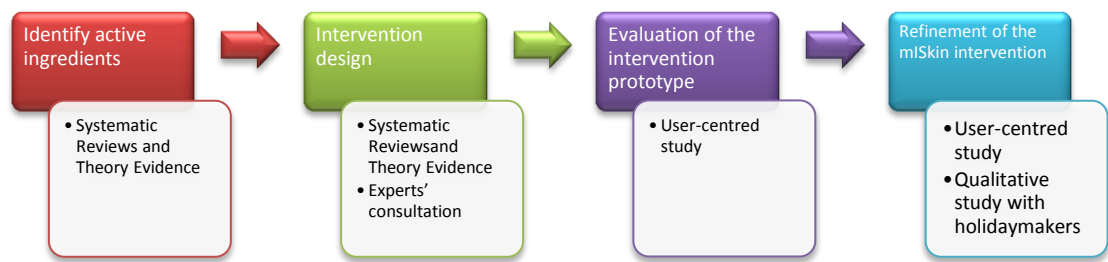
An important aspect of the development of new technologies for behaviour change is whether it suits its purpose and meets users' needs and expectations. User-centred design is an approach that entails the involvement of potential users in the design process of a product (e.g. intervention materials) by tackling their specific needs (Baek *et al.*, 2008). This process usually involves eliciting feedback from users by showing a prototype version of the intervention and implementing formative usability testing (Baek *et al.*, 2008). Using a user-centred design, Buller and colleagues (2013) designed and developed the Solar Cell mobile application for sun protection. Four rounds of usability testing were implemented by conducting focus groups with 22 potential users. The Solar Cell application uses the location of the mobile phone to download UV index forecast data and provides real-time feedback and information to users. Overall, participants rated the Solar Cell application highly and described it as being 'user friendly'. However, this application did not use evidence from the most recent systematic review in the area of skin cancer prevention (Rodrigues *et al.*, 2013). This intervention could benefit from using some of the strategies suggested by this review, such as stimulating social norms and providing appearance-based information about photoaging with ultraviolet photographs.

The present study explored potential users' attitudes towards a mobile-phone intervention to be delivered during holidays. This intervention integrates both the findings from the systematic review (Chapter 2) and the main facilitators and barriers identified in the interviews with potential holidaymakers (Chapter 3). The mobile phone application was developed for the Android platform and was shared with a group of potential users. On one hand, the aim was to understand how sun protection and the mobile-phone application can potentially fit into people's holidays. On the other hand, users' reactions to the prototype of the mobile-phone intervention were also investigated. More precisely, this study explored: a) users' set of routines when on holiday; and b) user-reactions to a mock up prototype of the developed mobile-phone application to promote sun-protection practices over holiday (acceptability).

### **4.3 Development process of the mISkin intervention**

The development process of the current intervention was conducted over four stages: a) identify active ingredients of behaviour change as well as theory evidence; b) concept development and intervention design; c) evaluation of the intervention prototype; and d) refinement of the mISkin intervention. Each phase included various sources of information, such as: systematic reviews and theory evidence; experts' consultation; user-centred study; and the qualitative study investigating holidaymakers' perceptions about sun protection (Chapter 3) (Please see Figure 4-1).

**Figure 4-1: Development process stages for the mISkin intervention.**



### **4.3.1 Identifying active ingredients and behaviour change theory evidence**

The completed systematic review provided pointers and constraints for the design of this intervention, allowing for an evidenced-based intervention development. This process also collected and analysed evidence from behaviour theory and other systematic reviews evaluating effective strategies for change in other non-related behaviours.

Even though it concluded that the evidence was weak and inconsistent, the systematic review and subsequent moderator analysis were used to inform the foundation of the new intervention (Chapter 2). The most frequent and most effective BCTs were included in the app. The findings from this systematic review provided indications of possible techniques to be included in an intervention. The behaviour change techniques (BCT) more frequently used by highly effective interventions were: a) stimulate supportive social norms for sun-protective behaviours (e.g. providing information about others' behaviour and social norms); and b) provide appearance-based information about skin photoageing, illustrated with UV photographs of skin damage.

While the findings of the systematic review are informative, they are not considered to be definitive and, therefore, other components were used to inform the development of the mISkin intervention.

The next step was to undertake a thorough examination of identified techniques in combination with theoretical models and other relevant evidence. Table 4-1 details all the techniques included in this intervention with evidence-based and theoretical reasons for inclusion.

**Table 4-1: Included behaviour change techniques within the intervention development phase with explicit evidence-based and theoretical reasoning.**

Included technique	Rational for inclusion (evidence-based and theory-based)
Information on why to do it (i.e. information about consequences)	<p><u>Evidence:</u> Systematic review (Chapter 2)</p> <p><u>Theory:</u> People tend to form outcome expectancies about the result of given actions (Bandura, 1998). In line with these outcome expectancies, people will engage in actions that are likely to produce positive outcomes and dismiss those that result in negative consequences (Bandura, 1998).</p>
Information on how to do it (i.e. information about specific skills)	<p><u>Evidence:</u> Systematic review (Chapter 2)</p> <p><u>Theory:</u> In the Social Cognitive Theory, instructions on how to engage in a specific behaviour are essential to translate a goal into action which will in turn foster self-efficacy and subsequent further behaviour change (Bandura, 1997).</p>
Prompting/cueing	<p><u>Evidence:</u> Systematic reviews (Fry and Neff, 2009; Dombrowski <i>et al.</i>, 2010; Chapter 2) and a previous trial on sunscreen use (Armstrong <i>et al.</i>, 2009).</p> <p><u>Theory:</u> The Social Cognitive Theory envisages prompting as a key strategy for behaviour change. Prompting enables individuals to experience mastery which promotes self-efficacy (Bandura, 1991).</p>
Social comparison	<p><u>Evidence:</u> Systematic review (Chapter 2).</p> <p><u>Theory:</u> Within the Social Cognitive Theory, referential performance is induced by a process of social self-judgement, where social comparison is central. The provision of opportunities for social comparisons is therefore an important strategy to influence referential performances and promote behaviour change (Bandura, 1998).</p>
Providing appearance-based information	<p><u>Evidence:</u> Various systematic reviews (Dodd and Forshaw, 2010; Williams <i>et al.</i>, 2013; Chapter 2). The desire to have a tan is a central motive for UV exposure, as most people believe that a tan will improve personal's appearance (e.g. (Jones and Leary, 1994; Turrisi <i>et al.</i>, 1998; Mahler <i>et al.</i>, 2003b). Research also shows that people find others more attractive when they have a tan (Jones and Leary, 1994; Mahler <i>et al.</i>, 2003b; Chapter 2). Thus, interventions that highlight the negative effects of UV exposure for one's appearance might lead to significant behaviour change (e.g. (Mahler <i>et al.</i>, 2003b; Chapter 2)</p> <p><u>Theory:</u> As mentioned above, people will engage in actions that are likely to produce positive outcomes based on outcome expectancies (Bandura, 1998).</p>
Self-regulatory strategies	<p><u>Evidence:</u> Even though no conclusive evidence was unveiled by the completed systematic review (Chapter 2), other systematic reviews have shown that these strategies can be effective in changing other</p>

	<p>behaviours (Dombrowski et al., 2010; Knittle et al., 2010).</p> <p><u>Theory:</u> According to the Control Theory (Carver and Scheier, 2001), feedback on performance provides external feedback on the achievements and can lead to behavioural change.</p>
Prompt self-monitoring of behaviour	<p><u>Evidence:</u> Previous systematic reviews have shown the efficacy of this strategy in changing behaviour (Michie <i>et al.</i>, 2009b; Dombrowski <i>et al.</i>, 2010).</p> <p><u>Theory:</u> Self-monitoring is a key strategy for behaviour change for both the Control theory (Carver and Scheier, 2001) and the Social Cognitive Theory (Bandura, 1997). Monitoring present behaviour can lead to comparisons between actual behaviour and standards and, subsequently, adjustments in performance in order to reach behavioural standards.</p>

Regarding modes of delivery, the moderator analysis from the systematic review (Chapter 2) showed that interventions using written information seemed to be more effective than interventions using interactive sessions. For all other features of intervention delivery, no clear associations with efficacy were observed.

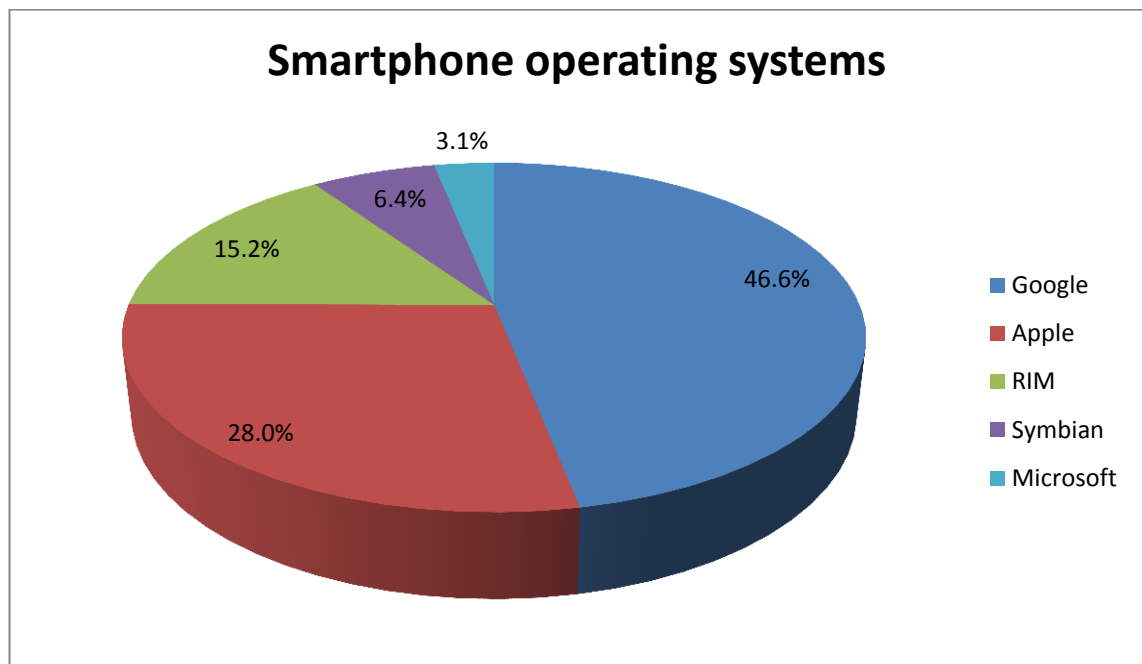
Even though the systematic review did not provide specific evidence regarding mobile-phone use as a possible mode of delivery for the intervention components, other evidence suggested that this might be a novel, convenient and feasible way of reaching the target population (Fry and Neff, 2009; Cole-Lewis and Kershaw, 2010; Heron and Smyth, 2010; Free *et al.*, 2013). Holidaymakers are a volatile population with varying locations which may make them difficult to reach. Therefore, a scalable and geographically flexible mobile-phone intervention might be an effective way of reaching this population.

Smartphones are a particularly relevant mode of delivery as they offer not only standard functions (e.g. call and text messaging services), but also advanced computing and communication features (e.g. internet access; geo-positioning systems; high-resolution cameras). Smartphones provide a profile of 'any time, any place' to individuals as connectivity is continuous and pervasive (Boulos *et al.*, 2011). This feature holds several advantages for behavioural medicine: a) embedded location information (e.g. GPS) can provide many important opportunities for hard to reach populations; b) continuous uninterrupted data log; c) capacity to support various multimedia applications; and d) portability (Boulos *et al.*, 2011).

Smartphone ownership in the UK has been rising rapidly. Ofcom's Communications Market Report (2013) reveals that half of all adults in the UK own a Smartphone (51%)

This number has nearly doubled over the past two years alone. Amongst Smartphone users, 47% of adults have downloaded an app (mostly free, music- and game-based apps). As shown in Figure 4-2, the majority of Smartphones owned in the UK run on Android operating system (comScore, 2012 ), which is the fastest growing operating system (46.6%), followed by Apple in second (28.0%) and Blackberry RIM operating system in third (15.2 %). According to recent trend analysis, these numbers are likely to increase to 80-90% of the UK population owning a smartphone within 10 years (Boulos *et al.*, 2011).

**Figure 4-2: Share of smartphone operating systems in the UK (Oct 2012), adapted from comScore MobiLens® (2012 ).**



### 4.3.2 Intervention design

#### Experts' consultation

After gathering, collecting and analysing information regarding state-of-the-art evidence, the design and development of the mobile-phone application process was overseen by an interdisciplinary group of experts:

- Falko Sniehotta - Reader in Health Psychology with experience in developing and evaluating theory-based interventions and psychological theories of behavioural change;
- Vera Araujo-Soares - Senior Lecturer in Health Psychology with extensive experience in the design and development of evidence- and theory-based behaviour change interventions both as a clinician as well as a researcher;



- Mark Birch-Machin - Professor of Dermatological Sciences with experience on the cutaneous response to ultraviolet radiation (UVR) in terms of skin ageing and cancer and expertise in sun-awareness education strategies.
- Patrick Olivier - Professor of Computing Science and his team with a vast amount of experience on the application of pervasive computing to health and wellbeing, as well as the development of new technologies for interaction.

The PhD student used the information retrieved from the systematic review (Chapter 2), as well as the information retrieved from the consultation with the experts mentioned above to draft the mISkin mobile-phone intervention prototype.

This was an iterative process of expert consultation as input was provided at different points in time from the initial design and concept to initial informal usability testing.

#### Description of the mISkin application: a personalised mobile-phone intervention

The proposed mobile-phone intervention ('mISkin' application) runs on the Android Operating System as a touch screen application ('mISkin' app). The app entails a behavioural intervention comprising several behaviour change techniques to promote sun-protective behaviours amongst holidaymakers. The elements within this intervention derive from a thorough process of evidence-based of intervention development.

The main behaviour change techniques (BCT's) used in the app are: provide general information about consequences; provide instructions for effective sun-protective behaviours; demonstrate effective sun-protective behaviours; and provide cues/prompts for action. Table 4-2 describes the main features of the mISkin app with explicit justification of inclusion based on evidence. Figure 4-3 details the workflow of the interaction process within the mISkin app. The interfaces (screenshots) of the resulting prototype intervention can be found in Appendix F.

**Table 4-2: Description of the mISkin app main features/behaviour change techniques and rational for inclusion.**

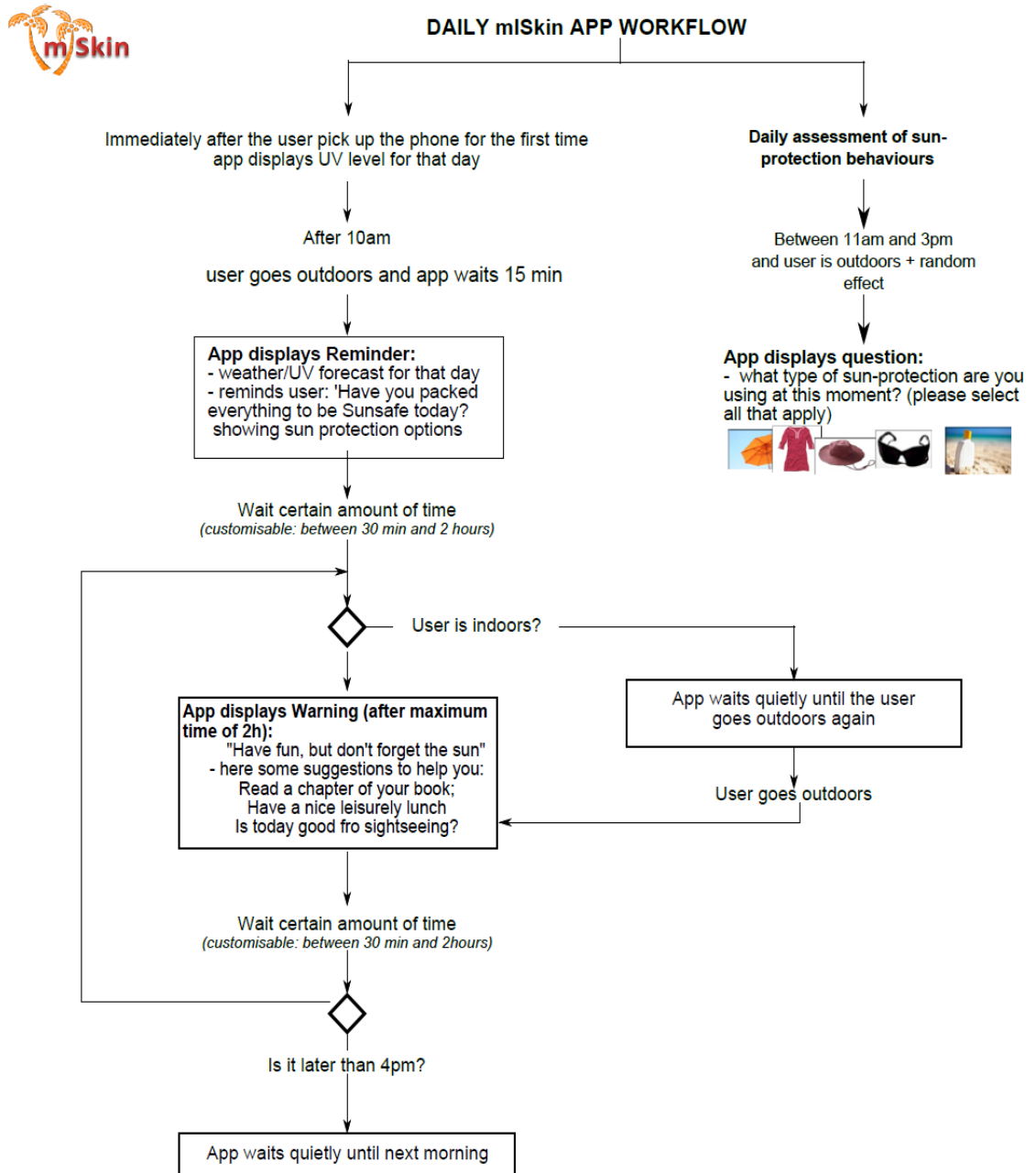
Feature name	Description	Rational for inclusion
<i>Skin sensitivity assessment with feedback</i>	<p>Set of 5 questions about skin reaction to the sun based on previous literature (e.g. (Fitzpatrick, 1988; Weinstock, 1992). After completion, participants receive feedback about their specific skin type and their reaction to sun (e.g. 'You have skin type III, Sometimes burns, usually tans').</p> <p>BCTs used<sup>15</sup>: Provide information on consequences of behaviour to the individual.</p>	<p>Understanding their personal risk to sunburn will help people understand how to better protect themselves from the sun.</p> <p>Evidence: systematic review (Chapter 2) outlines the importance of understanding the consequences of excessive sun exposure.</p>
<i>NHS Choices 'How to apply sunscreen' Video<sup>16</sup></i>	<p>The video provides information how to properly apply sunscreen, stating specific information about quantity, frequency, SPF, star rating system, apply before leaving the house, where to put it on and costs. The video also demonstrates how to apply sunscreen properly by showing a model doing it. The importance of other methods of sun protection is also discussed in the video (i.e. covering up and seeking shade). Special attention is devoted to children and the need for additional information about sun protection. The risk of sunburn and skin cancer is also highlighted in the video. A snapshot from the NHS Choices video 'How to be Sun Smart' was also included to foster social comparison on sun protection habits.</p> <p>BCTs used (Michie et al., 2010): Provide information on consequences of behaviour in general; Provide information on where and when to perform the behaviour; Provide instruction on how to perform the behaviour; Model/Demonstrate the behaviour.</p>	<p>The video tackles all important instructions regarding sunscreen application, providing a complete display of the 'how to do it' technique. The video also provides information about other methods of sun-protection and the consequences of excessive sun exposure.</p> <p>Evidence: systematic review (Chapter 2).</p>
<i>UV photos</i>	<p>The app submenu 'How to be SunSmart' also includes UV photos. Before displaying the pictures, a brief description is provided.</p>	<p>The inclusion of these types of photos helps highlight the harmful effects of UV exposure for people's appearance and, subsequently, promotes sun protection habits.</p>

<sup>15</sup> The BCTS classification is based on the taxonomy produced by Michie and colleagues (2010).

<sup>16</sup> Permission was granted by NHS Choices to be used in the mISkin application.

	BCTs used (Michie et al., 2010): Provide information on consequences of behaviour in general; Fear appeals.	Evidence: systematic review (Dodd and Forshaw, 2010; Williams <i>et al.</i> , 2013; Chapter 2).
'Sun safety Quiz'	<p>This component involves holidaymakers playing the 'Sun Safety Quiz' by answering true or false to questions on general principles of sun protection practices, and information on positive consequences of sun protection, tanning, vitamin D and the UV Index.. This is a gamification component, in which participants receive performance-based rewards (i.e. positive feedback and final score message).</p> <p>BCTs used (Michie et al., 2010): Provide feedback on performance; Provide information on consequences of behaviour in general; Provide information about others' approval; Provide normative information about others' behaviour; Facilitate social comparison.</p>	<p>Gamification is seen as a process that uses 'gaming' elements to motivate people outside of gaming contexts (King et al., 2013).</p> <p>In this quiz, not only the gamification aspect was included, but also the provision of relevant information relevant to promote sun protection.</p> <p>Evidence: Systematic review s (Primack <i>et al.</i>, 2012; King <i>et al.</i>, 2013; Chapter 2) .</p>
'Sun Alert service'	<p>An algorithm was designed to define main rules for interaction between the app and participants (Figure 1). This interaction is especially important to establish rules for the prompts for action. These prompts will occur between 10am and 4pm and will depend on participant location (indoors/outdoors information based on mobile-phone GPS). Participants will receive approximately 2/3 prompts per day. In these prompts, UV levels forecast will also be provided for the time participants are on their holidays.</p> <p>BCTs used (Michie et al., 2010): Prompt practice.</p>	<p>Several studies show that forgetfulness is a key barrier for sun protection (Araujo-Soares <i>et al.</i>, 2013a). We believe that prompting will help individuals to remember about sun protection methods at least at two moments: 1) start of the day, just before temperature starts increasing (i.e. 10am); and 2) at midday when sun protection is most needed.</p> <p>Evidence: systematic review (Chapter 2)</p>
Diary record: ecological momentary assessment	<p>A real-time data capture through the mobile-phone application is also used for assessment of sun protection practices. This assessment will occur randomly between 11am and 3pm if the individual is outside (as detected by the GPS on the mobile-phone). Sun protection practices will be represented by the use of symbols/pictures (Figure 2).</p> <p>BCTs used (Michie et al., 2010): Prompt self-monitoring</p>	<p>Self-report is prone to inaccuracies and biases in the reporting of behaviour (Stone et al., 2003). Smartphones can be an effective and feasible alternative to self-report for sun protection assessment, especially because these devices can collect behavioural events in natural settings and produce time- and date- stamp events (Stone and Broderick, 2007).</p> <p>Evidence: systematic review (Stone and Broderick, 2007).</p>

Figure 4-3: The mISkin app workflow.



### 4.3.3 Evaluation of the mISkin app prototype: user-centred study

After the initial prototype was developed there was the need to test for ease-of-use, graphics appeal and general comprehension and acceptability of the distinct features of the mISkin app, using a user-centred approach and semi-structured interview methods.

## Participants<sup>17</sup>

Participants were recruited through advertisement leaflets (Appendix B) placed across Newcastle University and Newcastle upon Tyne community settings (e.g. supermarkets notice board, nurseries notice board, sports groups/associations). Eligible participants had to be over 18 years old, own an Android smartphone, and had previous experience of holidays abroad. Participants comprised of 17 adults (13 women and 4 men) that fell within the age range of 21 to 62 years old (20-34y: n=9; 35-49y: n=5; 50-65y: n=3).

## Materials and procedure

The study was fully reviewed and approved by the Faculty of Medical Sciences Ethics Committee (Newcastle University) prior to commencement (Reference no: 00427\_2/2013).

Included participants were assessed for inclusion criterion by the researcher (AR) and were required to provide informed consent before participation. Participants were assured that all data collected through interviews would be kept confidential and would only be available to members of the research team. In line with good practice, all recordings will be kept for six years, making them available for re-analysis if necessary. Data was collected between May and June 2012 and interviews were conducted by a female researcher (AR) with experience in interviewing.

Interviews lasted between 30-50 minutes and were audio-recorded with respondents' consent. The recordings were anonymously transcribed verbatim before analysis.

Participants completed a standard self-reported questionnaire to assess skin sensitivity (Appendix 1) based on Fitzpatrick's skin types (Fitzpatrick, 1988). This also included questions about their estimated sun exposure without sun protection based on their self-reported skin type.

The semi-structured interviews were guided by a topic guide specifically designed for this study (Appendix G). The interview started by showing the mock-up of the mISkin app that included the main screens and all its features (Appendix F).

---

<sup>17</sup> The user-centred study was conducted with the same sample as used in Chapter 3, immediately after completing the semi-structured interview investigating perceptions of sun-related experiences. The interviews were organised in two parts: part 1 explored solely perceptions about sun protection as described in chapter 3; and part 2 followed the structure described in the topic guide (Appendix G). In order to avoid contamination from the information provided when viewing the app prototype to participants' knowledge and beliefs about sun protection, the user-centred study was conducted immediately after the qualitative work (Chapter 3).

Participants were then asked about their perceptions and feelings about the specific features of the mISkin app, including their perceived usefulness, relevance and their concerns about the app functionalities. Questions addressed participants' reactions to: a) a potential mobile intervention to be redeployed over holiday and b) the prototype, focusing on practical issues of the app such as layout, colours, number of prompts, written information and prompt content, video content and length, functionalities, sounds, and time constraints.

### Data analysis

All transcripts were imported into NVivo 10.0 (2010). Information regarding feedback on the prototype was summarised into main suggestions/thoughts, in order to refine the mobile phone app accordingly before the feasibility and acceptability pilot study.

### Results

Seventeen participants were shown the mISkin slideshow mock up (including all screenshots and interaction possibilities), where the researcher provided individuals with a brief demonstration of the main functionality of the app. Participants were asked to interact with the mock up and provide feedback, highlighting their likes and dislikes about the design, content and format. Individuals were also asked to provide suggestions for improvement.

#### *Ease-of-use of the mISkin app*

Overall, the intervention was well-received by participants and described as appealing and interesting to use.

*'Having the information is good as I don't think people know. Also the reminders are good as on holidays sometimes you forget and it's good to be reminded' (Female, 32, skin type III).*

*'I like the tone about you're on holidays, here is how to be on holiday without 'killing yourself', like the kind of how to enjoy your holiday' (male, 28y, skin type IV).*

The majority of users interviewed found that the app was useful and stated that they would use it on their holidays. There was a general satisfaction with the app as portrayed in the following participants' words:

*'It's probably something that I would use and particularly the reminders would be good as well' (male, 45y, skin type II).*

Most users mentioned the ease-of-use of the app, how the app is “easy to interact with” and information is easily understandable.

*‘Information needs to be there so that people know and can protect themselves. It was simple information and got the message over. I don’t think it was boring, it was informative and that’s something you need’ (female, 55y, skin type II).*

#### *Recommendation for improving the ease-of-use of the mISkin app*

From on the mock up shown to participants, some changes were suggested by users in order to improve acceptability and usability of the mISkin app. Table 4-3 summarizes users’ feedback on the specific features of the mISkin app and changes that were introduced to the app to improve ease-of-use.

The decision to keep the UV photos in the app was based on the data from the interview since all participants (even those whose opinion was not so favourable) thought it was important to show it. In addition, strong evidence from the completed systematic review suggested that the use of these types of images might be effective in motivating people to improve sun protection practices whilst on holiday.

#### Appeal of the different interfaces of the mISkin app

All participants provided positive feedback regarding the appearance of the mISkin app, stating that the background image, design, graphics and colour scheme were all appealing.

*‘I quite like the design’ (female, 55y, skin type II).*

All of the participants questioned stated that they would not pay for this kind of app, justifying their statements on the existence of similar health-related apps on the Play Store available for free.

**Table 4-3: Feedback on the mISkin app provided by participants in the user-centred study.**

Intervention component	Suggested changes (example quotes)	Changes implemented in the intervention
Skin assessment	<p>‘Information about specific skin types was quite useful.’</p> <p><u>Order of questions:</u>  ‘Having the question about the skin reaction before the colour of the skin in the skin assessment.’</p>	The questions about skin reaction were changed
Videos	<p><u>Video content:</u>  ‘It would be quite useful to see the clip again after seeing all the information in the little quiz or having the video after.’  ‘I like the practical advice about how much sunscreen to put on. I would say it would be more effective if it didn’t leap straight into skin cancer and it started with choose a good sunscreen and then link to the consequences of not doing it.’  ‘I think it would be quite good to have a checklist at some point that we could look up.’</p> <p><u>Video length:</u>  ‘Instead of having a very long video having the different sections.’</p>	<p>A video menu was added to make navigation through different sections easier (e.g. how to apply sunscreen, instructions for other sun-protection behaviours)</p> <p>Different snapshots of the videos were added to the menus, shortening information displayed  The video menu was organised so that skin cancer information is the last video displayed</p>
Sun safety quiz	<p><u>Content:</u>  ‘In the quiz, instead of saying just true or false, say something like you’re correct or that’s wrong.’  ‘I like the quiz bit; you can do it once.’</p> <p><u>Confusing statements in quiz questions:</u>  ‘Tricky question the one about sunburn doubles the risk of skin cancer.’</p>	<p>Explicit feedback on performance was added.</p> <p>The sentence was changed to ‘increase risk of melanoma’</p>



Prompts	<p><u>Content:</u>          'Like you say stay out of the sun between 10 and 4pm. Give some ideas how to do that. Like say have a nice long leisurely lunch sounds much better than you must stay in the shade between 10 and 4pm.'</p> <p><u>Frequency:</u>          'I quite like it particularly the prompts. I would probably like to have a bit more, have the opportunity to remind me a bit further.'          'I like the idea of a sunscreen reminder app that I could set up to my preference.'</p>	<p>Some suggestions on how to seek shade between 10am and 4pm were added to the reminders.</p> <p>A preference setting was added to the alert service, so that reminders are customizable (i.e. 30 min to 2hours).</p>
UV photos	<p><u>Reaction:</u>          'It's quite scary though, is it? I've seen a few of these before and it always makes you feel I should put more on.'          'It's a good idea to have it in and it's better than when that woman talking. Just put it a bit earlier in the app. it's the shock factor that would make you think: oh I don't want to look like this. So I suppose it should be in...'          'It's quite scary; it might put me off the app. that the last thing I want to see on holiday.'</p>	<p>UV photos were moved to the video menu and were placed as the last available option to be seen. A brief explanation was also added so that participants are aware of what it implies and know what to expect.</p>

#### **4.3.4 Refinement of the mISkin intervention**

The refinement of the mISkin intervention phase was informed by the results of the user-centred study and by the qualitative study conducted in parallel (Please see Chapter 3 for a full description of this study).

The qualitative study reported in Chapter 3 investigated perceptions of sun-related experiences and the relevant behavioural determinants of sun-protective behaviours. Findings suggest that respondents showed a desire to tan and attributed a high value to acquire a tanned appearance over holiday. The harming effects of sun exposure were universally recognised. Most respondents knew how to perform sun-protection behaviour, but several key barriers to sun protection were identified: the impact of these behaviours on the holiday experiences, the fear of social consequences, inconvenience of sun protection and lack of environmental resources. Some self-regulatory strategies were identified by participants as facilitators of sun protection. The conclusions from this study suggest that future public health messages should highlight the harmful effects of sunlight on appearance and strategies that demonstrate effective ways of performing sun protection practices (e.g. applying sunscreen properly).

Based on the user-centred approach, as well as on the results of the parallel qualitative study on the holiday experience, the prototype app was refined. The final version of the app can be consulted in Appendix H.

#### **4.4 Discussion**

This chapter describes a systematic approach to the development of an intervention to promote sun-protective behaviours amongst holidaymakers. Following closely the guidelines outlined by the MRC framework (Craig *et al.*, 2008; Craig *et al.*, 2010), this process was informed by both: state-of-art evidence and theory in order to increase the chances for meaningful behaviour change. The paper details the process by which evidence and theory informed the design of the intervention prototype app.

The MRC guidance on the development of complex interventions is widely recognised and entails a specific set of processes and methods that will enable replication and transparency (Craig *et al.*, 2008; Craig *et al.*, 2010). A systematic approach to the development of complex interventions will enrich the process whilst at the same time allow for thorough and well-documented development stages. The initial phase encompassed a systematic review (Chapter 2) on interventions to promote sun protection in holiday/touristic settings. Even though the key conclusions informed the development of the mISkin intervention, several limitations in the best available

evidence were also identified, such as the lack of: a) objective outcome measurement procedures; b) sufficient information about intervention procedures and components; and c) stated theoretical frameworks for the intervention' design. By explicitly outlining these limitations, the review sets up a path for future research, in which interventions should be developed following a systematic approach with a better description of the intervention and based on available evidence and theoretical frameworks. Recognising the dangers of only basing the development of the intervention on information retrieved from a systematic review that concluded evidence was weak, the development of the mISkin app incorporated other sources of information, such as other literature, experts' consultation and data from a user-centred study.

An important consideration for any intervention aiming to promote sun protection is the fact that this behaviour is very specific and seasonal. The developed mISkin intervention aims to support people during their holidays, but a limitation of this focus can be the lack of maintenance of sun protection in the future holidays. This shortcoming should be tackled in future versions of the app by using self-regulation BCTs (e.g. goal setting, planning, self-monitoring, feedback, and relapse prevention.) to promote the maintenance of sun protection.

A challenge to the mISkin intervention is how to involve people who might be less motivated to use sun protection, as it can attract users already fairly motivated. In future versions of the app or even for branding purposes, these aspects need to be tackled, in order to involve less motivated users. A possible way of marketing the app in the future could be to associate the sun safety messages with an app primarily branded as a weather app. Other possible marketing and dissemination strategy could be to involve travel agencies. These could offer the app (with more motivational active ingredients) as part of their customers' experience.

This study sought to use a user-centred approach by engaging potential holidaymakers in the refinement and further development of the mISkin app through usability (ease-of-use) and acceptability testing of the intervention prototype. Interviews were analysed in order to integrate feedback on the app into the refinement process before the internal pilot. All 17 participants were satisfied with the mISkin prototype and expressed willingness to use it. A few changes were introduced to optimise acceptability (e.g. customisable prompts, shortened videos) based on users' feedback.

The use of a ubiquitous system as mode of delivery for the mISkin intervention follows the evolution of technology in mobile-phones, by which subjects are always connected and can be reached at any location (Boulos *et al.*, 2011). This possibility is a clear

advantage as, on one hand, holidaymakers are a hard to reach population and, on another hand, it enables the scalability of the mISkin intervention.

Following the study by Buller and colleagues (2013) on the Solar Cell mobile application, the study reported in this chapter also shows that an mHealth intervention can be well-received by individuals and that there is great acceptance and willingness to engage with mobile-phone applications that target sun protection practices. A recent study by Dennison and colleagues (2013) also shows that young adults are interested in using health-related applications. However, based on individuals' suggestions, authors concluded that to increase acceptability and willingness to use, the app should include: a) features that are effortless and easy to interact with; b) avoid provoking adverse emotional reactions by providing relevant and timely support; and c) context sensing (e.g. emotional state by voice recognition) to identify if individuals are in a receptive mood to engage with the app features, and subsequently behaviour change.

As mentioned previously, recent evidence suggests the importance of appearance-based beliefs and how interventions in this area should aim at tackling those (Dodd and Forshaw, 2010; Williams *et al.*, 2013). One possible way is by showing personalised UV photos to people, as these are an excellent way to visualise sun damage (Dodd and Forshaw, 2010; Williams *et al.*, 2013). For practical reasons and resources available at the time of this study, this component was not personalised in the mISkin app, which might influence the impact of the intervention in changing sun protection behaviours. Future studies should explore if the effects of visualising non-personalised UV photos are equivalent to personalised UV photos.

Even though the use of gamification within the mISkin app is original, more efforts could be made in future versions to make this feature more interesting and help engage users' interest. The current quiz has a set of questions that, despite allowing participants to go through it several times, it is always the same. For this reason it will be very unlikely that users will really go to it more than once. A possible way to make this more attractive and further 'gamify' would be to allow questions to change over time and gradually increase in difficulty (i.e. people could work from being a novice towards being an expert). The study was limited by a small convenience sample, mostly driven from a university population, which limits the generalization of our findings. The study did, however, produce relevant information about users' perspectives on the acceptability and usability of the mISkin mobile-phone application. Another aspect that might have constrained the findings of this study was the fact that the sample was the same as the one used for the qualitative work described in chapter 3. Even though they were organised into distinct parts, the interviews were conducted

at the same time. In order to avoid contamination from the information provided when viewing the app prototype to participants' knowledge and beliefs about sun protection, the user-centred study was conducted immediately after the qualitative work (Chapter 3). Another limitation of this study is the fact that the views were based on only visualising a prototype intervention aimed to be delivered when on holiday abroad. Views of using the app could possibly change if participants actually interact with the mISkin app in a real situation of being on holiday. In addition, the user-centred study did not explore what participants would want to see in an app for sun protection during their holidays. Instead they were shown the prototype of the mISkin app, potentially losing their general and *a priori* ideas about what should be in a sun protection app. Nevertheless, to understand the scope for such an intervention in a holiday setting, the topic guide addressed aspects such as mobile use on holiday and holiday' lifestyle details. Even though the majority of participants said they would not pay for an app of this kind, it is important to note some of the limitations of how this topic was explored. This was assessed by a close-ended question, which might not have been appropriate. Future studies should explore this issue by using more appropriate methods, such as visual analogue willingness-to-pay. Finally, the mISkin app was developed for the Android operating system only and it was only accessible on Android devices (i.e. Android smartphones and tablets), limiting the possibility of including users owning smartphones on other platforms (e.g. iPhone, Blackberry). In conclusion, this study demonstrated the systematic development process of a mobile-phone intervention for sun-protection, following both the MRC framework approach with user-centred design. The prototype testing provided useful information regarding users' views and experiences of engaging the mISkin application. Suggestions made by participants were incorporated in the refinement and development of a fully functional mISkin application. The next step is to evaluate the acceptability and feasibility of the mISkin app to change sun protection practices of holidaymakers in touristic settings and validate that this specific mHealth intervention is a feasible vehicle to deliver an intervention aiming at improving sun protection.

# Chapter 5 Development of novel objective measures of sun protection behaviours

## 5.1 Abstract

Outcome measurement in studies assessing the impact of behavioural intervention to promote sun protection behaviours often relies on retrospective self-reports, often without information regarding reliability and validity. This chapter will explore the proof of principle of novel outcome measures to assess: a) patterns of sunscreen application (study 1); and b) consequences of sun exposure on the skin (study 2). This chapter will address the previously identified need for reliable and valid methods to assess patterns of sun protection behaviours and will provide more robust measures of sun exposure (using consequential damage in the epidermis as a marker of solar UV irradiation).

Study 1 explored the validity and feasibility of using accelerometry (AX3 sensors) to detect patterns of sunscreen application and develop the methods and process of identifying instances of sunscreen application. Study 2 evaluated whether a previously developed procedure to quantify a biomarker of sun-exposure from mitochondrial DNA (mDNA measure) could be adapted to allow skin damage assessment in the context of the mISkin trial.

Data from Study 1 suggested that residual sunscreen weight was considered to be a feasible method of assessing sunscreen use in a population of holidaymakers. A silicone band was designed and developed to attach an AX3 sensor to a sunscreen bottle and findings suggest that the classifier can detect sunscreen use events. In Study 2, a test for mitochondrial DNA (mDNA) damage as a result of solar UV exposure has been investigated as a possible method to assess sun protection behaviours by using a proxy measure, in this case the consequences of overexposure to sunlight on the human skin (epidermis). Participant skin samples were taken using a non-invasive technique (skin swab) and assessed using a previously established and routine laboratory method (qPCR).

Data from the two newly developed methods of outcome assessment (sunscreen use events classifier and UV-induced mDNA damage) have provided robust support for their use in the assessment of sun protection behaviours and skin damage over holiday. This work will contribute to the development of a full protocol for the outcome assessment in a future trial exploring the impact of a behavioural intervention on sun protection behaviours.

## 5.2 Introduction

Outcome measurements in the majority of trials included in the systematic review (Chapter 2) were based on retrospective self-reports, often without information regarding reliability and validity of the outcome measures. Self-report questionnaires are the conventional procedure to collect data about sun-protection practices. However, these methods are prone to recall and presentation bias. The reliability and validity of the generated data is often unknown. In addition, questionnaires frequently differ from study to study, making it difficult to directly compare effects between studies. Most studies included in the systematic review (Chapter 2) reported on a composite measure of sun-protective behaviours, summarising a range of self-reported sun-protective behaviours as primary outcome. While the use of self-report is often criticised for its risk of bias, more precisely recall bias (i.e. inaccuracies in reporting information about a given behaviour), self-reports can be useful to understand patterns of sun protection use.

Five studies included in the systematic review (Chapter 2) used a variety of observational methods that included covert recording of hat use (Mayer *et al.*, 2001) to body surface protection indices based on observation of different types of protection (Dietrich *et al.*, 1998; Glanz *et al.*, 2000; Buller *et al.*, 2005; Dupuy *et al.*, 2005). Although observation procedures are well established, this method is prone to observer bias (i.e. bias resulting from researchers' influences on their observations during the study), possibly influencing the data collected regarding sun-protective behaviour (Waddington, 2004). However, some limitations were also identified. Where observational measures were used, they often involved considerable risks for social desirability biases through insufficient blinding of assessors and participants (e.g., in one of the trials study personnel in branded clothing approached adolescents on the beach to ask questions on sunscreen use and record clothing).

Objective measures of sun protection behaviours are needed to support the development of a gold standard measure for sun-protective behaviours. An objective measure commonly used in similar studies to assess sun protection is residual sunscreen weight. This method was used by two studies (Dupuy *et al.*, 2005; Nicol *et al.*, 2007) included in the systematic review (Chapter 2). In both studies participants were given sunscreen bottles and sunscreen use was measured by weighing sunscreen bottles before and after the study. Even though the quantity of sunscreen applied is important, amount on its own does not guarantee an appropriate usage of sunscreen. The pattern of application and, more importantly, if and when sunscreen is reapplied provides additional information about effective use of sunscreen.

One unexploited opportunity to improve outcome assessment might be the use of new technologies since affordable and scalable handheld diaries, global positioning systems (GPS), UV dosimeters, and small scale accelerometers built into sunscreen bottles are a reality nowadays.

This chapter will focus on: a) exploring valid and feasible methods of assessing patterns of sunscreen application over holiday; and b) demonstrating that using the methods developed by Harbottle and colleagues (2010) viable samples of skin swabs can be obtained using a pre-specified protocol with holidaymakers. This chapter will describe the methods used to identify possible measures of sun protection behaviours. It will also describe the development of new measures to assess sun protection of the skin itself, with discussion of the methods used and subsequent findings. Finally, strengths and limitations will be highlighted, concluding with general remarks about sun protection outcomes measurement in future research.

## **5.3 Study 1: Patterns of sunscreen application**

### **5.3.1 Introduction**

This study aimed to explore possible ways of detecting patterns and timing of sunscreen application alongside traditional volumetric measurement of sunscreen use. Even though residual sunscreen weight provides important information about the quantity of sunscreen applied, it provides no information about the times and patterns of application.

A study conducted by Armstrong and colleagues (Armstrong *et al.*, 2009) used an electronic adherence monitor adaptable to different sunscreen bottles that detected sunscreen use each time the cap on the tube was removed. This system recorded dates and times of sunscreen use in a familiar environment, providing additional data regarding patterns of sunscreen use. Although novel, this system could be improved by making the technology smaller, more flexible and adaptable so it could be taken on holiday by the target population.

### **5.3.2 Sample**

This initial sensor testing included 15 testers who were filmed exploring different standardised scenarios of sunscreen application. Testers were identified within the university department and were asked to simulate the behaviour with the sensor system.

- These sessions targeted the following scenarios:
- Different sunscreen bottle volumes (almost empty, half bottle, full bottle);



- Handedness (left or right);
- Different patterns of application (complete sunscreen application on both arms, only one arm, slow movement application, squeezing the bottle, shaking to get final bit of sunscreen).

To facilitate the distinction between sunscreen events and background data (e.g. travelling), sensor testing also included sessions with 6 different types of transportation movements:

- Walking with sunscreen in hand (with and without stairs);
- Walking with sunscreen in a bag (with and without stairs);
- Running with sunscreen in a bag;
- Cycling with sunscreen in a bag;
- Bus journey with sunscreen in a bag;
- Car journey with sunscreen in a bag.

### **5.3.3 Materials**

To develop a more flexible system, a silicone band was designed and optimised to attach a AX3 sensor (accelerometer) to a specific type of sunscreen bottle (Ambre Solaire, Garnier™). For each session, the sunscreen bottle with an attached sensor was used and a unique record of the individual session was created.

### **5.3.4 Procedures**

This work was conducted in collaboration with the Computer Scientists team at Newcastle University and under the supervision of Professor Patrick Oliver. (<http://di.ncl.ac.uk/people/nplo>). Ethical approval for this study has been granted by the Faculty of Science, Agriculture and Engineering at Newcastle University.

After this initial product development stage, a pilot study was conducted to test the technology and aid the process of developing sensitive and reliable mathematical equations capable of identifying the specific movements associated with the use of sunscreen. This process also tested the sensors to address and prevent any malfunctions before including them in the trial's outcome assessment protocol.

Video footage of the different sunscreen applications for the sessions described above was taken. Data from the videos were synchronised with the sensor's data and annotated for every sunscreen event. In addition, for the sessions assessing the transportation movements, a diary of activities was completed by participants with specific details regarding dates, times and commuting modes and times.

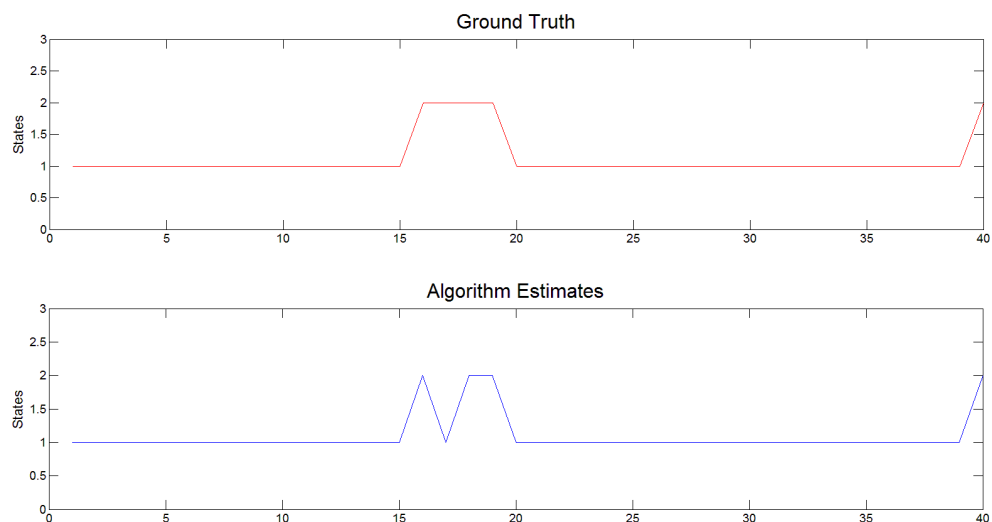
The newly developed classifier was tested using the k-Nearest Neighbours algorithm ('knn'). The approach of k-Nearest Neighbours is a common statistical method used for the classification of patterns (Cover and Hart, 1967). In addition, sensitivity (i.e. ability to identify positive results) and specificity (i.e. ability to identify negative results) of the 'knn' were also calculated.

### 5.3.5 Results

Based on the 15 sessions, a sunscreen application event classifier was developed and features were calculated following the approach suggested by Casale and colleagues (2011). The sensitivity and specificity of the 'knn' for the classifier were calculated as 91% and 98%, respectively. This finding demonstrates very good classifier sensitivity (i.e. predicts the majority of events as sunscreen events) and almost perfect specificity (i.e. does not predict the majority of background data as sunscreen events).

Figure 5-1 shows an example of the classification results based on classifier 'knn' for sunscreen events classifier. Two sessions were chosen as the test datasets and the rest of the sessions were used for foreground model training. In this example, state '2' denotes the sunscreen active detection and state '1' denotes the background data.

**Figure 5-1: Example of the Classification Results.**



### 5.3.6 Conclusion

A novel measure to assess patterns of sunscreen application has been validated. Findings show that the sunscreen use events can be reliably identified using the newly developed classifier. Accelerometers have been widely accepted as an appropriate tool to assess kinetic behaviour, mainly due to their compact size, low-power requirement, low cost, and capacity to provide data directly on movements (Casale *et al.*, 2011),

however this new piece of technology needed to be tested in a real scenario of holiday to ensure its ability to detect sunscreen events in a non-controlled environment. In light of that, more validation work about using the sensor in a real-world setting would be beneficial and failing to do so could be seen as a limitation of this work. More precisely, it would be important to appropriately explore how many sunscreen events would be expected during a typical holiday scenario (i.e. frequency and pattern). In addition, it would also be relevant to conduct some validation work between the use of the mISkin app and the detection of sunscreen events. Study 2: Assessing mDNA damage caused by UV exposure.

## **5.4 Study 2: Assessing mDNA damage caused by UV exposure**

### **5.4.1 Introduction**

In the systematic review (Chapter 2), eight studies reported incidence of sunburn as an outcome and three studies measured skin colour. Two studies measured the latter objectively by using a spectrophotometer. While spectrophotometer based methods provide promising measures of skin colour change (indicator of skin damage), they require expensive tools and are labour intensive, limiting the scope for use in larger trials.

Objective clinical measures have been suggested to indirectly measure sun-exposure by quantifying skin damage (Krishnan *et al.*, 2004; Harbottle and Birch-Machin, 2006; Birch-Machin and Swalwell, 2010). More precisely, the use of mitochondrial DNA (mDNA) as a biomarker of UV-induced skin damage, especially for cumulative UV exposure (Birch-Machin, 2006; Birch-Machin *et al.*, 2013; Tulah and Birch-Machin, 2013). The potential of using mDNA to study skin damage caused by UV exposure is mainly associated to the fact that mitochondria are deficient in nucleotide excision repair pathways and cannot repair UVR-induced photoproducts, which accumulate in mDNA (Birch-Machin *et al.*, 2013). Studies have shown that mDNA mutations are increased in sun-exposed skin compared to sun-protected skin (Birch-Machin *et al.*, 1998). Research has found that the common deletion '4977 bp' significantly increases in sun-exposed sites compared to sun-protected sites (Birch-Machin *et al.*, 1998). The '4977 bp' deletion was also detected in melanoma subjects (Poetsch *et al.*, 2004).

A study (Harbottle *et al.*, 2010) tested an innovative test for skin damage using skin epithelial swabs. This involved a using a simple technique (skin swab) to collect a skin sample that is tested for UV-induced mitochondrial DNA (mDNA) damage. Results demonstrated that mDNA damage was higher in skin samples taken from usually exposed to the sun (i.e. scalp, face, neck and ears) compared to occasionally exposed areas (i.e. shoulders, back and chest), in turn demonstrating the effectiveness of the

method in assessing mDNA damage caused by UV exposure. This study did not explore if these differences could also be identified by changing behaviour (e.g. sunscreen use) or changing exposure to the sun (i.e. over holiday). It would be important to test whether this is a reliable method to explore sun exposure over holiday as a primary outcome in a definitive randomised controlled trial.

More recently, a study (Oyewole *et al.*, 2014) has shown that cells exposed to UVA have a statistically significant increase in the levels of mDNA damage compared to a non-irradiated control sample. The cells were irradiated with maximum UVA dose of  $6.5 \times 10^4$  mJ/cm<sup>2</sup> is physiological, being equivalent to 1 minimal erythemal dose (MED) for skin type II. This type of exposure is equivalent to 20 min of sun exposure in Mediterranean country latitude (Webb & Engelsen, 2006). As a further validation of these findings, the same study was also able to demonstrate a similar pattern of UV-induced damage on nuclear DNA (Oyewole *et al.*, 2014).

In the public domain, the Birch-Machin's research group has coined the phrase 'sunburnt DNA' as an aid to represent the concept of sun-induced mDNA damage (Birch-Machin *et al.*, 2013)

#### 5.4.2 Sample

This section reports on several stages of the lab protocol pilot study. An approach by stages was used in order to allow for the protocol to be progressively tested, in which the findings or identified problems resulting from each phase informed the next phase. Table 5-1 outlines the distribution of samples through the several phases of this pilot study. Samples for phase one, two and three were taken from volunteers that consented to be involved in this study and were aged more than 18 years old.

**Table 5-1: Distribution of test subjects during pilot study different phases.**

Lab protocols optimisation <sup>18</sup>			
Stage one	<i>Aim:</i> initial testing of protocol as specified by Harbottle and colleagues (2010)	4 volunteers over the age of 18, 1 sample taken from the nose (N) from each	4 samples

<sup>18</sup> This section has been developed in collaboration with a final-year Biomedical Science Student (Newcastle University) as part of the supervised Dissertation.

Stage two	<i>Aim:</i> testing of the refinements introduced to the protocol based on findings from stage 1	2 volunteers over the age of 18, 2 samples taken from the inner arm (A) from each	4 samples
Stage three	<i>Aim:</i> Due to some inconclusive results from stage 2, two samples from cultured cells with known concentration were included to further test the protocol.	2 volunteers over the age of 18, 2 samples taken from the inner arm (A) from each, and 1 sample taken from the nose (N)	6 samples

### 5.4.3 Materials and procedures

This work was conducted in collaboration with the research group based at the Dermatological Sciences Lab, Newcastle University. Ethical Approval for this study has been granted by the Faculty of Medical Sciences at Newcastle University.

#### Collection of the skin sample

Skin swabs were taken using sterile cotton swabs (Integriswab; Lynn Peavey Corp., Lenexa, KS, USA). For stage one the sample area was sterilized with an alcohol wipe by rubbing down twice per side. The cotton swab was rubbed firmly up and down 20 times.

Refined collection protocol for stages two and three included increased alcohol sterilization (to four times per side), increased pressure while using the cotton swab and finally cotton swab was rubbed up and down 30 times.

#### DNA extraction and quantification

DNA was extracted from swabs using the QIAamp DNA Mini Kit (Qiagen; Manchester, UK) following the manufacturer's protocol, with a selection of adjustments, tested and optimised previously 'in-house', to maximise the amount of DNA extracted. Water was added to the heating block to ensure that the microcentrifuge tubes (Eppendorf; Fisher Scientific; Loughborough, UK) were heated evenly and the time was increased from 10 minutes to 15 minutes. The vortex elements were increased from 15 to 50 seconds (detailed information about the changes made can be found under the results section). PCR sterile water (DNase and RNase-free) was used for elution instead of the kit buffer and two different elution adjustments were tested. These changes and tests were made to optimise the procedure for acquiring the highest DNA yield possible.

### DNA concentration and purity: spectrophotometric assessment

The concentration and purity of the DNA (nucleic acid) sample was determined using the Nanodrop 2000 Spectrophotometer (Fisher Scientific; Loughborough, UK). A 1µl of each extracted sample from stages one and two were individually pipetted onto the pedestal. The DNA content and purity of the sample was measured and the data exported using the complimentary software. Analysis of the Stage three samples was completed on a different date. Each sample was measured on the Nanodrop twice and an average was calculated.

### Real-time quantitative polymerase chain reaction (qPCR) analysis of a 83bp and 500bp mitochondrial DNA

The 83 base pair (bp) real time qPCR assay can be used as a standardising assay which determines the relative copy number of the mDNA. This assay works under the principle that such a small segment of the 16,569bp mitochondrial genome is unlikely to contain multiple strand-breaks (Koch et al., 2001) however is specific enough to the mitochondrial genome to allow identification of the amount of mDNA as a percentage of the total DNA present in a sample. This allows normalisation of the amount of mitochondrial DNA sample used in a given test improving data validity and removing variability due to differences in mitochondrial presence from participant to participant. SYBR Green is a highly sensitive, non-specific dye which binds to all double stranded DNA product to emit fluorescence (Harbottle et al., 2010). The 83bp assay is not for detection but instead used to confirm mDNA concentration.

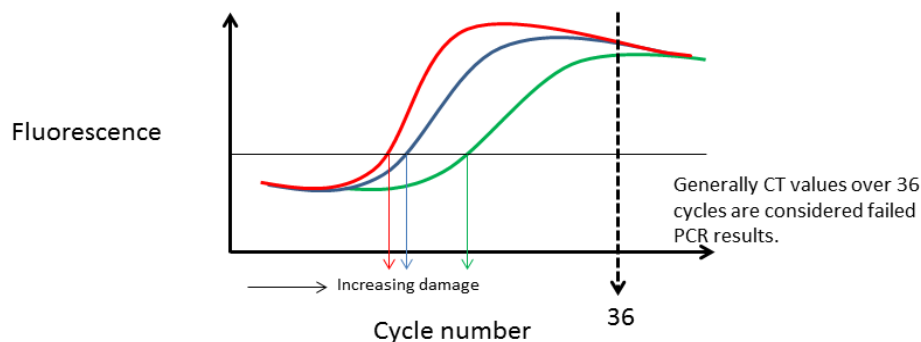
The 500bp qPCR assay is an 'in house' protocol (Birch-Machin unpublished data) which was used to determine the relative presence of mDNA strand breaks per sample. It is considered a reliable assessment mDNA of damage present based on previous experimentation within the research group. The 500bp assay was a suitable choice for this pilot study as it did not require DNA samples with a high concentration (i.e. less material).

Stage one and two qPCR 83bp assays ran together, followed by qPCR 500bp. Amplification reaction was carried out as 25µl triplicates in a fast-optical 96-well Microamp reaction plate (Life Technologies, Applied Biosystems; Paisley, UK). Each well contained 10ng of DNA, 8.5µl 2X SYBR Green Jumpstart (Applied Biosystems), 10µM of each primer. SYBR Green 1 fluorescence was monitored as a measure of sample amplification. The procedure was carried out using a StepOnePlus Real-Time PCR system (Applied Biosystems).

The 83bp and 500bp was carried out for stage three samples on a different date under the exact same conditions, however the 83bp reaction was carried out in duplicate (due to low sample availability) . For the proof of principle study, 83bp and 500bp reactions were carried out under the same conditions and were investigated in triplicate.

Amplification plots generated using SYBR green fluorescence data from the real-time qPCR assays were displayed as cycle number plotted against fluorescence intensity. Each amplification plot has a set threshold at a particular fluorescence intensity depending on the DNA input. The cycle threshold (CT) is the specific cycle number at which the individual DNA sample fluorescence crossed the amplification plot threshold. A sample crossing the amplification threshold at a lower cycle number than another is indicative of fewer strand breaks in the original mDNA present. The presence of fewer strand breaks is representative of less UV damaged mDNA. Figure 5-2 explains the principle of the amplification plot and CT values to determine mDNA damage. Results from the real-time PCR assays used are displayed on amplification plots displaying cycle number against fluorescence. Each amplification plot has a set threshold at particular fluorescence intensities depending on the DNA input. The CT is the specific cycle number at which the individual DNA sample fluorescence reaches above the plot threshold.

**Figure 5-2: The principle of the amplification plot and CT values to determine mDNA damage as seen on results from the real-time PCR assays.**



**Increased mtDNA damage will display a larger CT value:**

Increased damage results in a lower amount of dsDNA being formed despite equal amplification conditions and starting concentrations. SYBR Green only emits fluorescence when bound the dsDNA. Less dsDNA = less emission and therefore requires a greater number of cycle numbers to reach the threshold fluorescence.

## 5.4.4 Results

### Stage One and Two

The protocol optimisation for the skin swab technique procedure was conducted during stage one and two. DNA extracted from cultured cell samples was considerably more concentrated than that extracted from skin swab samples. Cultured cells damaged by

UV exposure had concentrations over 100ng/μl. Epidermis samples collected using cotton swabs were not expected to reach those concentration levels based on previous investigations in the laboratory. Previous experimentation had indicated that for a successful qPCR assay the swab sample concentrations need to be close to >5ng/μl. As presented in Table 5-2, concentrations were relatively low<sup>19</sup>.

**Table 5-2: The concentration of the stage one skin swab samples, obtained using the Nanodrop spectrophotometer.**

Sample	Concentration (ng/μl)	Additional Comments
T1N	0.9	No peak
T2N	0.5	No peak
T3N	1.8	No peak
T4N	10.1	No peak

The Nanodrop graphs did not display the typical peak at the 260nm wavelength, which indicated the likelihood of protein contamination. There was wide variation between first three samples and the final T4N concentration. The average stage one concentration was 3.3ng/μl, but if T4N sample is excluded the average is only 1.1 (n=3).

The sample collection technique was refined for stage two samples:

- Increased alcohol cleaning to 4x each side;
- Increased intensity of rubbing;
- Increased rubbing times from 15 to 30x up/down.

In addition, the extraction procedure was also refined for stage two:

- Time in heating block increased from 10min to 15min;
- Vortexing elements increased from 15s to 50s.

As presented in Table 5-3, the DNA concentrations achieved increased from stage one samples by using the new sample collection technique.

As observed in stage one, stage two concentrations showed an irregular result. The average concentration for stage two is 6.0ng/μl, almost twice the amount of what was observed in stage one. If T6A sample is excluded, the average concentration is 3.5 ng/μl (n=3).

<sup>19</sup> Samples have been named based on the test number (e.g. T1, T2) and the specific site (i.e. 'N' nose and 'A' arm) from where it was taken.



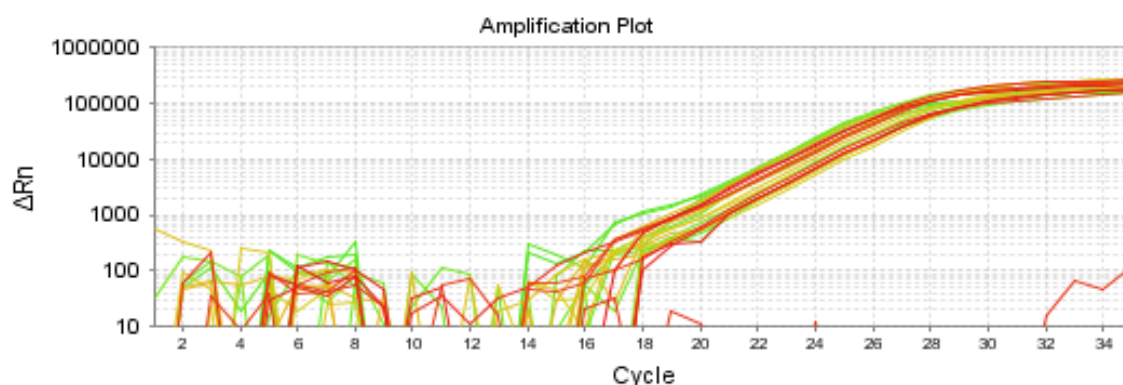
**Table 5-3: The concentration of the stage two skin swab samples, obtained from the Nanodrop spectrophotometer.**

Sample	Concentration (ng/μl)	Additional Comments
T5A	3.1	No Peak
T6A	13.6	No Peak
T7A	3.2	No Peak
T8A	4.2	No peak

PCR analysis of the 83bp mitochondrial DNA assay

As shown in Figure 5-3, the lines representing sample amplification values are close together. Each triplicate sample was sufficiently superimposed, demonstrating suitable standardisation between DNA samples.

**Figure 5-3: Log amplification plot of the 83bp qPCR standardising assay to confirm Nanodrop concentrations.**



X-axis is Cycle number; maximum number of cycles is 35. Y-axis is representative of fluorescence emission intensity. Y-axis (ΔRn) limits adjusted to 10-1000, 000.

The difference in CT value between the triplicates for each sample was small (less than 1). This confirmed the reliability of concentration values determined by the Nanodrop. The range between the mean CT values for the 8 samples is 1.9. For human swab samples, a 2-fold CT difference between sample triplicates was considered as acceptable.

**Table 5-4: Individual CT values for the 83bp assay.**

Sample Name	CT value per replicate	Range*	Mean CT
T1N	24.1	0.3	23.9
	23.9		
	23.8		
T2N	25.8	0.1	25.8
	25.9		
	25.8		
T3N	25.7	0.6	25.6
	25.9		
	25.3		
T4N	24.2	0.8	24.1
	24.5		
	23.7		
T5A	Undetermined <sup>20</sup>	0.3	24.8 (n=2)
	24.9		
	24.6		
T6A	25.4	0.8	25.8
	26.2		
	25.8		
T7A	24.6	1	24.3
	24.7		
	23.7		
T8A	24.7	0.7	24.7
	25.4		
	24		

\*Range between the highest and lowest CT value within the triplicates for each sample

The results from the Nanodrop and 83bp SYBR green qPCR assay indicate the DNA concentrations and the proportion of mDNA present in a given sample was relatively standardised, suggesting that identical volumes of each sample can be loaded as the template in the 500bp SYBR green qPCR assay.

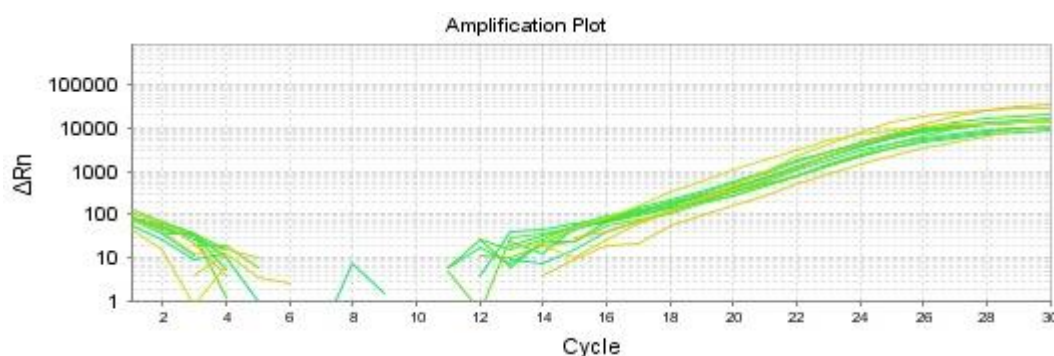
<sup>20</sup> An undetermined outcome can occur as a result of unspecified non-amplification, for example machine error or well contamination.

## PCR analysis of the 83bp and 500bp mitochondrial DNA assays

The 500bp assay assesses the actual mDNA damage of the samples by detecting the relative amount of general strand breaks induced by UV exposure. The volume of DNA extracted was insufficient for triplicates T1N, T3N and T5A and therefore a reliable CT values in the 500bp SYBR green qPCR assay remained undetermined.

The CT values from the viable samples are all below a CT of 36, providing proof that this was functional PCR data (Figure 5-4 and Table 5-5). There was no discernible difference between CT values from the usually exposed site samples (nose) and the occasionally exposed samples (inner arm) suggesting no difference in general, non-specific mDNA damage from the respective areas.

**Figure 5-4: Log amplification plot of the 500bp assay to determine non-specific mDNA strand breaks (general mDNA damage).**



**Table 5-5: The individual CT values for each triplicate sample.**

Sample Name	CT per replicate	Range	Mean CT
T1N	Undetermined	--	--
	Undetermined		
	Undetermined		
T2N	19.5	0.9	19.6
	20.1		
	19.2		
T3N	Undetermined	--	--
	Undetermined		
	Undetermined		
T4N	Undetermined	0.3	18.7 (n=2)
	18.8		
	18.5		

	Undetermined		
T5A	Undetermined	--	--
	Undetermined		
	20.9		
T6A	Undetermined	1	20.4 (n=2)
	19.9		
	19.4		
T7A	19.1	0.4	19.2
	19		
	17.8		
T8A	19.6	0	19.6 (n=2)
	19.6		

### Sample collection protocol optimisation

The protocol defining the procedure to collect skin swabs and extract mDNA from the samples was refined. Table 5-6 describes the main changes and refinements introduced to both the collection procedure and the extraction procedure.

**Table 5-6: Main changes introduced to the skin swabs protocol.**

Changes introduced	
Collection procedure	Extraction procedure
<ul style="list-style-type: none"> <li>- Increased alcohol cleaning to 4X each side;</li> <li>- Increased intensity of rubbing;</li> <li>- Increased rubbing times from 15 to 30x up/down.</li> </ul>	<ul style="list-style-type: none"> <li>- Water added to the heating block for even heating;</li> <li>- Time in heating block increased from 10min to 15min;</li> <li>- Double heating block step;</li> <li>- Vortexing elements increased from 15s to 50s;</li> <li>- Elution at the end: 1) PCR sterile water used instead of kit buffer; 2) Double elution using 100µl PCR water; and 3) 50/50 elution using 50µl twice worked well for increased concentration 80ul in the end.</li> </ul>

### Stage Three

Due to some inconclusive CT results from the previous 500bp assay, two samples from cultured cells with known concentration were included. One sample was dosed 7 times with UV and the other 15 times. The results corroborate the hypothesis that increased exposure to UV results in increased mDNA damage.

Individual duplicate ranges are <1 verifying the consistency of the Nanodrop method for identifying individual sample concentration. The range between the mean CT values was 4.15. This value represents a large spread that might potentially lead to bias differences in the 500bp assay. However, due to low the amount DNA sample available, it was advisable to conduct the 500bp assay and calculate a ratio between the 83bp and 500bp assay CT values (Koch *et al.*, 2001) to obtain reliable mDNA damage data. By comparing the 500bp CT value with the corresponding 83bp CT value for each sample as suggested by Koch and colleagues (2001) normalisation of the damage indicating (500bp) data to the actual number of original mDNA copies present in the qPCR experiment (83bp).

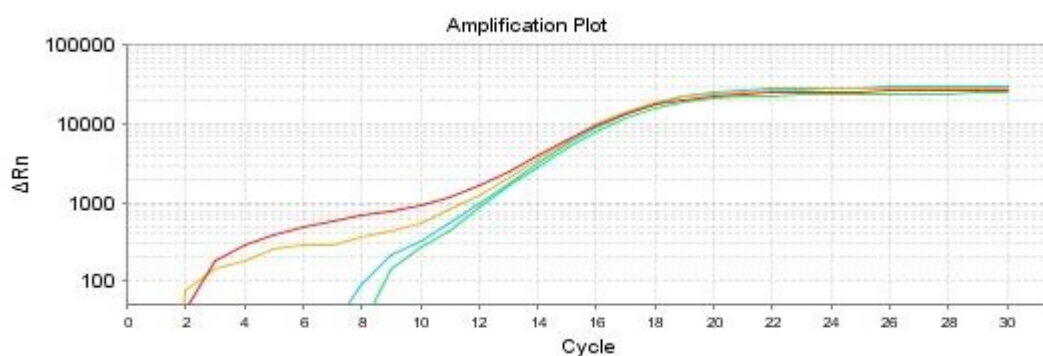
A final 500bp assay was conducted with the 6 samples from stage three alongside DNA extracted from cultured cells that have been exposed with UV in a cumulative fashion (Table 5-7).

**Table 5-7: Showing the average CT values from all human and cultured samples converted into actual number of DNA copies.**

Sample	Average CT		mDNA Copy Number	Copy number rounded 2d.p
	83bp	500bp	500bp/83bp	
T1N	23.9	/	/	/
T2N	25.8	19.6	0.759689922	0.76
T3N	25.6	/	/	/
T4N	24.1	18.7	0.77593361	0.78
T5A	24.8	/	/	/
T6A	25.8	20.4	0.790697674	0.79
T7A	24.3	19.2	0.790123457	0.79
T8A	24.7	19.6	0.793522267	0.79
T9A	25.9	19.6	0.756756757	0.76
T10A	25.35	20.1	0.792899408	0.79
T11N	21.75	17.5	0.804597701	0.8
T12A	24.35	19.4	0.796714579	0.8
T13A	25.1	19.7	0.784860558	0.78
T14N	22.45	18.4	0.819599109	0.82
D7	17.55	11.4	0.64957265	0.65
D15	17.8	12.4	0.696629213	0.7

Amplification plots from the 83bp assay demonstrated strong sample overlay, verifying that the same concentration of the two cultured samples was added to the 500bp assay. This confirmed that the CT difference was due to different amounts of UV exposure rather than variations in the amount of mDNA present, and that the protocol used for 6 samples was correct. Figure 5-5 shows a slight difference in mDNA damage in duplicates from cultured DNA samples. The lower CT values demonstrated by the red and yellow traces were from a sample dosed 7 times with UV and investigated in duplicate. The blue and green traces are from a sample dosed 15 times with UV investigated in duplicate. This figure corroborates the observed differences in mDNA damage depending on UV sun exposure.

**Figure 5-5: Log amplification plot of the 500bp assay to determine non-specific mDNA strand breaks (general mDNA damage). X-axis is Cycle Number; maximum number of 30 cycles. Y-axis is representative of fluorescence emission intensity.**



### 5.4.5 Conclusion

A protocol to assess mDNA damage caused by UV exposure over holiday was tested and refined. The protocol was adapted from Harbottle and colleagues (2010) and refined based on the findings from this study. The data presented in this chapter demonstrated that the 83bp assay (in conjunction with Nanodrop) is a reliable method to standardise the mDNA used as input for strand break analysis using a 500bp qPCR assay.

In addition, the 500bp SYBR green qPCR strand break assay has been demonstrated to be a reliable method to detect mDNA damage induced by UV exposure. This was corroborated by data from DNA extracted from cultured cells with and without UV exposure. The overall CT values for all stages (from non-holiday control skin swab samples) show minor differences suggesting 500bp assay may not be sensitive to detect differences between different body sites (nose/arm).

One limitation of the 500bp assay is a certain degree of subjectivity of the results produced. This is mainly due to the amount of functional mDNA in the assay, as the Nanodrop procedure does not provide information on the quality of the DNA present in samples only quantity. Adding the 83bp assay removes the subjectivity from the 500bp assay and reveals the amount of intact DNA in results. For these reasons, the results for mDNA values are expressed in a ratio between the 83bp assay and the 500bp assay.

Even though the amount of changes introduced to the research protocols might be seen as an instance of the subjectivity existent in this lab work, it can also, in contrast, be seen as an example of accuracy and thorough development of research protocol before assuming it is 'fit for trial'.

A strength of this study is the use of a method that has been validated before for its ability to detect UV-induced skin damage. This method has been used commercially by Mitimocs Company as one of their main commercial products - Sun Exposure Mitomic Test ([www.mitomicsinc.com](http://www.mitomicsinc.com)). In addition, anecdotal data from all participants involved in the study described in this section also demonstrated that the skin swabs are a painless technique. The main limitation to the laboratory study reported in this chapter was the very small number of samples that were collected justifying the impact of some of the irregular results.

## **5.5 General discussion**

The work described in this chapter explored possible methods of outcome assessment that could be implemented in a definitive trial to assess sun protection over holiday. Two new methods have been tested and further developed. They have provided promising evidence as valid and reliable methods of assessing sun protection behaviours and skin damage over holiday. In addition, self-report measures of sun protection behaviours and possible process variables (i.e. social cognitive predictors) were also adapted. A full protocol for the outcome assessment in a future trial exploring the impact of a behavioural intervention on sun protection behaviours has been produced (ISRCTN3943558). The new classifier developed to identify sunscreen events based on AX3 sensors (accelerometers) has been proven as a reliable and valid method to assess sunscreen use. Further testing within the internal pilot will allow analysing data on feasibility and acceptability of its usage by holidaymakers involved in a definitive randomised controlled trial.

The qPCR based procedures tested in Study 2 seem to form a reliable method to assess skin damage induced by UV exposure. In addition, the lab analyses conducted have accurately detected differences in exposure between the different body sites and

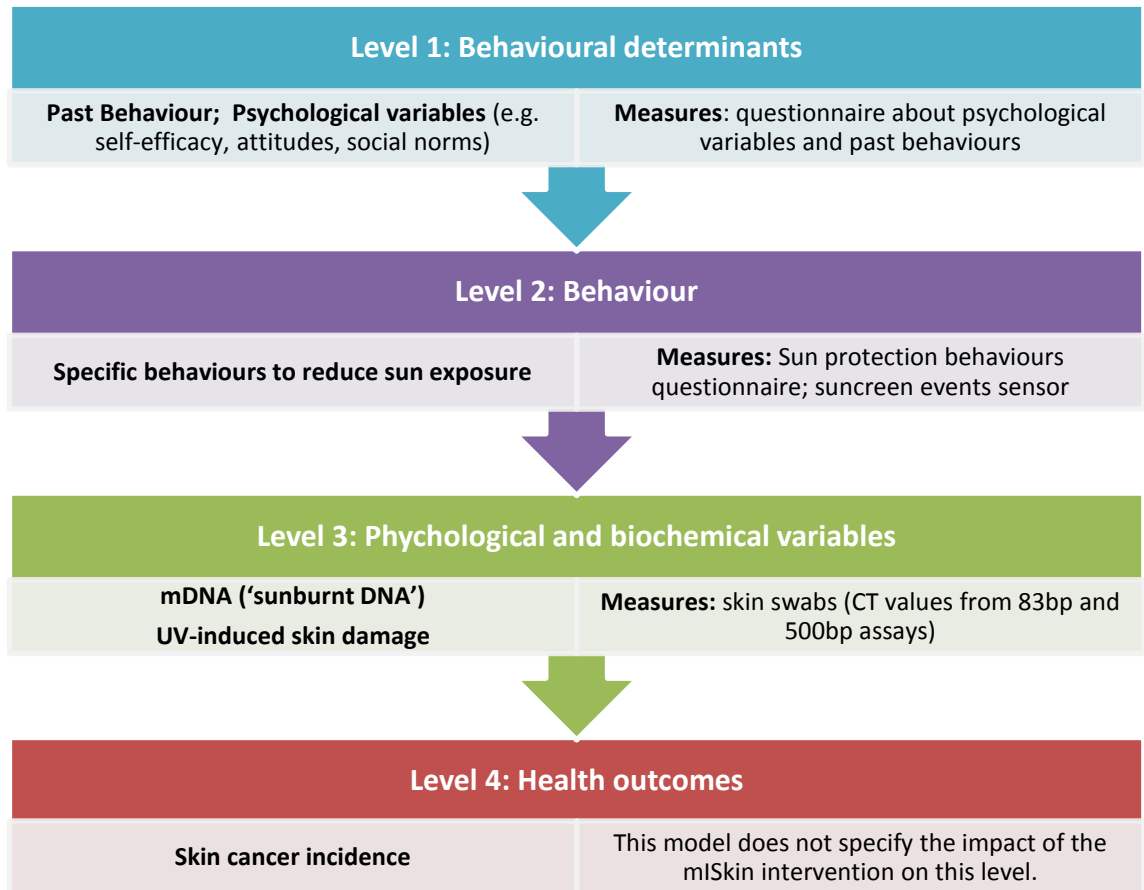
different levels of exposure. This finding indicated that the skin swab technique might help in detecting the expected difference between participants receiving the mobile-phone application and participants in the control group.

While these novel objective measures are feasible, they are not sufficiently validated to stand on their own and therefore questionnaires on self-reported sun protection will also be used. In order to understand the underlying processes leading to behaviour change, psychological process variables have also been compiled and will be used in a future feasibility study.

A challenge of complex interventions is the need for a careful and systematic development and the need to be based on a 'causal modelling' process (Hardeman *et al.*, 2005). In light with this, a process was undertaken to identify the specific causal model that is thought to influence the process of behaviour change for the behavioural intervention developed in this project (Figure 5-6). This comprehensive causal modelling approach enables the linkage between behavioural and disease determinants in a causal pathway (Hardeman *et al.*, 2005). Four levels can be observed in the causal pathway proposed (Figure 5-6) with associated measures: behavioural determinants, behaviour, physiological and biochemical variables and health outcomes.



**Figure 5-6: Causal modelling for the outcome assessment used in the mISkin project.**



As a result of this work, a full protocol for outcome assessment of behavioural effects of sun protection over holiday has been produced. This complete protocol will need to be tested for acceptability and feasibility in a pilot study.

# Chapter 6 The Question-behaviour Effect: Genuine effect or Spurious Phenomenon? A systematic review of randomized controlled trials with meta-analyses

## 6.1 Abstract<sup>21</sup>

Simply answering questions about a specific behaviour may change that behaviour. This is known as the mere measurement effect or the question-behaviour effect (QBE). This chapter aims at synthesizing the evidence for the QBE on health-related behaviours in general and, more precisely, on sun protection behaviours.

Included studies were randomized controlled trials which tested the effect of questionnaires or interviews about health-related behaviours and/or related cognitions compared with a no measurement control condition or with another form of measurement. Subgroup analyses were conducted to identify potential moderators.

Thirty-eight papers reporting 41 studies were included assessing a range of health behaviours. No studies assessing QBE on sun protection behaviours were identified. Meta-analyses showed a small overall QBE effect (SMD= 0.09; 95% CI= 0.04; 0.13). Studies showed moderate heterogeneity, variable risk of bias and evidence for publication bias. No dose-response relationships were found from studies comparing more with less intensive measurement conditions. Clearest evidence for a QBE was found for dental flossing, physical activity and screening attendance. Findings were not altered by whether behaviour or cognitions were measured; whether or not attitudes were measured; whether studies used questionnaires or interviews; or whether outcomes were taken objectively or by self-report.

There is some evidence for the QBE in relation to health-related behaviour. However, risk of bias within studies and evidence of publication bias indicates that the observed small effect size may be an over-estimate, especially given that some studies also included intervention techniques in addition to just providing questionnaires. Pre-registered high quality trials with clear specification of intervention content are needed to confirm if and when measurement leads to behaviour change.

## 6.2 Introduction

Despite the novel methods of measurement developed and described in Chapter 5, self-report measures of behaviour provide useful information about the specific pattern and intrinsic factors that may influence sun protection behaviours. In addition, the use

---

<sup>21</sup> This chapter and its appendices have been published as a journal article in *Health Psychology* (Rodrigues et al., 2014).

of self-report in combination with objective measures can potentially help to explore the validity and reliability of self-report.

Nevertheless, a concern of adding such a comprehensive set of measures as outcome assessment is whether or not this can have an impact on behaviour. A growing body of evidence suggests that measuring health-related behaviour and/or related cognitions may change the behaviour under investigation. This has been called the mere measurement effect (Sherman, 1980; Morwitz *et al.*, 1993) or, more recently, the “question-behaviour effect (QBE)” (French and Sutton, 2010; Godin *et al.*, 2012; Ayres *et al.*, 2013). If this is the case, more information needs to be gathered in order to understand the question-behaviour effect, as this information would need to inform the refinement of the developed assessment protocol for a definitive trial. If there is evidence that intensive assessment, as such, affects behaviour, then such effects of baseline assessment may obscure the evaluation of the intervention results and might have implications for the trial design.

The QBE has been reported for different types of behaviour including consumer and voting behaviour (Chapman, 2001; Spangenberg *et al.*, 2003; Morwitz and Fitzsimons, 2004). More recently, several studies have examined the QBE on health behaviours such as physical activity, blood donation and cervical screening (Godin *et al.*, 2008; Sandberg and Conner, 2009; Spence *et al.*, 2009). However, evidence for the QBE is not consistent across studies. For example, whilst some studies have shown that answering questions about safe sex behaviours affects subsequently measured safe sex behaviours (Knaus *et al.*, 2000), other studies have not found such effects (Kvalem *et al.*, 1996).

Investigation of the QBE on health-related behaviours is important for research as well as for evidence-based practice in healthcare (French and Sutton, 2010). The positive implications of the QBE on behaviour for healthcare practice is that many forms of measurement, such as self-report questionnaires, are inexpensive and could be distributed widely. If their completion is found to lead to desirable changes in behaviour, then distributing questionnaires could potentially be a viable and cost effective public health intervention. The implications for healthcare research are more challenging. In intervention trials, baseline assessment may affect behaviour in a similar way as effective interventions affect behaviour. For example, baseline questions about alcohol consumption may increase awareness and subsequently reduce instances of binge drinking because participants may realize that their alcohol intake is excessive through their interaction with a questionnaire. Therefore, in trials where an intervention designed to reduce drinking behaviour is tested against a control condition,

baseline assessment may mask or reduce observed intervention effects (McCambridge and Kypri, 2011). Moreover, in some trials, individuals allocated to an intervention group could receive different forms of measurement in order to tailor intervention components to participants. In this case, it may be difficult to disentangle measurement and intervention effects.

The QBE can also limit the external validity of a trial. For example, baseline measurement may stimulate a participant to deliberate about behaviour increasing their motivation to engage with the intervention. To better understand the potential interaction between baseline measurement and intervention effects, more sophisticated factorial trial designs are useful, such as the Solomon four-group design. In this design participants are allocated to receive baseline measurement or not to receive baseline measurement, and to receive the intervention or not to receive the intervention (McCambridge *et al.*, 2011).

The primary aim of this systematic review was to assess the effect of measurement by asking questions about sun protection and other health-related behaviours on subsequent behaviour. This was supplemented by subgroup analyses which examined whether there were differences in effects between studies characterized by lower risk of bias and those with higher risk of bias. This review also explored a possible dose-response relationship in the QBE and explored several possible moderators of effects: features of participants (student vs. other samples), interventions (type of measurement: questions about behaviour and/or questions about cognitions; format of measurement: questionnaire vs. interview) and outcomes (type of behaviour; objective vs. self-reported). The findings from this review will help inform the protocol of a RCT aimed at promoting sun protection.

## **6.3 Methods**

The protocol for this review was published in advance of the work commencing in the PROSPERO database (record number: CRD42011001467) (Hobbs *et al.*, 2011).

### **6.3.1 Inclusion criteria**

Trials randomly allocating participants to measurement or no measurement control conditions or trials where groups were randomly allocated to different forms of measurement (i.e. differences in length or content of measures) were included in this review. Studies were eligible for inclusion if they reported health-related behaviour as outcomes, defined as behaviour judged to reduce the risk or severity of diseases or promote health including preparatory behaviours, such as buying condoms or food (Marteau *et al.*, 2010) . Studies that only reported predictors of behaviour (e.g.,

intention or self-efficacy) as outcomes were excluded. The measurement condition could include assessments of cognitions, behaviour, or cognitions and behaviour by questionnaire (paper and pencil or online) or interview. Studies that used objective forms of measurement as interventions (e.g. pedometers, blood pressure monitors) were not eligible for inclusion. We included studies with any length of follow-up that reported either objectively assessed or self-reported health-related behaviours.

### **6.3.2 Search Strategy**

The following electronic databases were searched from the earliest available date to December 2012: MEDLINE, Cochrane Central Register of Controlled Trials (CENTRAL), EMBASE and PsycINFO. ERIC database was searched until March 2011 (see Appendix I). An iterative process was used to develop a sensitive and specific search strategy with guidance from an information specialist. The search included studies providing an English language title and abstract. Publications in any language were eligible for inclusion. Reference lists of included studies were reviewed for additional eligible studies and key authors in the research field were invited to provide any additional published literature that fulfilled the inclusion criteria.

### **6.3.3 Study Selection and Data Extraction**

Two reviewers (AR and NH) independently screened all titles and abstracts to identify eligible studies. There was 100% agreement between the reviewers regarding which papers to retrieve for full text examination. Full texts were retrieved for 63 papers and the two reviewers independently assessed each study for eligibility based on the inclusion and exclusion criteria ( $\kappa = 0.73$ ). For five papers, the reviewers could not decide on inclusion and consensus was reached in discussion with a third reviewer (FFS). Data from each study were extracted independently by two reviewers (AR and NH) into a data extraction form developed for this review. One reviewer (AR) entered data into RevMan Software (version 5.0) (Review Manager, 2011) and another reviewer (NH) independently verified entries. In cases where statistical data were missing, the authors were contacted and asked to make this data available to facilitate calculation of effect sizes.

### **6.3.4 Assessment of Risk of Bias and Critical Appraisal**

Risk of bias was appraised using the Cochrane collaboration tool (Higgins and Green, 2011). For each of eight criteria (adequate sequence generation, allocation concealment, blinding (participants, personnel and assessors), incomplete outcome data addressed, free of selective outcome reporting, free of other bias) studies were categorized as low, unclear or high risk of bias, scoring 0, 1 or 2 respectively. An overall score between 0 and 16 was computed, where higher scores indicate higher

risk of bias. For postal/online studies where no information was available about allocation concealment, studies were classified as 'low risk of bias' for those criteria. When information about blinding was not available and studies included an automated or online outcome assessment (including self-report), studies were classified as 'low risk of bias'. Risk of bias was assessed by two reviewers independently (AR and NH) resulting in very good overall agreement of kappa = 0.92 aggregated over all eight criteria.

### **6.3.5 Analytic strategy**

Odds ratios (ORs) or standardized mean differences (SMDs) with 95% confidence intervals (CI) were calculated for all included studies, with the exception of two studies for which data were not available. Results from comparable studies were pooled using a random effects model (inverse-variance approach based on weighted odds ratios and weighted SMDs, calculated by RevMan version 5.0 software (2011)). Dichotomous and continuous outcomes were merged using Comprehensive Meta-Analysis software version 2 (Borenstein *et al.*, 2005) to produce SMD (Cohen's *d*) for all included studies. For behavioural outcomes with more than one time point assessed, data reported at the first follow-up time point was used for meta-analyses. Where studies reported multiple behaviours as outcomes, the data were merged and the pooled effect was used for the main meta-analyses. Effect sizes for all outcomes were calculated. Heterogeneity across studies was assessed using Cochran's *Q* statistic and *I*<sup>2</sup> test statistic to quantify the effect of heterogeneity (Higgins and Green, 2011).

The main comparison performed was measurement vs. no measurement conditions. Subgroup analyses were conducted to examine whether there were differences in effects on the basis of risk of bias. Studies were grouped into 'higher' and 'lower' risk of bias studies using a median cut-off split (Median = 3) of overall risk of bias score. A secondary comparison was conducted to identify a dose-response relationship comparing the most intensive measurement conditions with the least intensive measurement conditions (i.e. frequency/duration of assessment).

Subgroup analyses were also performed for the following pre-specified factors: features of participants (student vs. other samples), interventions (type of measurement: questions about behaviour and/or questions about cognitions<sup>22</sup>; format of measurement: questionnaire vs. interview) and outcomes (type of behaviour; objective vs. self-reported). The Cochran *Q* statistic was used to detect sources of heterogeneity in the subgroup analyses, and when a study had more than two

---

<sup>22</sup> There were insufficient studies to allow meaningful comparisons for more specific comparisons between constructs.

conditions and a significant subgroup difference was observed, Z tests were used to determine between which groups the difference existed.

Publication bias was examined by plotting the inverse of the standard errors of effect estimates using 'funnel plots' to explore symmetry. These were assessed visually to see if the effect decreased with increasing sample size and there was evidence of considerable asymmetry. Egger's regression test (Higgins and Green, 2011) was used to formally test for the presence of publication bias.

This report follows the PRISMA guidance for reporting systematic reviews (Moher *et al.*, 2009a).

## **6.4 Results**

### **6.4.1 Description of included studies**

Thirty-eight papers reporting 41 studies met the inclusion criteria. The paper by Conner, Godin, Norman, and Sheeran (2011) reported two studies and Levav and Fitzsimons' (2006) paper reported three studies. Figure 6-1 shows the flow diagram of the study inclusion and exclusion, providing reasons for exclusion<sup>23</sup>. The characteristics of included studies are displayed in Table 6-1.

#### Participants

The review represents a total of 71,362 participants (Range: 31 – 7,008). Seventeen of the included studies involved student samples, with 16 studies including university students and one study with high school students. Fifteen studies took place in healthcare settings; three studies recruited in emergency departments, one in a treatment centre for alcohol, one in a centre for drug abuse, two in hospitals, three in blood donation agencies, and one in a central agency for cervical screening. Seven studies were conducted within community settings. One study included both community and university samples, and one study recruited participants in a health club.

#### Measurement manipulations

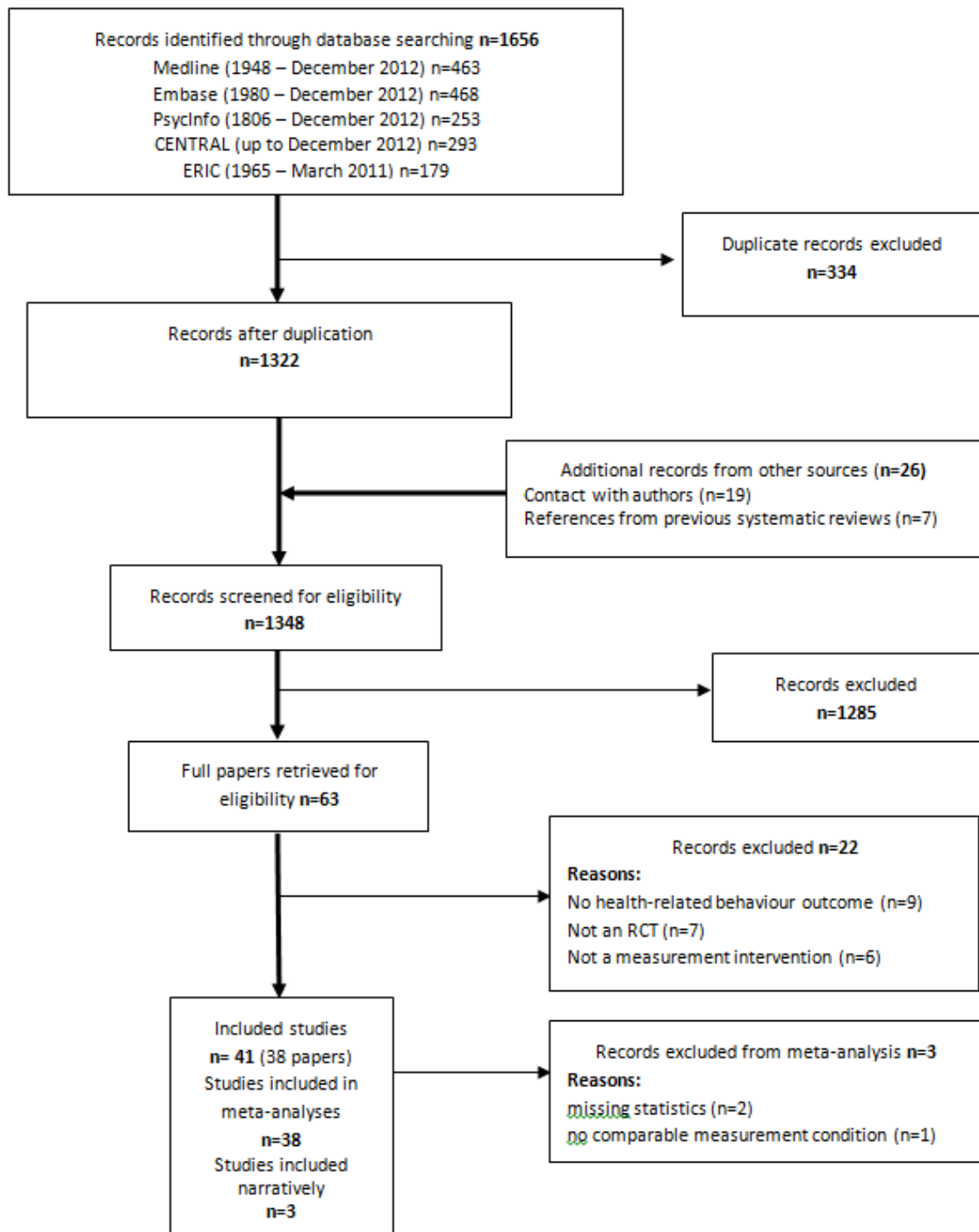
Of the 41 studies in total, the majority (n=33) utilized questionnaires as the format of measurement, whilst seven used interviews and one used both questionnaires and interviews. In 14 studies, the measurement condition involved questions about the behaviour under investigation. In 12 studies, the measurement condition involved questions about cognitions towards the health-related behaviour. In the remaining 15 studies, the measurement condition consisted of questions about both behaviour *and*

---

23 Two of the included studies (Knaus *et al.*, 1999; Knaus *et al.*, 2000) had to be excluded from the meta-analyses as statistical data were missing and could not be obtained after contact with authors.

related cognitions. For those studies assessing cognitions, ten used constructs abstracted from the Theory of Planned behaviour.

**Figure 6-1: Trial selection flow diagram (adapted from PRISMA (Moher et al., 2009a))**





**Table 6-1: Characteristics of included studies**

Study ID	Format of measurement	Type of measure	Content of measurement	Health-related outcome	Follow-up	Country	Study Setting	Population age and gender composition	Sample size at follow up	Risk of bias score 0 (low risk) to 16 (high risk)
Ayres <i>et al.</i> (2013)	Questionnaire	Dichotomous	Intention, attitudes and anticipated regret	Health plan uptake (objective)	Immediately after measurement	UK	Community	Mean age: 53.4 (71.2 % female)	Measurement condition: 67 No measurement condition: 79	0
Bernstein <i>et al.</i> (2010)	Questionnaire	Continuous	Drinking behaviour, other health behaviours, patient health questions and PTSD symptoms	Alcohol use (self-report)	12 months	USA	Paediatric emergency department	Age ≤ 17y = 114 ≥18y = 739	Measurement condition: 209 No measurement condition: 198	4
Berry and Carson (2010)	Questionnaire	Continuous	behaviour and attitude	Physical activity (self-report)	7-10 days	Canada	University and community	Students sample: mean age 19.7 (73.7% female) Community sample: mean age 72.0 (75.4% female)	Measurement condition: 117 No measurement condition: 54	7

Study ID	Format of measurement	Type of measure	Content of measurement	Health-related outcome	Follow-up	Country	Study Setting	Population age and gender composition	Sample size at follow up	Risk of bias score 0 (low risk) to 16 (high risk)
Carey <i>et al.</i> (2006)	Interview	Continuous	Behaviour	Alcohol use (self-report)	1, 6 and 12 months	USA	University	Mean age: 19.2 (65% female)	Measurement condition: 197 No measurement condition: 197	8
Cherpitel <i>et al.</i> (2010)	Questionnaire	Continuous	Behaviour	Alcohol use (self-report)	12 months	Poland	Emergency Department	39% <30 years (16% female)	Screened only: 87 Assessed: 97	4
Cioffi and Garner (1998)	Questionnaire	Dichotomous	Cognitions only	Blood donation behaviour (objective)	1-week	USA	University	Not provided	Measurement condition: 277 No measurement condition: 370	3
Clifford <i>et al.</i> (2007)	Interview	Continuous	Behaviour	Alcohol use (self-report)	6 and 12 months	USA	Treatment Centre for alcohol and other drugs abuse	Mean age: 40.01 (37% female)	Intensive assessment: 59 Least intensive assessment: 62	3
Conner <i>et al.</i> (2011)a	Questionnaire	Dichotomous	Theory Planned behaviour cognitions	Health check attendance (objective)	4 months	England	GP practice	Mean age: 36.4 (52.3% female)	Measurement condition: 199 No measurement condition: 185	0
Conner <i>et al.</i> (2011)b	Questionnaire	Dichotomous	Theory Planned behaviour cognitions	Vaccination uptake (objective)	2 months	Canada	Public hospital	Mean age: 38.1 (83.4% female)	Measurement condition: 600 No measurement condition: 600	2

Study ID	Format of measurement	Type of measure	Content of measurement	Health-related outcome	Follow-up	Country	Study Setting	Population age and gender composition	Sample size at follow up	Risk of bias score 0 (low risk) to 16 (high risk)
Daeppe <i>et al.</i> (2007) <sup>24</sup>	Interview	Dichotomous	Behaviour	% of hazardous drinkers (self-report)	12 months	Switzerland	Emergency department	Mean age: 36.7 (21.8% female)	Measurement condition: 277 No measurement condition: 257	3
Dignan <i>et al.</i> (1996)	Interview	Dichotomous	Knowledge, intentions and behaviour	Pap smear screening attendance (self-report)	12 months	USA	Tribal community: Cherokee Indian	63.8% <45 years (100% female)	Measurement condition: 448 No measurement condition: 367	7
Dignan <i>et al.</i> (1998)	Interview	Dichotomous	Knowledge, intention and behaviour	Pap smear screening attendance (self-report)	12 months	USA	Tribal community: Lumbee Native American	Mean age: 42.4 (100% female)	Measurement condition: 413 No measurement condition: 426	8
Godin <i>et al.</i> (2008)	Questionnaire	Continuous	Theory Planned behaviour cognitions	Blood donation behaviour (objective)	6 and 12 months	Canada	Blood Donors agency	Mean age control: 43.8 (38.7% female) Mean age measurement: 44.7 (38.3% female)	Measurement condition: 2900 No measurement condition: 1772	1

<sup>24</sup> Revman could not compute an effect size for this study as counts and events were equal in both groups. For this reason a value was removed in events for each group.

Study ID	Format of measurement	Type of measure	Content of measurement	Health-related outcome	Follow-up	Country	Study Setting	Population age and gender composition	Sample size at follow up	Risk of bias score 0 (low risk) to 16 (high risk)
Godin <i>et al.</i> (2010) <sup>25</sup>	Questionnaire	Continuous	Anticipated regret and intention	Blood donation behaviour (objective)	6 and 12 months	Canada	Blood Donors agency	Mean age: 30.4 (53 % female)	Measurement condition: 879 No measurement condition: 888	2
Godin <i>et al.</i> (2011)	Interview	Continuous	Theory Planned behaviour cognitions, anticipated regret, moral and descriptive norms, self-efficacy, facilitating factors and positive feelings	Physical activity (self-report)	3 months	Canada	Quebec city community	Mean age: 40.2 (47 % female)	Measurement condition: 194 No measurement condition: 180	2
Krauss <i>et al.</i> (2000)	Questionnaire	Dichotomous	Knowledge, perceived partner risk, behaviour	Safe sex Index (self-report)	7 weeks	USA	Community : public spaces	Mean age: 36.7 (100 % female)	Measurement condition: 45 No measurement condition: 28	2

<sup>25</sup> For this study, groups assessing implementation intentions were not included in the analyses.

Study ID	Format of measurement	Type of measure	Content of measurement	Health-related outcome	Follow-up	Country	Study Setting	Population age and gender composition	Sample size at follow up	Risk of bias score 0 (low risk) to 16 (high risk)
Kvalem <i>et al.</i> (1996)	Questionnaire	Dichotomous	Behaviour	Condom use (self-report)	6 and 12 months	Norway	High school	16-20 years (50 % female)	Measurement condition: 148 No measurement condition: 133	9
Kypri <i>et al.</i> (2006)	Questionnaire	Continuous	Behaviour	Alcohol use (self-report)	6 and 12 months	New Zealand	Primary Health-care clinic	Mean age control: 20.1; Mean age measurement: 20.3 (52.2 % female)	Measurement condition: 126 No measurement condition: 126	0
Kypri and McAnally (2005) <sup>26</sup>	Questionnaire	Dichotomous	Behaviour	Fruit and veg consumption, alcohol consumption, and physical activity frequency (self-report)	6 weeks	New Zealand	University primary Health-care clinic	Mean age: 20.2 (49 % female)	Measurement condition: 64 No measurement condition: 60	2

<sup>26</sup> Outcomes were merged to produce a single health-related outcome.

Study ID	Format of measurement	Type of measure	Content of measurement	Health-related outcome	Follow-up	Country	Study Setting	Population age and gender composition	Sample size at follow up	Risk of bias score 0 (low risk) to 16 (high risk)
Levav and Fitzsimons (2006)a	Questionnaire	Continuous	Intention to floss	Flossing (self-report)	2-weeks	USA	University	Not provided	Measurement condition: 51 No measurement condition: 46	6
Levav and Fitzsimons (2006)b	Questionnaire	Dichotomous	Behaviour	Choice of low or high fat snack (self-report)	Immediately after pre-test	USA	University	Not provided	Measurement condition: 25 No measurement condition: 23	4
Levav and Fitzsimons (2006)c	Questionnaire	Continuous	Intention to floss	Flossing (self-report)	1-week	USA	University	Not provided	Measurement condition: 30 No measurement condition: 30	8
McCamb ridge <i>et al.</i> (2007)	Questionnaire	Continuous	Questionnaire (General Health questionnaire-GHQ, history of trauma scale – HTS, and alcohol use - AUDIT)	Alcohol use – AUDIT (self-report)	2-3 months	England	University	Mean age control: 20.7 (66 % female); Mean age measurement: 20.6 (67 % female)	Measurement condition: 156 No measurement condition: 144	0

Study ID	Format of measurement	Type of measure	Content of measurement	Health-related outcome	Follow-up	Country	Study Setting	Population age and gender composition	Sample size at follow up	Risk of bias score 0 (low risk) to 16 (high risk)
Moreira <i>et al.</i> (2012)	Questionnaire	Continuous	Behaviour, behaviour-related problems, perceived norms, positive expectancies)	Alcohol use (self-report)	6 and 12 months	UK	University	58.5% 17-19 years (61 % female)	Measurement condition: 369 No measurement condition: 332	4
O' Sullivan <i>et al.</i> (2004)	Questionnaire	Dichotomous	Perceptions of susceptibility and severity of colorectal cancer and attitudes and personal beliefs	Colorectal cancer screening uptake (objective)	6-weeks	UK	Community	Age between 50 and 69 years	Measurement condition: 1944 No measurement condition: 10,413	0
Rimer <i>et al.</i> (1987)	Interview	Dichotomous	behaviour and disease-related information, knowledge and concerns about pain regimens, perceived personal control and anxiety	Medication regimens adherence (self-report)	4 weeks	USA	Hospitals	Age: 53.9% more than 60y (44.3 % female)	230 participants	7

Study ID	Format of measurement	Type of measure	Content of measurement	Health-related outcome	Follow-up	Country	Study Setting	Population age and gender composition	Sample size at follow up	Risk of bias score 0 (low risk) to 16 (high risk)
Sandberg and Conner (2011)	Questionnaire	Continuous	Theory Planned Behaviour cognitions	Physical activity (objective)	2-weeks	UK	University	Mean age: 19.7 (62.0 % female)	TPB only: 192 TPB + regret: 384	2
Sandberg and Conner (2009)	Questionnaire	Dichotomous	Theory Planned Behaviour cognitions, anticipated regret	Cervical screening attendance (objective)	4 months	England	Central Agency responsible for cervical screening	Mean age: 39.1 (100 % female)	Measurement condition: 1426 No measurement condition: 1277	2
Spangenberg (1997)	Questionnaire	Continuous	Behaviour	Health club attendance (objective)	10 days and 6 months attendance	USA	Health club	Not provided	Measurement condition: 73 No measurement condition: 69	4
Spence <i>et al.</i> (2009)	Questionnaire	Continuous	Behaviour, illness perceptions, self-efficacy, intention	Walking behaviour (self-report)	1 week	Canada	University	95% <30 years (100 % female)	Measurement condition: 15 No measurement condition: 16	5
Sprott <i>et al.</i> (2004) <sup>b</sup>	Questionnaire	Dichotomous	Behaviour	Health and fitness assessment attendance (self-report)	Immediately after pre-test	USA	University	Not provided	Measurement condition: 61 No measurement condition: 60	4



Study ID	Format of measurement	Type of measure	Content of measurement	Health-related outcome	Follow-up	Country	Study Setting	Population age and gender composition	Sample size at follow up	Risk of bias score 0 (low risk) to 16 (high risk)
Sprott <i>et al.</i> (2003)a	Questionnaire	Dichotomous	Behaviour	Choice of low-fat or higher fat snack (self-report)	Immediately after pre-test	USA	University	Age not provided (100 % female)	Measurement condition: 36 No measurement condition: 44	4
Todd and Mullan (2011)	Questionnaire	Continuous	Behaviour, prototypes and Theory Planned Behaviour cognitions,	Alcohol use (self-report)	2 weeks	Australia	University	Mean age: 19 (100 % female)	Measurement condition: 44 No measurement condition: 42	4
van Dongen <i>et al.</i> (2012)	Questionnaire	Dichotomous	Intention, attitudes (affective and cognitive), subjective, descriptive and moral norms, self-efficacy and role identity	Blood donation behaviour (objective)	6 months	The Netherlands	Blood Donors agency: new donors	Mean age: 33.4 (67 % female)	Measurement condition: 3518 No measurement condition: 3490	2
van Sluijs <i>et al.</i> (2006)	Questionnaire and accelerometers (without display)	Dichotomous	Behaviour and barriers to PA, knowledge, health process of change, social support and self-efficacy	Physical activity (self-report)	6 months	The Netherlands	GP practices	Mean age: 55.7 (54% female)	Measurement condition: 155 No measurement condition: 172	3

Study ID	Format of measurement	Type of measure	Content of measurement	Health-related outcome	Follow-up	Country	Study Setting	Population age and gender composition	Sample size at follow up	Risk of bias score 0 (low risk) to 16 (high risk)
van Valkengoed <i>et al.</i> (2002)	Questionnaire	Dichotomous	Behaviour	Chlamydia screening attendance (objective)	Not provided	Netherlands	Primary care practice	15-40 years (63.2% female)	Measurement condition: 143 No measurement condition: 149	3
Walters <i>et al.</i> (2009)	Questionnaire	Continuous	Behaviour, readiness to change, normative beliefs	Peak blood alcohol concentration (self-report)	12 months	USA	University	Mean age: 19.8 (66 % female)	Intensive assessment: 63 Least intensive assessment: 66	1
Yardley <i>et al.</i> (2011)	Questionnaire	Continuous	Theory Planned Behaviour cognitions, perceived risk of infection	Hand washing (self-report)	4 weeks	England	GP practices	Mean age: 49.8 (64 % female)	Measurement condition: 77 No measurement condition: 80	4
<b>Studies excluded from meta-analysis</b>										
Kalichman <i>et al.</i> (1997)	Interview and questionnaire	Continuous	Behaviour	Sexual risk behaviours (self-report)	2 weeks	USA	Community : African American	Mean age: 34.0 (100 % female)	158 participants	10
Knaus and Austin (1999)	Questionnaire	--	Perceptions, self-efficacy, behaviour	Sexual risky behaviour Index (self-report)	8 weeks	USA	University	Mean age: 19.41 (54 % female)	237 participants	7

<b>Study ID</b>	<b>Format of measurement</b>	<b>Type of measure</b>	<b>Content of measurement</b>	<b>Health-related outcome</b>	<b>Follow-up</b>	<b>Country</b>	<b>Study Setting</b>	<b>Population age and gender composition</b>	<b>Sample size at follow up</b>	<b>Risk of bias score 0 (low risk) to 16 (high risk)</b>
Knaus <i>et al.</i> (2000)	Questionnaire	--	behaviour	Safe sex behaviours Index (self-report)	7-8 weeks	USA	University	Mean age: 19 (53.9 % female)	Measurement condition: 47 No measurement condition: 61	9

### Outcomes: health-related behaviours

No studies were identified that assessed QBE on sun protection behaviours. Outcomes included alcohol consumption (n=10), physical activity (n=5), sex-related behaviours (n=5), blood donation (n=4), cancer screening attendance (n=4), choice of low or high fat snacks (n=2), dental flossing (n=2), attendance for a health assessment (n=2), uptake of a health plan (n=1), health club attendance (n=1), participation in chlamydia screening (n=1), vaccination uptake (n=1), medication adherence (n=1), and hand washing (n=1). One study assessed and reported multiple behaviours as outcomes, including fruit and vegetable consumption, alcohol consumption and physical activity frequency (Kypri and McAnally, 2005). The majority of studies reported self-reported outcomes (n=29) whilst 12 studies reported objectively assessed outcomes. Outcomes were reported both as a dichotomous measures (n=19) and continuous measures (n=22).

### Risk of bias

Table 6-1 shows risk of bias scores for each included study in this review. Overall there was considerable risk of bias. Eighteen studies reported adequate random sequence allocation of participants to conditions. Twenty-one studies were considered to have utilized appropriate procedures for allocation concealment. Thirty studies stated numbers and reasons for participant dropout or used adequate methods to deal with incomplete outcome data. Six studies had considerable risk of attrition bias. Reporting bias was not a risk for 29 studies, but was considered to be a problem for 12 studies. Nineteen studies stated that participants were blinded to their allocation. Twenty-four studies reported effective blinding procedures for outcome assessors and 21 studies for intervention providers. It was unclear whether 'other' risk of bias was present in four studies due to missing baseline information about groups/participants (n=2) or information about how the outcome measure was computed (n=2). Only one study (Moreira and Foxcroft, 2008) was pre-registered on a public database, a key requirement of the CONSORT guidance (Schulz et al., 2010).

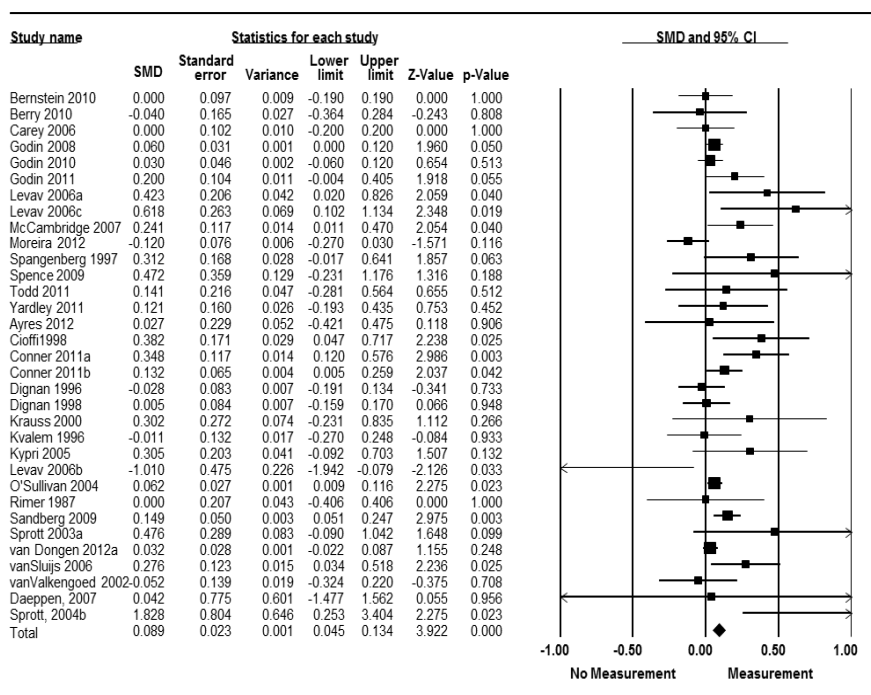
## **6.4.2 Does answering questions change behaviour?**

### Comparison of studies with measurement v no measurement conditions

For n=33 studies comparing measurement and no measurement conditions, there was an overall small but significant QBE (Figure 6-2: SMD= 0.09; 95% CI= 0.04; 0.13). Statistical heterogeneity was moderate with an  $I^2$  of 44% and a Q of 57.39 (df=32,  $p=0.004$ ).

Two additional studies did not provide sufficient information for meta-analysis. No significant difference was identified between participants randomized to measurement or no measurement conditions in these studies (Knaus and Austin, 1999; Knaus *et al.*, 2000).

**Figure 6-2: Forest plot of standardized mean differences (SMD) and 95% confidence intervals for health-related behaviours in measurement vs. no measurement conditions.**



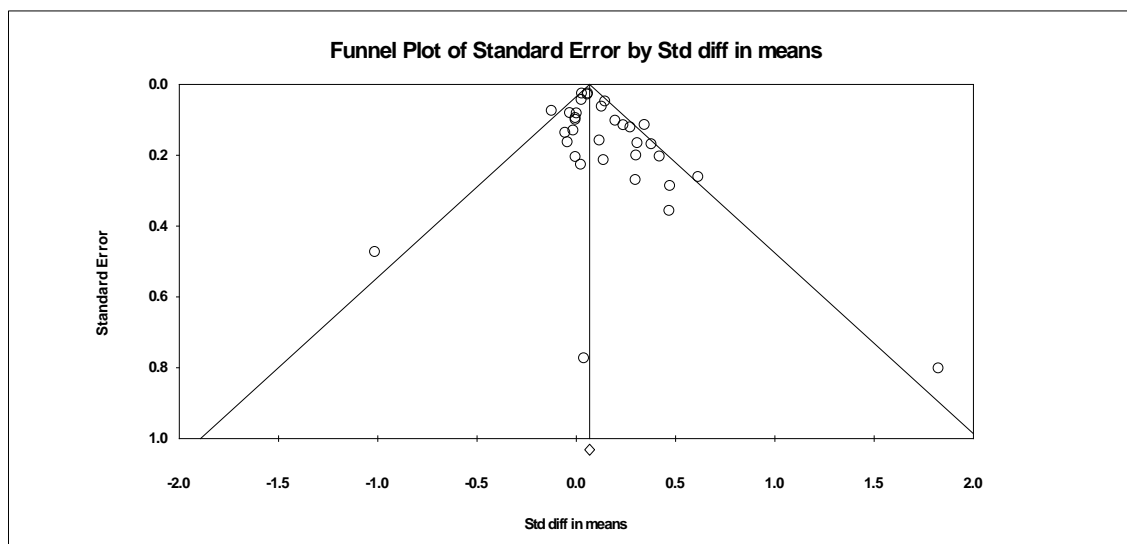
### Long term effects

In addition to the Moreira et al (2012) study which only assessed relevant outcomes at 12 months and was entered in the main meta-analysis, three further studies reported additional outcomes at 12 months. In line with Moreira et al (2012), Carey et al. (2006), Godin et al. (2010) and Kvalem et al. (1996) did not find QBE at 12 months. Only Godin et al., 2008 found a sustained significant QBE at 12 months (SMD=0.08, 95% CI = 0.02, 0.14).

### Publication bias

Egger's regression test shows that there was significant evidence of publication bias ( $p=0.01$ ; illustrated in Figure 6-3). Under the assumption of a normal distribution of effect sizes, there was evidence that studies with smaller or no effects were less likely to be published.

**Figure 6-3: Funnel plot of trials reporting health-related behaviour outcomes.**



#### Subgroup analysis by risk of bias of trials

There was no evidence that effects were moderated by risk of bias. There was a significant effect in favour of the measurement condition for both studies with a lower risk of bias (SMD=0.14, 95% CI=0.02 to 0.27,  $I^2=53%$ ) and with a higher risk of bias (SMD=0.07, 95% CI=0.03 to 0.17,  $I^2=36%$ ). Q-test shows that there were no significant differences between subgroups ( $Q=1.18$ ,  $p=.28$ ) by risk of bias.

#### Comparison of most intensive versus least intensive measurement

Meta-analysis of five trials comparing conditions with different intensity of measurement did not find a difference between the most intensive measurement conditions (e.g. brief screening plus full assessment; repeated assessments points) and the least intensive measurement conditions on health-related behaviours (SMD= 0.02, 95% CI=-0.28; 0.33). Statistical heterogeneity was high with an  $I^2$  of 84% and a Q of 25.14 (df=4,  $p<0.001$ ).

### **6.4.3 Possible moderators of the QBE**

#### Type of participants

Subgroup analysis comparing student and non-student samples showed small significant QBEs in both student samples (SMD = 0.17, 95% CI = 0.01, 0.32) and non-student samples (SMD = 0.07, 95% CI = 0.04, 0.11). The difference was not significant between subgroups ( $Q=1.38$ ,  $p=.24$ ) (Table 6-2).

**Table 6-2: Standardized mean differences (Cohen's d) for question-behaviour effect by moderator variables.**

Moderator variable	Measurement group N	No Measurement group N	Q	SMD	95% CI
<i>Type of participants</i>					
Students	926	1035	1.38	0.17	0.01-0.32
Non-students samples	4599	3444		0.07	0.04-0.11
<i>Content of measurement</i>					
Behaviour only	752	739	1.19	0.11	-0.09-0.30
Cognitions only	3860	2736		0.05	0.05-0.15
Cognitions plus behaviour	923	1004		0.05	-0.04-0.14
<i>Measurement of attitudes</i>					
Yes	11193	18392	0.00	0.09	0.05-0.13
No	3922	3945		0.09	0.01-0.18
<i>Format of measurement</i>					
Questionnaires	4558	3647	2.02	0.10	0.05-0.15
Interviews	877	832		0.03	-0.06-0.12
<i>Type of health-related behaviour</i>					
Flossing	81	76	13.96	0.50	0.18-0.81
Blood donation	7574	6520		0.05	-0.00-0.10
PA	573	598		0.20	0.08-0.32
Screening	4374	12632		0.06	0.003-0.12
Drinking	1262	1281		0.04	-0.08-0.16
Diet	124	130		0.08	-0.09- 0.61
Sexual behaviour	193	161		0.05	-0.20-0.31
<i>Type of outcome</i>					
Objective	3852	2729	0.39	0.08	0.04-0.13
Self-report	1683	1750		0.10	0.01-0.19

Cochrane's Q = heterogeneity for the subgroup analysis  
Standardised Mean Difference (SMD) = Cohen's d = pooled effect size  
\*\*p< .01

### Interventions: content of measurement

Subgroup analysis showed no significant effect in favour of measurement condition when only behaviour was measured (SMD = 0.11, 95% CI = -0.09, 0.30); a small significant effect when only cognitions were measured (SMD = 0.10, 95% CI = 0.05, 0.15); and no significant effect when both behaviour and cognitions were measured (SMD = 0.05, 95% CI = -0.04, 0.14) (Table 6-2). No significant difference between subgroups was identified (Q=1.19, p=.55).

### *Interventions: measurement of attitudes*

Subgroup analysis showed no differences (Q=0.00, p=.98) between measurement conditions when attitudes were measured (SMD = 0.09, 95% CI = 0.05, 0.13) and when no attitudes were measured (SMD = 0.09, 95% CI = 0.01, 0.18) with both subgroups showing significant QBEs on health-related outcomes (Table 6-2).

### Interventions: format of measurement

A small significant effect in favour of the measurement condition was identified when using questionnaires (SMD = 0.10, 95% CI = 0.05, 0.15) but not when using interviews (SMD = 0.03, 95% CI = -0.06, 0.12); however, no significant difference between subgroups was identified ( $Q=2.02$ ,  $p=.15$ ) (Table 6-2). An additional study that tested the effect of using a questionnaire and an interview separately and thus could not be meta-analysed as it was not comparable to other studies, (Kalichman *et al.*, 1997) found no difference between these two modes of assessment on sexual behaviour (OR = -0.10, 95% CI = -0.79, 0.59).

### Outcomes: type of health-related behaviour

For dental flossing behaviour, a significant medium size effect was found in favour of the measurement condition (SMD = 0.50, 95% CI = 0.18, 0.81). Small but significant effects were also found for physical activity (SMD = 0.20, 95% CI = 0.08, 0.32) and screening attendance (SMD = 0.06, 95% CI = 0.003, 0.12). No effects were found for blood donation (SMD = 0.05, 95% CI = -0.00, 0.10), alcohol consumption (SMD = 0.04, 95% CI = -0.08, 0.16), dietary (SMD = 0.08, 95% CI = -0.68, 0.84) or sexual behaviours (SMD = 0.05, 95% CI = -0.20, 0.31). However, no significant differences between subgroups were identified (Table 6-2) ( $Q=13.96$ ,  $p=.052$ );

### Outcomes: type of measurement

Small significant effects were found for both objective outcome measures (SMD = 0.08, 95% CI = 0.04, 0.13) and self-report measures of behaviour (SMD = 0.10, 95% CI = 0.01, 0.19) (Table 6-2). There were no differences between subgroups ( $Q=0.14$ ,  $p=.71$ ).

## **6.5 Discussion**

To our knowledge, this is the first systematic review with meta-analysis synthesizing evidence for the effects of measurement on health-related behaviours. Previous reviews with more optimistic conclusions were not systematic and did not focus on health-related behaviour (Spratt *et al.*, 2006; Dholakia, 2010). We found evidence of a typically small but significant QBE on health-related behaviours with moderate levels of heterogeneity of effects. Studies comparing more with less intensive measurement conditions did not suggest dose-response relationships. Subgroup analyses were conducted to identify potential moderators of effects. Clearest evidence for the QBE was found for dental flossing, physical activity and screening attendance. These findings were not altered in studies where students or other samples were studied;



cognitions, behaviour or both were measured; attitudes were measured or not measured; questionnaires or interviews were used; or outcomes were taken objectively or as self-reports. We also found no significant difference in QBEs between behaviours. After the completion of this review, a new trial was published comparing five different measurement conditions (intention only, interrogative intention, intention plus moral norm, intention plus regret and intention plus self-positive image) and one implementation intention intervention with a no intervention control condition (Godin *et al.*, 2013). The comparison between the five measurement conditions and the control condition yielded an aggregated small effect size of 0.16 (95% CI = 0.09, 0.23). This effect is slightly higher than the main effect size found in the present meta-analysis.

Three key findings of this review need to be highlighted, which may suggest some caution regarding the evidence for the QBE. Firstly, methodological quality of the included studies was variable and several studies showed considerable risk of bias, in particular due to selective reporting (outcomes which suggest a significant QBE might be more likely to be reported), lack of blinding of participants (knowledge of allocation may affect question elaboration or desirability bias in self-reported outcomes) and incomplete outcome data not appropriately addressed. Only seven of the 33 studies entered in the main meta-analysis explicitly stated conducting intention-to-treat analysis, thus introducing the risk that loss to follow-up in different trial arms might differ in terms of numbers or participant features. While subgroup analyses for risk of bias did not show a significant difference, trends for higher effects in studies with a greater risk of bias were observed. It cannot be ruled out that the already small effects found in this review are inflated through systematic methodological bias in the included trials.

Secondly, there was evidence of publication bias. Randomly allocating participants to varying forms of measurement is an inexpensive addition to a range of study designs and implemented for a range of reasons. It is possible that studies with random measurement allocation are less likely to be reported in the published literature, if the different measurement conditions do not result in differences in behaviour. In this case, the small effects found in this review might be an artefact of publication bias. With the exception of one study (Moreira and Foxcroft, 2008), which was pre-registered and for which a full protocol has been published (and reported subsequently a null finding), none of the trials included in this review were pre-registered. Thus, there are no safeguards to ensure that comparisons, outcomes and analyses were specified a-priori and that the studies were actually statistically powered to detect small effects.

Thirdly, intervention procedures are often insufficiently described and therefore it is difficult to conclude that the measurement conditions in this review were not confounded with other procedures potentially affecting outcomes. For example, it is good practice in survey research to send reminders to those who do not respond to an initial questionnaire (McColl *et al.*, 2002). In question-behaviour effect studies, larger response rates are thought to lead to higher reactivity effects as more participants engage with the questions (Spence *et al.*, 2009). Three large randomized controlled trials of measurement on blood donation were included in this review (Godin *et al.*, 2008; Godin *et al.*, 2010; van Dongen *et al.*, 2012). The Van Dongen *et al.* (2012) and Godin *et al.* (2010) trials showed that completing questionnaires did not change blood donations in two Dutch and one Canadian sample, which is in contrast with the Godin *et al.* (2008) trial that showed a significant effect on blood donations. In their 2008 study, Godin and colleagues sent reminders and 'thank you' notes to participants in the measurement condition, resulting in a return rate of 82%. By contrast the Van Dongen and Godin (2010) trials did not send reminders and observed a return rate of 64-65% and 49.5% respectively. It is impossible to conclude if these procedures relate to QBEs due to the poor standard of reporting in some studies, and the field would benefit from full reporting of procedures and response rates in future studies on QBEs. Based on these considerations, it is not entirely clear whether the QBE is a genuine effect or the result of an accumulation of sources of bias in trials, failure to publish trials with null findings and reporting trial procedures in insufficient detail.

Findings for alcohol consumption differed slightly from those reported in a recent review of measurement reactivity effects in trials of brief alcohol interventions (McCambridge and Kypri, 2011), which found that measurement does affect Alcohol Use Disorders Identification Test (AUDIT: (Bush *et al.*, 1998)) measures but no other measures of consumption. Our review does not find an overall effect of measurement on alcohol consumption. Differences between both reviews are in the aggregation of outcome data between the AUDIT and other measures of consumption and in the exclusion of one trial in this review which did not use a randomized controlled design (Richmond *et al.*, 1995).

#### Implications for research and practice

The current evidence base is characterized by variable methodological quality and publication bias. With 41 randomized trials in this review, future trials are more likely to make a considerable contribution to knowledge if they adopt the most rigorous methodologies reducing the bias in the evidence base. To deal with the problem of publication bias, we strongly recommend to journals the principle of publishing QBE

trials only if study protocols have been pre-registered, thereby avoiding the reinforcement of results based on publication bias and bias introduced through selective reporting of outcomes. To continue publishing studies that have not had protocols pre-registered may result in the accumulation of more studies displaying bias, which is unlikely to help clarify this literature.

From a theoretical perspective, there is not sufficient evidence to date to allow synthesizing the effects for different theoretical measures and possible mechanisms at this stage. The majority of the studies assessing cognitions used questionnaires abstracted from the Theory of Planned Behaviour (Ajzen, 1991). Studies using ‘think aloud’ technique (French *et al.*, 2007; Darker and French, 2009) have shown that using questionnaires based on the ‘Theory of Planned Behaviour’ can result in participants forming beliefs about topics which they have previously devoted little thought. This may thereby increase the salience of beliefs about specific features or aspects of performing that behaviour (Morwitz and Fitzsimons, 2004). In a similar way, measurement can also form attitudes towards the behaviour itself and/or make specific aspects of performing a behaviour more accessible, thereby fostering performance (Morwitz and Fitzsimons, 2004). It is possible that the mere fact of being measured influences the formation of judgments and/or accessibility of these for respondents (Chandon *et al.*, 2005).

Research comparing QBEs for different theoretical measures and/or different constructs has been published in recent years (Godin *et al.*, 2008; Conner *et al.*, 2011) and it is likely that these comparative trials will enhance our understanding of if, how and when measurement changes behaviour. The range of cognitive measures investigated to date has predominantly focused around constructs abstracted from the Theory of Planned Behaviour as well as on anticipated regret. Other measures such as identity (van Dongen *et al.*, 2012), self-image (Godin *et al.*, in press) and more emotion-related measures such as worry may deserve additional attention in future research. Effects may also differ due to features of the study population and the period of follow-up (Godin *et al.*, in press).

Current evidence of small effects with moderate heterogeneity suggests that it might be worthwhile to estimate small increases in control conditions when establishing the required sample size for randomized trials. To date there is no compelling evidence for baseline measurement by intervention interaction effects from Solomon trials (cf. McCambridge *et al.* (2011)), suggesting that there might not be a systematic bias in the evidence base about behaviour change interventions as a result of baseline measurement in trials.

Disappointingly, no trials assessing the effect of measurement reactivity on sun protection were found. Since no evidence was available for QBE on sun protection, there is no suggestion that it might affect behaviour. For this reason, it would be risky to suggest the non-inclusion of self-measures in any trial conducted in the area of skin cancer prevention. Also, considering that the observed impact of QBE on other health-related behaviours was small, no implications are envisaged to inform the protocol and, more precisely, the study design of future interventions in the area of sun protection. Implications for practice are more difficult to identify at this stage. The evidence for sending questionnaires to increase behavioural uptake is limited. However, first robust evidence for a QBE has to be accumulated. Second, before the QBE should be used as a behaviour change strategy, it has to be shown to not only exist, but also to produce greater changes in behaviour than simply sending reminders to perform the behaviour.

In summary, this systematic review advances the field by a) providing a comprehensive synthesis of the evidence; b) including evidence from various health-related behaviours; c) providing quantification of effects sizes with moderator analyses; and d) identifying and critically appraising potential sources of systematic bias. Small QBEs were found with moderate heterogeneity between studies. Future QBE trials should focus on reducing risk of bias and providing detailed description of procedures in each trial arm. Pre-registration of trials is paramount to allow a more precise assessment of measurement reactivity.

# **Chapter 7 An internal pilot study of a definitive randomised controlled trial of the mISkin Smartphone intervention to prevent excess sun exposure amongst holidaymakers**

## **7.1 Abstract**

This chapter aimed to 1) describe the protocol for a definitive randomised controlled trial (RCT) to evaluate the effects of a novel evidence-informed and user-centred designed mobile-phone intervention in reducing excess UV-exposure amongst holidaymakers and 2) assess its acceptability and feasibility in an internal pilot study.

Holidaymakers owning an Android smartphone and travelling to sunny destinations participated in the internal pilot of a 2 (mISkin vs. control) x 2 (SPF15 vs. SPF30) assessor-blinded randomized controlled trial (trial registration: ISRCTN63943558). Primary outcomes for the internal pilot study are acceptability and feasibility of the trial procedures and interventions, as well as fidelity of the 'mISkin app' intervention. Secondary outcomes were assessed at baseline and shortly after holidays and included: mDNA skin-damage, sunscreen use (residual weight and movement patterns of provided bottles with built-in accelerometers) and self-reported sun protection practices.

Out of 142 assessed for eligibility, 42 participants were randomized (76.2% female; mean-age = 35.5 (SD=9.7)). High participant retention rate and participants' feedback suggested good acceptance and feasibility of intervention and trial procedures. Baseline and follow up assessments (including skin swabs) were completed by all participants who provided consent to participate. Residual weight of sunscreen bottles provided by the research team was obtained for 41 participants (97.6%) and online questionnaires were completed by 90.4% (N=38) at baseline and 97.6% (N=41) at follow up.

The mISkin built-in internal pilot trial is the first RCT to evaluate a mobile-phone app designed to protect holidaymakers from excess UV-exposure. The trial and intervention procedures were found to be acceptable and feasible.

## **7.2 Introduction**

Skin cancer are the most common form of all types of cancer diagnosed in the UK (Cancer Research UK, 2013b). In 2010, about 12,818 new non-melanoma skin cancer (NMSC) and 99,549 new melanoma cases were registered in the UK (Cancer Research UK, 2013c). The same source states that 2,209 deaths from melanoma were registered in the UK during 2010. The age-standardised melanoma incidence rate for 2010 was 17.1 per 100,000 in UK. Malignant melanoma was the fifth most common cancer in UK during 2010.

Overall, skin cancer result from a complex interaction of endogenous non-modifiable risk factors (i.e. skin phenotype, propensity to develop and number of nevi, freckles, susceptibility to sunburn and family history of skin cancer) with exposure to ultraviolet radiation, associated with behaviour choices. In particular, intermittent sun-exposure (e.g. summer holidays in sunny settings) has been shown to increase melanoma risk considerably (Gandini *et al.*, 2005).

Epidemiologic studies suggest that implementation of sun-protective behaviours would decrease the amount of intermittent sun-exposure and would have an important impact on the reduction of skin cancer incidence (English and Armstrong, 1988; Armstrong and Kricger, 2001). According to World Health Organisation (2002), four out of five cases of skin cancer could be prevented by sun-protective behaviours (e.g., staying in the shadow; avoiding the midday sun; appropriate clothing; using sunscreen).

Even though sunscreen is seen as a method of sun protection, there seems to be some contradiction regarding the recommendation about the specific protection factor. NICE currently suggests the need for a sun protection factor (SPF) of 15, whilst the British Association of Dermatologists, Cancer Research UK and the British Skin Foundation recommend the use of SPF30 (The British Skin Foundation, 2011).

Tourism settings are of particular interest for skin cancer prevention interventions since intermittent UV exposure has been shown to be an important risk factor for melanoma (Gandini *et al.*, 2005). According to World Health Organisation (2002), the British population receives around 30% of their annual UV exposure in their two-week summer vacations. Therefore, effective interventions are needed to reduce intermittent sun-exposure and, consequently, prevent skin cancer. A systematic review of interventions to promote sun-protective behaviours in recreational settings found weak and heterogeneous evidence for the effectiveness interventions on sun-protective behaviours (Chapter 2). Effective interventions were more likely to utilise intervention strategies highlighting supportive social norms for sun-protective behaviours and providing appearance-based information about skin photo-ageing illustrated with UV photographs of skin damage.

Even though the completed systematic review did not provide direct evidence regarding the use of mobile-phones as a possible mode of delivery for the intervention components, other evidence suggested that the use of mobile technologies to promote health-related behaviours might be a novel, convenient and feasible way of reaching the target population (Fry and Neff, 2009; Boulos *et al.*, 2011; Free *et al.*, 2013). Holidaymakers are a volatile population which location might vary vastly and be difficult to reach. Therefore, a scalable

and geographically flexible mobile-phone intervention might be an effective way of reaching this population. Smartphones are a particularly relevant platform for delivery as they offer not only standard communication functions (e.g. call and text messaging services), but also advanced computing and communication features (e.g. internet access; geo-positioning systems; high-resolution cameras, etc.). Smartphone ownership in the UK has been rising rapidly. Ofcom's Communications Market Report (2013) reveals that half of all adults in the UK owned a Smartphone (take-up of 51%), showing that this proportion has doubled over the past two years.

Two RCTs have previously used text reminders to modify sun-protective behaviours (Armstrong et al., 2009; Gold et al., 2011). Armstrong and colleagues (2009) conducted a study to evaluate the effectiveness of a text messaging intervention prompting sunscreen use in Canada. Participants allocated to the intervention condition were prompted over a period of 6 weeks. The reminders had two components: daily local weather forecast and a text reminder related to sunscreen use. An electronic monitor built in the sunscreen cap recorded every time the sunscreen bottle opened. Text message reminders were found to significantly increase daily adherence rate to sunscreen application (intervention group: adherence rate 56.1%, control group = 30%) after adjusting for daily weather patterns (Armstrong et al., 2009). A number of interesting points can be made about this study. Even though this is the first study to use electronic monitors to assess daily sunscreen application, no information was retrieved regarding the quantity used of sunscreen. This would further support findings from the electronic monitors. In addition, participants suggested that the prompts used should be customised to their personal preferences. Finally, the fact the study was conducted over autumn (with only 17 sunny days) might play a role in explaining adherence rates, as sun protection is usually a practice associated with summer.

In another study, younger Australian adults (16-29 years old) were recruited through mobile advertising offers (Gold *et al.*, 2011). The study tested the effectiveness of SMS to increase knowledge and promote beneficial behaviour change related to sun safety among over a 4-month period. The total of eight text messages were sent fortnightly over the summer period during a pre-specified broadcast period. The messages were humorous, short, used informal language and aimed at increasing knowledge; reinforcing protective behaviours, changing attitudes and increasing perceived behavioural control. The results showed no significant differences in the reported frequency of seeking shade, tanning preferences or wearing non-protective clothing (Gold *et al.*, 2011).

## 7.3 Aims

This chapter describes the internal pilot of a RCT evaluating the first evidence-informed behaviour change intervention to promote sun protection amongst holidaymakers following the Medical Research Council (MRC) guidance for developing and evaluating complex intervention (Craig *et al.*, 2008; Craig *et al.*, 2010). More precisely, the study aimed at:

1. Testing the acceptability of recruitment, allocation, measurement and intervention procedures.
2. Testing the developed intervention and methodological procedures and obtain feedback regarding satisfaction with the intervention (acceptability);
3. Assessing the feasibility of a mobile-phone intervention to promote sun-protective behaviours amongst British holidaymakers (feasibility);
4. Exploring how participants engaged with the intervention and its active ingredients (fidelity of mobile-phone intervention).

## 7.4 Methods

The mISkin definitive trial and the internal pilot have been registered (ISRCTN3943558). Ethics approval was obtained from the Faculty of Medical Sciences at Newcastle University.

### 7.4.1 Study design

This study is a single centre assessor-blinded factorial waiting list randomised controlled trial with internal pilot. This study used a 2 (mISkin app intervention vs. no intervention) x 2 (Sunscreen provision: SPF 15 vs. SPF 30) factorial design that randomly assigned participants to the conditions (Figure 7-1). The internal pilot study was conducted from September 2012 to November 2013. The RCT is ongoing.

An internal pilot was considered appropriate to test the acceptability and feasibility of the protocol for the definitive RCT for several reasons. Firstly, feasibility was established prior to the definitive trial and unknowns related to this trial were minimal. Notably, evidence retrieved from the user-centred study described in chapter 4 suggested that participants involved were satisfied and found the mISkin to be acceptable. Also, the feasibility and acceptability of the outcome assessment was also evident in Chapter 5. Secondly, an internal pilot constituted an economic approach of using the available resources for the definitive trial (i.e. personnel and consumable, recruitment efforts, and participants), given that, if successful, data collected for an internal pilot can be added to the full trial data.

During the trial, it became obvious from participants' feedback that the random allocation to the SPF conditions was not acceptable or feasible (described later). Even though the



random allocation to sunscreen SPF was still in place, the protocol was amended to give participants the following three options: a) two bottles of SPF 15, b) two bottles of SPF 30, or c) one bottle of SPF 15 and one bottle of SPF 30. The main reason behind this decision was to allow for the main four group analyses every time participants agreed with their allocation and keep numbers about any disagreements.

**Figure 7-1: Participants randomised in the internal pilot of the mISkin trial.**

		Sunscreen provided	
		Sunscreen SPF 15	Sunscreen SPF 30
mISkin intervention	Yes	10	11
	No	9	12

### 7.4.2 Participants

Holidaymakers from the North East of England travelling for up to two weeks were recruited for this study. To be included in this study, participants needed to be more than 18 years old and own an Android™ smartphone, as the mISkin app was only available for Android™ at the time of this study. The exclusion criteria were:

- People part of the same travelling group of a participant already included;
- People with dermatological conditions;
- People with known allergic reactions to sunlight and sunscreen;
- People taking photosensitive drugs for whom UV exposure is undesirable;
- People experiencing ill health;
- Non-English speakers;
- Pregnant women.

The recruitment strategy involved placing posters (Appendix J) in local spaces within Newcastle city centre, Newcastle University and a local travel agency. Email invitations were also sent to staff within 3 large companies, one large healthcare institution, a local library and 5 city councils in the North East of England. Social media was also used through posts on Twitter and the mISkin Facebook page. The main difficulty with recruitment was the difficulty of involving a high street travel agency as a gatekeeper to recruit holidaymakers.

### 7.4.3 Interventions description

Following consent (Appendix L and M) and baseline data collection, participants were randomly allocated to intervention or control groups.

### mISkin Intervention group

Participants randomised to the intervention group engaged in a behavioural intervention ('mISkin') delivered through their mobile-phones (Android™ Smartphones) during their next holiday. The behaviour change strategies utilised in this app are based on a systematic review (Chapter 2) and the interventions have been developed using user-centred design principles (Chapter 4).

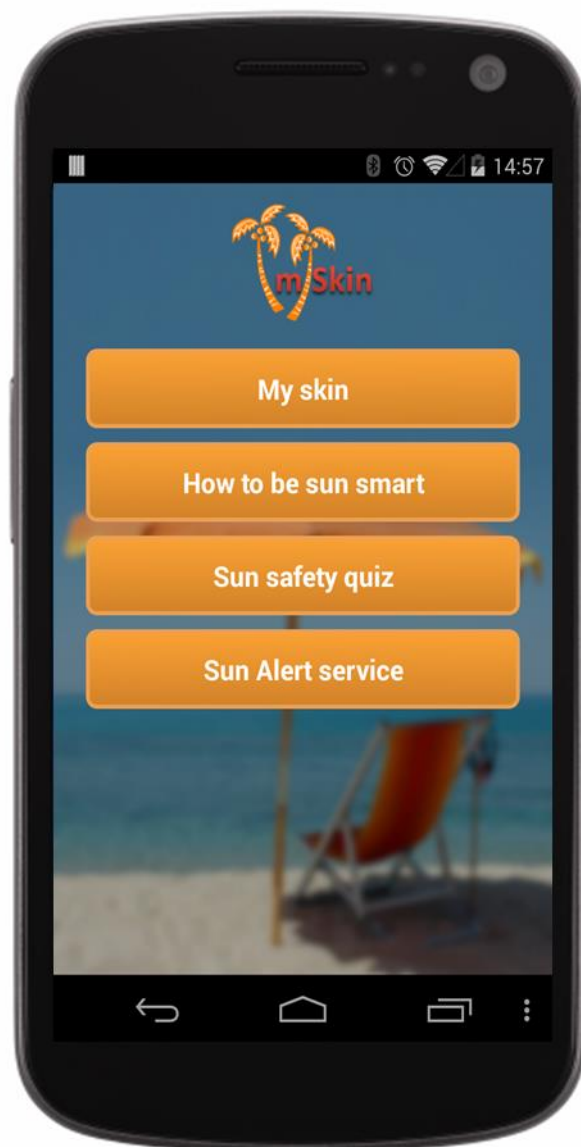
The main features of the mISkin mobile-phone intervention are: general information about consequences of unprotected sun-exposure, appearance-related concerns, instructions for sun-protection, demonstrations (modelling), prompts for effective sun-protective behaviours when outside (via mobile phone GPS), and feedback on exposure and protective behaviours. The application also includes a skin assessment questionnaire. Participants are prompted daily (minimum of 2 times per day) by the application. Each day participants are also prompted to respond, through the application, to answer brief questions about their sun-protection practices (Ecological momentary assessment).

The mISkin application (Figure 7-2) has four main menus (Please see Chapter 4, Table 4-2 for detailed information on the mISkin intervention):

- 'My skin': Skin sensitivity questionnaire with general feedback on skin type (Behaviour change techniques (BCTs) used: provide information on consequences of behaviour to the individual);
- 'How to be sun smart': videos about sun protection recommendations ('How to apply sunscreen', 'Choosing a good sunscreen', 'Other methods of sun protection', 'Preventing damage', 'Protecting children', 'Other's use of sunscreen') and skin damage information on UV photos (BCTs used on videos: provide information on consequences of behaviour in general; provide information on where and when to perform the behaviour; provide instructions on how to perform the behaviour; model/demonstrate the behaviour; BCTs used on UV photos: provide information on consequences of behaviour in general; appearance-based fear appeals);
- 'Sun safety quiz': quiz about sun protection and tanning beliefs, with provision of feedback and information on general recommendations for sun protection (BCTs used: provide feedback on performance; provide information on consequences of behaviours in general; provide information about others' approval; provide normative information about others' behaviour; facilitate social comparison);

- 'Sun alert service': prompts about sun protection service, with a minimum of 2 per days and with the option to customise prompts (e.g. times, frequency) (BCT used: prompt practice);
- UV levels forecast sent through a text message (BCT used: prompt practice);
- Self-monitoring: assessment of sun protection practices between 11am and 3pm if the individual is outside at least once a day (BCT used: prompt self-monitoring).

**Figure 7-2: Main screen of the mSkin application.**



No mobile app control group

Participants allocated to the control condition completed baseline measures, before going on holiday, and post-intervention assessments, after holiday. These participants randomised to

the control condition were part of a waiting list and were offered the intervention/application next time they go on holiday.

### Sun Protection Factor

All participants received two bottles of sunscreen (Ambre Solaire™, 200ml), and they were randomly allocated to receive sunscreen with either SPF15 or SPF30.

## **7.4.4 Outcomes and methods of assessment**

### Primary outcomes: process evaluation phase

The process evaluation phase measured the quality and quantity of the delivery of the trial procedures and the intervention, providing important information on how much the intervention was used and by whom, which components were implemented and if these were used as planned initially by the researchers (Steckler and Linnan, 2002; Saunders *et al.*, 2005). It also focused on the acceptability of the trial procedures and the intervention to holidaymakers included in this study.

The process evaluation phase in this study assessed:

1. Acceptability and feasibility of trial procedures – procedures used to recruit holidaymakers, materials provided, meeting arrangement, outcomes assessment and group allocation;
2. Acceptability and fidelity of the intervention – holidaymakers' satisfaction (general question about overall satisfaction) with the intervention and the amount of the intervention participants interacted.

To achieve this, post-holiday (post-test) semi-structured interviews were conducted to obtain detailed information regarding acceptability and feasibility of recruitment, allocation, outcome measurement procedures and intervention components (see topic guide in Appendix N). A general question about their overall satisfaction with the mISkin app was also asked ('How would you describe your satisfaction with the overall app features?'). These interviews were conducted with the first 30 participants involved in the internal pilot providing consent to be recruited to the interviews, and lasted less than 30 minutes. The analyses focused on the general feedback and the main issues raised for each trial component.

## Secondary outcomes

### *Primary outcome for definitive trial: mitochondrial DNA damage*

Skin damage caused by UV exposure was measured objectively using a reliable epithelial skin swab to test for mitochondrial DNA (mDNA) damage before and after holiday. This is a simple skin swab that tests for mDNA damage caused by UV exposure. These samples were taken by an assessor blinded to participants' allocation with cotton swabs from sterilized skin rubbed from the nose bridge and forearm and stored in a sterile collection tube until extraction according to standard procedures by Harbottle and colleagues (Harbottle *et al.*, 2010) and further methods developed as reported in Chapter 5.

### *Sunscreen use*

Participants were also given sunscreen bottles with a built-in tri-axial accelerometer (AX3) (time- and date-stamped) registering the pattern of participants' application of sunscreen. This information provides relevant information about frequency of sunscreen use events during holidays. This method has been developed in collaboration with computer scientists (Newcastle University) and has been shown to have a sensitivity of 91% and specificity of 98% in detecting sunscreen use events (Please see Chapter 5). Allocation to the sensors was based on availability at time of recruitment.

Moreover, sunscreen use (quantity) was also measured by weighing provided sunscreen bottles at baseline and post-test. The same scale was used for all assessments of sunscreen bottle weight and standard operating procedures described when and how measurements were taken.

### *Self-reported sun protective behaviours*

A standard online self-reported questionnaire with 7 items on sun-protective behaviours based on Glanz and colleagues (Glanz *et al.*, 2008) was also completed by all participants. This questionnaire assessed exposure times, sunscreen, hat, t-shirt and sunglasses usage and seeking shade. Experience of sunburn was assessed by a single item.

### *Process assessment*

For process assessment, participants also completed an online questionnaire at baseline and post-test, adapted from previous studies (Ajzen, 1991; Jackson and Aiken, 2000; Bandura, 2001; Mahler *et al.*, 2003a) (see Appendix O for the complete online questionnaire), including psychological measures of:

- *Knowledge*: 4 items, (e.g. 'What is the UV index?'). These items were selected based on the information provided through the 'mISkin app' and that control groups had not have access to;
- *Intention*: 3 items on sun protection (e.g. 'I intend to seek shade when I go out in the midday sun'); one item on tanning (e.g. 'I intend to sunbathe to get a suntan');
- *Attitudes towards sun protection*: 3 items on affective and short-term attitudes (e.g. 'For me, using sun-protection in the midday sun would be... Uncomfortable/ Comfortable'); 5 items on rational and short-term attitudes (e.g. 'For me, using sun-protection in the midday sun would decrease my risk of sunburn'); 4 items on long-term attitudes (e.g. 'In the long run, using sun protection in the midday sun will make me feel more comfortable about my skin');
- *Attitudes towards a tanned appearance*: 4 items (e.g. 'For me, to get a tan would make me feel more attractive');
- *Self-efficacy*: 7 items (e.g. 'I am confident that I can apply sunscreen properly (i.e. how and where to put it on, the quantity, how much time to wait before going out in the sun)');
- *Social influences on sun protection* (injunctive and descriptive): 2 items (e.g. 'The people whose opinions I value Use/Do not use sun protection when they go out in the midday sun');
- *Social influences on a tanned-appearance* (injunctive and descriptive): 2 items (e.g. 'The people whose opinions I value Get a tan/Do not get a tan during their holidays');
- *Time perspective* (Adams, 2012)- *Consideration of future consequences*: 5 items (e.g. 'I consider how things might be in the future, and try to influence those things with my day to day behaviour'); and *Consideration of immediate consequences*: 7 items (e.g. 'I only act to satisfy immediate concerns, figuring the future will take care of itself').

Previous studies have shown the role of temporal frame on using sunscreen (Orbell and Kyriakaki, 2008). The inclusion of the latter variable – time perspective – could help understanding whether people are more responsive to current and certain consequences of their behaviour (e.g., skin damage) than to future and uncertain consequences (e.g., the risk of developing melanoma).

#### **7.4.5 Sample size**

##### Internal Pilot (Feasibility) Study

To ensure the feasibility of the trial procedures, we have defined the period until the first 30 participants have completed the study as the internal pilot study. For this internal pilot, the

main outcomes are: a) acceptability (measured by completion rates and post study interviews); b) feasibility (measured by attrition rates); and c) fidelity of intervention measured by user engagement with the mobile-phone intervention.

### *Stopping guidelines*

The stop rules built within this trial were the following:

- If more than 10 out of the first 30 participants do not accept their group allocation, measurement procedures or other aspects of the trial procedures or if the post-holiday interviews identify any significant problems with the acceptability of the trial protocol, the protocol would be either modified to enhance acceptability and feasibility based on the insights gained, or the trial would be discontinued.
- If during this period no significant problems with acceptability and feasibility were detected, the data from the internal pilot will become part of the main dataset and analysed as part of the trial.
- If any major modifications to the protocol needed to be implemented, the data from the internal pilot will not be analysed alongside the main trial.

The sample exceeded the initial target of 30 participants due to unforeseen reasons. The initial recruitment rate (low season) was low and intensified subsequent activities to increase recruitment (see below) led to a peak in response resulting in an additional 12 participants randomised during this pilot period. Only the first 30 participants were interviewed for the process evaluation phase, where data on acceptability and feasibility of trial procedures and intervention were collected.

### Definitive RCT

The primary outcome for the definitive trial is mDNA damage. The sample size calculation assumed an effect size of a standardised mean difference of 0.50. With 200 participants (100 intervention groups; 100 control groups), the main trial was determined to have 95% power to detect this effect size as statistically significant at the 5% (two-sided) level.

Therefore, it was proposed to recruit and randomise 100 participants per group to give a total sample size of 200 participants.

The sample size calculation presented here does not take into account any losses to follow-up. This calculation will be adjusted once data from the internal pilot study provides initial estimates of attrition values for this trial. The following calculation will be used to adjust the sample size based on attrition rate ( $a$ ):  $N = n / (1-a)$ .

#### **7.4.6 Randomisation**

A simple randomisation with a 1:1:1:1 allocation ratio was implemented to assigned participants to the experimental conditions. This was performed using a telephone-based randomisation service blinded to the identity of individuals. This allocation concealment prevents participants and data collectors being aware of which group participants would be assigned to. Only after baseline assessment would researchers assign participants to research groups.

#### **7.4.7 Blinding**

Participants and research personnel installing the mISkin intervention were aware of condition allocations. At baseline the outcome assessor was blinded to allocation. At follow up assessors were aware of the participants' allocation, but it was hypothesised that outcome assessors could not influence outcomes measurements as they are either objective or completed online. Researchers conducting the lab analyses for skin damage were blinded to participants' allocation, as all samples were given a code beforehand unrelated to the trial ID. The coding procedure was performed by a lab researcher independent from the research team.

#### **7.4.8 Statistical methods**

As a feasibility study, the analyses focused on descriptive data regarding recruitment rates and attrition from the intervention, as well as acceptability and participants' satisfaction with the intervention. The main goal is to test whether or not the research protocol proposed is viable for a definitive trial. For this set of analyses about experiences, the allocation by groups as implemented would be considered (4 participants asked to change their random SPF allocation and for 2 participants the app installation was not possible due to technical difficulties).

Participants' characteristics and trial outcomes (means and standard deviations) at baseline and follow-up were displayed by group as allocated, as well as by condition actually received (implemented allocation).

### **7.5 Results**

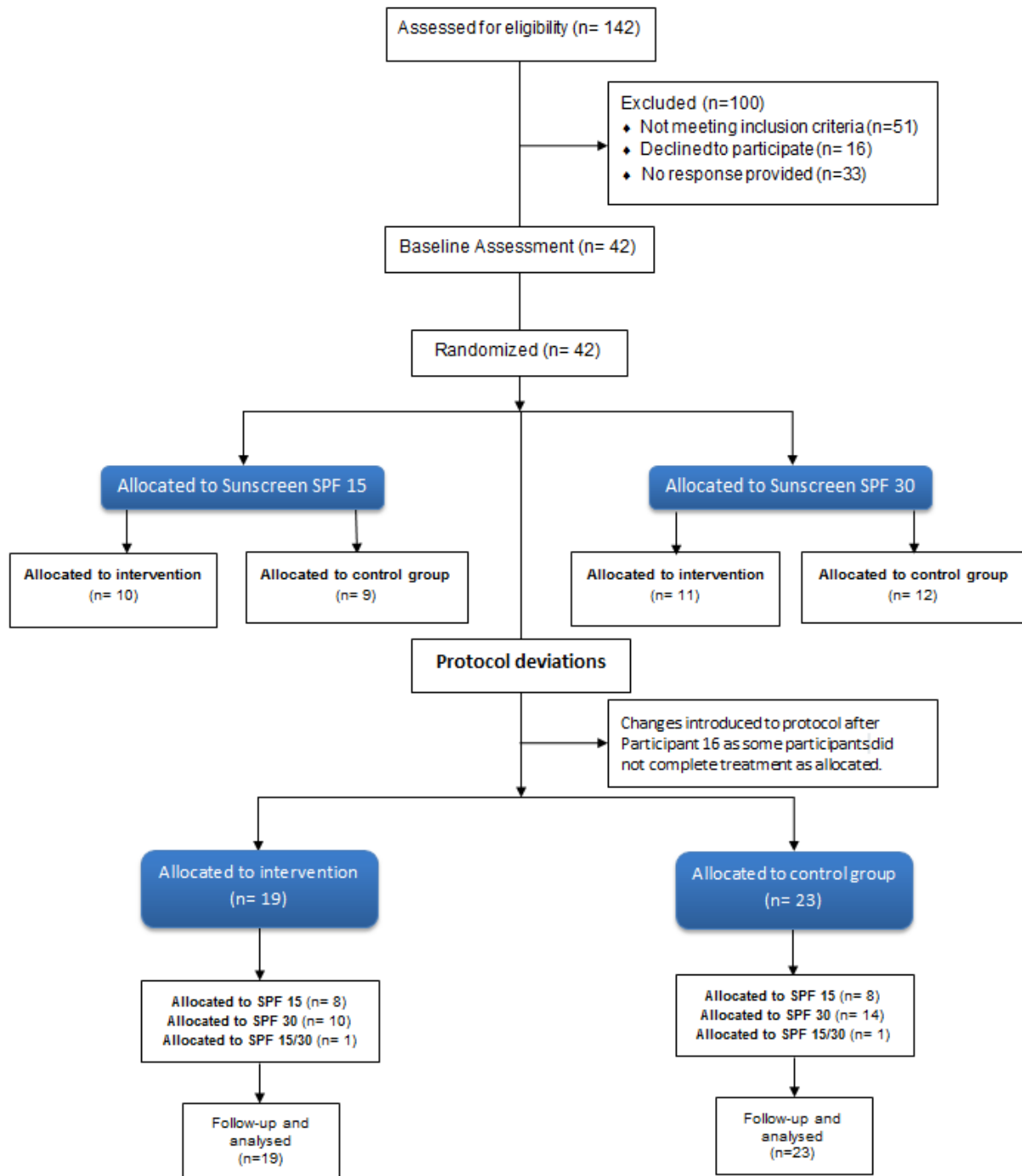
#### **7.5.1 Participants**

Forty-two participants were recruited between December 2012 and October 2013. Figure 7-3 shows the flow of participants through the feasibility study. As seen on the flow diagram, there were six protocol deviations. Two participants could not receive the mISkin app due to technical problems on their smartphones and four participants asked to change their



allocation to the sunscreen SPF received. These protocol deviations led to a change in the random allocation to SPF 15 vs. SPF 30 after the initial 16 participants. Detailed information about the identified problems and changed made can be found under the acceptability section of results.

**Figure 7-3: Flow diagram (adapted from CONSORT (Moher et al., 2001)).**



Participants’ characteristics and demographics can be found in Table 7-1. The mean age of the participants was 35.5 years (SD= 9.7 years, N= 42), with more female volunteers (N= 32;

76.2%). Data collection also provided information on skin type. The majority of participants reported that they usually burn and tan minimally (N= 15; 34.9%) and have a pale skin colour (N= 18; 41.9%).

Most frequent holiday destinations were: Spain (N=12; 28.6%); France (N=5; 11.9%); USA (N=5; 11.9%); Turkey (N=4; 9.5%) and Greek Islands (N=4; 9.5%). Additionally, most frequent holiday durations were: more than 14 days (N=15; 35.7%); 8-14 days (N=9; 21.4%); 8 days (N=9; 21.4%) and less than 8 days (N=9; 21.4%).

**Table 7-1: Demographics of Study Participants by Group (N=42).**

Variables	SPF 15		SPF 30		Total (N=42)
	mISkin App (N=10)	Control (N=9)	mISkin App (N=11)	Control (N=12)	
Age, mean (SD)	37.2y (11.2y)	34.2y (9.1y)	36.6y (9.3y)	34.0y (10.1y)	35.5y (9.7y)
Gender, N (%female)	5 (50.0)	7 (77.8)	9 (81.1)	11 (91.7)	32 (76.2)
Skin reaction, % (N) <sup>27</sup>					
Burns easily, never tans	0.0 (0)	0.0 (0)	0.0 (0)	8.3 (1)	2.6 (1)
Burns easily, tans minimally	30.0 (3)	14.3 (1)	33.3 (3)	25.0 (3)	26.3 (10)
Burns and tans moderately	20.0 (2)	14.3 (1)	66.7 (6)	41.7 (5)	36.8 (14)
Burns minimally, tans easily	40.0 (4)	57.1 (4)	0.0 (0)	16.7 (2)	26.3 (10)
Rarely burns, tans profusely	10.0 (1)	14.3 (1)	0.0 (0)	0.0 (0)	5.3 (2)
Never burns, tans profusely	0.0 (0)	0.0 (0)	0.0 (0)	8.3 (1)	2.6 (1)

### 7.5.2 Primary outcomes for the internal pilot: Acceptability

#### Acceptability of trial procedures

To explore the acceptability of trial procedures, data was collected about three main areas of the trial procedures: consent, assessment and allocation to interventions. During the process evaluation phase, thirty interviews were conducted (mISkin App: N=13; No app: N=17) and feedback was fully analysed from twenty-nine<sup>28</sup>.

<sup>27</sup> Only 38 participants completed the online questionnaire at baseline (mISkin App SPF 15: N=10; No app SPF 15: N=7; mISkin App SPF 30: N=9; No app SPF 30: N=12).

<sup>28</sup> One interview was lost due to recording problems.

### Acceptability of consent procedures

All interviewees stated that information given prior to or during enrolment was very informative, easy to understand and clear. All participants were also very positive about the arrangements made for the meetings that accounted for their availability.

### Acceptability of the allocation procedures

All participants were satisfied with the randomised group allocation to get the mISkin app or control group.

With regard to the allocation to the mISkin app, all participants were satisfied with their allocation to either the mISkin app or the control group. Three interviewees mentioned that they would like to see it as they were curious about the mISkin app. The possibility of getting the app on their next holiday was given to all participants and one participant showed interested in getting the app installed after the trial.

The randomised group allocation to sunscreen SPF 15 vs. SPF30 was not acceptable to many participants. Eleven participants raised concerns about the random allocation to sunscreen SPF. From this, 10 were unwilling to be randomly allocated to SPF 15 as it was considered to be too low for them. Only one participant expressed the willingness to receive SPF 15 as a sunscreen with SPF 30 was seen as too high. Overall, 7 people (out of 142; 5%) declined participation based on the random allocation to SPF. Taking into account this information, after the initial 16 participants trial procedures were changed to give participants the option to choose from three options: a) two bottles of SPF 15, b) two bottles of SPF 30, or c) one bottle of SPF 15 and one bottle of SPF 30. With the introduction of this change, 6 participants asked to change their allocation to the SPF group. The new allocation procedure is not a preference-based design, instead it is a random allocation procedure with the option to change allocation based on participant's preference regarding sunscreen SPF.

### Acceptability of assessment procedures

Regarding the outcome assessment procedures, some issues were raised about the skin swabs, sensors and questionnaires.

#### *Epidermal mDNA skin damage*

The skin swabs procedure was described as painless and made easy by the provision of information detailing the procedure. Some participants reported that it might be helpful to mention that the swabs will remove the makeup, in case they want to bring more to reapply.

### *Sunscreen use patterns (accelerometry)*

All participants mentioned that they did not experience problems with carrying the AX3 sensors attached to the sunscreen bottle with a silicone band. The majority of participants mentioned that their silicone band snapped, which in some cases led to missing data for the specific sensor. Participants were advised, during the initial meeting, that this was a possibility as some silicone bands were faulty. To overcome this, when possible, participants were given an extra silicone band and were instructed on what to do if the silicone band snapped (substitute band and fit it tightly).

### *Self-reported sun protection behaviours and psychological variables*

Questionnaires were described as being straightforward, easy to understand and the length was considered good. One participant mentioned that questions about social norms and skin colour were a bit confusing.

### Acceptability of the mISkin app intervention

Thirteen participants were interviewed to collect data on acceptability of the mISkin app.

One interview was lost due to recording problems, resulting in only 12 participants allocated to the mISkin app providing feedback on intervention acceptability.

Data collected showed that holidaymakers were 6/12 were very satisfied with the app, 4/12 were somehow satisfied and 2/12 were dissatisfied. All participants commented and made suggestions about possible ways of improving the mISkin app. Additionally, those not entirely satisfied with the app provided reasons. These data is summarised in Table 7-2.

Participants were highly satisfied with the initial skin type identification, the videos and the 'Sun safety quiz'. Few suggestions were made regarding ways of improving these features. The main problem reported about the mISkin app was the 'Sun Alert Service'. Participants suggested that this feature could be improved by having a systems that is able to learn participants' sun protection habits, preferences and personal risks to sunburn, and personalise prompts according to these (e.g. time until sunburn risk). A few technical problems regarding the GPS functionality to detect indoor/outdoor location were also reported (e.g. GPS not detecting location, detecting outside when participant was indoors and vice versa). Participants also recommended that the UV levels forecast information should be integrated with the 'Sun Alert Service', therefore creating a more integrated and parsimonious system. Another common reported issue was the fact that participants allocated to the mISkin app were asked to keep their phone on British Time (Greenwich

Mean Time) so the sensor data could be synchronised with the app log usage data. This was described as somehow disruptive as time shown on the phones was incorrect and led to prompts not being received adequately.

**Table 7-2: Feedback on the mISkin app provided by participants in the internal pilot study (N=12).**

mISkin menus	Comments on the app menus (quotes from interviews)	Suggested changes (example quotes)
Skin assessment	'It was good. It was useful.' (P4, Male, SPF15, 27y) <sup>29</sup>	<b>More information on recommended protection:</b> 'It would have been useful if it would tell you what the skin type actually meant a bit more information about the skin type and protection.' (P4, Male, SPF15, 27y)
'How to be SunSmart' menu (videos and UV photos)	<p><b>Positive:</b> 'I did watch the videos. I think they were good. I didn't realise sunscreen wasn't a total protection against UV. I thought you put sunscreen on and that was it, you were protected all the time.' (P1, Female, SPF15, 33y)</p> <p>'They were short and there weren't boring, straight to the point.' (P4, Male, SPF15, 27y)</p> <p>'There was a couple of little things that kind of stuck with me, like forgetting the top of the ears and how much to put it on.' (P901, Female, SPF30, 27y)</p> <p><b>Negative:</b> 'The thing that confuse me a bit was that I needed to press back to go back to the video menu.' (P4, Male, SPF15, 27y)</p> <p>'The videos were not working properly. Every time you watched a video it ticked box, and I wanted all the boxes to be ticked, but every time I watched a video it stopped half way through and I couldn't finish. I could only finish some of them and those worked fine and were good.' (P7, Male, SPF30, 32y)</p> <p><b>UV Photos:</b> 'Photos are good; you get a good picture of what might happen.' (P11, Female, SPF30, 39y) 'It's amazing really, you wouldn't think how much it damages your skin. I wasn't scared; I was a bit amazed, a bit shocked. I am quite cautious anyway.' (P901, Female, SPF30, 27y)</p>	<p><b>More videos:</b> 'Maybe more videos because they were very short. So I longer list would be better.' (P7, Male, SPF30, 32y)</p> <p><b>Information on videos transferred to text:</b> 'Maybe instead of videos, have it in text information. Cos sometimes you don't want the noise.' (P11, Female, SPF30, 39y)</p> <p>No suggestions were made.</p>

<sup>29</sup> Quotes references are organised by participant ID, gender, SPF allocation and age.

<p>'Sun safety quiz' menu</p>	<p><b>Positive:</b>  'I like those kind of things and I think it was useful especially if you don't have any background knowledge it kind of helps you.' (P4, Male, SPF15, 27y)</p> <p>'I went through the quiz and it was useful, good. I think it was good information, not a lot, fair amount.' (P7, Male, SPF30, 32y)</p> <p>'Most of the stuff I already knew but it was a good reinforcement.' (P11, Female, SPF30, 39y)</p> <p><b>Negative:</b>  'That was all common sense. Possibly a little simplistic.' (P1, Female, SPF15, 53y)</p>	<p>No suggestions were made.</p>
<p>'Sun Alert service' menu (prompts and sun protection habits monitoring)</p>	<p><b>Positive:</b>  'I liked the suggestions it had as well, because it wasn't like demands of you, like 'put more sunscreen!, it was more kind of suggestions it was things that you would think it was sun protection, like suggestions to go for lunch inside. And it is your choice still. I think it's different from the normal kind of advice you get about sun protection, like you must, must, must.' (P4, Male, SPF15, 27y)</p> <p>'Too many reminders? no, in fact I've turned the reminders up, because I know that I burn easily. So I had it on every hour so I was more aware of what it was going on so that I would remember. They always worked fine.' (P4, Male, SPF15, 27y)</p> <p>'The GPS worked fine, it was always on. As soon as I went outside I would check my phone to see if it was detecting properly. Actually the house that I was in had a terrace and it would sometimes pick it up.' (P4, Male, SPF15, 27y)</p> <p>'The alerts were very good. Because normally I think people they are used to receive texts to remind them about bank accounts. But when you get a text like this, maybe you are thinking about drinking or eating and you are aware again of what you are up to, how the environment is. The suggestions didn't make a difference for me, because I was already engaging in something and it wouldn't change my mind.' (P7, Male, SPF30, 32y)</p> <p>'I did it manually. It's a bit of reminder and it tells you how long you've been out you don't realise sometimes how long you've been out.'(P901, Female, SPF30, 27y)</p> <p><b>Negative:</b>  'The other thing was I thought it would ask more questions and it was quite easy to have a look at what it said 'have you packed everything for the day?' and it's too easy just to press ok and forget</p>	<p><b>System more interactive and intelligent:</b></p> <p>'Maybe something about what you are doing that day and then maybe relating that to how you should be protecting yourself. Cos it might vary quite a lot from day to day. I think it would make it better.' (P8, Female, SPF30, 31y)</p> <p>'If you know what temperature is going to be for the specific location or the UV and if you can tell how long people have been in the sun and also my skin type, like a sort of timer that you tell you when to reapply.' (P9, Female, SPF15, 53y)</p> <p>'Also over time the app could also learn how the users interact. If someone's always being sun smart, then you can sort of fade it into the background and only periodically interact again. As it not always applicable really.' (P18, Male, SPF30, 31y)</p> <p>'I felt that the app wasn't really</p>

<p>about it or if you are off doing things you don't hear it bip. And I thought it would prompt throughout the day 'have you put in more sunscreens, have you been in water'.' (P1, Female, SPF15, 33y)</p> <p>'I didn't find the suggestions very useful at all. If you are you lying on a beach, you are not going for a stroll if the reminders tell me to.' (P9, Female, SPF15, 53y)</p> <p>'On the days it was cloudier; it was still giving me those tips, which wouldn't apply to me. But on the sunnier days, it worked properly. I got more used to do it as the week went on and I would do it during lunchtime and everything.' (P901, Female, SPF30, 27y)</p> <p>'It would start automatically at 9am and it would say I was outdoors. GPS was on all the times. It wasn't picking up indoors or outdoors and sometimes I was changing indoors/outdoors, but I didn't remember to do it all the time.' (P15, Female, SPF30, 51y)</p> <p>'Apart from not knowing how to turn it on and off, that was perhaps the only downside and also I don't think it ever properly connected with the GPS. On the app it would only say initializing GPS, but it never gave an indication that there was a GPS connection and it never displayed the GPS icon like it does in maps or other apps. So I'm not sure if it was working properly and it capture the location properly.' (P18, Male, SPF30, 31y)</p> <p>'I didn't receive any of the prompts. The only thing I saw was the questions about what I was using. My mobile didn't work properly. I guess if the reminders worked it would have been better and useful.' (P22, Female, SPF15, 42y)</p> <p>'Sometimes it would say 'you've outdoors for x amount time' and it wouldn't be correct. GPS was on all the time.' (P30, Female, SPF30, 24y)</p> <p>'I didn't get the alerts. I only got the one where you have to say what methods of sun protection you are using. Every day.' (P30, Female, SPF30, 24y)</p> <p>'Battery life was poor by running GPS and the phone needed constantly charging. I stayed in the same resort 90% of the time so why GPS constantly required.' (P32, Male, one SPF30/one SPF15, 58y)</p> <p>'Locked between 8am to 6pm and if not out of sun at 6 then next morning assumed still in sun. Also I was getting up for a run at 7.30 and applying sun screen but could not record it on the app.' (P32, Male, one SPF30/one SPF15, 58y)</p> <p>'My biggest complaint was that the app seemed to be constantly nagging me to do what I was</p>	<p>interested in what I was doing cos after adding the information about what I was doing it wasn't adding much to the information given. Some feedback or praise would probably make it better. Or made stating the benefit once in a while but then you also run into the problem of message being repeated too often.' (P18, Male, SPF30, 31y)</p> <p><b>Extra option on system about weather:</b></p> <p>'It wasn't relevant if it wasn't sunny. Maybe have an option I'm outside but it's not sunny/hot.' (P901, Female, SPF30, 27y)</p> <p><b>GPS and phone battery:</b></p> <p>'I wonder if there is a way to make it to run in the background without using so much battery. Maybe a way without using GPS. And give you push notifications without you needing to start the app at all times.' (P11, Female, SPF30, 39y)</p>
--	---



	<p>aware I could do, anyway. It was like being on holiday with my mother.’ (P32, Male, one SPF30/one SPF15, 58y)</p> <p>‘[EMA] I guess it didn’t offer too much, there was more a data collection tool than anything else so I was asking me about my sun protection habits, but it I don’t think it did that too much proactively to make me think about using sunscreen or sun protection in general.’ (P18, Male, SPF30, 31y)</p> <p>‘[EMA] No OK button when changing in the details – never quite sure if data has been accepted.’ (P32, Male, one SPF30/one SPF15, 58y)</p>	
<p>UV levels texts</p>	<p><b>Positive:</b></p> <p>‘They helped me. You look at the window and you see how much sun you have and you correlate with the information you try to understand it better.’ (P7, Male, SPF30, 32y)</p> <p>‘Receiving the texts to remind you about the UV index worked as a prompt to remember to put sunscreen on. I think this actually the first time in a while that I don’t have a sunburn at all.’ (P11, Female, SPF30, 39y)</p> <p>‘With the texts messages it was quite nice to get at the end of message ‘have fun or enjoy your holidays.’ (P18, Male, SPF30, 31y)</p> <p><b>Negative:</b></p> <p>‘The UV messages were really helpful. But I did think that based on the fact that I had absolutely no idea what spectrum the UV ranges 3 or 4 – if there are high – but I thought based on that you would have prompted more or it might be that that is quite low – I don’t know. But I did think it would say ‘have done this, have you done that’. I just think it would make me think more ‘oh I better take the sunscreen’. But cos it wasn’t as interactive as I thought it would be, it was easy to ignore and just press ok.’ (P1, Female, SPF15, 33y)</p> <p>‘There were useful. But what does UV 7 mean? I kind of looking outside I know it would mean it was a strong sun. But I guess if it was cooler I might not know what a UV level would mean and how I should be protecting from the sun.’ (P4, Male, SPF15, 27y)</p> <p>‘No, it wouldn’t really mean anything. I wasn’t sure what to do based on that. I would like to know more what things I would have to do to protect myself based on that.’ (P15, Female, SPF30, 51y)</p> <p>‘Texts message were helpful. It always gave the UV index level and I never really understood what it was and what does that mean. What am I meant to do with that information?’ (P18, Male, SPF30, 31y)</p>	<p><b>Integrated in Sun Alert Service:</b></p> <p>‘It would be useful if the information I receive through the text messages could be integrated in the app and the notifications. It didn’t seem unified.’ (P18, Male, SPF30, 31y)</p> <p><b>More explanations on UV levels Index meaning:</b></p> <p>‘If there was sort of a scale explaining what the difference would be about getting sunburn, personalised risk information.’ (P18, Male, SPF30, 31y)</p>

	<p>'UV state was constant 7 – why not send initial text then one when anticipated change?' (P32, Male, one SPF30/one SPF15, 58y)</p>	
<p>General feedback</p>	<p><b>General benefits:</b></p> <p>'I think apart me remembering to use it, which by the end of holidays I was doing that. It was quite good because it trigger me to apply sunscreen and to apply more and more often.' (P9, Female, SPF15, 53y)</p> <p>'But having the app installed and having it running in the background, every time you open your phone I see the icon right there and it makes you think a little bit.' (P18, Male, SPF30, 31y)</p> <p>'A constant reminder. If you're not very strict with sunscreen then it's good to keep getting reminders because sometimes goes by very quickly and you don't think even notice time going by and that you need to top up on sunscreen.' (P30, Female, SPF30, 24y)</p> <p><b>Easiness of use and interaction:</b></p> <p>'The symbols were clear and the app is quite easy to interact with and straightforward.' (P1, Female, SPF15, 33y)</p> <p>'I think everything that is in the app needs to be there and it made sense why it was all there. It wasn't surprising.' (P4, Male, SPF15, 27y)</p> <p>'I don't think there was too much information on the app, cos you could pace it suit yourself.' (P9, Female, SPF15, 53y)</p> <p><b>Attractiveness:</b></p> <p>'The app itself is attractive.'(P1, Female, SPF15, 33y); 'I liked the colours, it was appealing.' (P22, Female, SPF15, 42y)</p> <p><b>More information about how to use the app:</b></p> <p>'More information about what to do with app before.' (P15, Female, SPF30, 51y)</p> <p>'A leaflet explaining the app would be good.' (P1, Female, SPF15, 33y)</p> <p><b>Type of holiday or practicality:</b></p> <p>'So it probably depends what kind of holiday you are going on (...).I don't know how practical it would be to carry my phone around all the time on holiday.' (P1, Female, SPF15, 33y)</p> <p><b>Drained of battery:</b></p> <p>'Battery life was poor and the phone needed constantly charging.' (P32, Male, one SPF30/one SPF15, 58y)</p>	

### Acceptability of the sunscreen SPF intervention

Some participants described positive and negative experiences related to the specific sunscreen SPF. One participant allocated to SPF 15 reported being slightly sunburnt at the beginning of the holiday. This contrary was also observed. A few participants allocated to SPF 30 mentioned that using this SPF prevented them from being sunburnt. However, others also reported the lack of a tan after their holidays as a consequence of using SPF30.

## **7.5.3 Primary outcomes for the internal pilot: Feasibility**

### Feasibility of recruitment

Out of the 142 participants assessed for eligibility, 42 (29.6%) met the inclusion criteria and provided consent to participate in this study (Figure 7-3). A precise estimation of the number of participants reached is difficult, as several channels were used as recruitment strategies, especially within the community with no exact numbers of individuals included.

For those where information was provided, the main reasons for exclusion were: 1) having another type of smartphone (e.g. iPhone) (n=31; 21.8%); and 2) unwillingness to be randomised to SPF15 or SPF30 before changing the procedure (n=5; 3.5%). Other reasons for exclusion included having a travelling partner already enrolled in the study, not having a smartphone or not living in the North East of England. For some participants, reasons for non-participation could not be identified (n=39; 27.5%).

### Feasibility of randomisation

Two breaches in the trial protocol occurred, as two participants were allocated to receive the mISkin app but the app could not be installed on their phones. In one case, the participant misidentified their Windows smartphone for an Android smartphone and this was only detected after the trial allocation procedure. In the other case, the app could not be installed on the participant's phone after several attempts and no cause for this occurrence was found.

These two participants were treated as allocated in the main analyses performed in this chapter (Intention-to-treat principle).

### Feasibility of outcome assessment procedures

All participants consenting to participate in the study completed baseline and follow up assessments.

### *Epidermal mDNA skin damage*

The skin swabs were obtained for all participants at both time points (100%). Data on mDNA skin damage for the nose bridge was retrieved from 34 (80.9%) holidaymakers at baseline and 33 (78.6%) at follow up. For the arm mDNA skin damage, data was available for 31 (73.8%) holidaymakers at baseline and 36 (85.7%) at follow up.

Two reasons explain this missing data: 1) data was undetermined when performing PCR analyses (n= 7; 4.2%)<sup>30</sup>; and 2) samples was mislabelled during analyses and therefore lost when decoding (n= 27; 16.1%). This first problem might be due to low levels of DNA in the specific sample that lead to undetermined results in the PCR analyses and cannot be prevented. However, the mislabelled samples during lab analyses can easily be prevented by making the blinding procedure easier with more user-friendly coding and by ensuring a meticulous examination when labelling samples during the lab analyses.

### *Residual sunscreen weight*

Sunscreen weight was available for 41 out of 42 holidaymakers at both baseline and follow-up. The site in which one of assessments was performed did not provide feasible conditions (unstable surface) to obtain a reliable value.

### *Sunscreen use patterns (accelerometry)*

AX3 sensors measuring sunscreen use events were allocated to 28 participants out of 42 holidaymakers (App SPF15: 7; No-app SPF 15: 7; App SPF30: 6; No-app SPF 30: 8). This was mainly due to a lack of sensors available at assessment meetings to allocate to participants. Reliable data from the accelerometry sensors detecting sunscreen use was extracted from 28 participants<sup>31</sup> (100%), though due to loss of sensors' battery some events might have been missed on the final days of holiday for 14 participants. The battery life of the sensors lasts approximately 2 weeks, but sometimes the time between the initial assessment and the post-holiday assessment would be longer than 2 weeks. In future, this problem can be solved by providing participants with a charger and specific instructions about the procedure.

---

<sup>30</sup> The total number of mDNA samples was 168 since a total of 4 samples were taken from each participant (nose and arm; before and after holiday).

<sup>31</sup> Due to shortage of sensors, these were allocated to participants on the basis of sensors availability at time of baseline assessment. A total of 28 participants received AX3 sensors attached to the sunscreen bottles.

### *Self-reported sunburn and sun protection practices*

The survey was completed at baseline by 38 participants (90.4%) and at follow up by 41 participants (97.6%) out of 42 participants. There was only one missing value from all the data collected through online questionnaires - one sun exposure item in one participant.

### Fidelity: engagement with mISkin intervention components

**Data about the usage of the mISkin app was retrieved from 19 participants out of 21 and can be seen in**

Table 7-3. Two participants did not receive the app as the mISkin app could not be installed on their phones.

**Table 7-3: Descriptive statistics about the mISkin app usage.**

<b>mISkin app features</b>	<b>Descriptive statistics</b>
Login events (M, SD)	7.02 (SD= 5.30)
Cues acknowledged (%)	57.69 (range: 0-92)
Videos watched (M, SD)	2.21 (SD=2.74)
Videos, any (%, N)	47.4, n=9
Video 'Protecting sensitive skin' (%, N)	31.6, n=6
Video 'Sun protection tips' (%, N)	26.3, n=5
Video 'Choosing a good sunscreen' (%, N)	36.8, n=7
Video 'How to apply sunscreen' (%, N)	42.1, n=8
Video 'Preventing damage' (%, N)	36.8, n=7
Video 'Protecting children' (%, N)	31.6, n=6
Video 'Other's use of sun protection' (%, N)	15.8, n=3
Sun safety quiz (%, N)	89.5, n=17
EMA (M, SD)	0.34 (SD= 0.27)

Rates of usage were high, with an average of 7.02 (SD= 5.30) login events<sup>32</sup> per day. A more detailed look into these login events showed that the median proportion of cues acknowledged by participants was 57.69% (range: 0-92%). The videos 'How to apply sunscreen' (42.1%; n=8), 'Choosing a good sunscreen' (36.8%; n=7) and 'Preventing damage' (36.8%; n=7) were the most watched. The least watched video was 'Other's use of sun protection' (n=3). The average number of videos watched by participants was 2.21 (SD=2.74). The 'Sun safety quiz' was completed by 17 participants (89.5%).

<sup>32</sup> A login event is classified as an entry in the mISkin app system.

The ecological momentary assessment about sun-protection practices was completed on average 0.34 times a day (SD= 0.27) by participants.

#### Optimisation of the trial protocol

Based on participants' feedback and main problems identified in the sections above some changes were introduced to the trial protocol in order to increase acceptability and feasibility (Table 7-4). The main change introduced was the possibility of participant to choose the sunscreen SPF they are allocated to: a) two bottles of SPF 15, b) two bottles of SPF 30, or c) one bottle of SPF 15 and one bottle of SPF 30.

**Table 7-4: Main problems and changes introduced to the trial protocol.**

<b>Trial procedures</b>	<b>Problems</b>	<b>Changes introduced</b>
<b>Recruitment</b>	Initial low recruitment rate	Recruitment was scaled up and holiday duration was enlarged to three weeks
	mISkin app installation problems	Standard operating procedure (SOP) was changed in order to fully check participants' smartphone suitability for the mISkin app installation before the randomisation procedure.
<b>Measurement</b>	Samples lost during blinding procedure	Skin swabs blinding SOP was changed to ensure that trial number can be fully retrieved by keeping the original skin swab package where both trial number and new labelling is written.
	Samples lost due to incorrect labelling during analyses	Skin swabs samples labelling SOP during lab analyses was changed to ensure samples have a more meaningful label (i.e. date plus numbers from 1 until 24), ensuring that staff responsible for labelling procedure will not conducted more than 24 samples per day. SOP also now recommends that lab analyses are conducted in sets of 24 samples to prevent tiredness of the researcher and potential mistakes.
<b>Randomisation</b>	Random allocation to SPF15 or SPF30 reported as problematic	SOP and materials were changed to give participants the possibility to choose from three options: a) two bottles of SPF 15, b) two bottles of SPF 30, or c) one bottle of SPF 15 and one bottle of SPF 30.
<b>Intervention</b>	The need to keep phone time on British time (Greenwich Mean time) reported as problematic	SOP was changed in order to allow participants to keep their time preference on their smartphone. Data from sensors will be analysed taking into account details provided by participants on the holiday location and local time.

#### Optimisation of the mISkin Intervention

Although participants were highly satisfied with the mISkin app, several suggestions were made for improvements (Table 7-2). Acceptability of the mISkin app would be highly improved if the UV levels forecast could be integrated within the 'Sun alert service'. An attempt is currently in place to resolve the issue, but the application programming interface (API) provider for the UV functionality will release this new piece of programming during 2014.

Within the '*Sun alert service*' functionality, more information will also be provided in order to better explain the meaning of UV levels meaning and sun protection recommendations based on these, as UV levels information is only available through the '*Sun safety quiz*'. Participants' feedback also suggests that acceptability and satisfaction would be improved if the technical problems in the Sun alert service prompting functionality are solved. Solutions to these problems are currently in development and will be in place in a future update of the mISkin app.

Additionally, the suggestion to make the '*Sun alert service*' more interactive and proactive is also under consideration as improving this system would also increase participants' satisfaction and compliance with the mISkin app.

Another important issue made salient both during recruitment and process evaluation stages was the need to develop an iOS version of the mISkin app that would enable the app to run on iPhones and iPads.

#### **7.5.4 Primary outcome for the definitive RCT: Epidermal mDNA skin damage**

Table 7-5 shows the main findings for the primary and secondary outcomes with raw data for the four experimental groups as allocated. Participants allocated to App SPF 15 showed an increase of mDNA skin damage on both the nose and arm from baseline to follow-up. For the participants to No-app SPF 15 and App SPF30, mDNA skin damage on the nose decreased from baseline to follow-up and increased on the arm. For participants in the group No-app SPF 30 mDNA, skin damage on the nose decreased from baseline to follow-up and no change was observed on the arm. Similar patterns were found between the four experimental groups on mDNA skin damage when considering the implemented allocation instead.

#### **7.5.5 Secondary outcomes**

##### Residual sunscreen weight

There was a trend for a higher average of daily use of sunscreen over holiday for the participants allocated to SPF 15 (App SPF15 mean: 15.76 grams; No-app SPF 15 mean: 15.48 grams) than to SPF30 (App SPF30 mean: 14.84 grams; No-app SPF 30 mean: 12.27 grams). Similar patterns were found between the four experimental groups when considering the implemented allocation instead.



### Sunscreen use patterns (accelerometry)

Results in Table 7-5 show also a trend for a higher daily average of sunscreen use events for participants allocated to App SPF 30 (Mean: 9.75), No-app SPF 15 (Mean: 5.98) and No-App SPF 30 (Mean: 5.91). Similar patterns were found between the four experimental groups when considering the implemented allocation instead.

### Self-reported sunburn and sun protection practices

Questionnaires findings revealed a trend for holidaymakers allocated to No- app SPF15 for an increased number of sunburn during their holidays, whilst participants allocated to other experimental groups seemed to show a reduction on the number of reported sunburn. A similar finding was found when considering the implemented allocation instead.

Approximately half of the participants in all conditions spent more than 4 hours (per day) exposed to the sun during their most recent holiday. Holidaymakers allocated to App SPF 15 and No-app SPF 30 either maintained or reduced their exposure to the sun during their holidays. When considering the implemented allocation instead, only the conditions allocated to the app showed this pattern.

There seems to be a trend for participants allocated to the App SPF 30 condition showing higher levels of sunscreen use (100%), hat use (54.5%) and seeking shade (36.4%). Sunglasses were used more by holidaymakers allocated to No-app SPF15 (100%) and App SPF 30 (100%) conditions. Holidaymakers allocated to App SPF 15 used more times t-shirt as a method of sun protection during holidays (20%). When considering the implemented allocation instead, similar patterns were observed with the exception of hat use and seeking shade that were used more by participants allocated to No-app SPF 15.

To validate all the behavioural measures of sun-protection, correlations were computed between self-reported sun protection practices with sunscreen use events (measured by tri axial accelerometer AX3) and residual sunscreen weight, as well as the proxy measures of skin damage caused by UV exposure testing for mDNA (Table 7-6). Sun protection practices at baseline was positively correlated with sun protection practices during holidays ( $r=.57^{**}$ ). A positive correlation was also found between sun exposure during holidays and sun exposure at baseline ( $r=.65^{**}$ ) and residual sunscreen weight ( $r=.34^*$ ). There were positive correlations between mDNA from the nose with mDNA from the arm at both baseline ( $r=.47^*$ ) and after holiday ( $r=.39^*$ ). mDNA from the arm at baseline was also positively correlated with mDNA from the nose after holiday ( $r=.47^*$ ). Sunscreen use events were also positively correlated with mDNA from the nose after holiday ( $r=.48^*$ ).

In addition, reliability analyses were also computed and the Cronbach's alpha for the sun exposure items was .88 and .50 for sun protection behaviours items, suggesting good and poor internal consistency respectively.

**Table 7-5: Means and standard deviations of primary and secondary outcomes by allocation (N=42) at baseline and post-holiday.**

	Baseline					Post-holiday				
	SPF 15		SPF 30		Total	SPF 15		SPF 30		Total
	mISkin App	Control	mISkin App	Control		mISkin App	Control	mISkin App	Control	
<b>Skin damage (CT values)</b>										
mDNA skin damage: Nose	1.43 (.30) (N=8)	1.51 (.11) (N=7)	1.51 (.14) (N=9)	1.58 (.10) (N=10)	1.51 (.18) (N=34)	1.57 (.09) (N=9)	1.46 (.09) (N=7)	1.42 (.11) (N=8)	1.52 (.16) (N=9)	1.50 (.12) (N=33)
mDNA skin damage: Arm	1.49 (.17) (N=7)	1.49 (.10) (N=7)	1.42 (.12) (N=9)	1.50 (.11) (N=8)	1.47 (.13) (N=31)	1.57 (.18) (N=8)	1.51 (.14) (N=7)	1.53 (.15) (N=10)	1.50 (.13) (N=11)	1.53 (.15) (N=36)
<b>Sunscreen use</b>										
Sunscreen weight (g)	496.80 (75.74) (N=10)	470.89 (5.93) (N=9)	477.70 (2.31) (N=10)	477.67 (1.44) (N=12)	480.85 (37.30) (N=41)	335.30 (82.11) (N=10)	296.11 (119.01) (N=9)	324.41 (87.77) (N=10)	341.92 (106.37) (N=12)	325.98 (97.44) (N=41)
Daily sunscreen use (no of events)	--	--	--	--	--	5.29 (7.80) (N=7)	5.98 (3.92) (N=7)	9.75 (4.30) (N=6)	5.91 (5.35) (N=8)	6.60 (5.54) (N=28)
<b>Self-reported sun protection practices</b>										
Sun exposure weekdays (% ≥ 4 hours)	50.0% (n=5)	83.3% (n=5)	80.0% (n=8)	66.7% (n=8)	68.4% (n=26)	50.0% (n=5)	87.5% (n=7)	81.8% (n=9)	83.3% (n=10)	75.6% (n=21)
Sun exposure weekends (% ≥ 4 hours)	60.0% (n=6)	83.3% (n=5)	80.0% (n=8)	75.0% (n=9)	73.7% (n=28)	40.0% (n=4)	87.5% (n=7)	81.8% (n=9)	75.0% (n=9)	48.8% (n=20)
Sunscreen use (% often and always)	60.0% (n=6)	100.0% (n=6)	90.0% (n=9)	83.3% (n=10)	81.6% (n=31)	90.0% (n=9)	87.5% (n=7)	100.0% (n=11)	91.7% (n=11)	92.7% (n=38)
T-shirt use (% often and always)	30.0% (n=3)	33.3% (n=2)	40.0% (n=4)	8.3% (n=1)	26.3% (n=10)	20.0% (n=2)	12.5% (n=1)	18.2% (n=2)	16.7% (n=2)	17.1% (n=7)
Hat use (% often and always)	20.0% (n=2)	16.7% (n=1)	40.0% (n=4)	25.0% (n=3)	26.3% (n=10)	10.0% (n=1)	50.0% (n=4)	54.5% (n=6)	16.7% (n=2)	31.7% (n=13)
Seek shade (% often and always)	10.0% (n=1)	16.7% (n=1)	20.0% (n=2)	8.3% (n=1)	13.2% (n=5)	20.0% (n=2)	25.0% (n=2)	36.4% (n=4)	33.3% (n=4)	29.3% (n=12)
Sunglasses use (% often and always)	80.0% (n=8)	50.0% (n=3)	90.0% (n=9)	83.3% (n=10)	78.9% (n=30)	80.0% (n=8)	100.0% (n=8)	100.0% (n=11)	83.3% (n=10)	90.2% (n=37)
<b>Number of sunburn (≥1)</b>	80.0% (n=8)	16.7% (n=1)	50.0% (n=5)	41.7% (n=5)	50.0% (n=19)	60.0% (n=6)	25.0% (n=2)	36.4% (n=4)	16.7% (n=2)	34.1% (n=14)

**Table 7-6: Bivariate correlations on behavioural measures of sun protection before and after holiday.**

	1	2	3	4	5	6	7	8	9	10
<b>Self-reported sun protection behaviours</b>										
1. past sun exposure		.65**	.15	.08	.05	.25	-.02	-.16	-.30	.06
2. sun exposure over holiday			-.02	.13	.17	.34*	-.12	-.16	-.28	-.04
3. past sun protection				.57**	-.09	.17	.02	-.03	-.20	.02
4. sun protection over holiday					.23	.20	-.05	-.02	-.07	.03
<b>Sunscreen use</b>										
5. events (accelerometry data)						-.32	.12	.28	.48*	.02
6. residual weight							-.20	.12	.19	.24
<b>Skin damage (mDNA values)</b>										
7. nose (baseline)								.47*	-.08	.16
8. arm (baseline)									.47*	.36
9. nose (post-holiday)										.39*
10. arm (post-holiday)										

Note. \*  $p < .05$ ; \*\*  $p < .01$ ;

### Process measures and psychometric properties of psychological variables

Results displayed in Table 7-7 reveal a trend suggesting that intentions to use sun protection during the next holiday ( $M=5.39$ ;  $SD= 1.07$ ), short-term affective attitudes towards sun protection ( $M=5.61$ ;  $SD= 0.97$ ), long-term attitudes towards sun protection ( $M=5.83$ ;  $SD=0.84$ ) and self-efficacy ( $M=5.99$ ;  $SD= 0.68$ ) were higher for those allocated to the No-app SPF 30 condition.

Short-term rational attitudes towards sun protection ( $M=5.82$ ;  $SD=0.62$ ) and attitudes towards a tanned appearance ( $M=5.73$ ;  $SD=0.66$ ) seemed to be higher for those allocated to the App SPF 15 condition. A trend suggests that more favourable social norms for sun protection ( $M=1.68$ ;  $SD= 1.25$ ) and more unfavourable social norms about getting a tan ( $M=3.91$ ;  $SD= 1.59$ ) were reported by holidaymakers allocated to the App SPF 30 condition. Results also seem to suggest that participants allocated to the App SPF 30 condition reported lower intention to tan (Median= $3.00$ ; IQR=  $4.00$ ). Participants allocated to the No-app SPF 15 condition also seemed to report a greater consideration of future consequences ( $M=3.14$ ;  $SD= 0.46$ ). Consideration of immediate consequences was similar in all experimental groups. Similar patterns were found between the four experimental groups when considering the implemented allocation instead.

**Table 7-7: Means (SDs) and psychometric properties of psychological variables by allocation (N=42) at baseline and post-holiday.<sup>33</sup>**

Variables	Baseline					Post-holiday				
	SPF 15		SPF 30		Total (N=38)	SPF 15		SPF 30		Total (N=41)
	mISkin App (N=10)	Control (N=6)	mISkin App (N=10)	Control (N=12)		mISkin App (N=10)	Control (N=8)	mISkin App SPF 30 (N=11)	Control (N=12)	
Intention to use sun protection ( $\alpha = .62$ )	4.07 (1.25)	5.24 (.69)	5.00 (1.15)	4.61 (1.28)	4.68 (1.19)	4.87 (1.25)	4.38 (1.57)	5.06 (1.21)	5.39 (1.07)	4.98 (1.26)
Intention to suntan <sup>34</sup>	5.50	5.00	4.00	5.50	5.00 (IQR=4)	5.50	5.50	3.00	4.50	5.00 (IQR=4)
Attitudes										
Short-term, affective ( $\alpha = .91$ )	5.17 (1.51)	5.95 (1.21)	4.70 (.82)	5.78 (1.34)	5.39 (1.31)	4.93 (1.99)	4.83 (1.39)	4.58 (1.82)	5.61 (.97)	5.02 (1.58)
Short-term, rational ( $\alpha = .50$ )	5.56 (.97)	5.40 (.74)	5.62 (.79)	5.30 (.68)	5.46 (0.78)	5.82 (.62)	5.15 (.67)	5.49 (.85)	5.42 (.88)	5.48 (0.78)
Long-term ( $\alpha = .81$ )	4.63 (1.35)	5.43 (1.21)	5.25 (1.61)	5.56 (.99)	5.22 (1.29)	5.73 (.92)	5.13 (1.13)	5.18 (1.53)	5.83 (.84)	5.49 (1.14)
Attitudes towards a tan ( $\alpha = .92$ )	5.82 (.88)	5.00 (1.16)	5.31 (1.71)	4.52 (1.39)	5.14 (1.37)	5.73 (.66)	5.25 (.79)	4.43 (1.91)	5.02 (1.34)	5.08 (1.36)
Self-efficacy ( $\alpha = .78$ )	4.91 (.85)	5.49 (.49)	5.14 (.79)	5.64 (.76)	5.30 (0.78)	5.66 (.73)	5.16 (.68)	5.68 (.98)	5.99 (.68)	5.66 (0.81)
Social norms for sun protection ( $\alpha = .72$ )	2.30 (1.14)	1.64 (.75)	2.06 (1.10)	1.71 (1.08)	1.93 (1.04)	2.05 (1.04)	2.13 (.64)	1.68 (1.25)	1.75 (1.25)	1.88 (1.08)
Social norms for tanning ( $\alpha = .73$ )	2.85 (.78)	3.21 (1.75)	3.72 (1.15)	3.17 (.98)	3.22 (1.15)	3.20 (.86)	2.56 (.94)	3.91 (1.59)	3.50 (1.57)	3.35 (1.36)
Consideration of Future Consequences ( $\alpha = .41$ )	3.06 (.42)	3.14 (.46)	2.60 (.42)	2.92 (.55)	2.92 (0.49)	--	--	--	--	--
Consideration of Immediate Consequences ( $\alpha = .48$ )	2.83 (.31)	2.88 (.35)	2.87 (.66)	2.86 (.38)	2.86 (0.43)	--	--	--	--	--
Knowledge	--	--	--	--	--	2.15 (.44)	2.25 (.33)	2.23 (.24)	2.44 (.43)	2.27 (0.37)

33 Data presented as mean (SD). At baseline 38 participants completed the questionnaires and 41 completed the questionnaires after holiday.

34 Data presented as median (interquartile range - IQR) as construct based on a single item.

## 7.6 Discussion

This chapter reports on an internal pilot study aimed at testing acceptability and feasibility of a systematically developed behaviour change intervention for holidaymakers, as well acceptability of trial procedures.

The trial procedures and the mobile-phone intervention mISkin app were found to be mostly acceptable and feasible, with the exception of the planned allocation to SPF15 vs. SPF 30 which was found not to be sufficiently acceptable to be viable in the definitive trial protocol. In light of this, the SPF allocation procedures were modified and a range of smaller changes were implemented to improve the trial protocol for a full trial.

Trial procedures, such as information and material provided before enrolment and meeting arrangements, were all found to be highly acceptable to all participants. All 42 participants who consented and were randomised completed baseline and post-holiday assessments showing that, after being involved in the trial, procedures are highly acceptable. However, the allocation to sunscreen SPF 15 or SPF 30 was sometimes not well received. Some participants were not willing to be randomly allocated to SPF15 or SPF30 and this led to the introduction of a change in the trial procedures by allowing participants to select their sunscreen SPF allocation. Some limitations of this procedure can be anticipated, especially when people choose SPF 15. People who want SPF 15 may be more motivated to get tan or a “safe tan”. The general recommendation regarding sunscreen is at least SPF 15. As mentioned before, several associations (The British Skin Foundation, 2011) have urged for the need to change this general recommendation for a higher SPF for sensitive skins, especially when travelling to place with high UV levels. Nevertheless, NICE still advocates the use of sunscreen SPF $\geq$ 15 and the mISkin trial cannot be seen as sending mixed messages. If participants show a strong preference for SPF 15, they should be given this option in the definite trial. Some recommendations were made by participants to improve the mISkin intervention, with the key issue reported being the ‘*Sun alert service*’. Improving this feature based on participants’ feedback should be considered and further improvements to the mISkin app should be made. The need for more intelligent and interactive systems was also reported by participants in Dennison and colleagues study (2013). Additionally, the study by Buller and colleagues (2013) also shows that participants were interested in a system that would: a) display how long they could be exposed to the sun without burning, taking also into consideration for this time needed for vitamin D synthesis; b) show daily UV levels for the specific location; c) advice on recommended SPF; and d) send prompts to reapply sunscreen.

The changes introduced to optimise the intervention will not significantly change the intervention (active behaviour change techniques) and the trial procedures. Therefore, the definitive trial should continue after the internal pilot. Nevertheless, the definitive trial might benefit from a further round of process evaluation interviews aimed at exploring acceptability and satisfaction of updated version of the mISkin app and feasibility of the iOS version of the app, after changes are implemented.

Regarding the feasibility of recruitment, out of the 142 participants who were screened, 42 were eligible for participation in the study. Recruitment rate was limited by the inclusion requirement to own an Android™ smartphone. Several participants (N=31) were excluded because they owned other smartphones, showing the need to improve the interoperability of the mISkin app, especially for iOS system. Ofcom data shows that iPhone users currently represent 28% of the smartphone users share in the UK, which combined with Android users represent 74.6% of the market (comScore, 2012). These numbers are encouraging, since with an iPhone version of the mISkin app, the recruitment rate would likely be more satisfactory.

In addition, some participants allocated to the mISkin app reported problems on the reception of prompts related to the fact that they were asked to keep their phone on British Time (Greenwich Mean Time). Even though this can provide useful information about the relationship between prompts and actual behaviour (sunscreen use as measured by the sensors), more efforts need to be made to address this issue. A possible solution might be to discontinue this procedure and use solely the information about their travelling destination and jet lag details.

The high completion rates suggest good feasibility of outcome measurements. The findings suggest that no major changes should be made to main procedures of the trial. Nevertheless, some data about the epidermal mDNA skin damage was lost either during the blinding and labelling process or because the PCR analyses could not determine the mDNA level. The logistics of blinding and labelling should be improved in the definitive trial to avoid data loss by limiting decoding impossibility.

The process evaluation study conducted is a key element of the design of this study and provides relevant information on how the mISkin intervention and the trial procedures in general can be enhanced. Feedback from the trial procedures and the mISkin intervention was collected through face-to-face interviews. This could positively influence the self-reported acceptability and satisfaction with the behavioural intervention and trial procedures. Further studies should explore the use of other process evaluation methods alongside a feasibility study, in order to disentangle these types of influences on outcomes of interest. Another concern is the high proportion of



women (76.2%) in the trial population, which can lead to an unbalanced representativeness of gender within the trial. Nevertheless, the systematic review reported in Chapter 2 shows that most studies included more female than male participants (52.5 % to 100 % female), with two studies including only women. In addition, experimental groups seem to be slightly unbalanced with more women allocated to the control groups.

This evidence-informed behaviour change study is characterised by: a) the use of an innovative design that draws on information from a user-centred design study, and b) the novelty of outcome measurements explored. Epidermal mDNA skin damage is an objective proxy measure of sun protection over holiday and has proven to be reliable and feasible for studies involving holidaymakers. In addition, the objective measures of sunscreen use also improve the reliability and specificity of outcome measurements used. Yet, the study could be improved by using an objective measure of UV exposure that will reliably provide information on the number of hours holidaymakers were exposed to direct sunlight, and retrieve information on the intensity of the sun rays. This information would facilitate the understanding of sun exposure patterns and also contribute to develop more comprehensive advice on ideal levels of sun protection for this population.

The findings presented in this chapter support the estimated number of contacts required for the definitive trial. Extrapolating from the pilot data and assuming a scenario where no changes to the protocol are introduced, it is expected that approximately 620 subjects would have to be contacted and assessed for inclusion to achieve a total sample size of 200 participants randomised in the definitive trial. Taking these figures into consideration overall recruitment rates would be greatly improved if there was a iOS version of the mISkin app and if access to holidaymakers was facilitated by a gatekeeper (e.g. high-street travel agency, airport lounge access).

In addition, 2 out of 21 participants (9.5%) allocated to the mISkin app could not have the app installed in their phones. The introduction of a change to the standard operating procedure to detect if the participants have suitable smartphones for the study before randomisation will prevent these breaches in the protocol from happening. Even though only 1/42 participants were interested in getting the app installed after the trial, this was not routinely offered after the trial. For the definitive trial this should be changed and made as a systematic procedure where all controls get the opportunity to download the mISkin app and receive specific instructions about it.

Likewise, 7 (4.2%) mDNA samples resulted in undetermined values during lab analyses. This has implications for the recruitment into the definitive trial, meaning that

approximately 9 more participants will have to be recruited to reach the total number of 200 valid participants (following formula presented in methods section for sample size calculation).

Considering the group differences observed, participants allocated the two SPF 15 conditions showed an increased use of sunscreen (residual weight of sunscreen bottle). This is in line with the expected pattern of application as people using a SPF 15 will need to reapply sunscreen more often (Diffey, 2001). Overall, sunscreen use was low, with an average daily use of 14.46 grams. This is a special concern if the average exposure time of 5.36 hours per day is taken into consideration. The general guideline for sunscreen application thickness is 2 mg/cm<sup>2</sup> (The British Association of Dermatologists, 2013). According to Diffey (1996), a full body application of a typical adult (body surface area of 1.73m<sup>2</sup> approx.) will consist of 35 grams of the sunscreen, which is roughly one third of a bottle per application. These figures demonstrate that the sample used a much lower quantity of sunscreen than the one recommended. In line with our findings, a study conducted by Nicol and colleagues (2007) with 364 beachgoers, shows that the daily amount of sunscreen used was 7.67 g/day and 9.33 g/day for the two intervention groups in the study. The study described in Chapter 3 also shows that the majority of participants uses less than the recommended sunscreen quantity (median application quantity: 0.04 mg/cm<sup>2</sup>). Broad spectrum sunscreens protect against UVB and UVA, and both can damage DNA in the skin. UVA is linked to UVB is responsible for the majority of sunburns and UVB penetrates deeper into the skin. It ages the skin, but contributes much less towards sunburn. Protecting only from sunburns does not eliminate other forms of damage to the skin. Based on these findings, future preventive strategies should provide more explicit instructions of how much to use in each sunscreen application. This could be better integrated in the mISkin intervention by prompting for the specific quantity of sunscreen that needs to be applied (i.e. prompts could instruct for specific quantities, possibly related to various recreational activities, e.g. 'as much as a golf ball or a full shot glass' for whole body coverage). In addition, self-reported sunscreen use was high at baseline, suggesting a highly motivated sample of sunscreen users. This fact can potentially affect the findings of the mISkin trial by introducing a biased sample and opening the possibility of ceiling effects. The definitive trial should arguably select people who are less consistent with sunscreen use, where any intervention strategy will likely generate a larger effect size and significant public health change.

The differences in the primary and secondary outcomes discussed in this chapter are only exploratory and should not be overemphasised as the study was not powered to detect group differences. Group differences should be explored further in a full trial with

a larger sample of holidaymakers to ensure the statistical and clinical significance of the findings. In addition, results described in this chapter did not adjust statically for important variables, such skin type and gender, and these should be explored in the definitive trial. In addition to psychological predictors, demographic characteristics such as gender and skin sensitivity have also been found to influence sun-protection practices (Kasparian et al., 2009). In general, females are significantly more likely to use sunscreen than males (Berndt et al., 2011; Bränström et al., 2001; Cokkinides et al., 2001; de Vries et al., 2006; Geller et al., 2002; Livingston et al., 2003; Schofield et al., 2001). Some contradicting results have, however, been reported with no gender differences identified in sun-safety practices (Andreeva et al., 2008; Lower et al., 1998). Protective behaviours also tend to vary depending on skin sensitivity with people with fairer skin (Types 1 and 2) reporting more sun-protection (Berndt et al., 2011; Bränström et al., 2001; Cokkinides et al., 2001; Geller et al., 2002; Livingston et al., 2007; Robinson et al., 1997; Schofield et al., 2001; Wichstrøm, 1994). In conclusion, the systematically developed mISkin intervention was found to be acceptable and feasible. Participants involved in the process evaluation interviews made relevant suggestions for intervention refinement that would greatly influence their satisfaction with the mISkin application. The systematic development of the mISkin application has shown the importance of piloting an intervention before conducting a large scale RCT.

Trial procedures were also found to be feasible and acceptable. However, changes in recruitment strategies are needed to ensure adequate numbers are randomised for the definitive trial. The possibility of participants choosing their allocation to sunscreen SPF15 vs SPF 30 improved the trial acceptability and feasibility.

The changes introduced to the trial procedures are minor enough to allow the sample of 42 from this pilot study to be analysed as part of the definitive trial.

Finally, even with the changes introduced both to the trial procedures and intervention, the current feasibility study provides enough evidence that the trial should proceed to a full RCT as the main changes will only increase the already positive acceptability of the trial.

## Chapter 8 General Discussion

### 8.1 Introduction

In the UK, malignant melanoma was responsible for 2,209 deaths in 2010 and was the 5th most common cancer in 2010 (Cancer Research UK, 2013c). Intermittent sun exposure to high UV levels and a history of sunburn is highly related to the risk of malignant melanoma (Gandini *et al.*, 2005). These risk factors seem to be commonly experienced during holidays in places of high-intensity sunlight (Lens and Dawes, 2004). Unlike the majority of cancers, the incidence of malignant melanoma seems to be associated with affluence (Shack *et al.*, 2008). Epidemiologic studies suggest that implementation of sun-protection behaviours, such as staying in the shade, avoiding the midday sun, appropriate clothing and using sunscreen would decrease skin cancer incidence (Armstrong and Kricger, 2001).

Recent guidance published by the National Institute for Health and Clinical Excellence (NICE) (2011) established recommendations for the development of strategies to prevent skin cancer, by raising awareness and increasing knowledge of the risks of UV exposure; modifying attitudes towards sun protection; and prompting sun protection behaviour change. Within this guidance, a set of research recommendations were also made about future strategies aimed at preventing skin cancer in the UK, including:

1. Determine the incidence and prevalence of skin cancer, including possible demographic trends;
2. Explore what type of information provision is effective and cost-effective;
3. Identify newly developed primary prevention interventions that are effective and cost effective, excluding provision of information;
4. Research feasible proxy outcome measures to be used in primary studies on skin cancer prevention.

In line with these guidelines, the project described throughout this PhD thesis aimed to answer some of the questions stated in objectives 2, 3 and 4, fitting the remit of the above guidelines.

The starting point for this research was to synthesise the evidence for the effectiveness of existent interventions designed to promote sun-protection behaviours in recreational/tourist settings and identify active features associated with intervention effectiveness (Chapter 2). The main conclusions of this systematic review were that unprotected UV exposure can be reduced through behavioural interventions, but that effects were modest in size and highly heterogeneous. Three main challenges were identified whilst assessing the evidence-base: a) poor reporting of intervention

development, design and contents; b) poor outcome measurement; and c) poor study methodology.

In this final chapter, the findings obtained in relation to these three main challenges are discussed. The evidence for each challenge is appraised in relation to how the studies in this thesis contribute to the existing literature, focusing particularly on the strengths and limitations of the work undertaken. Finally, this chapter will also address the implications of the findings for future research, making recommendations for practice and finalising with concluding remarks.

## **8.2 Interventions development, design and reporting**

According to the MRC guidelines (Craig *et al.*, 2008; Craig *et al.*, 2010), the development of complex interventions encompasses the use of the best available evidence and theory in successive phases of piloting, in order to identify challenges in the design and methodology before proceeding to an exploratory and definitive evaluation. The same guidelines also state the importance of monitoring the implementation process.

The systematic review of sun protection studies (Chapter 2) showed that the majority of included interventions were not based on systematic evidence and did not provide a thorough description of the theory-base used to inform the intervention. In addition, most studies did not provide sufficient information about intervention procedures and components.

This PhD thesis reports on the systematic development of an evidence-based intervention to promote sun protection behaviours amongst holidaymakers. To identify the relevant evidence base of this project, a systematic review was initially conducted (Chapter 2). Even though the moderator analyses performed were exploratory, they provided potential avenues for the development of future interventions in the field. The findings suggested that interventions using behaviour change techniques facilitating social norms for sun-protection behaviour (e.g., providing information about others' behaviour and social norms) and using appearance-based information about photoaging illustrated with UV photographs (e.g., pictures of cases of skin damage) appeared to be more likely to result in larger than median effect sizes. The information gathered in this review was used to inform the development of a prototype intervention.

The newly developed prototype mobile-phone intervention (mISkin application) was tested in a user-engagement study which provided information on how the mISkin app could be further improved. Overall, participants were satisfied with the mISkin prototype and expressed willingness to use it. Feedback from participants was used to introduce

changes in order to optimise acceptability. The involvement of 'users' allows for the development of interventions, which are likely to result in higher levels of implementation (Craig *et al.*, 2008). Other studies have utilized a user-centred design in the development of behavioural interventions (Michie *et al.*, 2012; Buller *et al.*, 2013) and have shown that this approach takes into account the effects of the interaction between various factors (e.g. personal, social economic, technological, educational) in a given intervention. The importance of users' involvement might be even more vital in studies exploring the design of new technologies, such as mobile-phone applications, embedded in complex interventions (Pagoto and Bennett, 2013). The study by Buller and colleagues (Buller *et al.*, 2013) constitutes a good example of the use of a user-centred design for the development of a mobile-phone application to promote sun-protection. Likewise, the study reported in Chapter 4 obtained feedback from potential users to ensure that the final product met users' needs and showed good levels of satisfaction.

The intervention development was further improved by insights obtained from the qualitative study (Chapter 3) conducted with potential holidaymakers. This study aimed to explore perceptions of sun-related experiences and investigate relevant behavioural barriers and facilitators for the implementation of sun-protection behaviours. Findings from this study showed that the importance attributed to a tanned appearance emerged as a potential motivational barrier for sun-protection, increasing overexposure amongst those holidaymakers interviewed. Suggested public health messages to circumvent this should highlight the harmful effects of sunlight on physical appearance and strategies that demonstrate effective ways of performing sun protection practices. The information presented in Chapter 3 helps understand what sun protection means for potential holidaymakers and the possible determinants of this behaviour. The findings are in line with the existent literature that shows the importance attributed to a tanned-appearance (Mahler *et al.*, 2003b; Mahler *et al.*, 2006; Dodd and Forshaw, 2010).

Information gathered through the systematic review on sun protection interventions (Chapter 2), the interviews exploring sun protection perceptions amongst holidaymakers (Chapter 3) and the user engagement study (Chapter 4) informed the development of a novel mobile-phone intervention (mISkin application) to promote sun protection amongst holidaymakers. Previous authors explored the relevance of mHealth for behavioural change interventions, highlighting the significance of real time interaction (Pagoto and Bennett, 2013). Studies by Buller and colleagues (2013) and Armstrong and colleagues (2009) have demonstrated the potential for mHealth to promote sun protection behaviours. Scalable, affordable and geographically flexible interventions to promote sun-protection behaviours are needed.

The mISkin application runs on the Android™ operating system. Recent figures show that Android™ smartphones are the fastest growing operating system (46.6%) followed by Apple (28.0%) and Blackberry RIM operating system (15.2 %) (comScore, 2012 ).

Results from the internal pilot study described in Chapter 7 show that the mISkin app was acceptable and feasible. Nevertheless, findings from the process evaluation study (Chapter 7) demonstrate the need to optimise the mISkin system. One of the main suggestions made by participants was the willingness to engage with a more interactive and proactive system. More precisely, participants suggested that the ‘Sun Alert Service’ could be improved by having a system that is able to learn participant’s sun protection habits, preferences and personal risks of sunburn, and personalise prompts according to these (e.g. likely time until sunburn risk given the participant’s skin type and past experience). The need for more sophisticated feedback in health behaviour apps has been described as vital to improving engagement amongst users (Pagoto and Bennett, 2013). The current possibilities made available not only by the panoply of digital technologies (e.g. sensors, mobile-phones, social networks), but also by the knowledge derived from behavioural science (e.g. evidence about effective behaviour change techniques) can support the development of more intelligent and complex systems of feedback.

Recruitment into the pilot study was also affected by the fact that the mISkin app only runs on the Android™ operating system. This led to the exclusion of holidaymakers owning smartphones from other platforms and shows the importance of increasing the interoperability of the mISkin app. Nevertheless, the numbers are promising, since if holidaymakers owning an iPhone version of the mISkin app were to be included in the sample (n=31; 21.8%), the recruitment rate would have been satisfactory. Despite the very good levels of acceptability and feasibility of the mISkin app some technical issues did arise. Approximately 10% (n=2) of holidaymakers allocated to receive the app could not have the app installed on their phones. In one case, the participant misidentified their Windows smartphone as an Android smartphone and this was only detected after the trial allocation procedure. In the other case, the app could not be installed on the participant’s phone after several attempts and no cause for this occurrence could be identified. This problem highlights the need to change the standard operating procedure, in order to ensure any possible technical problems are detected before the randomisation process, preventing possible breaches in the protocol.

Even though social influences are integrated within the mISkin app, this component could be leveraged by embedding features from online social networks to promote sun

protection. Online social networks have been described as a useful resource to promote health behaviour (Pagoto and Bennett, 2013; Burke-Garcia and Scally, 2014), providing the access to relevant information and emotional support for behaviour change (Hwang *et al.*, 2010). For example, Twitter and Facebook have been used successfully to promote weight loss (Napolitano *et al.*, 2013; Turner-McGrievy and Tate, 2013). The use of online social networks was discussed intensively throughout the development of the mISkin app. However, the fact that holidaymakers would incur extra roaming charges to access online social networks made the implementation of this idea problematic. In future studies, it is important to address this problem by finding other possible ways of including social networks in similar apps, which would ideally be free of charge.

As mentioned previously, the mISkin intervention development followed the systematic approach suggested by the MRC framework. The main aim of this project was to develop a behavioural intervention to promote sun protection amongst holidaymakers, with a particular interest in exploring its feasibility and acceptability. In this initial step, the main concern was to test for its internal validity and explore the efficacy for individual behaviour change. The importance of this phase cannot be underestimated and the efficacy of the mISkin app in changing individuals' sun protection behaviour should be appraised before moving forward. However, an important question has not been addressed with this project: 'How can we get people to actually use this app routinely?'. Findings from Chapter 7 suggest that more efforts are needed to engage people at higher risk, which can be a challenge as this population might not be for ways to reduce their risk and so would not be likely to download an app on their own initiative. It is, therefore, important to identify barriers to uptake by this population and strategies to engage this population and disseminate the mISkin app. A suggestion would be to take this work further by updating the app based on the findings from the pilot study and from the definitive trial and by repackaging the mISkin app. Possibly the later could be achieved by labelling the mISkin app as a 'holiday or weather app and by fostering collaborations with entities undoubtedly linked to sun protection, such as Cancer Research UK or the sunscreen industry.

### **8.3 Outcome measurement**

One of the aims of this PhD thesis was to advance the measurement of sun-protection behaviours, by exploring a reliable, valid and replicable method of assessing this type of behaviour. In Chapter 2, it was concluded that most of the studies included in the systematic review relied on retrospective self-reports and observational methods with considerable risks for social desirability bias.



This project is the first to measure sun exposure over holiday using a biomarker of UV-induced skin damage (Chapter 5 and Chapter 7). The methods were developed through a series of piloting and testing studies that explored the potential to assess skin damage (Chapter 5) and were based on methods previously developed by Harbottle and colleagues (2010). This objective method of assessing UV exposure represents an acceptable and feasible proxy measure of sun protection behaviours.

Although this is a novel way of assessing sun exposure, some problems were identified in the measurement of epidermal mDNA skin damage. Firstly, the protocol for the blinding procedures had some limitations that led to the loss of a number of samples during this process. This problem can easily be solved, within the standard operating procedures, by increasing the amount of times samples are carefully and thoroughly checked. Secondly, data on epidermal mDNA skin damage was lost during the lab analysis. This was due to undetermined results from some samples during the PCR analysis. Although this cannot be improved by changing the standard operational procedures, knowledge about this problem can inform the recruitment procedures for the definitive trial. Based on the values of unobtainable data, more participants (n=8) would have to be recruited to reach a total number of 200 valid samples.

Another important contribution of this PhD thesis to the outcome measurement issue is the innovative, objective and time specific approach used to assess sunscreen use. Although, the use of residual sunscreen use (weight) is not a new approach to sunscreen use assessment (Nicol *et al.*, 2007), the use of technology by means of sensors to detect sunscreen use events is a recent method. In a previous study by Armstrong and colleagues (Armstrong *et al.*, 2009), the potential of digital technologies to assess sunscreen use had already been explored.

The newly developed way of recording real time information about the use of sunscreen involved the use of accelerometers. In order to develop detection mode and create a reliable algorithm to detect sunscreen use events, a series of testing and validation experiments were conducted and analysed (Chapter 5). However, a limitation of this development work for the validation of sensors was the fact that this work did not occur in a real holiday scenario (i.e. full description of a sunscreen application process through a typical holiday day) and instead occurred in a controlled environment.

The combined use of time and date-stamped information from the sensors and the residual use of sunscreen (weight) helped to understand how much was used per day, how much is used per application and when these applications take place. Together, these data will potentially contribute to the identification of daily patterns of sunscreen

application. Nevertheless, this system could be improved by integrating a weight-sensing mechanism within the sensors to measure exactly how much is used in each application and the specific time and data for this information. In addition, this system could also be improved by linking the prompts sent by the mISkin app and the sunscreen use patterns. This would provide useful information to adjust the frequency and type of prompt that holidaymakers receive so that it reflects their own personal preferences and patterns of sunscreen use. This type of advice could be integrated in the mISkin app by, for example, sending prompts at specific times, more prompts during initial days, and just after detecting a travel pattern.

In addition, the complex relationships between the variables investigated in the internal pilot study (Chapter 7) are missing. This is mainly due to the small sample of participants involved in this study. At the moment, only trends can be observed, but these might become significant in a definitive trial with a larger sample of holidaymakers. Nevertheless, the main aim of the internal pilot study was to explore acceptability and feasibility of interventions and trial procedures. A comprehensive list of necessary changes to trial procedures has been compiled and some suggestions have been made by holidaymakers in order to optimise the mISkin app. The intervention optimisation will not significantly change the intervention content (i.e. active behaviour change techniques) and procedures. If the change is implemented, the definitive trial might benefit from a further round of testing, aimed at exploring the acceptability of and satisfaction with an updated version of the mISkin app and feasibility of an iOS version.

Finally, the possibility of measurement reactivity was a concern, especially considering the comprehensive list of self-reported outcomes assessed in the internal pilot study. However, the completed systematic review on the topic (Chapter 6) did not find any study assessing QBE on sun protection behaviour and concluded that the 'question-behaviour effect' on health-related behaviour is small and was therefore not taken into consideration when designing the trial protocol.

## **8.4 Trial methodology**

Rigorous and well-designed trials are needed in the area of sun-protection to better understand their impact on behaviour. As previously described, only a few studies included in the systematic review (Chapter 2) detailed information about randomisation and blinding procedures and analyses based on intention-to-treat. This systematic review also concluded that better reporting would benefit the evidence base on interventions promoting sun-protection behaviour.

In this PhD thesis, efforts were made to design a robust evaluation of the mISkin app based on thorough methodological procedures. Firstly, the generated allocation within the trial was implemented by using allocation concealment. The assignment to groups was performed by a 'third-party', based on a telephone based randomisation service blinded to the identity of individuals. This type of allocation assignment is thought to be more desirable in randomised controlled trials as it prevents the risk of selection bias (Schulz *et al.*, 2011). Secondly, the trial protocol established that outcome assessors at baseline and lab data analysts were kept blinded to the allocation, preventing the risk of performance bias. Blinding of outcome assessors was not possible at the follow-up outcome assessment. However, blinding of outcome assessors is unlikely to be a source of bias when objective outcomes are used (Schulz *et al.*, 2011). Thirdly, the outcome analyses presented for the primary and secondary outcomes for the internal pilot study (Chapter 7) were analysed using intention-to-treat and involved all holidaymakers randomly allocated to the four experimental groups. Finally, the full protocol of this trial described in Chapter 7 was pre-registered (ISRCTN3943558). This procedure increases transparency and prevents selective reporting and is now a frequent requirement in scientific journals when publishing results from trials (Chan, 2008; Schulz *et al.*, 2011). Both systematic reviews (Chapter 2 and Chapter 6) elaborate on the importance of thorough reporting of trials and interventions. The systematic review on QBE (Chapter 6) also suggests the relevance of pre-registering trials in order to prevent the publication of predominantly positive results and avoid deviations from the initial published analysis plan to answer the main research questions (e.g. only report unpowered significant findings)

A possible limitation of the sequential approach used to develop the mISkin mobile-phone application to promote sun protection is the slow process that it involves, especially when considering the pace of innovation growth. There is the risk of the app becoming obsolete by the time the phases of development, feasibility and efficacy testing are fully completed (Pagoto and Bennett, 2013). Some authors highlight that the use of RCTs might be best for testing an app when it is on a more 'mature' level of development (Kumar *et al.*, 2013). In an initial stage, other methodological approaches might be more helpful and provide useful information for further refinements, such as well-design single studies (*n-of-1* designs), small uncontrolled studies (before and after designs) or time-series designs (Kumar *et al.*, 2013; Baker *et al.*, 2014).

## **8.5 Implications for practice**

The findings from this PhD thesis highlight the importance that participants perceived of having a tanned-appearance (Chapter 3). Future public health campaigns should incorporate more appearance-based strategies. A possible way is to integrate specific

messages aimed at tackling these beliefs. The work by Hillhouse and colleagues (Hillhouse and Turrisi, 2002; Hillhouse *et al.*, 2008; Stapleton *et al.*, 2010) with sunbed users and Pagoto and colleagues (Pagoto *et al.*, 2010) with beachgoers offers some suggestions on how this could be done: use of sunless alternatives and appearance-enhancing alternatives to tanning (e.g. exercise, make up/cosmetics, hairstyle, bright-coloured clothing) (Robinson *et al.*, 2010). This type of information could also be incorporated in an updated version of the mISkin app by providing more appearance alternatives to tanning.

In addition, there seems to be a lack of information about practical aspects of applying sunscreen properly and, more broadly, how to effectively use other methods of sun protection (Chapter 3). Simple and informative strategies could also be developed to tackle this aspect, such as seasonal media campaigns about sun protection methods. Findings from Chapter 3 (interviews) and Chapter 7 (pilot) also showed that participants applied small amounts of sunscreen. Future strategies should emphasize the recommended quantity of sunscreen for each application. This could be done by demonstrating the procedure, but also by providing real-life comparisons that would make amounts more explicit (e.g. as much as a golf ball/shot glass) and more easily understood.

The conclusions from Chapter 4 (development) and Chapter 7 (pilot) also show that holidaymakers are interested in using mobile-phone applications that prompt them to use sun-protection. However, users want more intelligent systems that are able to learn based on their preferences and adjust the type of advice and prompts given. One of the benefits of mobile-phone applications is the potential to support holidaymakers' sun protection habits in an easy and free fashion that is available on-site (i.e. holiday location).

## **8.6 Implications for future research**

The work described in this thesis highlights the benefits of involving users at different stages of the development and design of health interventions, and mHealth interventions in particular. Future studies would benefit from the use of user testing, especially if the aim is to develop mobile-phone interventions that are acceptable and feasible for participants.

The newly developed mISkin app was tested in a feasibility study and its efficacy is currently being explored in a definitive trial. Nevertheless, similar mobile-phone applications could benefit from future research which explores how different components can alter behaviour, integrating findings from qualitative studies and systematic reviews into individual features which are tested separately.

Another important recommendation for future studies would be the use of samples with higher risk behaviours. As mentioned previously, the sample included in the pilot study (Chapter 7) showed a high self-reported sunscreen use at baseline. Future studies should make efforts to recruit less consistent users of sun-protection by, for example, repackaging the app as a 'holiday or weather app'.

Finally, the findings presented throughout this thesis also draw attention to the importance of using biomarkers of UV-induced skin damage as a proxy measure of sun exposure and use of sun protection. The use of this type of measures in combination with self-reports of sun protection behaviours can help understand the influence of different patterns of sun protection on human skin. In addition, future research should also aim to explore the impact of different types of sunscreen SPF regarding skin damage, which could then inform the recommended sunscreen SPF.

## **8.7 Overall conclusions**

This PhD thesis has successfully addressed the three challenges identified in the systematic review on sun protection interventions in touristic sites. The mISkin intervention was developed based on the most recent evidence base available. The development of this intervention followed a systematic approach, with a thorough report of the process and description of intervention. The use of digital technologies followed the most recent advances in the area of behavioural science with a close involvement of users in the design and development of the mISkin mobile phone application.

In addition, behavioural outcome measurements were improved by tackling this problem previously identified in the literature and using a combination of biologic, technological and self-report outcome measures to understand and successfully assess sun protection behaviours.

Finally, the mISkin intervention was also subject to intensive pilot testing, following the pre-registered methods of a definitive trial. The methodology implemented aims to reduce the risk of bias as reported in the systematic review (Chapter 2) by using robust procedures of blinding, allocation concealment and intention-to-treat analyses.

This PhD thesis also follows the research recommendations set by NICE (2011) by: a) appraising the literature and providing useful information on efficacy of intervention aiming at promoting sun-protection behaviours; and b) proving possible avenues for future outcome assessment within primary studies on skin cancer prevention.

# Appendices

**Appendix A: Development of an Intervention to Promote Sun-Protective Behaviours in Recreational Settings**

**Appendix B: Study Advertisement Leaflet (Interviews & user-centred study)**

**Appendix C: Participant information sheet**

**Appendix D: Informed consent for interviews**

**Appendix E: Topic guide for interviews**

**Appendix F: Interfaces (screenshots) of the resulting prototype intervention**

**Appendix G: Topic guide for user-centred study**

**Appendix H: Final version of the mISkin app**

**Appendix I: Database searches MEDLINE from inception to December 2012**

**Appendix J: Study advertisement information (Pilot study)**

**Appendix L: Participant information sheet (Pilot study)**

**Appendix M: Informed consent (pilot study)**

**Appendix N: Topic guide for interviews for process evaluation study (Pilot study)**

**Appendix O: Holidaymakers' perceptions about engaging in sun-protection: study questionnaire**

## **Appendix A: Development of an Intervention to Promote Sun-Protective Behaviours in Recreational Settings**

### **Background**

### **Definition**

Skin cancer can be differentiated between malignant melanoma and non-melanoma skin cancer (NMSC). NMSC include different forms of cancer and most common amongst these are squamous cell carcinoma (SCC) and basal cell carcinoma (BCC).

### **Prognosis**

NMSC treatment, if done in initial phase, is simple and with a full recovery prognosis. However, when diagnosis and treatment occur in an advanced stage, this is more invasive, painful and causes disfiguration (WHO, 2006)

Malignant melanoma is a very lethal and aggressive form of cancer. Early diagnosis and treatment is associated with a favourable prognosis. Later diagnosis and treatment implies a more advanced phase of the disease and reduces drastically the chances of recovery, increasing the potential for metastases and death (WHO, 2006).

### **Epidemiology**

NMSC are much more common than malignant melanomas and affects mainly older people. Malignant melanoma affects, more commonly, people from younger ages.

In 2000, approximately 26 100 males and 33 300 females were diagnosed with melanomas in Europe, and around 8300 males and 7600 females died of this disease (de Vries & Coebergh, 2004). In 2005, more than 76,000 new cases of non-melanoma skin cancer were registered in the UK (Cancer Research UK, 2008). For melanoma, about 9,600 new cases were diagnosed in 2005 (Cancer Research UK, 2008). Skin Cancer is the seventh most common cancer overall in UK.

In general, results reveal higher skin cancer rates in Northern Europe than in Southern. These patterns are usually attributed to the lighter skin type of the northern populations. Moreover, their affluence is also recognized as an indirect effect, since it allows for the possibility of holiday in sunny destinations, where they are intensively and intermittently exposed to the sun (de Vries & Coebergh, 2004). The British population receives around 30% of their annual UV exposure in their two-week summer vacations (WHO, 2002).

Therefore, recreational sun-exposure is associated with enlarged numbers of melanoma (Armstrong & English, 1996).

## **Causes**

NMSC are generally related to continuous and life-long exposure to sun light, whilst melanoma is linked to intense and intermittent sun-exposure with sun burns (WHO, 2006).

Skin cancer result from an interaction between sun exposure and endogenous factors (e.g. Armstrong & Kricger, 2001). Endogenous risks factors (not modifiable) include skin phenotype, propensity to develop nevi, number of nevi and family history of skin cancer (e.g. Armstrong & Kricger, 2001). Modifiable behavioural risk factors are such behaviours as sun exposure, intermittent sun exposure and history of sunburn. These behavioural factors are the major etiologic factors for melanoma (e.g. Armstrong & Kricger, 2001) and are modifiable.

The increase in skin cancer rate can also be attributed to changes in lifestyle, such as the popularity of sunbathing and tanning closely linked to increases in intermittent sun-exposure (e.g. de Vries & Coebergh, 2004).

Four out of five cases of skin cancer could be prevented by sun-protective behaviours (WHO, 2002). With the ongoing depletion of the ozone layer and the resultant increase of ultraviolet light (UV) concentration, health promotion targeting modifiable behavioural risk factors aiming at avoiding direct UV exposure (e.g., staying in the shadow; avoiding the midday sun; appropriate clothing, using sunscreen) will become increasingly important for skin cancer prevention.

## **Evidence-Based Research**

A systematic review of interventions to prevent skin cancer (Saraiya et al., 2004) found conclusive evidence for the effectiveness of interventions in recreational/tourism settings targeting adult and children's sun-protective behaviours.

The most effective interventions involved a family-based approach at the holiday/recreational site (e.g. 'Pool Cool Program', e.g. Glanz, Lew, Song. & Murakami-Akatsuka, 2000) and included strategies such as: providing information (e.g. leaflets); activities aiming to change knowledge, attitudes, beliefs, and intentions; activities to influence behaviour (e.g. modelling); and environmental policies (e.g. provision of shade).



However, the review did not find conclusive evidence supporting specific intervention techniques or suggesting specific theoretical mechanisms of behaviour change associated with efficacy.

Several problems with the evidence base were identified by this review, such as: 1) measurement strategies (e.g. self-reported measures of behaviour without reference to actual UV exposure at site, lack of objective measures); 2) study designs (e.g. mainly uncontrolled before-after designs, no reference to sample selection); 3) intervention descriptions (e.g. insufficient details for further replication); 4) insufficient measurement of mediating factors and behavioural/health outcomes; 5) poor description of theory base; and 6) all interventions (except Dey, Collins & Woodman, 1995) have been delivered when subjects were already involved in recreational activities (e.g. beaches, swimming pools), leaving questions of generalizability of intervention effects unanswered.

### **Why it is important to do this review**

As stated before, skin cancer numbers are increasing worldwide, especially in industrialized countries, making it a global important health-related concern.

Although there is a previous review addressing effectiveness of recreational interventions to promote sun-protective behaviours (Saraiya et al., 2004), the scope of the review proposed here highlights specific characteristics of interventions, such as the role of specific behaviour change techniques and modes of delivery in interventions efficacy.

In addition, the systematic review will show if the conclusions of the Saraiya et al. (2004) review are still up-to-date and if the problems previously identified have been addressed in the meantime. Finally, this review will also provide information on effect sizes of studies included and will aim at presenting meta-analytic data for a more parsimonious reporting of the results.

## **Objectives**

### **Main objective**

To assess the efficacy of interventions to promote sun-protective behaviours in recreational settings.

### **Specific objectives**

The following questions will be addressed:

- Are there any differences in intervention efficacy related to the age of participants (adults v. youths)?
- Are specific behavioural techniques associated with changes in sun-protective behaviours?
- Are specific environmental/policy techniques associated with changes in sun-protective behaviours?
- Are specific modes of delivery (how, where, when and by whom) associated with changes in sun-protective behaviours?

## Methods

### Inclusion Criteria for studies in this review

#### Types of studies

##### *Randomised controlled trials*

We will include randomised controlled trials (RCTs), as well as cluster randomised controlled trials. The studies could be comparing either two or more types of interventions or one intervention with no intervention or standard practice.

##### *Non-randomised trials*

We will also include non-randomised studies, because high quality RCT might be rare in the field. However, for this type of study we will only present a narrative synthesis of findings.

Within non-randomised trials, we will only include controlled before-after (CBA) studies.

#### Types of participants

We will only include in this review studies that involve participants in recreational/tourism settings (e.g. beaches, swimming pools, skiing settings).

#### Types of interventions

We will consider the following types of interventions:

##### *Individual-directed or group-directed strategies*

Informational and behavioural interventions/counselling aimed at individuals or groups.

##### *Environmental and policy interventions*

Physical, social or informational environment changes and policies that support sun protection and promote sun-safety practices.

### *Media campaigns*

Media strategies such as print media (e.g., newspaper, magazines), broadcast media (e.g., radio, television), and the Internet, with the goal to disseminate information and behavioural guidance supporting sun protection and promoting sun-safety practices.

### *Community-wide and multi-component interventions*

Population-wide programs or campaigns developed in a specific geographic area (city, state, province, or country), using a variety of approaches.

### Types of comparators

In the case of RCTs, we will include trials that include any type of comparator: no intervention, standard practice or alternative interventions/strategies.

### Types of outcomes

We plan to include studies that report on any type of the following primary outcomes:

#### *Primary outcomes*

Sun-protective Behaviours (e.g. sun-exposure measures, seeking shade, use of protective clothes, sunscreen behaviour)

Experience of sunburn

## **Search Methods for identification of studies**

### Electronic searches

Searches will be conducted in different databases to retrieve a relevant and specified set of trials. We will search in the following databases:

- Cochrane Central Register of Controlled Trials (CENTRAL),
- MEDLINE (from 1950),
- EMBASE (from 1980),

- CINAHL (from 1981),
- PsycINFO (from 1967),
- ERIC (from 1965).

#### Search strategy for MEDLINE (OVID)

This strategy was developed having as basic reference the protocol for a Cochrane systematic review on educational programmes (Naldi et al., 2004) and a previous systematic review on interventions to prevent skin cancer (Saraiya et al., 2004). To devise and complete this strategy some relevant articles in the field were analysed in order to retrieve their index terms and include the most frequent. This specific strategy also follows guidelines provided by Jackson (2004) on locating studies relevant to public health and health promotion.

A pilot study of this search strategy was conducted in order to test its feasibility. This pilot study retrieved several relevant papers in the field and for this review.

The search strategy developed for MEDLINE (OVID) is displayed on Table 1.

Table 1: Search strategy for MEDLINE (OVID)

1. exp Melanoma/pc
2. exp Carcinoma, Basal Cell/pc
3. exp Carcinoma, Squamous Cell/pc
4. (skin cancer\$ or melanoma or NMSC or non-melanoma).tw.
5. exp Skin Diseases/
6. exp Skin Neoplasms/pc
7. exp Nevus/
8. exp Melanosis/
9. Keratosis, Actinic/ or exp Keratosis/
10. Skin Aging/
11. ((skin adj3 mole\$) or freckle\$ or nevi or nevus or actinic keratos\$ or solar keratos\$ or sun damage or photodamage).tw.
12. Sunburn/pc
13. sunburn\$.tw.
14. Suntan/
15. (tan\$ or suntan\$.tw.
16. (suntan\$ adj3 (prevent\$ or avoid\$ or risk)).tw.
17. (skin cancer adj3 (prevent\$ or treat\$ or avoid\$ or risk)).tw.
18. (melanoma adj3 (prevent\$ or treat\$ or avoid\$ or risk)).tw.
19. or/1-18
20. exp Health Education/
21. exp Health Promotion/
22. exp Health Behavior/
23. exp Attitude/
24. exp Public Health/
25. Primary Prevention/
26. knowledge/
27. Health Knowledge, Attitudes, Practice/
28. Awareness/
29. exp Public Policy/
30. primary prevention\$.tw.
31. Counseling/
32. counsel?ing.tw.
33. (knowledge\$ or health knowledge, attitudes, practice or awareness\$.tw.
34. (intervention\$ adj3 (suntan or sunburn or sun\$ or sun exposur\$)).tw.
35. (program\$ adj3 (suntan or sunburn or sun\$ or sun exposur\$)).tw.
36. Mass Media/
37. Program Evaluation/
38. exp Sunscreening Agents/
39. sunscreen.tw.
40. Sunlight/ or sunlight\$.tw.

41. Sunbathing/ or sunbath\$.tw.
42. (sun exposur\$ or sun protect\$ or solar exposur\$ or solar protect\$ or sun safe\$.tw.
43. Protective Clothing/ or protective cloth\$.tw.
44. exp Eye Protective Devices/
45. (eye protective devices or sunglass\$.tw.
46. exp Head Protective Devices/
47. (head protective devices or hat).tw.
48. Ultraviolet Rays/ or ultraviolet ray\$.tw.
49. Radiation Protection/ or radiation protect\$.tw.
50. ultraviolet radiation\$.tw.
51. intention/ or intention.tw.
52. exp Motivation/ or motivation.tw.
53. willing\$.tw.
54. belief\$.tw.
55. (social\$ adj4 (support\$ or control\$ or norm\$ or influenc\$)).tw.
56. or/20-55
57. exp Recreation/
58. Bathing Beaches/
59. Swimming Pools/
60. Skiing/
61. Holidays/
62. exp Travel/
63. Seasons/
64. recreation\$.tw.
65. beach\$.tw.
66. tourism.tw.
67. swimming pool\$.tw.
68. skiing.tw.
69. holiday\$.tw.
70. or/57-69
71. 19 and 56 and 70
72. Animals/
73. Animals/ and Humans/
74. 72 not 73
75. 71 not 74

The first eighteen points of this search strategy aim at retrieving trials related to the health condition under study. From point 20 until 55, the purpose is to locate relevant health interventions and specific outcomes of the research question. Points 57 to 69 were included to retrieve studies related to the specific setting of the research question (i.e. recreational sites).

The last four points limit the search to human studies, with no language limitations.

A study design filter to locate RCTs was not included since non-randomised trials will be included in this review, as suggested by Jackson (2004). Therefore, after the search is completed we will apply the inclusion criteria to all citations.

Finally, this strategy will be adapted to idiosyncrasies of each database in order to retrieve relevant studies.

### Searching other resources

Besides electronic searches, we also plan to search other resources: a) hand searching of relevant journals; and b) checking references from relevant published studies to assess the reliability of the search strategy.

## **Data collection and analysis**

### Study selection

Eligible studies will be selected according to topic, design, population, setting or intervention, based on title and abstract.

Selected studies will be checked for inclusion and those that do not meet criteria for inclusion will be excluded, based on title, abstract and key words. Two reviewers (AR, VAS or FFS) will independently assess first 20% of references. Therefore, results from kappa tests will be calculated to evaluate agreement.

When it is unclear whether the study meets the inclusion criteria, the full text will be retrieved to clarify doubts. If there is disagreement between reviewers about studies, the third reviewer will resolve discrepancies. Excluded studies and reasons for exclusion will be documented.

### Assessment of methodological quality

Two reviewers will independently (AR, VAS or FFS) assess methodological quality on 20% of the included studies before analysis. Kappa tests will be calculated to evaluate agreement.

The following criteria will be considered to evaluate validity of the included RCT studies:

- 1) Odds of selection bias: evaluation of adequacy of sequence generation and allocation concealment procedures;
- 2) Odds of attrition bias: evaluation of withdrawals and dropout description; intention-to-treat analysis;
- 3) Odds of performance and detection bias: blinding of participants, personnel and outcome assessors;
- 4) Odds of reporting bias: presence of incomplete outcome data and selective outcome reporting;
- 5) Other potential threats to validity.

Each criterion will have as a summary of assessment for risk of bias the following rate: 'low risk for bias', 'unclear risk for bias' and 'high risk for bias'.

For non-randomised studies, the quality assessment will be based on the criteria provided by EPOC group (2002).

All the data gathered will be summarized in a table of quality criteria, along with a description of quality of each study.

#### Data extraction

Two reviewers (AR, VAS or FFS) will independently extract 20% of the data from included studies and enter it in a data extraction form. If there is any disagreement during this procedure, the third reviewer will resolve discrepancies.

One reviewer (AR) will enter data into RevMan and another reviewer (VAS or FFS) will independently verify it. No blinding procedures will be used for data pertaining author names, journal or institutions.

The information extracted from each study and presented in the 'characteristics of included studies' table will be:

- 1) *Study design details*
  - Country
  - Type of study
  - Method of recruitment and sampling
  - Units of randomization
  - Flow diagram
  - Intervention duration
  - Follow up duration



- Appropriate analysis (input provide by a statistician)

## 2) *Participants*

- Type of population and setting
- Inclusion and exclusion criteria
- Baseline characteristics
- Sample size calculations
- Recruitment rates
- Informed consent
- Attrition rates at follow up
- Intention to treat analysis

## 3) *Programme*

- Type of intervention
- Focus and theoretical basis of intervention
- Evaluation points
- Intervention delivery procedures
- Behaviour change techniques coding

## 4) *Outcomes evaluated*

- Sun-protective behaviours and sunburn (measurement description)

Besides this information, information will also be extracted on the behaviour change techniques utilised (using a reliable taxonomy – De Bruin et al., 2010), and modes of delivery (Davidson, 2004).

## Analysis

The analyses performed in this review will try mainly to answer four questions (as suggested by Cochrane Handbook, 2009):

1. What is the direction of effect?
2. What is the size of effect?
3. Is the effect consistent across studies?
4. What is the strength of evidence for the effect?

We will use both a narrative synthesis and meta-analysis to examine the data from this review.

Data synthesis will include a descriptive summary of the included studies, providing initial descriptive information about findings.

As continuous outcomes, we expect to find some of the following: sun-protective behaviours, numbers of sunburn and colorimeter values. For these outcomes, weighted mean differences will be calculated, as well as weighted standardised mean differences if measures are in different scales.

In the case of dichotomous outcomes (e.g. incidence of severe sunburn), odds ratio and 95% confidence interval (CI) will be calculated.

For categorical measures (e.g. sun-protective behaviour presented in scores), these will be converted into continuous or dichotomous, depending whether they are longer or shorter ordinal scales respectively. If ordinal scales are made into continuous, mean differences or standardized mean differences will be calculated to describe intervention effects. If ordinal scales are transformed into dichotomous, odds ratio will be calculated for intervention effects purpose.

We intend to perform a meta-analysis in order to calculate treatment effect across studies. This decision will be determined by judgment on whether a meta-analysis is appropriate. If included trials report on several arms, the decision will be to include the most intensive arm in the meta-analysis.

Finally, subgroup analyses will also be conducted based on age of target participants by comparing adults to youths. In order to examine the effects of specific behavioural change techniques, environmental/policy techniques and modes of delivery subgroup analyses will also be performed.

**Appendix B: Study Advertisement Leaflet (Interviews & user-centred study)**

Institute of  
Health&Society



# **How does sun exposure affect your skin?**

**Tell us how you normally protect yourself from the  
sun during your holidays?**

**Try out the newest Android™ mobile phone  
application for sun-protection and let us have your  
thoughts about this new app.**

- join this research
  - give your opinion on sun-protection
  - share your experiences
  - test out this new mobile app for sun protection
- your voice, your thoughts, your contribution!**

If you are interested, please contact Angela Rodrigues on  
**07908747891** or via email on [a.rodrigues@newcastle.ac.uk](mailto:a.rodrigues@newcastle.ac.uk)

## Appendix C: Participant information sheet



### **Holidaymakers' perceptions and attitudes towards sun-protective behaviours: mISkin Study**

*You are being invited to take part in a research study. Before you decide, it is important to understand why the research is being done and what it will involve. Please read the following information carefully. Please feel free to ask if anything is not clear, if you would like more information and or wish to discuss it with others.*

#### **1. What is the purpose of this study?**

The purpose of this study is to understand if and how holidaymakers:

- focus on sun protection during holidays;
- find ways to protect their skin from the sun;
- think of a new mobile phone app that could be used on holidays to sunny destinations.

We need to know more about holidaymakers' views of sun-protection behaviours. Results from this study will support the development of a new and improved mobile phone intervention/app that it is hoped will help prevent skin damage by changing the behaviours of holidaymakers.

#### **2. Should I take part?**

Your participation is voluntary.

If you do agree to take part you will be given this information sheet to keep and be asked to sign a consent form (a copy of which you will keep). We are happy to answer any questions you may have before you decide.

Once you have agreed to take part you are still free to change your mind and withdraw at any time and without giving any reason. If you withdraw from the study any information already gathered from you will be either kept securely and confidentially or destroyed if you wish.

### **3. What will happen if I take part?**

You will be invited to take part in a one-to-one interview. The purpose of the interview is to explore: a) your views of sun-protection during holidays; b) your views on a mobile-phone app to promote sun-protection behaviours during holidays; and c) your view on how this app could be improved, in order to help people to stay engaged and satisfied with it.

If you agree to this interview, we will audio record the conversation to make sure we collect your views accurately. The interview will take approximately 45-60 minutes. All interviews will be held at a time and location convenient for you.

### **4. What are the possible benefits of taking part?**

We hope to improve the prototype version of this mobile phone app to promote sun protection habits. The final version will then be tested with other people like you that go on holidays to sunny destinations.

### **5. What if something goes wrong?**

None of the parts of this study imposes any kind of danger, the study is considered safe, and there is little or no chance of anything happening to you. In the highly unlikely event that you would be harmed by taking part in this research there are no special compensation arrangements. If you are harmed due to negligence, you may have grounds for a legal action, but you may have to pay for it.

### **6. Will my participation be kept confidential?**

Yes! All information that is collected about you during the course of the research will be kept strictly confidential. The recording of your interview will be kept confidential and access will be restricted to the research team. The researcher transcribing the interview will remove any information that could identify you from the transcript. We will keep the original recording at Newcastle University, where we will keep it in a secure location.

### **7. What will happen to the results of the research study?**

Results obtained in this study will be published in medical and academic journals, and presented at academic conferences. Data will only be published in anonymous form; it will never be possible to identify individual participants.

The findings of this study will help the development of a subsequent feasibility study to test the new app.

### **8. Who is organising and funding this research?**

The study is based at Newcastle University. It is being funded by the Portuguese Research Council (FCT) (Reference: SFRH/BD/60392/2009).

### **9. Who has reviewed the study?**

This study has been approved by Newcastle University.

### **10. What do I do now?**

If you are happy to take part in this research, please sign the enclosed CONSENT form and return it to the researcher using the freepost envelope.

If you would prefer to speak to one of the researchers before making a decision, please call/email the study office using the details below.

### **11. Contact for further information**

Angela Rodrigues

Tel: 0191 2226083

Email: [a.rodrigues@newcastle.ac.uk](mailto:a.rodrigues@newcastle.ac.uk)

Academic supervisor

Dr. Vera Araujo-Soares

Tel: 0191 2226083

Email: [vera.araujo-soares@newcastle.ac.uk](mailto:vera.araujo-soares@newcastle.ac.uk)

**Thank you for reading this information sheet, and if it is possible, participating in the study.**

## Appendix D: Informed consent for interviews



Please mark your response with a cross and sign.

1.	I confirm that I have read and understood the information sheet and have had the opportunity to ask questions.	
2.	I understand that my personal data and all measurement data are confidential and only the research team involved in the study will have access to it.	
3.	I understand that data collected during the study may be used in scientific reports in an anonymised form.	
4.	I understand that my participation is voluntary and that I can withdraw at any time, without providing any reason. In such case, I have the option to request any information I have already given to be destroyed.	
5.	I agree that the interviews will be audio-recorded and transcribed. I understand that this data will be treated confidentially and stored securely.	
6.	I agree to be interviewed for this study.	

Name of Participant: \_\_\_\_\_ Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Researcher Signature: \_\_\_\_\_ Date: \_\_\_\_\_



# Appendix E: Topic guide for interviews



## Introduction

The purpose of this study is: 1) to understand perceptions of holidaymakers about protecting the skin from the sun; and 2) to understand how they enjoy their holidays. In this interview, we would like you to: 1) share your thoughts on protecting your skin from the sun while on holidays; and 2) provide feedback on a new mobile phone intervention that could support holidaymakers in protecting their skin.

There are no right or wrong answers to the questions. Take your time to answer each question and, if you prefer, take a few minutes to think about it before answering.

## Part 1: perceptions of sun-protective behaviours

### 1. Skin assessment:

Which of the following best describes your reaction to an initial sun exposure of 45-60 minutes (without sun protection) around midday in the early UK summer?

- I. Burn easily, never tan
- II. Burn easily, tan minimally with difficulty
- III. Burn moderately, tan moderately
- IV. Burn minimally, tan moderately and easily
- V. Rarely burn, tan profusely
- VI. Never burn, tan profusely

### 2. Opening question:

How would you describe a typical day during your holidays? (Prompt for schedule during morning, afternoon, evening; typical clothes you use on the beach; what you usually take with you to the beach; if you take mobile phone with you to the beach)

### 3. Knowledge

**3.1** Considering your skin type, how much time do you think you can spend exposed to the sun without sun protection?

**3.2** Do you know of any methods for sun protection?

**3.3** Are you aware of the recommendations for sun protection? (Prompt for specific knowledge of these recommendations (specify SPB based)).

**3.4** What time of the day do you think sun protection is most needed? (Prompt for cloudy day)

If they don't know, please show the laminated card mentioning sun-protective measures according to WHO.

- **Seek shade** when UV rays are the most intense (between 10am to 4pm),
- **Wear protective clothing** ( hat with a wide brim, sunglasses, and tightly woven, loose fitting clothes),
- **Use sunscreen.** Apply a broad-spectrum sunscreen of SPF 15+ liberally and re-apply every two hours, or after working, swimming, playing or exercising outdoors.

### 4. Nature of behaviours

**4.1** In terms of aiming to improve [specify behaviours]:

. What do you think you might need to do differently?

. What would you do differently, when, where, how, how often and with whom?

**4.2** Can the context be used to prompt these behaviours?

**4.3** How do you know whether the behaviour has happened? (Prompt to sunburn)

## 5. Skills

**5.1** Do you know how to apply sunscreen? (Prompt for quantity, where to apply (body parts), and how much time before sun exposure)

**5.2** What is the sunscreen SPF that you usually use?

**5.2** How easy or difficult would it be for you to apply sunscreen?

**5.3** Could you please cream your forearm? [Sunscreen bottle will be weighted before and after procedure]

**5.4** Do you know how to choose from different types of [shade/protective clothes/hat/sunglasses]?

**5.5** [Various types of hats will be shown to participants] which of these hats is similar to the one you usually use?

## 6. Social influences (norms)

**6.1** What would your family and friends think of you using [specify behaviours]?

. What do you think their views might be?

. How might the views of your family and friends affect you doing [specify behaviours]?

## 7. Social/professional role and identity

**7.1** Do you think these behaviours [show card again] are compatible with your identity/personality (i.e. way you view yourself) (Prompt to different roles that may influence: parent, professional, friend)?

## 8. Beliefs about capabilities

**8.1** How confident are you about doing [specify behaviours]?

**8.2** What problems do you think you might encounter in doing [specify behaviours]?

**8.3** What would help you to overcome these problems?

**8.4** What would make it easier for you?

### 9. Beliefs about consequences

**9.1** What do you think would happen if you do [specify behaviour]? (Prompt for positive/negative, long/short term consequences, e.g. : vitamin D issues, physical comfort/discomfort of sunscreen)

**9.2** What are the costs of [specify behaviour]?

**9.3** Do benefits of doing [specify behaviours] outweigh the costs?

**9.4** What do you think will happen if you don't do [specify behaviours]?

**9.5** How would you feel if you don't do [specify behaviours]?

### 10. Motivation and goals (intention)

**10.1** How much do you want to do [specify behaviour]?

**10.2** Does performing [specify behaviours] conflict/interfere with any of the other goals you might have for your holiday?

### 11. Memory, attention and decision processes

**11.1** What are your reasons for not doing [specify behaviour] during your holiday (prompt for forgetting, keeping track on time, competing activities, etc.)?

Possible questions to prompt further information:

. Will you need to think to do [specify behaviour]?

. How much attention will you have to pay to keep track of time for sunscreen use?

. Will you remember to do [specify behaviour]? What strategies do you use, if any, to remember?

## 12. Environmental context and resources

**12.1** To what extent do other factors help/stop you from [specify behaviours] (prompt for shade availability, store nearby, UV display or information, money)?

## 13. Emotion

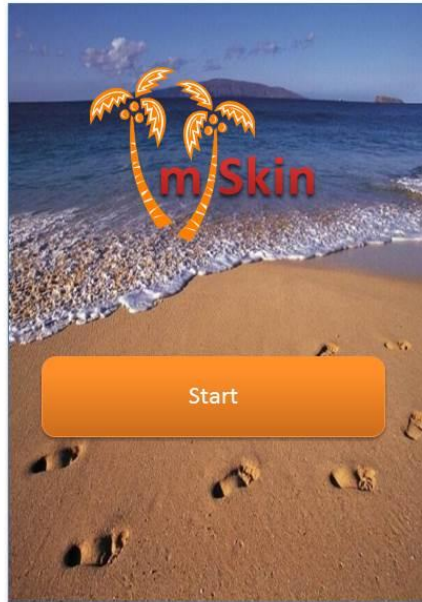
**13.1** How do you feel about spending time in the shade from 10am to 4 pm while on holiday?

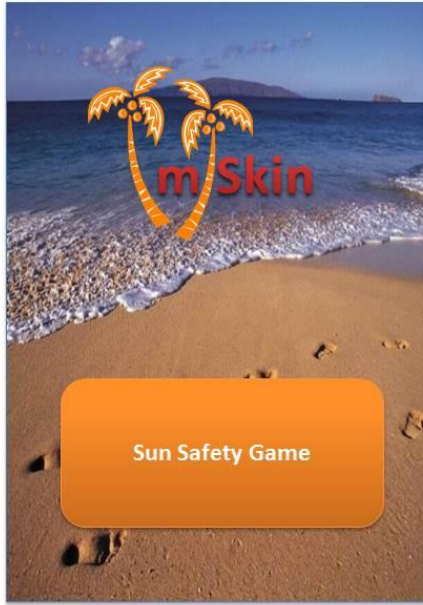
## 14. Behavioural regulation


**14.1** How would you organise your holiday to [specify behaviours]? For example, would you plan ahead or have any set routines?

**14.2** Have you found any ways of helping yourself remember to do [specify behaviour]. If yes, what ways have you used?

## Appendix F: Interfaces (screenshots) of the resulting prototype intervention








Age:

Gender:

- Male
- Female

Next




**Your skin sensitivity:**

1. What is the colour of your skin (non exposed areas)?

- Very pale/Reddish
- Pale
- Beige
- Light brown (lightly tanned)
- Moderate brown or tanned
- Dark brown or black


Back      Next





**Your skin sensitivity:**  
2. Compare and select the image that best describes your skin colour (click on view)

View



Type 1

Type 2


Type 3

Type 4

Type 5

Type 6

Submit




**Your skin sensitivity:**

3. Which of the following best describes your reaction to an initial sun exposure of 45-60 minutes (without sun protection) around midday in the early UK summer?

1. Burn easily, never tan;
2. Burn easily, tan minimally with difficulty;
3. Burn moderately, tan moderately;
4. Burn minimally, tan moderately and easily
5. Rarely burn, tan profusely
6. Never burn, tan profusely

**Back** **Next**



**Your skin sensitivity:**

4. What is the natural colour of your hair?

- Red
- Blond
- Light Brown
- Brown
- Dark brown or black

**Back** **Finish**



**Your skin sensitivity:**

You have skin type I.  
Your skin is highly sensitive: always burns, never tans.



[Home](#)



**Sun safety Game:**

1. You can only get sunburnt when it is hot outside.

**TRUE OR FALSE?**

**TRUE**      **FALSE**




The correct answer is **FALSE!**

The intensity of ultraviolet rays and the outside temperature are unrelated. The UV Index is the best indicator of the intensity of UV and not temperature. 

Truth is you need to consider sun-protection everyday and not just when it's very warm outside.


Even on a cloudy day, 30 to 60% of the UV can reach the Earth's surface. 

**See UV Index**



**UV INDEX**

This is a simple measure of the UV. The values range on a scale from 1 (low) to 11+ (extremely high), the greater the potential to harm your skin and eyes in less time.



Next



**Sun safety Game:**

2. I don't need protection if I already have a slight tan.

**TRUE OR FALSE?**


TRUE FALSE



The correct answer is **FALSE!**

A tan gives about the same protection as sunscreen with an SPF of **2-4**. Your protection will depend mostly on UV Index level.

**Types of sun-protection**



UV levels	Action needed
Low	
Moderate	
High or very high	
Extreme	

**Next**




**Sun safety Game:**

3. Sunburns can increase your risk of skin cancer


**TRUE OR FALSE?**

**TRUE** **FALSE**



The correct answer is **TRUE!**

An history of sunburns can increase your chance of getting skin cancer.



**Check out recent news!**



**A recent survey shows that:**

- 25% of British men and nearly 40% of British women say sunburn has made them feel unattractive on holiday;
- 15% of British holiday makers had to miss a night out and a day on the beach because of sunburn.

**Don't let sunburn ruin your holidays!**

**Next**




**Sun safety Game:**

**4. Skin type is a risk factor for skin cancer.**

**TRUE OR FALSE?**

**TRUE** **FALSE**





The correct answer is  
**TRUE!**  
People with fair skin  
that burn easily are  
more likely than others  
to develop skin cancer.  
Protect yourself taking  
into account your skin  
type

[My sun-protection](#)

Skin type 1&2



Considering UV levels for your  
location (**7 or more**) and the  
fact that you have skin type X,  
you are at **very high risk!**

Be sure to stay in the shade  
between 10am and 4pm,  
cover up and use a sunscreen  
with minimum 30 factor.

[Worried about Vitamin D?  
Read more!](#)

Skin type 3&4



Considering UV levels for your location (7 or more) and the fact that you have skin type X, you are at **high risk!**

Cover up and spend time in the shade between 10am and 4pm. Use a sunscreen on exposed skin with minimum 30 factor.

**Worried about Vitamin D?  
Read more!**

Skin type 5&6



Considering UV levels for your location (7 or more) and the fact that you have skin type X, you are at **medium risk!**

Be sure to stay in the shade between 10am and 4pm, cover up and use a sunscreen with minimum 30 factor.

**Worried about Vitamin D?  
Read more!**



### A little sunlight goes a long way!

Sunlight is the main source of vitamin D, but it is also the main cause of skin cancer.

The amount of time you need in the sun to make enough vitamin D depends on things like skin type, time of day, time of year, and location.

Vitamin D is also present in foods such as eggs, fatty fish, fish liver oils and some fortified cereals.

Next




### A little sunlight goes a long way!

For people with lighter skin types, the time needed is usually **less than** the amount that causes skin **redness** and **burn**.

Now consider the sunlight where you are! You'll need less time of sun-exposure before redness and burn!

Next



**Sun safety Game:**

5. Tanning makes you look older quicker.

**TRUE OR FALSE?**

**TRUE** **FALSE**



The correct answer is **True!**

Sunlight speeds up skin aging and the loss of skin elasticity, resulting in wrinkles and dry skin.



**Is there such a thing as a safe tan?**



A tan is a **SOS** signal from your skin.

The only safe tan is a fake tan!

If you really want to change the colour of your skin, it's safer to use a fake tan product on your skin than direct UV exposure.

See what others have to say about tanning

Next



Sun safety Game:

6. Sunscreen is enough!

**TRUE OR FALSE?**

TRUE

FALSE



The correct answer is **FALSE!**

Although sunscreen is a method of sun-protection, you should consider using it alongside other options, especially when UV levels are very high and during midday hours (from 11am to 3pm).

Check how direct the sun's rays are




A very practical way to check on how direct the sun's rays are is to use the **Shadow**

**Test:** "When your shadow is shorter than you are tall, you can burn, so remember to cover up."




Next




A way of showing skin damage beyond the human eye is through UV photographs. Dark spots on UV photographs indicate sun damage, with more and larger spots indicating greater damage.

[See examples](#)



**Sun safety Game:**

Well done, you've completed the sun safety game.



You've got 5 out of 6 correct!

[Home](#)





The image displays the mSkin logo at the top right, featuring two palm trees and the text 'mSkin'. Below the logo is a survey form with three questions, each followed by a text input field. The questions are: 'What time did you get to the beach/swimming pool today?', 'What time did you leave the beach/swimming pool today?', and 'How many hours where you in the sun today?'. The background of the entire image is a beach scene with waves and sand. At the bottom center, there is an orange button with the text 'Submit'.



# **Appendix G: Topic guide for user-centred study**

## **Introduction**

The purpose of this study is to understand how they enjoy their holidays. In this interview, we would like you to provide feedback on a new mobile phone intervention that could support holidaymakers in protecting their skin.

There are no right or wrong answers to the questions. Take your time to answer each question and, if you prefer, take a few minutes to think about it before answering.

## **Feedback on the mobile phone intervention app**

### **Procedures:**

Participants will be given a prototype of the mobile phone app on an Android™ phone and will interact with it for about 5-10 minutes. After this initial procedure participants will be asked about the specific content and graphical aspect of the app.

### **Opening questions:**

Would you anticipate any advantages/disadvantages of a mobile-phone intervention like this, to use during your holiday? (Prompts: usefulness, intrusiveness, holidays' interference – tailor to information gathered in part 1 opening question).

### **Feedback prompts for each feature of the app:**

Comprehension, understanding, if information was appealing/interesting, motivation to comply; information specific to your skin type; what things would you do differently or think should be improved?

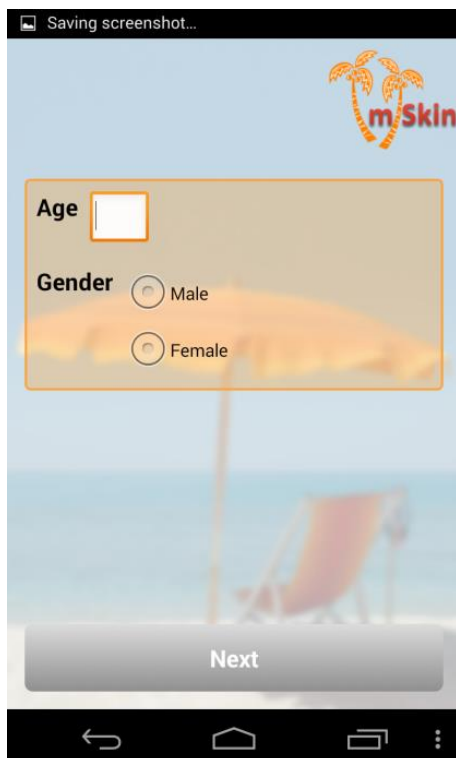
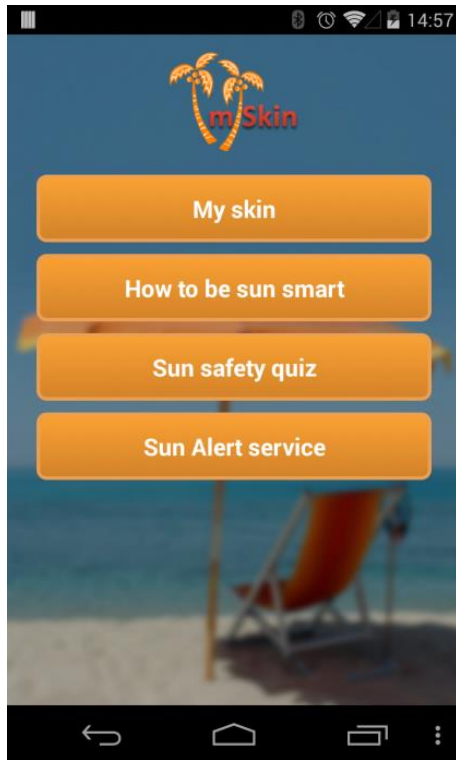
### **Final questions:**

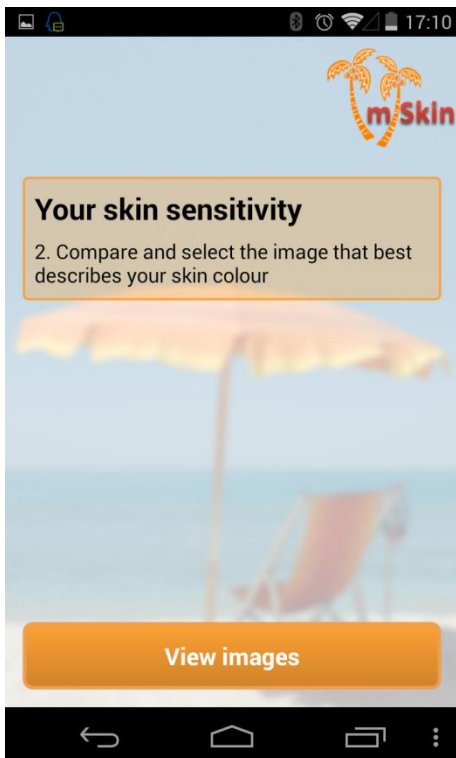
Do you think this intervention would help you to protect your skin from the sun? If yes, how?

Would you use this app? How much would you be willing to pay for this intervention?

If you want to use this app, would this motivate you to take your mobile with you on your holidays and to the beach?

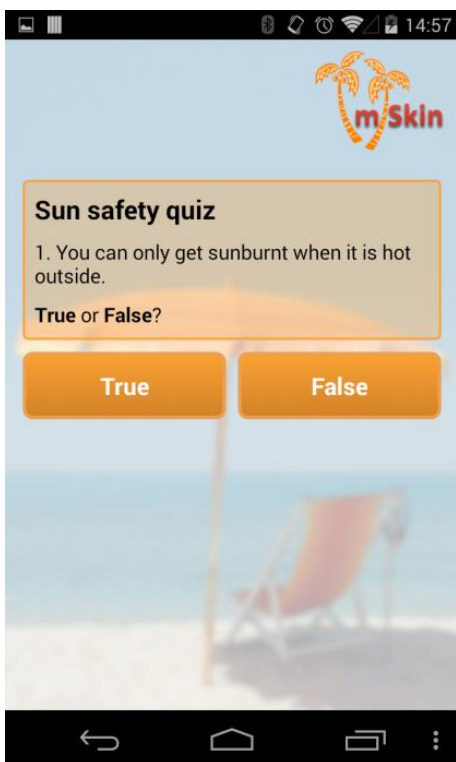
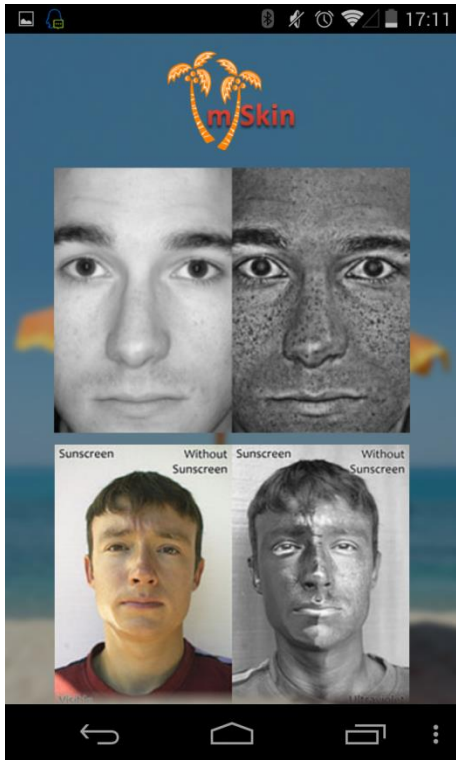
## Appendix H: Final version of the mISkin app

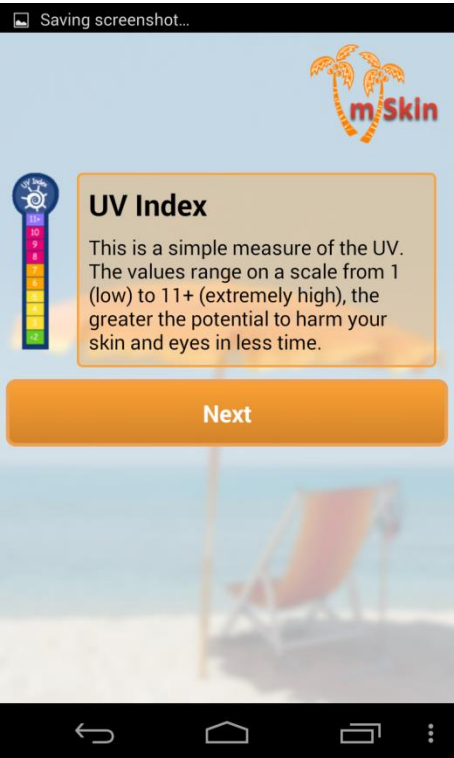
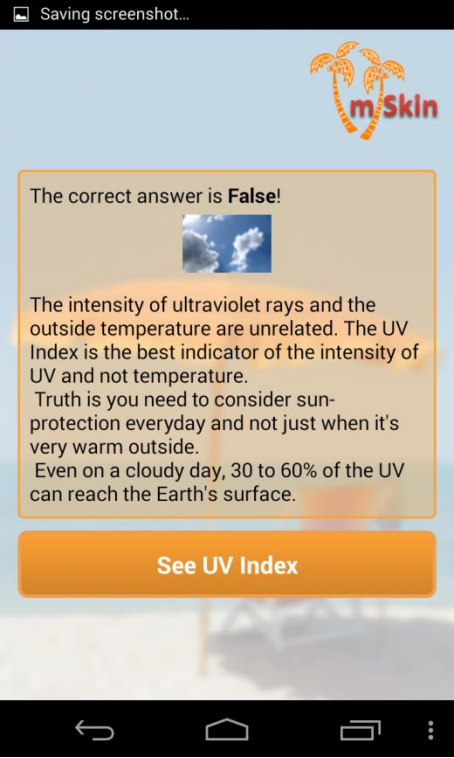


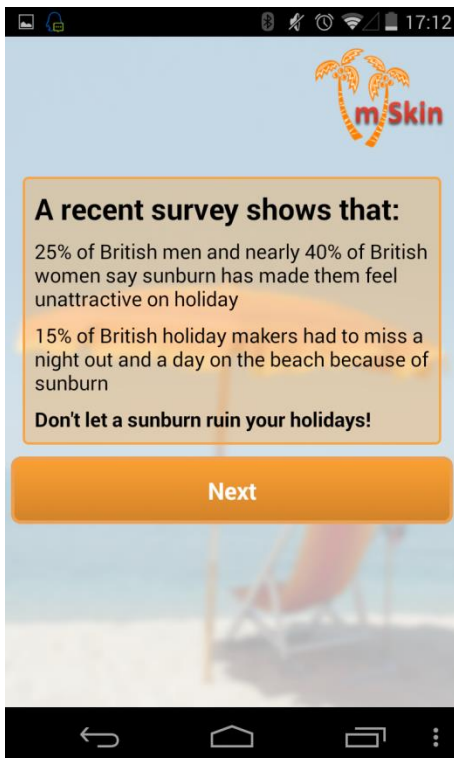




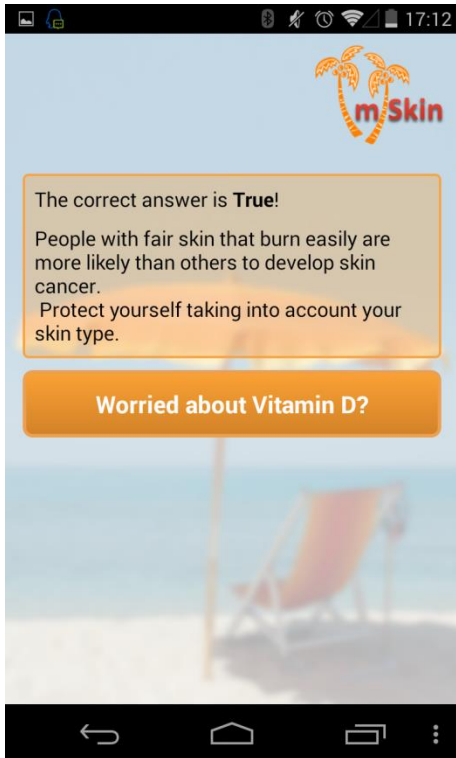


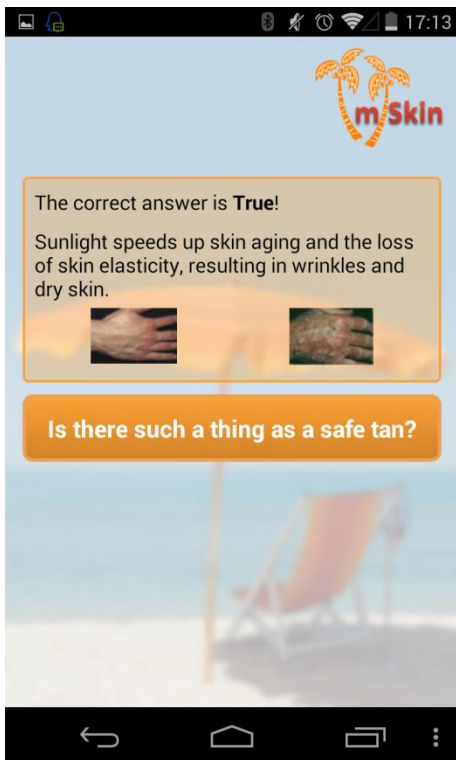
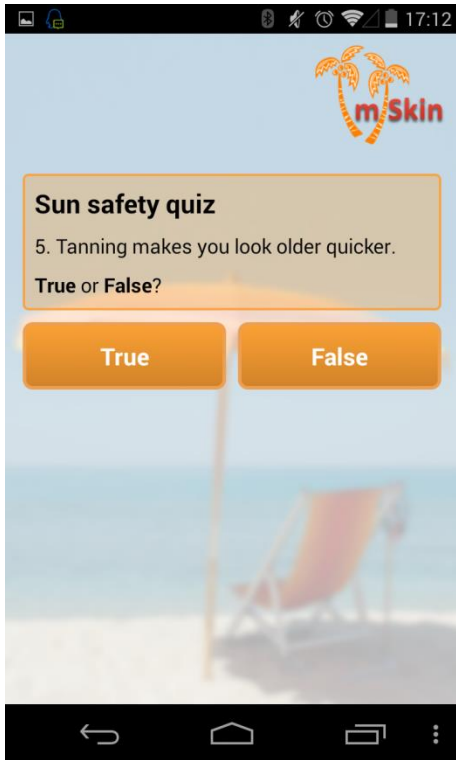


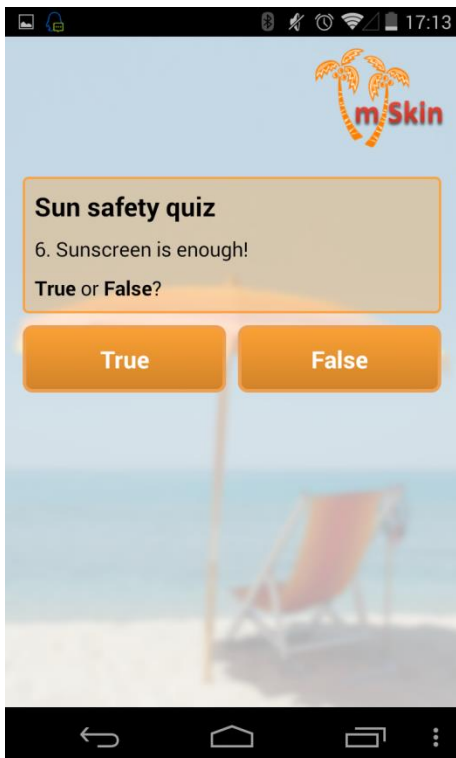
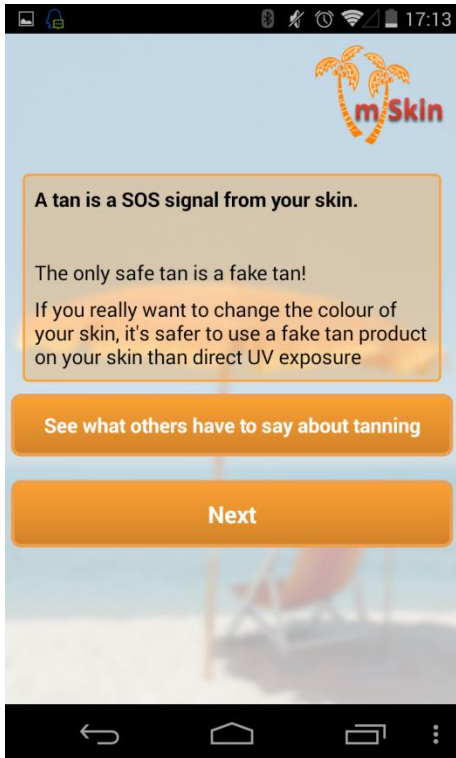


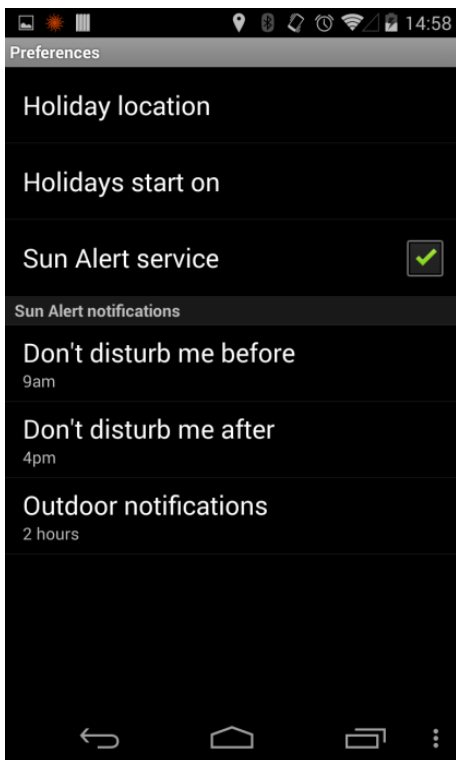
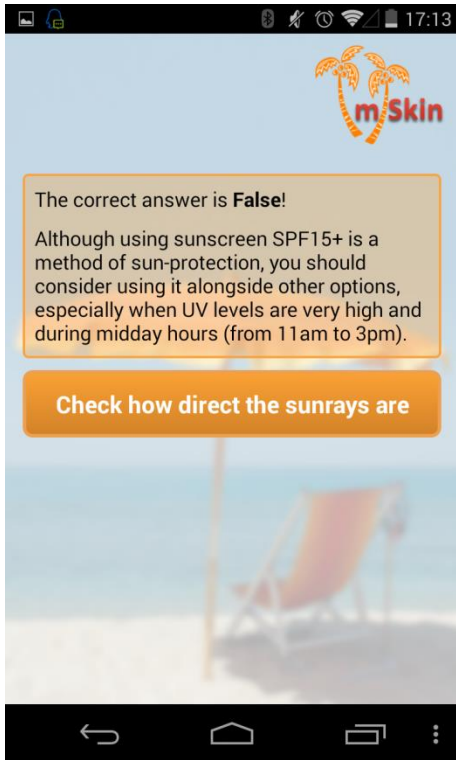


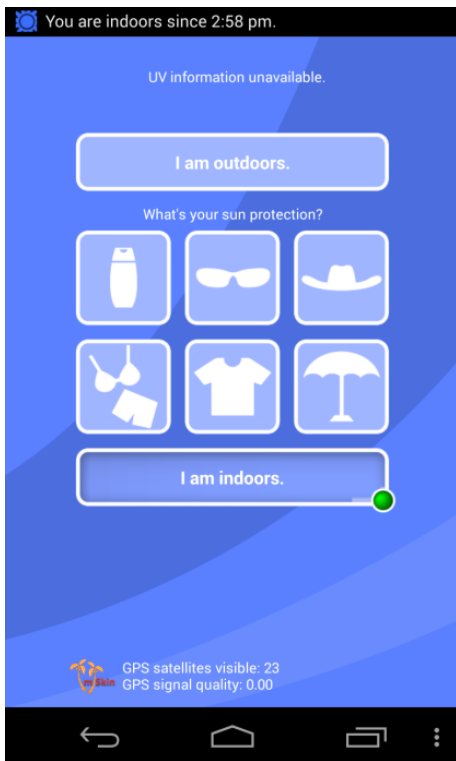


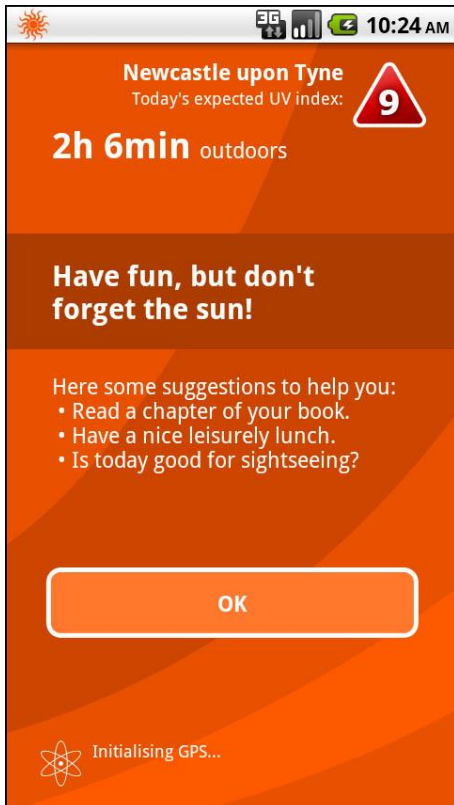


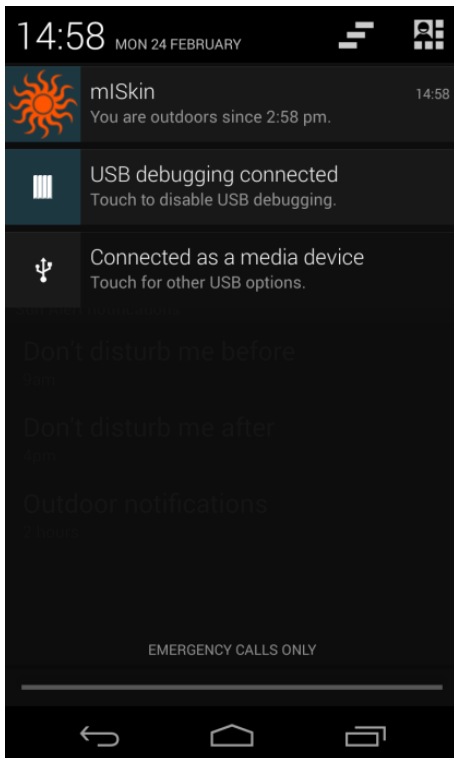
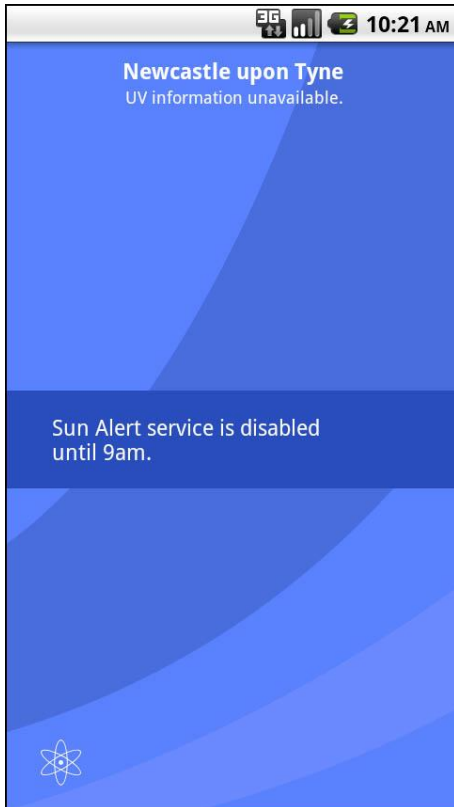












## Appendix I: Database searches MEDLINE from inception to December 2012

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. placebo.ab.
5. drug therapy.fs.
6. randomly.ab.
7. trial.ab.
8. groups.ab.
9. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
10. exp animals/ not humans.sh.
11. 9 not 10
12. interview/
13. Interview, Psychological/
14. questionnaires/
15. health care surveys/
16. exp "Weights and Measures"/
17. (complet\* adj3 (measure\* or scale\* or interview\* or survey\* or questionnaire\* or test\*)).tw.
18. "Outcome Assessment (Health Care)"/
19. (panel\* adj3 survey\*).tw.
20. exp Mass Screening/
21. ("follow up" adj1 (outcome\* or measure\* or score\* or interview\* or assessment\*)).tw.
22. (behavio?r\* adj4 measure\*).ti.
23. 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22
24. (behavio?r adj2 measure\*).ti.
25. Behavioral Research/
26. Health Behavior/
27. exp patient compliance/
28. exp self-examination/
29. treatment refusal/
30. feeding behavior/
31. fasting/
32. food habits/
33. food preferences/
34. illness behavior/
35. exp reproductive behavior/
36. risk reduction behavior/
37. risk-taking/
38. exp sexual behavior/
39. exp "tobacco use cessation"/
40. motor activity/
41. Alcohol Drinking/
42. ("physical exercise\*" or "physical activit\*").tw.
43. Alcoholism/
44. (drink\* adj1 (alcohol\* or pattern\* or problem\* or addict\*)).tw.
45. 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44
46. (panel\* adj2 conditioning).tw.
47. (pretest\* adj2 (response\* or effect\* or bias\* or reactivity)).tw.



48. (test\* adj2 (response\* or effect\* or bias\* or reactivity)).tw.
49. (measurement\* adj2 (response\* or effect\* or bias\* or reactivity)).tw.
50. (assessment\* adj2 (response\* or effect\* or bias\* or reactivity)).tw.
51. (question\* adj2 (response\* or effect\* or bias\* or reactivity)).tw.
52. (interview\* adj2 (response\* or effect\* or bias\* or reactivity)).tw.
53. (reactiv\* adj2 (response\* or effect\* or bias\* or measure\*)).tw.
54. "generated validity".tw.
55. mere measur\$.tw.
56. "self prophecy".tw.
57. (solomon adj3 (group\$ or design\$ or trial\$ or study or studies)).tw.
58. (solomon adj2 island\$).tw.
59. 57 not 58
60. 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 59
61. 11 and 23 and 45 and 60

## Appendix J: Study advertisement information (Pilot study)



### How does sun exposure during holidays affect your skin?

Researchers at Newcastle University need volunteers to help study sun-protection habits and the effects of sun exposure during holidays.

The study will include:

- a skin assessment,
- completing a questionnaire before and after your holidays,
- **two** bottles of **free Ambre Solaire** sunscreen (200ml each),
- receiving a new app on your Android™ Smartphone over a holiday period of up to **2 weeks**

Feedback will be provided on your sun-protection practices as well as on how sun exposure has affected your skin.

If you are interested, and you;

- Are going on holidays to any sunny destination for up to 2 weeks;
- Own a Smartphone Android™;
- Are more than 18 years old;
- Are not allergic to sunscreen;
- Do not have any dermatological conditions;
- Are willing to participate in this study;
- Are not pregnant.

then please contact Angela Rodrigues on **0191 222 8974** or via email on [a.rodrigues@newcastle.ac.uk](mailto:a.rodrigues@newcastle.ac.uk)

**Details about the routes and organisations through which the trial has been advertised and recruitment has been attempted**

<b>Organisations approached:</b>	<b>Organisations that have agreed to support trial:</b>	<b>Other recruitment methods:</b>
<ul style="list-style-type: none"> <li>- Mainstream travel agencies</li> <li>- Newcastle airport &amp; Easyjet Newcastle</li> <li>- Go North East (public transport)</li> <li>- Arriva (public transports)</li> <li>- RVI to advertise on intranet and staff rooms (contact person: Paddy Stevenson)</li> <li>- Newcastle University HR (by Faculty)</li> <li>- Cancer Research UK</li> <li>- Newcastle Travel clinic in Boots</li> <li>- Sports Teams going on Easter Tours (TEAM Newcastle)</li> <li>- The Courier (Newcastle University paper) &amp; Newcastle University student radio</li> <li>- North East Radios (e.g. metroradio)</li> </ul>	<ul style="list-style-type: none"> <li>- School of Psychology (students and staff)</li> <li>- MSc Health Psychology Students</li> <li>- MSc Public Health students</li> <li>- University staff SharePoint</li> <li>- Newcastle Newsletter (press office help)</li> <li>- Newcastle volunteers newsletter</li> <li>- Norseman Travel agency (leaflets w/ tickets)</li> <li>- Newcastle City libraries (staff and posters in common areas)</li> <li>- Nexus (public transports) - staff</li> <li>- Stagecoach bus travel - staff</li> <li>- Association of North East councils- staff</li> <li>- Gateshead city council- staff</li> <li>- Newcastle city council</li> <li>- Durham city council- staff</li> <li>- Sunderland city council - staff</li> <li>- Oxfam bookstore (leaflet in travel guides)</li> </ul>	<ul style="list-style-type: none"> <li>- Personal contacts (friends)</li> <li>- Social media (Twitter and Facebook);</li> <li>- Gumtree;</li> <li>- Announcements on main events within IHS an SharePoint;</li> <li>- Brainstorm exercise in health psychology group workshop;</li> <li>- Dermatology group</li> <li>- Possibility: NCJ Media Advertising Running a quarter page advert in both the Evening Chronicle and Journal will be as follows: 17cm x 13.8cm; Evening Chronicle - 1 Insertion; Journal - 1 Insertion; Total Cost £900 + vat</li> </ul>

## Appendix L: Participant information sheet (Pilot study)



### **A feasibility trial of a behavioural intervention to promote sun-protection practices amongst holidaymakers: mISkin Study**

*You are being invited to take part in a research study. Before you decide, it is important to understand why the research is being done and what it will involve. Please read the following information carefully. Please feel free to ask if anything is not clear or if you would like more information and time to discuss it with others.*

#### **1. What is the purpose of this study?**

The purpose of this study is to explore the possibility of conducting research to test the success of a mobile-phone intervention/app to promote sun-protective behaviours amongst holidaymakers.

We want to find out whether taking this mobile-phone app on holidays helps to promote sun-protective behaviours and reduce the experience of sunburn.

To fully answer the above question we would need to conduct a 'randomised controlled trial' (RCT). But before we can be sure that such a trial is possible, a small feasibility RCT study needs to be conducted. This is what we are asking you to take part in.

#### **2. What is a RCT?**

A randomised controlled trial (RCT) is the best type of research to test new interventions. A RCT compares the results derived from participants in two or more groups. The results are compared to see

which one is better. To make sure that the groups are identical at the beginning of the research, participants are allocated to groups at random (hence the word randomised). The group's selection is performed by a computer with no information on the participants.

### **3. What's the plan of the research?**

We will ask all participants to install and use a mobile-phone app in their Android™ Smartphone. There is 50% of chance that you will be given this application called 'mISkin' (1 in 2 chances).

After the end of the study period – up to 2 weeks, we will compare skin sun-damage in each group of participants and will then evaluate whether the use of the new app has had any effect on sun-protective behaviours.

### **4. Should I take part?**

Your participation in this study is voluntary. If you do agree to take part, you will be given this information sheet to keep and be asked to sign a consent form (a copy of which you will keep). We are happy to answer any questions you may have before you decide. Once you have agreed to take part you are still free to change your mind and withdraw at any time and without giving any reason. If you withdraw from the study any information already gathered from you will be either kept securely and confidentially or destroyed if you wish.

### **5. What will happen if I take part?**

#### Feasibility study

If you agree to help with this study, a meeting with a researcher will be arranged at your convenience. We will be happy to discuss any queries or concerns you might have and, if you decide to take part in this study, you will be asked to sign a consent form.

#### Questionnaires

After you have given consent, you will be asked to complete a questionnaire at the beginning and at the end of the study about:

- 1) Your experiences and your views of the study;
- 2) Your sun-protective behaviours during holidays, as well as your perceptions about sun-protection.

At the beginning of the study, questionnaires will take approximately 20 minutes to complete and 25 minutes at the end of study. If you prefer, we can and will assist you with completing it.

### Skin swabs

All participants will have skin swabs taken at the beginning (before going on holiday) and at the end of the study (after returning from holiday). This is a painless technique which consists of rubbing the bridge of your nose and inner forearm; each of these areas will be rubbed with cotton swabs 15 times and samples will then be stored in a sterile collection tube until analysis.

This procedure has been tested in the past; it is commonly used and was not considered by previous participants to be a cause of discomfort or pain.

### Group allocations

You will then be allocated at random to one of four groups: there are two 'mISkin' groups and two control groups. The difference between them is the type of sunscreen you will receive: medium Sun Protection Factor (SPF 15) or high Sun Protection Factor (SPF 30), as well as receiving or not the app. There is a general agreement for the need of sunscreen use with a SPF of 15 or higher (SPF 15+).

If you are in the 'mISkin' groups, you will be invited to download the mobile-phone app to your Android™ Smartphone and will be asked to take it with you on your holidays. General information about this application will be provided in verbal and written format. The researcher will also help you with the initial configuration of this app on your Smartphone. The 'mISkin' app will provide you with general information on how to protect your skin from sun damage. It will also provide you with effective strategies to enhance sun-protection behaviours.

This app will work alongside the GPS in your mobile-phone – **only** information about your indoor and outdoor location will be retrieved. The app will provide you with specific information on sun-protection considering your destination and your skin type.

If you are in the control group, you will only receive the mobile-phone intervention on your next holiday. A skin swab will still be taken from you.

### Sunscreen

Participants in all groups ('mISkin' or control) will receive sunscreen to take to their holidays. Those allocated to the 'mISkin' groups will be given sunscreen bottles with a built-in sensor to monitor patterns of sunscreen use during your holiday.

### When you return

After returning from your holiday, you will be asked to fill out the questionnaire (described above) and another skin swab will be taken.

## Interview

Additionally, if allocated to the 'mISkin' groups, you *may* be asked to take part in an interview; this will involve a one-to-one talk with a researcher on your thoughts regarding your experience with the mobile-phone app ('mISkin') during your holidays. Your participation is voluntary; if you agree to an interview, we will audio record the conversation to make sure we collect your views accurately. The interview will take approximately 30 minutes. All interviews will be held at a time and location convenient for you.

### **6. What are the benefits of taking part?**

You will contribute to the development of an intervention delivered through a mobile phone app that can, if proven effective, help to prevent skin cancer. Without your participation in our research, we cannot know if this new intervention is effective.

Effective sun-protective interventions are needed to support skin cancer prevention. You will also find that participating in this study might help you make some behaviour changes and improve your own sun-protective behaviours.

### **7. What if something goes wrong?**

No part of this study imposes any kind of danger, the study is considered safe, and there is little or no chance of anything happening to you. In the highly unlikely event that you would be harmed by taking part in this research there are no special compensation arrangements. If you are harmed due to someone's negligence, you may have grounds for a legal action, but you may have to pay for it.

### **8. Will my participation be kept confidential?**

Yes! All information that is collected about you during the course of the research will be kept strictly confidential. The identification information that you give us will be separated from your answers to the questionnaires. Any information about you that leaves the research unit will have your name and address removed so that you cannot be recognised.

In addition, the recording of your interview will be kept confidential and access will be restricted to the research team. Any information that could identify you from the transcript will be removed. We will keep the original recording at Newcastle University, in a secured location.

### **9. What will happen to the results of the research study?**

Results obtained in this study will be published in medical and academic journals, and presented at academic conferences. Data will only be published in anonymous form; it will never be possible to identify individual participants. The findings of this study will help the development of a subsequent bigger study to test the effectiveness of this new intervention.

**10. Who is organising and funding this research?**

The study is based at Newcastle University. It is being funded by the Portuguese Research Council (FCT) (Reference: SFRH/BD/60392/2009) and the Newcastle Institute for Research on Sustainability (NIReS).

**11. Who has reviewed the study?**

This study has been approved by Newcastle University.

**12. What do I do now?**

If you are happy to take part in this research, please contact the researcher using contact details below.

If you would prefer to speak to one of the researchers before making a decision, please call/email the study office using the details below.

**13. Contact for further information**

Angela Rodrigues  
Tel: 07908747891  
Email: [a.rodriques@newcastle.ac.uk](mailto:a.rodriques@newcastle.ac.uk)

Academic supervisor  
Dr. Vera Araujo-Soares  
Tel: 0191 2226083  
Email: [vera.araujo-soares@newcastle.ac.uk](mailto:vera.araujo-soares@newcastle.ac.uk)

**Thank you for reading this information sheet, and if it is possible, participating in the study.**



## Appendix M: Informed consent (pilot study)



After reading each point, please tick the boxes and sign.

1.	I confirm that I have read and understood the information sheet and have had the opportunity to ask questions.	
2.	I understand that my personal data and all measurement data are confidential and only the research team involved in the study will have access to it.	
3.	I understand that data collected during the study may be used in scientific reports in an anonymised form.	
4.	I understand that my participation is voluntary and that I can withdraw at any time, without providing any reason. In such case, I have the option to request any information I have already given to be destroyed.	
5.	I understand that my participation will involve: 1) some appointments with researchers; 2) completing a questionnaire before and after the study; 3) taking skin swabs; 4) bringing sunscreen bottles with a sensor on my holidays.	
6.	I understand that researchers will access GPS data concerning only my indoor/outdoor location throughout my holiday (via my mobile-phone) and I accept this information to be retrieved.	
7.	I agree to participate in this study.	

Name of Participant: \_\_\_\_\_ Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Researcher Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## **Appendix N: Topic guide for interviews for process evaluation study (Pilot study)**



### **Introduction**

In this interview, we would like you to provide feedback about your participation in this study and about the mobile phone intervention that you have used during your recent holiday.

There are no right or wrong answers to the questions. Take your time to answer each question and, if you prefer, take a few minutes to think about it before answering.

### **Feedback about general procedures:**

What did you think about the information you received prior to enrolment?

How would you describe your experiences with study staff members and procedures before and during the study? (Prompt: recruitment strategies, questionnaires, skin swabs)

How did you feel about the group you were allocated to?

Do you remember how the weather was? Could you please briefly describe?

Do you feel you use more sunscreen than you would normally?

### **Feedback about intervention procedures:**

How would you describe the app itself and your interaction with its features?

How would you describe your satisfaction with the overall app features?

What are the main benefits/disadvantages of this app you can think of?

How helpful did you find specific app features? (Prompt: 'sun safety game', video, prompts, sunscreen bottles, questions about sun protection habits)

How easy/difficult was it to interact with this app?

Did you find the interaction with app was time-consuming? Beside time, did you find other barriers that made it difficult to engage with this app?

How do you think this intervention could be improved? (Prompt: content, interaction, other features)

# Appendix O: Holidaymakers' perceptions about engaging in sun-protection: study questionnaire

[delivered through Qualtrics™]

## **Section 1 -Sun Habits** (Adapted from Glanz et al. 2008)

Think about your most recent holidays abroad. For each question listed, please select the one answer that is the best response to the question. There is no right or wrong answer.

**1. On average, how many hours/day were you outside between 10 am and 4 pm...on WEEKDAYS (Monday-Friday) ? (Please tick your answer).**

30 minutes or less .....

31 minutes to 1 hour.....

2 hours .....

3 hours .....

4 hours .....

5 hours .....

6 hours .....

**2. On average, how many hours/day were you outside between 10 am and 4 pm...on WEEKEND DAYS (Saturday & Sunday) ? (Please tick your answer).**

30 minutes or less .....

31 minutes to 1 hour.....

2 hours .....

3 hours .....

4 hours .....

5 hours .....

6 hours .....

**3. In your recent holidays, how many times did you have a red OR painful sunburn that lasted a day or more? (Please tick your answer).**

0                      1                      2                      3                      4                      5 OR MORE  
                                                                                                             

**4. For the following questions, think about what you did when you were outside during your recent holidays on a warm sunny day. (Please tick your answers).**

	NEVER	RARELY	SOMETIMES	OFTEN	ALWAYS
4. How often did you wear <b>SUNSCREEN?</b> .....	<input type="radio"/>				
5. How often did you wear a <b>SHIRT WITH SLEEVES that cover your shoulders?</b> .....	<input type="radio"/>				
6. How often did you wear a <b>HAT?</b> .....	<input type="radio"/>				
7. How often did you stay in the <b>SHADE or UNDER AN UMBRELLA?</b> .....	<input type="radio"/>				
8. How often did you wear <b>SUNGLASSES?</b> .....	<input type="radio"/>				

**Skin sensitivity Assessment**

**For each question listed, please select the one answer that is the best response to the question. There is no right or wrong answer. Please tick your answer.**

1. How would you best describe the colour of your skin?

- I. Very pale/Reddish
- II. Pale
- III. Beige
- IV. Light brown (lightly tanned)

- V. Moderate brown or tanned
- VI. Dark brown or black

2. Compare and select the image that best describes your skin colour. Laminated card will be shown to participants with 6 different skin types according to CR UK.

**[images presented here]**

3. Which of the following best describes your reaction to an initial sun exposure of 45-60 minutes (without sun protection) around midday in the early UK summer?

- VII. Burn easily, never tan
- VIII. Burn easily, tan minimally with difficulty
- IX. Burn moderately, tan moderately
- X. Burn minimally, tan moderately and easily
- XI. Rarely burn, tan profusely
- XII. Never burn, tan profusely

4. What is the natural colour of your hair?

- I. Red
- II. Blond
- III. Light Brown
- IV. Brown
- V. Dark brown or black

## **Section 2 – Perceptions about sun-protection**

We are very interested in your views on sun experiences during your holiday. The following questions will help us to find out more about your experiences and preferences about sun protection.

**1. Let's start with some general questions about how much you know about sun protection.** [only assessed at follow up]

During which of the following time periods is sun protection most needed?

- a) 11am -3pm
- b) 12 noon - 1pm
- c) 1pm - 4pm
- d) 11am - 1pm

When buying a sunscreen what do you need to consider

- a) Expiry date
- b) Sun Protection Factor (SPF)
- c) Provided protection against UVA and UVB

- d) All of the above

What is the best way to protect your skin from sun damage?

- a) Avoiding sun exposure
- b) Finding shade, wearing a hat, clothing, sunglasses and sunscreen SPF 15+
- c) Using sunscreen SPF 15+
- d) Having a tan before going on holidays

What is the UV index?

- a) A tool to measure waves length
- b) A measurement of the intensity of the sun's ultraviolet (UV) radiation
- c) A weather tool used to report hours of daylight
- d) Don't know

**What do we mean by sun protection during your holiday?**

- **Seeking shade between 11am and 3 pm.**
  - Avoid the direct sun light under trees, umbrellas, canopies or indoors when the sun is at its strongest;
- **Cover-up with protective clothing**
  - Wear tightly woven clothes, hats with a wide brim and sunglasses that provide 99 to 100% UV-A and UV-B protection) when you go out in the midday sun;
- **Use sunscreen with at least a Sun Protection Factor (SPF) of 15**
  - Apply sunscreen generously and regularly every two hours, or after swimming, playing or exercising outdoors) when outside in the midday sun.

Please, answer to the following questions below by selecting the option that best represents your views and experiences.

**1. Your intentions**

In this section, we are interested in your plans for sun protection and sun exposure during your holiday. For each statement, please circle the number in each line that best describes your opinion.

	Strongly disagree	1	2	3	4	5	6	7	Strongly agree
I intend to seek shade when I go out	Strongly	1	2	3	4	5	6	7	Strongly

in the midday sun	disagree									agree
I intend to cover-up with protective clothing when I go out in the midday sun	Strongly disagree	1	2	3	4	5	6	7		Strongly agree
I intend to use sunscreen with SPF 15 or higher when I go out in the midday sun	Strongly disagree	1	2	3	4	5	6	7		Strongly agree
I intend to sunbathe to get a suntan	Strongly disagree	1	2	3	4	5	6	7		Strongly agree

**2. People have different views about sun exposure. In the following questions, we would like to ask you to respond to a few statements about sun protection and sunbathing during your holiday.**

For me, **using sun-protection in the midday sun** would be ...

Uncomfortable	1	2	3	4	5	6	7	Comfortable
Unenjoyable	1	2	3	4	5	6	7	Enjoyable
Unpleasant	1	2	3	4	5	6	7	Pleasant

For me, **using sun-protection in the midday sun** would...

	Extremely unlikely	1	2	3	4	5	6	7	Extremely likely
... decrease my risk of sunburn	Extremely unlikely	1	2	3	4	5	6	7	Extremely likely
... make me tan less	Extremely unlikely	1	2	3	4	5	6	7	Extremely likely
... be costly/expensive?	Extremely unlikely	1	2	3	4	5	6	7	Extremely likely
... decrease my risk of skin cancer	Extremely unlikely	1	2	3	4	5	6	7	Extremely likely
... protect my skin from	Extremely	1	2	3	4	5	6	7	Extremely



aging?	unlikely									likely
--------	----------	--	--	--	--	--	--	--	--	--------

**In the long run, using sun protection** in the midday sun will make me feel...

	Extremely unlikely	1	2	3	4	5	6	7	Extremely likely
... more attractive	Extremely unlikely	1	2	3	4	5	6	7	Extremely likely
... more comfortable about my skin	Extremely unlikely	1	2	3	4	5	6	7	Extremely likely
... feel better about myself	Extremely unlikely	1	2	3	4	5	6	7	Extremely likely
... feel safer	Extremely unlikely	1	2	3	4	5	6	7	Extremely likely

For me, to **get a tan** would make me...

	Strongly disagree	1	2	3	4	5	6	7	Strongly agree
... feel more confident about my appearance	Strongly disagree	1	2	3	4	5	6	7	Strongly agree
... feel more attractive	Strongly disagree	1	2	3	4	5	6	7	Strongly agree
... feel healthier	Strongly disagree	1	2	3	4	5	6	7	Strongly agree
... receive compliments about my appearance	Strongly disagree	1	2	3	4	5	6	7	Strongly agree

### 3. SELF EFFICACY

Some aspects of sun protection are more difficult than others. Would you please indicate below how confident you are that you can do the following steps during your holiday?

I am confident that I can...	Not at all confident	1	2	3	4	5	6	7	Extremely Confident
Pick a good sunscreen (i.e. SPF15+, both UVA and UVB protection, expiry date)	Not at all confident	1	2	3	4	5	6	7	Extremely Confident
Apply sunscreen properly (i.e. how and where to put it on, the quantity, how much time to wait before going out in the sun)	Not at all confident	1	2	3	4	5	6	7	Extremely Confident
Re-apply sunscreen properly (i.e. how often, after which activities)	Not at all confident	1	2	3	4	5	6	7	Extremely Confident
Use the right level of protection for my individual skin type and sun intensity	Not at all confident	1	2	3	4	5	6	7	Extremely Confident
Seek out shade when I go out in the midday sun	Not at all confident	1	2	3	4	5	6	7	Extremely Confident
Cover-up with protective clothing when I go out in the midday sun	Not at all confident	1	2	3	4	5	6	7	Extremely Confident
Get a suntan without burning	Not at all confident	1	2	3	4	5	6	7	Extremely Confident

**4. Sometimes we consider what others are doing and what others are thinking. In the following questions, we are interested in your perceptions about what others do or think regarding sun protection and sunbathing experiences.**

The people whose opinions I value...

Use 

1	2	3	4	5	6	7
---	---	---	---	---	---	---

 do not use  
**sun protection** when they go out in the midday sun during their holidays

The people whose opinions I value...

Get a tan 

1	2	3	4	5	6	7
---	---	---	---	---	---	---

 do not get a tan  
During their holidays

The people whose opinions I value think that...

I should 

1	2	3	4	5	6	7
---	---	---	---	---	---	---

 I should not

**Use sun protection** when I go out in the midday sun during my holidays

The people whose opinions I value think that...

I should 

1	2	3	4	5	6	7
---	---	---	---	---	---	---

 I should not

**Get a suntan** during my holidays

**5. The next block of questions focus on how you generally make decisions about present day behaviours, and how you consider both the future benefits and any present day costs of such behaviours. [only at baseline]**

	Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree
I consider how things might be in the future, and try to influence those things with my day to day behaviour.					
Often I engage in a particular behaviour in order to achieve outcomes that may not result for many years.					
I am willing to sacrifice my immediate happiness or well-being in order to achieve future outcomes.					
I think it is important to take warnings about negative outcomes seriously even if the negative outcome will not occur for many years.					
I think it is more important to perform a behaviour with important distant consequences than a behaviour with less important immediate consequences.					
I only act to satisfy immediate concerns, figuring the future will					

take care of itself.					
My behaviour is only influenced by the immediate (i.e., a matter of days or weeks) outcomes of my actions.					
My convenience is a big factor in the decisions I make or the actions I take.					
I generally ignore warnings about possible future problems because I think the problems will be resolved before they reach crisis level.					
I think that sacrificing now is usually unnecessary since future outcomes can be dealt with at a later time.					
I only act to satisfy immediate concerns, figuring I will take care of future problems that may occur at a later date.					
Since my day to day work has specific outcomes, it is more important to me than behaviour that has distant outcomes.					

## References

- Abroms, L., Jorgensen, C.M., Southwell, B.G., Geller, A.C. and Emmons, K.M. (2003) 'Gender Differences in Young Adults' Beliefs About Sunscreen Use', *Health Education & Behavior*, 30(1), pp. 29-43.
- Adams, J. (2012) 'Consideration of immediate and future consequences, smoking status, and body mass index', *Health Psychology*, 31(2), p. 260.
- Agredano, Y.Z., Chan, J.L., Kimball, R.C. and Kimball, A.B. (2006a) 'Accessibility to air travel correlates strongly with increasing melanoma incidence', *Melanoma Research*, 16(1), pp. 77-81.
- Agredano, Y.Z., Chan, J.L., Kimball, R.C. and Kimball, A.B. (2006b) 'Accessibility to air travel correlates strongly with increasing melanoma incidence\*', *Melanoma Research*, 16(1), pp. 77-81 10.1097/01.cmr.0000195696.50390.23.
- Ajzen, I. (1991) 'The theory of planned behavior', *Organizational Behavior and Human Decision Processes*, 50(2), pp. 179-211.
- Ajzen, I. and Madden, T.J. (1986) 'Prediction of goal-directed behavior: Attitudes, intentions, and perceived behavioral control', *Journal of Experimental Social Psychology*, 22(5), pp. 453-474.
- American Cancer Society (2011) *Skin Cancer - Melanoma* [Web page]. Available at: <http://www.cancer.org/cancer/skincancer-melanoma/index> (Accessed: 30 April 2011).
- Araujo-Soares, V., Rodrigues, A., Pesseau, J. and Sniehotta, F.F. (2013a) 'Adolescent sunscreen use in springtime: a prospective predictive study informed by a belief elicitation investigation', *J Behav Med*, 36(2), pp. 109-23.
- Araujo-Soares, V., Rodrigues, A., Pesseau, J. and Sniehotta, F.F. (2013b) 'Adolescent sunscreen use in springtime: a prospective predictive study informed by a belief elicitation investigation', *Journal of Behavioral Medicine*, 36(2), pp. 109-123.
- Armstrong, A.W., Watson, A.J., Makredes, M., Frangos, J.E., Kimball, A.B. and Kvedar, J.C. (2009) 'Text-Message Reminders to Improve Sunscreen Use: A

Randomized, Controlled Trial Using Electronic Monitoring', *Arch Dermatol*, 145(11), pp. 1230-1236.

Armstrong, B.K. and Kricger, A. (1994) 'Cutaneous melanoma', *Cancer Surveys*, 19-20, pp. 219-40.

Armstrong, B.K. and Kricger, A. (2001) 'The epidemiology of UV induced skin cancer', *J Photochem Photobiol B*, 63(1-3), pp. 8-18.

Avenell, A., Broom, J., Brown, T.J., Poobalan, A., Aucott, L., Stearns, S.C., Smith, W.C.S., Jung, R.T., Campbell, M.K. and Grant, A.M. (2004) 'Systematic review of the long-term effects and economic consequences of treatments for obesity and implications for health improvement', *Health Technology Assessment*, 8(21), pp. 1-182.

Ayres, K., Conner, M., Prestwich, A., Hurling, R., Cobain, M., Lawton, R. and O'Connor, D.B. (2013) 'Exploring the question-behaviour effect: Randomized controlled trial of motivational and question-behaviour interventions', *British Journal of Health Psychology*, 18(1), pp. 31-44.

Baek, E.-O., Cagiltay, K., Boling, E. and Frick, T. (2008) 'User-centered design and development', *Handbook of research on educational communications and technology*, pp. 659-670.

Baker, B.T., Gustafson, H.D. and Shah, D. (2014) 'How Can Research Keep Up With eHealth? Ten Strategies for Increasing the Timeliness and Usefulness of eHealth Research', *J Med Internet Res*, 16(2), p. e36.

Bandura, A. (1991) 'Social cognitive theory of self-regulation', *Organizational behavior and human decision processes*, 50(2), pp. 248-287.

Bandura, A. (1997) *Self-Efficacy: The Exercise of Control*. Worth Publishers.

Bandura, A. (1998) 'Health promotion from the perspective of social cognitive theory', *Psychology & Health*, 13(4), pp. 623-649.

Bandura, A. (2001) 'Social Cognitive Theory: An Agentic Perspective', *Annual Review of Psychology*, 52(1), pp. 1-26.

Bataille, V. (2013) 'Sunbed use increases risk of melanoma; risk increases with greater number of sessions and first use at younger age', *Evidence Based Nursing*, 16(4), pp. 107-108.

Bentham, G. and Aase, A. (1996) 'Incidence of Malignant Melanoma of the Skin in Norway, 1955–1989: Associations with Solar Ultraviolet Radiation, Income and Holidays Abroad', *International Journal of Epidemiology*, 25(6), pp. 1132-1138.

Bernstein, J., Heeren, T., Edward, E., Dorfman, D., Bliss, C., Winter, M. and Bernstein, E. (2010) 'A brief motivational interview in a pediatric emergency department, plus 10-day telephone follow-up, increases attempts to quit drinking among youth and young adults who screen positive for problematic drinking', *Academic Emergency Medicine*, 17 (8), pp. 890-902.

Berry, T.R. and Carson, V. (2010) 'Ease of imagination, message framing, and physical activity messages', *British Journal of Health Psychology*, 15(1), pp. 197-211.

Birch-Machin, M.A. (2006) 'The role of mitochondria in ageing and carcinogenesis', *Clinical and Experimental Dermatology*, 31(4), pp. 548-552.

Birch-Machin, M.A., Russell, E.V. and Latimer, J.A. (2013) 'Mitochondrial DNA damage as a biomarker for ultraviolet radiation exposure and oxidative stress', *British Journal of Dermatology*, 169, pp. 9-14.

Birch-Machin, M.A. and Swalwell, H. (2010) 'How mitochondria record the effects of UV exposure and oxidative stress using human skin as a model tissue', *Mutagenesis*, 25(2), pp. 101-107.

Birch-Machin, M.A., Tindall, M., Turner, R., Haldane, F. and Rees, J.L. (1998) 'Mitochondrial DNA deletions in human skin reflect photo-rather than chronologic aging', *Journal of investigative dermatology*, 110(2), pp. 149-152.

Boniol, M., Autier, P., Boyle, P. and Gandini, S. (2012) 'Cutaneous melanoma attributable to sunbed use: systematic review and meta-analysis', *BMJ*, 345.

Borenstein, M., Hedges, L., Higgins, J. and Rothstein, H. (2005) *Comprehensive Meta-analysis* (Version 2) [Computer program]. Biostat.

Boulos, M.N.K., Wheeler, S., Tavares, C. and Jones, R. (2011) 'How smartphones are changing the face of mobile and participatory healthcare: an overview, with example from eCAALYX', *Biomedical engineering online*, 10(1), p. 24.

Bränström, R., Kristjansson, S. and Ullén, H. (2006) 'Risk perception, optimistic bias, and readiness to change sun related behaviour', *The European Journal of Public Health*, 16(5), pp. 492-497.

Branstrom, R., Ullen, H. and Brandberg, Y. (2004) 'Attitudes, subjective norms and perception of behavioural control as predictors of sun-related behaviour in Swedish adults', *Preventive Medicine*, 39(5), pp. 992-9.

Braun, V. and Clarke, V. (2006) 'Using thematic analysis in psychology', *Qualitative Research in Psychology*, 3(2), pp. 77-101.

Buller, D., Berwick, M., Shane, J., Kane, I., Lantz, K. and Buller, M. (2013) 'User-centered development of a smart phone mobile application delivering personalized real-time advice on sun protection', *Translational Behavioral Medicine*, 3(3), pp. 326-334.

Buller, D.B., Andersen, P.A., Walkosz, B.J., Scott, M.D., Cutter, G.R., Dignan, M.B., Zarlengo, E.M., Voeks, J.H. and Giese, A.J. (2005) 'Randomized trial testing a worksite sun protection program in an outdoor recreation industry', *Health Education & Behavior*, 32(4), pp. 514-35.

Burke-Garcia, A. and Scally, G. (2014) 'Trending now: future directions in digital media for the public health sector', *Journal of Public Health*.

Bush, K.R., Kivlahan, D.R., McDonell, M.B., Fihn, S.D. and Bradley, K.A. (1998) 'The audit alcohol consumption questions (audit-c): An effective brief screening test for problem drinking', *Archives of internal medicine*, 158(16), pp. 1789-1795.

Cafri, G., Thompson, J.K., Jacobsen, P. and Hillhouse, J. (2009) 'Investigating the role of appearance-based factors in predicting sunbathing and tanning salon use', *Journal of Behavioral Medicine*, 32(6), pp. 532-544.

Cancer Research UK (2011a) *Advice for tour operators* [web page]. Available at: <http://www.sunsmart.org.uk/advice-and-prevention/touroperators/> (Accessed: 28 April 2011).



Cancer Research UK (2011b) *SunSmart campaign research* [Web page]. Available at: <http://www.sunsmart.org.uk/skin-cancer-facts/> (Accessed: 28 April 2011).

Cancer Research UK (2013a) *Advice for tour operators* [web page]. Available at: <http://www.sunsmart.org.uk/advice-and-prevention/touroperators/> (Accessed: 10 november 2013).

Cancer Research UK (2013b) *Skin cancer facts* [Web page]. Available at: <http://www.sunsmart.org.uk/skin-cancer-facts/> (Accessed: 10 November 2013).

Cancer Research UK (2013c) *Skin Cancer Statistics*. Available at: <http://www.cancerresearchuk.org/cancer-info/cancerstats/types/skin/>.

Cancer Reserach UK (2009) *SunSmart campaign research*. Available at: <http://www.sunsmart.org.uk/about-sunsmart/campaignresearch/>.

Carey, K.B., Carey, M.P., Maisto, S.A. and Henson, J.M. (2006) 'Brief motivational interventions for heavy college drinkers: A randomized controlled trial', *Journal of consulting and clinical psychology*, 74(5), pp. 943-954.

Carver, C.S. and Scheier, M.F. (2001) *On the self-regulation of behavior*. Cambridge University Press.

Casale, P., Pujol, O. and Radeva, P. (2011) 'Human Activity Recognition from Accelerometer Data Using a Wearable Device', in Vitrià, J., Sanches, J. and Hernández, M. (eds.) *Pattern Recognition and Image Analysis*. Springer Berlin Heidelberg, pp. 289-296.

Chan, A.-W. (2008) 'Bias, Spin, and Misreporting: Time for Full Access to Trial Protocols and Results', *PLoS Med*, 5(11), p. e230.

Chandon, P., Morwitz, V.G. and Reinartz, W.J. (2005) 'Do Intentions Really Predict Behavior? Self-Generated Validity Effects in Survey Research', *Journal of Marketing*, 69(2), pp. 1-14.

Chapman, K.J. (2001) 'Measuring intent: There's nothing "mere" about mere measurement effects', *Psychology and Marketing*, 18(8), pp. 811-841.

Chapter 2 (2014) 'The efficacy of interventions to promote sun-protection behaviours in recreational settings: A systematic review with meta-analyses and moderator analyses'.

Chartered Institute of Environmental Health (2004) *Local Authority Skin Cancer Prevention Survey 2004*. Health, C.I.o.E. [Online]. Available at: [http://www.cieh.org/policy/skin\\_cancer.html](http://www.cieh.org/policy/skin_cancer.html).

Chen, J.G., Fleischer, A.B., Smith, E.D., Kancler, C., Goldman, N.D., Williford, P.M. and Feldman, S.R. (2001) 'Cost of Nonmelanoma Skin Cancer Treatment in the United States', *Dermatologic Surgery*, 27(12), pp. 1035-1038.

Cherpitel, C.J., Korcha, R.A., Moskalewicz, J., Swiatkiewicz, G., Ye, Y. and Bond, J. (2010) 'Screening, Brief Intervention, and Referral to Treatment (SBIRT): 12-month outcomes of a randomized controlled clinical trial in a Polish emergency department', *Alcoholism: Clinical and Experimental Research*, 34(11), pp. 1922-1928.

Cioffi, D. and Garner, R. (1998) 'The Effect of Response Options on Decisions and Subsequent Behavior: Sometimes Inaction is Better', *Personality and Social Psychology Bulletin*, 24(5), pp. 463-472.

Clarke, C.A., Moy, L.M., Swetter, S.M., Zadnick, J. and Cockburn, M.G. (2010) 'Interaction of Area-Level Socioeconomic Status and UV Radiation on Melanoma Occurrence in California', *Cancer Epidemiology Biomarkers & Prevention*, 19(11), pp. 2727-2733.

Clarke, V., Williams, T. and Arthey, S. (1997) 'Skin Type and Optimistic Bias in Relation to the Sun Protection and Suntanning Behaviors of Young Adults', *Journal of Behavioral Medicine*, 20(2), pp. 207-222.

Clifford, P.R., Maisto, S.A. and Davis, C.M. (2007) 'Alcohol treatment research assessment exposure subject reactivity effects: Part I. Alcohol use and related consequences', *Journal of Studies on Alcohol and Drugs*, 68 (4), pp. 519-528.

Cochrane Effective Practice and Organisation of Care Review Group (EPOC) (2002) *Data collection Checklist*.

Cole-Lewis, H. and Kershaw, T. (2010) 'Text messaging as a tool for behavior change in disease prevention and management', *Epidemiologic reviews*, 32(1), pp. 56-69.

comScore (2012) *EU5 Smartphone Penetration Reaches 55 Percent in October 2012*. Available at:  
[http://www.comscore.com/Insights/Press\\_Releases/2012/12/EU5\\_Smartphone\\_Penetration\\_Reaches\\_55\\_Percent\\_in\\_October\\_2012?utm\\_source=feedburner&utm\\_medium=feed&utm\\_campaign=Feed%3A+comscore+%28comScore+News%29](http://www.comscore.com/Insights/Press_Releases/2012/12/EU5_Smartphone_Penetration_Reaches_55_Percent_in_October_2012?utm_source=feedburner&utm_medium=feed&utm_campaign=Feed%3A+comscore+%28comScore+News%29) (Accessed: 11 november 2013).

Conner, M., Godin, G., Norman, P. and Sheeran, P. (2011) 'Using the question-behavior effect to promote disease prevention behaviors: two randomized controlled trials', *Health psychology*, (3), pp. 300-9 [Online] DOI: 10.1037/a0023036.

Coups, E.J., Manne, S.L. and Heckman, C.J. (2008) 'Multiple Skin Cancer Risk Behaviors in the U.S. Population', *American Journal of Preventive Medicine*, 34(2), pp. 87-93.

Cover, T. and Hart, P. (1967) 'Nearest neighbor pattern classification', *Information Theory, IEEE Transactions on*, 13(1), pp. 21-27.

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I. and Petticrew, M. (2008) 'Developing and evaluating complex interventions: the new Medical Research Council guidance', *BMJ*, 337.

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I. and Petticrew, M. (2010) 'Developing and evaluating complex interventions: an introduction to the new Medical Research Council guidance', in Killoran, A. and Kelly, M.P. (eds.) *Evidence-based public health: effectiveness and efficiency*. Oxford University Press.

Creech, L. and Mayer, J. (1997) 'Ultraviolet radiation exposure in children: A review of measurement strategies', *Annals of Behavioral Medicine*, 19(4), pp. 399-407.

Daepfen, J.-B., Gaume, J., Bady, P., Yersin, B., Calmes, J.-M., Givel, J.-C. and Gmel, G. (2007) 'Brief alcohol intervention and alcohol assessment do not influence alcohol use in injured patients treated in the emergency department: a randomized controlled clinical trial', *Addiction*, 102(8), pp. 1224-1233.

Darker, C.D. and French, D.P. (2009) 'What sense do people make of a theory of planned behaviour questionnaire?: A think-aloud study', *Journal of Health Psychology*, 14(7), pp. 861-871.

Davidson, K., Goldstein, M., Kaplan, R., Kaufmann, P., Knatterud, G., Orleans, C., Spring, B., Trudeau, K. and Whitlock, E. (2003) 'Evidence-based behavioral medicine: What is it and how do we achieve it?', *Annals of Behavioral Medicine*, 26(3), pp. 161-171.

de Vries, E., Schouten, L.J., Visser, O., Eggermont, A.M.M. and Coebergh, J.W.W. (2003a) 'Rising trends in the incidence of and mortality from cutaneous melanoma in the Netherlands: a Northwest to Southeast gradient?', *European journal of cancer (Oxford, England : 1990)*, 39(10), pp. 1439-1446.

de Vries, E., Schouten, L.J., Visser, O., Eggermont, A.M.M., Coebergh, J.W.W. and Working Group of Regional Cancer, R. (2003b) 'Rising trends in the incidence of and mortality from cutaneous melanoma in the Netherlands: a Northwest to Southeast gradient?', *European Journal of Cancer*, 39(10), pp. 1439-46.

de Vries, H., Mesters, I., Riet, J.V., Willems, K. and Reubsaet, A. (2006) 'Motives of Belgian adolescents for using sunscreen: the role of action plans', *Cancer Epidemiol Biomarkers Prev*, 15(7), pp. 1360-6.

Dennison, L., Morrison, L., Conway, G. and Yardley, L. (2013) 'Opportunities and Challenges for Smartphone Applications in Supporting Health Behavior Change: Qualitative Study', *J Med Internet Res*, 15(4), p. e86.

Department of Health (2007) *Cancer reform strategy*.

Desmond, R.A. and Soong, S.J. (2003) 'Epidemiology of malignant melanoma', *Surgical Clinics of North America*, 83 (1), pp. 1-29.

Dey, P., Collins, S., Will, S. and Woodman, C.B.J. (1995) 'Randomised controlled trial assessing effectiveness of health education leaflets in reducing incidence of sunburn', *BMJ*, 311(7012), pp. 1062-1063.

Dholakia, U.M. (2010) 'A critical review of question-behavior effect research', *Review of Marketing Research*, 7, pp. 145-197.

Dietrich, A.J., Olson, A.L., Sox, C.H., Stevens, M., Tosteson, T.D., Ahles, T., Winchell, C.W., Grant-Petersson, J., Collison, D.W. and Sanson-Fisher, R. (1998) 'A community-based randomized trial encouraging sun protection for children', *Pediatrics*, 102(6), p. E64.

Diffey, B.L. (1996) 'People do not apply enough sunscreen for protection', *BMJ*, 313(7062), p. 942.

Diffey, B.L. and Norridge, Z. (2009) 'Reported sun exposure, attitudes to sun protection and perceptions of skin cancer risk: a survey of visitors to Cancer Research UK's SunSmart campaign website', *British Journal of Dermatology*, 160(6), pp. 1292-8.

Dignan, M., Michielutte, R., Blinson, K., Wells, H.B., Case, L.D., Sharp, P., Davis, S., Konen, J. and McQuellon, R.P. (1996) 'Effectiveness of health education to increase screening for cervical cancer among eastern-band Cherokee Indian women in North Carolina', *Journal of the National Cancer Institute*, 88(22), pp. 1670-6.

Dignan, M., Michielutte, R., Wells, H.B., Sharp, P., Blinson, K., Case, L.D., Bell, R., Konen, J., Davis, S. and McQuellon, R.P. (1998) 'Health education to increase screening for cervical cancer among Lumbee Indian Women in North Carolina', *Health Education Research*, 13(4), pp. 545-556.

Dobbinson, S., Wakefield, M., Hill, D., Girgis, A., Aitken, J.F., Beckmann, K., Reeder, A.I., Herd, N., Fairthorne, A. and Bowles, K.-A. (2008) 'Prevalence and determinants of Australian adolescents' and adults' weekend sun protection and sunburn, summer 2003-2004', *Journal of the American Academy of Dermatology*, 59(4), pp. 602-614.

Dodd, L.J. and Forshaw, M.J. (2010) 'Assessing the efficacy of appearance-focused interventions to prevent skin cancer: a systematic review of the literature', *Health Psychology Review*, 4(2), pp. 93-111.

Dombrowski, S., Sniehotta, F. and Avenell, A. (2007) 'Current issues and future directions in Psychology and Health: Towards a cumulative science of behaviour change: Do current conduct and reporting of behavioural interventions fall short of best practice?', *Psychology & Health*, 22(8), pp. 869 - 874.

Dombrowski, S.U., Sniehotta, F.F., Avenell, A., Johnston, M., MacLennan, G. and Araújo-Soares, V. (2010) 'Identifying active ingredients in complex behavioural

interventions for obese adults with obesity-related co-morbidities or additional risk factors for co-morbidities: a systematic review', *Health Psychology Review*, 6(1), pp. 7-32.

Donnelly DW, Gavin AT and H, C. (2009) 'Cancer in Ireland 1994-2004: A comprehensive report'. May 2014. Ireland: Northern Ireland Cancer Registry/National Cancer Registry.

Dupuy, A., Dunant, A., Grob, J.-J. and Reseau d'Epidemiologie en, D. (2005) 'Randomized controlled trial testing the impact of high-protection sunscreens on sun-exposure behavior', *Archives of dermatology*, 141(8), pp. 950-6.

English, D.R. and Armstrong, B.K. (1988) 'Identifying people at high risk of cutaneous malignant melanoma: results from a case-control study in Western Australia', *British Medical Journal Clinical Research Ed.*, 296(6632), pp. 1285-8.

Fader, D.J., Wise, C.G., Normolle, D.P. and Johnson, T.M. (1998) 'The multidisciplinary melanoma clinic: A cost outcomes analysis of specialty care', *Journal of the American Academy of Dermatology*, 38(5), pp. 742-751.

Ferlay, J., Shin, H.R., Bray, F., Forman, D., Mathers, C. and Parkin, D.M. (2010) *GLOBOCAN 2008 v1.2*. Available at: <http://globocan.iarc.fr>, accessed on 22/03/2012. (Accessed: 10).

Fitzpatrick, T.B. (1988) 'The validity and practicality of sun-reactive skin types i through vi', *Archives of Dermatology*, 124(6), pp. 869-871.

Foy, R., Francis, J., Johnston, M., Eccles, M., Lecouturier, J., Bamford, C. and Grimshaw, J. (2007) 'The development of a theory-based intervention to promote appropriate disclosure of a diagnosis of dementia', *BMC Health Services Research*, 7(1), p. 207.

Francis, J.J., Johnston, M., Robertson, C., Glidewell, L., Entwistle, V., Eccles, M.P. and Grimshaw, J.M. (2009a) 'What is an adequate sample size? Operationalising data saturation for theory-based interview studies', *Psychology & Health*, 25(10), pp. 1229-1245.

Francis, J.J., Stockton, C., Eccles, M.P., Johnston, M., Cuthbertson, B.H., Grimshaw, J.M., Hyde, C., Tinmouth, A. and Stanworth, S.J. (2009b) 'Evidence-based

selection of theories for designing behaviour change interventions: Using methods based on theoretical construct domains to understand clinicians' blood transfusion behaviour', *British Journal of Health Psychology*, 14(4), pp. 625-646.

Free, C., Phillips, G., Galli, L., Watson, L., Felix, L., Edwards, P., Patel, V. and Haines, A. (2013) 'The effectiveness of mobile-health technology-based health behaviour change or disease management interventions for health care consumers: a systematic review', *PLoS medicine*, 10(1), p. e1001362.

French, D.P., Cooke, R., McLean, N., Williams, M. and Sutton, S. (2007) 'What Do People Think about When They Answer Theory of Planned Behaviour Questionnaires?: A 'Think Aloud' Study', *Journal of Health Psychology*, 12(4), pp. 672-687.

French, D.P. and Sutton, S. (2010) 'Reactivity of measurement in health psychology: How much of a problem is it? What can be done about it?', *British Journal of Health Psychology*, 15(3), pp. 453-468.

Fry, J.P. and Neff, R.A. (2009) 'Periodic prompts and reminders in health promotion and health behavior interventions: systematic review', *Journal of medical Internet research*, 11(2).

Gandini, S., Sera, F., Cattaruzza, M.S., Pasquini, P., Picconi, O., Boyle, P. and Melchi, C.F. (2005) 'Meta-analysis of risk factors for cutaneous melanoma: II. Sun exposure', *European Journal of Cancer*, 41(1), pp. 45-60.

Garside, R., Pearson, M. and Moxham, T. (2010) 'What influences the uptake of information to prevent skin cancer? A systematic review and synthesis of qualitative research', *Health Education Research*, 25(1), pp. 162-182.

Geller, A.C., Glanz, K., Shigaki, D., Isneq, M.R., Sun, T. and Maddock, J. (2001) 'Impact of skin cancer prevention on outdoor aquatics staff: the Pool Cool program in Hawaii and Massachusetts', *Preventive Medicine*, 33(3), pp. 155-161.

Gibbons, F.X., Gerrard, M., Lane, D.J., Mahler, H.I. and Kulik, J.A. (2005) 'Using UV photography to reduce use of tanning booths: a test of cognitive mediation', *Health psychology : official journal of the Division of Health Psychology, American Psychological Association*, 24(4), pp. 358-363.

Gies, P. and McLennan, A. (2012) 'Ready To Wear Sun Protection: Clothing Fits the Bill', *The Skin Cancer Foundation Journal*, xxx, pp. 70-73.

Glanz, K., Geller, A.C., Shigaki, D., Maddock, J.E. and Isnec, M.R. (2002) 'A randomized trial of skin cancer prevention in aquatics settings: the Pool Cool program', *Health Psychology*, 21(6), pp. 579-587.

Glanz, K., Gies, P., O'Riordan, D.L., Elliott, T., Nehl, E., McCarty, F. and Davis, E. (2010a) 'Validity of self-reported solar UVR exposure compared with objectively measured UVR exposure', *Cancer Epidemiology Biomarkers and Prevention*, 19 (12), pp. 3005-3012.

Glanz, K., Lew, R.A., Song, V. and Murakami-Akatsuka, L. (2000) 'Skin cancer prevention in outdoor recreation settings: effects of the Hawaii SunSmart Program', *Effective Clinical Practice*, 3(2), pp. 53-61.

Glanz, K., Maddock, J.E., Lew, R.A. and Murakami-Akatsuka, L. (2001) 'A randomized trial of the Hawaii SunSmart program's impact on outdoor recreation staff', *Journal of the American Academy of Dermatology*, 44(6), pp. 973-8.

Glanz, K., Saraiya, M. and Briss, P.A. (2004) 'Impact of intervention strategies to reduce UVR exposure', in David J. Hill, J. Mark Elwood and English., D.R. (eds.) *Prevention of skin cancer*. The Netherlands: Kluwer Academic Publishers.

Glanz, K., Schoenfeld, E.R. and Steffen, A. (2010b) 'A Randomized Trial of Tailored Skin Cancer Prevention Messages for Adults: Project SCAPE', *American Journal of Public Health*, 100(4), pp. 735-741.

Glanz, K., Yaroch, A.L., Dancel, M., Saraiya, M., Crane, L.A., Buller, D.B., Manne, S., O'Riordan, D.L., Heckman, C.J., Hay, J. and Robinson, J.K. (2008) 'Measures of Sun Exposure and Sun Protection Practices for Behavioral and Epidemiologic Research', *Arch Dermatol*, 144(2), pp. 217-222.

Godar, D.E., Wengraitis, S.P., Shreffler, J. and Sliney, D.H. (2001) 'UV Doses of Americans', *Photochemistry and Photobiology*, 73(6), pp. 621-629.

Godin, G., Bélanger-Gravel, A., Amireault, S., Vohl, M.C. and Pérusse, L. (2011) 'The effect of mere-measurement of cognitions on physical activity behavior: a



randomized controlled trial among overweight and obese individuals', *The International Journal of Behavioral Nutrition and Physical Activity*, p. 2.

Godin, G., Bélanger-Gravel, A., Vézina-Im, L.-A., Amireault, S. and Bilodeau, A. (2012) 'Question-behaviour effect: A randomised controlled trial of asking intention in the interrogative or declarative form', *Psychology & Health*, 27(9), pp. 1086-1099.

Godin, G., Germain, M., Conner, M., Delage, G. and Sheeran, P. (2013) 'Promoting the Return of Lapsed Blood Donors: A Seven-Arm Randomized Controlled Trial of the Question-Behavior Effect', *Health Psychology*, p. In Press.

Godin, G., Sheeran, P., Conner, M., Delage, G., Germain, M., Belanger-Gravel, A. and Naccache, H. (2010) 'Which survey questions change behavior? Randomized controlled trial of mere measurement interventions', *Health Psychology*, 29 (6), pp. 636-644.

Godin, G., Sheeran, P., Conner, M. and Germain, M. (2008) 'Asking questions changes behavior: Mere measurement effects on frequency of blood donation', *Health Psychology*, 27(2), pp. 179-184.

Gold, J., Aitken, C.K., Dixon, H.G., Gouillou, M., Spelman, T., Wakefield, M. and Hellard, M.E. (2011) 'A randomised controlled trial using mobile advertising to promote safer sex and sun safety to young people', *Health education research*, 26(5), pp. 782-794.

Gollwitzer, P.M. and Sheeran, P. (2006) 'Implementation Intentions and Goal Achievement: A Meta[hyphen (true graphic)]analysis of Effects and Processes', in Mark, P.Z. (ed.) *Advances in Experimental Social Psychology*. Academic Press, pp. 69-119.

Green, A.C. and Williams, G.M. (2007) 'Point: Sunscreen Use Is a Safe and Effective Approach to Skin Cancer Prevention', *Cancer Epidemiology Biomarkers & Prevention*, 16(10), pp. 1921-1922.

Harbottle, A. and Birch-Machin, M.A. (2006) 'Real-time PCR analysis of a 3895[thinsp]bp mitochondrial DNA deletion in nonmelanoma skin cancer and its use as a quantitative marker for sunlight exposure in human skin', *Br J Cancer*, 94(12), pp. 1887-1893.

Harbottle, A., Maki, J., Reguly, B., Wittcock, R., Robinson, K., Parr, R. and Birch-Machin, M.A. (2010) 'Real-time polymerase chain reaction analysis of a 3895-bp mitochondrial DNA deletion in epithelial swabs and its use as a quantitative marker for sunlight exposure in human skin', *British Journal of Dermatology*, 163(6), pp. 1291-1295.

Hardeman, W., Sutton, S., Griffin, S., Johnston, M., White, A., Wareham, N.J. and Kinmonth, A.L. (2005) 'A causal modelling approach to the development of theory-based behaviour change programmes for trial evaluation', *Health Education Research*, 20(6), pp. 676-687.

Health Education Authority (Skin cancer prevention: policy guidelines for local authorities.) 1998. London: Health Education Authority.

Healthypeople.gov (2010) *Topics & Objectives Index - Healthy People* [Web page]. Available at: <http://www.healthypeople.gov/2020/topicsobjectives2020/default.aspx> (Accessed: 5 May 2011).

Heron, K.E. and Smyth, J.M. (2010) 'Ecological momentary interventions: incorporating mobile technology into psychosocial and health behaviour treatments', *British journal of health psychology*, 15(1), pp. 1-39.

Higgins, J.P.T. and Green, S. (2011) *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0*. The Cochrane Collaboration. Available at: [www.cochrane-handbook.org](http://www.cochrane-handbook.org).

Higgins, J.P.T. and Green S (2011) *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0*. The Cochrane Collaboration. Available at: [www.cochrane-handbook.org](http://www.cochrane-handbook.org).

Hillhouse, J. and Turrisi, R. (2002) 'Examination of the Efficacy of an Appearance-Focused Intervention to Reduce UV Exposure', *Journal of Behavioral Medicine*, 25(4), pp. 395-409.

Hillhouse, J., Turrisi, R., Stapleton, J. and Robinson, J. (2008) 'A randomized controlled trial of an appearance-focused intervention to prevent skin cancer', *Cancer*, 113(11), pp. 3257-3266.

Hillhouse, J.J., Adler, C.M., Drinnon, J. and Turrisi, R. (1997) 'Application of Azjen's Theory of Planned Behavior to Predict Sunbathing, Tanning Salon Use, and Sunscreen Use Intentions and Behaviors', *Journal of behavioral medicine*, 20(4), pp. 365-378.

Hobbs, N., Rodrigues, A., Sniehotta, F.F., French, D.P. and Glidewell, L. CRD42011001467 (2011) 'Does measurement change health-related behaviour? A systematic review' 2011. PROSPERO. Available at: [http://www.crd.york.ac.uk/PROSPERO/display\\_record.asp?ID=CRD42011001467](http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42011001467).

Hollands, G.J.H., Matthew; Marteau, Theresa M (2010) 'Visual feedback of individuals' medical imaging results for changing health behaviour', *Cochrane Database of Systematic Reviews*, Issue 1, p. Art. No: CD007434.

Hrisos, S., Eccles, M., Johnston, M., Francis, J., Kaner, E., Steen, N. and Grimshaw, J. (2008) 'An intervention modelling experiment to change GPs' intentions to implement evidence-based practice: using theory-based interventions to promote GP management of upper respiratory tract infection without prescribing antibiotics.', *BMC Health Services Research*, 8(1), p. 10.

Hwang, K.O., Ottenbacher, A.J., Green, A.P., Cannon-Diehl, M.R., Richardson, O., Bernstam, E.V. and Thomas, E.J. (2010) 'Social support in an Internet weight loss community', *International Journal of Medical Informatics*, 79(1), pp. 5-13.

ISD Scotland 'Cancer Statistics. Cancer of the Skin'. May 2014. ISD Scotland.

ISRCTN3943558 (2013) 'A factorial randomised controlled trial of the mISkin Smartphone intervention and sunscreen with SPF 15 vs. SPF 30 to prevent epidermal DNA skin damage amongst holidaymakers'. London: Current Controlled Trials, c/o BioMed Central. Available at: <http://www.controlled-trials.com/isrctn/pf/63943558>.

Jackson, K.M. and Aiken, L.S. (2000) 'A Psychosocial Model of Sun Protection and Sunbathing in Young Women: The Impact of Health Beliefs, Attitudes, Norms, and Self-Efficacy for Sun Protection', *Health Psychology*, 19(5), pp. 469-478.

Jones, F., Abraham, C., Harris, P., Schulz, J. and Chrispin, C. (2001) 'From knowledge to action regulation: Modeling the cognitive prerequisites of sun screen use in Australian and UK samples', *Psychology & Health*, 16(2), pp. 191-206.

Jones, J.L. and Leary, M.R. (1994) 'Effects of appearance-based admonitions against sun exposure on tanning intentions in young adults', *Health Psychology*, 13(1), p. 86.

Kalichman, S.C., Kelly, J.A. and Stevenson, L. (1997) 'Priming effects of HIV risk assessments on related perceptions and behavior: An experimental field study', *AIDS and Behavior*, 1(1), pp. 3-8.

King, D., Greaves, F., Exeter, C. and Darzi, A. (2013) 'Gamification': Influencing health behaviours with games', *Journal of the Royal Society of Medicine*, 106(3), pp. 76-78.

Knaus, C.S. and Austin, E.W. (1999) 'The AIDS Memorial Quilt as preventative education: a developmental analysis of the Quilt', *AIDS education and prevention : official publication of the International Society for AIDS Education*, 11(6), pp. 525-540.

Knaus, C.S., Pinkleton, B.E. and Weintraub Austin, E. (2000) 'The Ability of the AIDS Quilt to Motivate Information Seeking, Personal Discussion, and Preventative Behavior as a Health Communication Intervention', *Health Communication*, 12(3), pp. 301-316.

Knittle, K., Maes, S. and de Gucht, V. (2010) 'Psychological interventions for rheumatoid arthritis: Examining the role of self-regulation with a systematic review and meta-analysis of randomized controlled trials', *Arthritis Care & Research*, 62(10), pp. 1460-1472.

Koch, H., Wittern, K.-P. and Bergemann, J. (2001) 'In human keratinocytes the Common Deletion reflects donor variabilities rather than chronologic aging and can be induced by ultraviolet A irradiation', *Journal of investigative dermatology*, 117(4), pp. 892-897.

Krauss, B.J., Goldsamt, L., Bula, E., Godfrey, C., Yee, D.S. and Palij, M. (2000) 'Pretest assessment as a component of safer sex intervention: a pilot study of brief one-session interventions for women partners of male injection drug users in New York City', *Journal of Urban Health*, 77(3), pp. 383-95.

Kricker, A., Armstrong, B.K. and English, D.R. (1994) 'Sun exposure and non-melanocytic skin cancer', *Cancer Causes & Control*, 5(4), pp. 367-92.

Kricker, A., Armstrong, B.K., English, D.R. and Heenan, P.J. (1995) 'Does intermittent sun exposure cause basal cell carcinoma? a case-control study in Western Australia', *International Journal of Cancer*, 60(4), pp. 489-94.

Kricker, A., Armstrong, B.K., Goumas, C., Litchfield, M., Begg, C.B., Hummer, A.J., Marrett, L.D., Theis, B., Millikan, R.C., Thomas, N., Culver, H.A., Gallagher, R.P., Dwyer, T., Rebbeck, T.R., Kanetsky, P.A., Busam, K., From, L., Mujumdar, U., Zanetti, R. and Berwick, M. (2007) 'Ambient UV, personal sun exposure and risk of multiple primary melanomas', *Cancer Causes and Control*, 18 (3), pp. 295-304.

Krishnan, K.J., Harbottle, A. and Birch-Machin, M.A. (2004) 'The Use of a 3895 bp Mitochondrial DNA Deletion as a Marker for Sunlight Exposure in Human Skin', *J Investig Dermatol*, 123(6), pp. 1020-1024.

Kumar, S., Nilsen, W., Pavel, M. and Srivastava, M. (2013) 'Mobile Health: Revolutionizing Healthcare Through Transdisciplinary Research', *Computer*, 46(1), pp. 28-35.

Kvalem, I.L., Sundet, J.M., Rivø, K.I., Eilertsen, D.E. and Bakketeig, L.S. (1996) 'The Effect of Sex Education on Adolescents' Use of Condoms: Applying the Solomon Four-Group Design', *Health Education & Behavior*, 23(1), pp. 34-47.

Kypri, K., Langle, J.D., Saunders, J.B. and Cashell-Smith, M.L. (2006) 'Assessment may conceal therapeutic benefit: Findings from a randomized controlled trial for hazardous drinking', *Addiction*, 102 (1), pp. 62-70.

Kypri, K. and McAnally, H.M. (2005) 'Randomized controlled trial of a web-based primary care intervention for multiple health risk behaviors', *Preventive medicine*, 41(3-4), pp. 761-766.

Lake, J.R., Thomson, C.S., Twelves, C.J. and Davies, E.A. (2013) 'A qualitative investigation of the motivations, experiences and views of female sunbed users under the age of 18 in England', *Journal of Public Health*.

Lautenschlager, S., Wulf, H.C. and Pittelkow, M.R. (2007) 'Photoprotection', *Lancet*, 370 (9586), pp. 528-537.

Lens, M.B. and Dawes, M. (2004) 'Global perspectives of contemporary epidemiological trends of cutaneous malignant melanoma', *Br J Dermatol*, 150(2), pp. 179-85.

Levav, J. and Fitzsimons, G.J. (2006) 'When Questions Change Behavior: The Role of Ease of Representation', *Psychological Science*, 17(3), pp. 207-213.

Ling, T.C., Faulkner, C. and Rhodes, L.E. (2003) 'A questionnaire survey of attitudes to and usage of sunscreens in northwest England', *Photodermatology, photoimmunology & photomedicine*, 19(2), pp. 98-101.

Livingston, P.M., White, V.M., Ugoni, A.M. and Borland, R. (2001) 'Knowledge, attitudes and self-care practices related to sun protection among secondary students in Australia', *Health Education Research*, 16(3), pp. 269-278.

Mahler, H.I., Kulik, J.A., Gibbons, F.X., Gerrard, M. and Harrell, J. (2003a) 'Effects of appearance-based interventions on sun protection intentions and self-reported behaviors', *Health Psychol*, 22(2), pp. 199-209.

Mahler, H.I.M., Kulik, J.A., Gerrard, M. and Gibbons, F.X. (2006) 'Effects of Two Appearance-Based Interventions on the Sun Protection Behaviors of Southern California Beach Patrons', *Basic and Applied Social Psychology*, 28(3), pp. 263-272.

Mahler, H.I.M., Kulik, J.A., Gibbons, F.X., Gerrard, M. and Harrell, J. (2003b) 'Effects of appearance-based interventions on sun protection intentions and self-reported behaviors', *Health Psychology*, 22(2), pp. 199-209.

Mahler, H.I.M.K., James A.; Gerrard, Meg; Gibbons, Frederick X. (2007) 'Long-term effects of appearance-based interventions on sun protection behaviors.', *Health Psychology*, 26(3), pp. 350-360.

Manning, D.L. and Quigley, P. (2002) 'Sunbathing intentions in Irish people travelling to Mediterranean summer holiday destinations', *European Journal of Cancer Prevention*, 11(2), pp. 159-63.

Marks, R. (1995) 'The epidemiology of non-melanoma skin cancer: who, why and what can we do about it', *J Dermatol*, 22(11), pp. 853-7.

Marteau, T.M., French, D.P., Griffin, S.J., Prevost, A.T., Sutton, S., Watkinson, C., Attwood, S. and Hollands, G.J. (2010) 'Effects of communicating DNA-based disease risk estimates on risk-reducing behaviours', *Cochrane Database Syst Rev*, 10.

Mayer, J.A., Lewis, E.C., Eckhardt, L., Slymen, D., Belch, G., Elder, J., Engelberg, M., Eichenfield, L., Achter, A., Nichols, T., Walker, K., Kwon, H., Talosig, M. and Gearen, C. (2001) 'Promoting sun safety among zoo visitors', *Preventive Medicine*, 33(3), pp. 162-9.

Mayer, J.A., Slymen, D.J., Eckhardt, L., Johnston, M.R., Elder, J.P., Sallis, J.F., Creech, L., Lui, K.J., Rosenberg, C., Souvignier, S.T. and Stepanski, B. (1997) 'Reducing Ultraviolet Radiation Exposure in Children', *Preventive Medicine*, 26(4), pp. 516-522.

McCambridge, J., Butor-Bhavsar, K., Witton, J. and Elbourne, D. (2011) 'Can Research Assessments Themselves Cause Bias in Behaviour Change Trials? A Systematic Review of Evidence from Solomon 4-Group Studies', *PloS one*, 6(10), p. e25223.

McCambridge, J. and Kypri, K. (2011) 'Can Simply Answering Research Questions Change Behaviour? Systematic Review and Meta Analyses of Brief Alcohol Intervention Trials', *PloS one*, 6(10), p. e23748.

McCambridge, J., Slym, R.L. and Strang, J. (2007) 'Randomized controlled trial of motivational interviewing compared with drug information and advice for early intervention among young cannabis users', *Addiction*, 103(11), pp. 1809-18.

McColl, E., Jacoby, A., Thomas, L., Soutter, J. and Bamford, C. (2002) 'Design and use of questionnaires: a review of best practice applicable to surveys of health service staff and patients', *Health Technology Assessment*, 5(31), p. 256.

Michie, S., Abraham, C., Whittington, C., McAteer, J. and Gupta, S. (2009a) 'Effective Techniques in Healthy Eating and Physical Activity Interventions: A Meta-Regression', *Health Psychology*, 28(6), pp. 690-701.

Michie, S., Abraham, C., Whittington, C., McAteer, J. and Gupta, S. (2009b) 'Effective techniques in healthy eating and physical activity interventions: a meta-regression', *Health Psychology*, 28(6), p. 690.

Michie, S., Ashford, S., Sniehotta, F.F., Dombrowski, S.U., Bishop, A. and French, D.P. (2010) 'A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: The CALO-RE taxonomy', *Psychology & Health*.

Michie, S., Brown, J., Geraghty, A., Miller, S., Yardley, L., Gardner, B., Shahab, L., McEwen, A., Stapleton, J. and West, R. (2012) 'Development of StopAdvisor', *Translational Behavioral Medicine*, 2(3), pp. 263-275.

Michie, S., Johnston, M., Abraham, C., Lawton, R., Parker, D. and Walker, A. (2005) 'Making psychological theory useful for implementing evidence based practice: a consensus approach', *Quality and Safety in Health Care*, 14(1), pp. 26-33.

Michie, S., van Stralen, M. and West, R. (2011) 'The Behaviour Change Wheel: a new method for characterising and designing behaviour change interventions', *Implementation Science*, 6(1), p. 42.

Moher, D., Liberati, A., Tetzlaff, J. and Altman, D., G. (2009a) 'Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement', *BMJ*, 339.

Moher, D., Liberati, A., Tetzlaff, J. and Altman, D.G. (2009b) 'Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement', *BMJ*, 339.

Møller, H., Fairley, L., Coupland, V., Okello, C., Green, M., Forman, D., Møller, B. and Bray, F. (2007) 'The future burden of cancer in England: incidence and numbers of new patients in 2020', *British journal of cancer*, 96(9), pp. 1484-1488.

Montague, M., Borland, R. and Sinclair, C. (2001) 'Slip! Slop! Slap! and SunSmart, 1980-2000: Skin Cancer Control and 20 Years of Population-Based Campaigning', *Health Education & Behavior*, 28(3), pp. 290-305.

Moreira, T. and Foxcroft, D.R. (2008) 'The effectiveness of brief personalized normative feedback in reducing alcohol-related problems amongst University students: Protocol for a randomized controlled trial', *BMC public health*, 8(113).

Moreira, T., Oskrochi, R. and Foxcroft, D.R. (2012) 'Personalised Normative Feedback for Preventing Alcohol Misuse in University Students: Solomon Three-Group Randomised Controlled Trial', *PLoS ONE*, 7(9).



MORRIS, S., COX, B., BOSANQUET, N. (2005) 'Cost of skin cancer in England', *Tanaka Business School Discussion Papers: TBS/DP05/39*, [Online]. Available at: <http://www3.imperial.ac.uk/pls/portallive/docs/1/43013.PDF>.

Morwitz, V.G. and Fitzsimons, G.J. (2004) 'The Mere-Measurement Effect: Why Does Measuring Intentions Change Actual Behavior?', *Journal of Consumer Psychology*, 14(1-2), pp. 64-74.

Morwitz, V.G., Johnson, E. and Schmittlein, D. (1993) 'Does measuring intent change behavior?', *Journal of consumer research*, pp. 46-61.

Myers, L.B. and Horswill, M.S. (2006) 'Social cognitive predictors of sun protection intention and behavior', *Behav Med*, 32(2), pp. 57-63.

Napolitano, M.A., Hayes, S., Bennett, G.G., Ives, A.K. and Foster, G.D. (2013) 'Using facebook and text messaging to deliver a weight loss program to college students', *Obesity*, 21(1), pp. 25-31.

National Statistics (2010) *International Travel* [Web page]. Available at: <http://www.statistics.gov.uk/cci/nugget.asp?id=352> (Accessed: 16 May 2010).

Newcastle University Ethics Committee (2006) *Code of Good Practice in Research*. Available at: <http://www.ncl.ac.uk/research/ethics/goodpractice.htm>.

NICE (2011) *Skin Cancer: how the NHS and local authorities can help prevent skin cancer using public information, sun protection resources and by making changes to the environment* (Public health guidance PH32). National Institute for Health and Clinical Excellence. [Online]. Available at: <http://guidance.nice.org.uk/PH32> (Accessed: December 2013).

Nicol, I., Gaudy, C., Gouvernet, J., Richard, M.A. and Grob, J.J. (2007) 'Skin protection by sunscreens is improved by explicit labeling and providing free sunscreen', *Journal of Investigative Dermatology*, 127(1), pp. 41-8.

O'Riordan, D.L., Glanz, K., Gies, P. and Elliott, T. (2008a) 'A pilot study of the validity of self-reported ultraviolet radiation exposure and sun protection practices among lifeguards, parents and children', *Photochemistry & Photobiology*, 84(3), pp. 774-8.

O'Riordan, D.L., Lunde, K.B., Steffen, A.D. and Maddock, J.E. (2006) 'Validity of beachgoers' self-report of their sun habits', *Archives of dermatology*, 142(10), pp. 1304-11.

O'Riordan, D.L., Nehl, E., Gies, P., Bundy, L., Burgess, K., Davis, E. and Glanz, K. (2009) 'Validity of covering-up sun-protection habits: Association of observations and self-report', *Journal of the American Academy of Dermatology*, 60(5), pp. 739-744.

O'Riordan, D.L., Steffen, A.D., Lunde, K.B. and Gies, P. (2008b) 'A Day at the Beach While on Tropical Vacation: Sun Protection Practices in a High-Risk Setting for UV Radiation Exposure', *Arch Dermatol*, 144(11), pp. 1449-1455.

O' Sullivan, I., Orbell, S., Rakow, T. and Parker, R. (2004) 'Prospective Research in Health Service Settings: Health Psychology, Science and the 'Hawthorne' Effect', *Journal of Health Psychology*, 9(3), pp. 355-359.

Ofcom (2013) *Communications Market Report* (10th). Available at: [http://stakeholders.ofcom.org.uk/binaries/research/cmr/cmr13/2013\\_UK\\_CMV.pdf](http://stakeholders.ofcom.org.uk/binaries/research/cmr/cmr13/2013_UK_CMV.pdf) (Accessed: 11 November 2013).

Olson, A.L., Gaffney, C., Starr, P., Gibson, J.J., Cole, B.F. and Dietrich, A.J. (2007) 'SunSafe in the middle school years: a community-wide intervention to change early-adolescent sun protection', *Pediatrics*, 119(1), pp. e247-56.

Orbell, S. and Kyriakaki, M. (2008) 'Temporal framing and persuasion to adopt preventive health behavior: moderating effects of individual differences in consideration of future consequences on sunscreen use', *Health Psychology*, 27(6), p. 770.

Oyewole, A.O., Wilmot, M.-C., Fowler, M. and Birch-Machin, M.A. (2014) 'Comparing the effects of mitochondrial targeted and localized antioxidants with cellular antioxidants in human skin cells exposed to UVA and hydrogen peroxide', *The FASEB Journal*, 28(1), pp. 485-494.

Pagoto, S. and Bennett, G. (2013) 'How behavioral science can advance digital health', *Translational Behavioral Medicine*, 3(3), pp. 271-276.

Pagoto, S., McChargue, D. and Fuqua, R.W. (2003) 'Effects of a multicomponent intervention on motivation and sun protection behaviors among midwestern beachgoers', *Health Psychology*, 22(4), pp. 429-433.

Pagoto, S.L., McChargue, D.E., Schneider, K. and Werth Cook, J. (2004) 'Sun protection motivational stages and behavior: skin cancer risk profiles', *American Journal of Health Behavior*, 28(6), pp. 531-41.

Pagoto, S.L., Schneider, K.L., Oleski, J., Bodenlos, J.S. and Ma, Y. (2010) 'The Sunless Study: A Beach Randomized Trial of a Skin Cancer Prevention Intervention Promoting Sunless Tanning', *Arch Dermatol*, 146(9), pp. 979-984.

Potente, S., Coppa, K., Williams, A. and Engels, R. (2011) 'Legally brown: using ethnographic methods to understand sun protection attitudes and behaviours among young Australians 'I didn't mean to get burnt—it just happened!'", *Health Education Research*, 26(1), pp. 39-52.

Primack, B.A., Carroll, M.V., McNamara, M., Klem, M.L., King, B., Rich, M., Chan, C.W. and Nayak, S. (2012) 'Role of Video Games in Improving Health-Related Outcomes: A Systematic Review', *American journal of preventive medicine*, 42(6), pp. 630-638.

Prochaska, J.O., DiClemente, C.C., Velicer, W.F., Ginpil, S. and Norcross, J.C. (1985) 'Predicting change in smoking status for self-changers', *Addictive behaviors*, 10(4), pp. 395-406.

QSR International Pty Ltd (2010) *NVivo qualitative data analysis software* (Version 10) [Computer program].

Quinn, M. and Britain, G. (2001) *Cancer trends in England and Wales 1950-1999*. Stationery Office.

Review Manager (2011) (*RevMan*) (Version Version 5.1) [Computer program]. The Nordic Cochrane Centre, The Cochrane Collaboration.

*Review Manager (RevMan)* (2011) (Version Version 5.1) [Computer program]. The Nordic Cochrane Centre, The Cochrane Collaboration.

Richmond, R., Heather, N., Wodak, A., Kehoe, L. and Webster, I.A.N. (1995) 'Controlled evaluation of a general practice-based brief intervention for excessive drinking', *Addiction*, 90(1), pp. 119-132.

Rimer, B., Levy, M.H., Keintz, M.K., Fox, L., Engstrom, P.F. and MacElwee, N. (1987) 'Enhancing cancer pain control regimens through patient education', *Patient Education and Counseling*, 10(3), pp. 267-277.

Roberts, D.C. and Black, D. (2009) 'Comparison of interventions to reduce sun exposure', *Behavioral Medicine*, 35(2), pp. 67-76.

Robinson, J.K., Hillhouse, J. and Turrisi, R. (2010) 'Intentional tanning: More than one hammer needed to change behavior', *Archives of Dermatology*, 146(9), pp. 1029-1030.

Rodrigues, A., Sniehotta, F. and Araujo-Soares, V. (2013) 'Are Interventions to Promote Sun-Protective Behaviors in Recreational and Tourist Settings Effective? A Systematic Review with Meta-analysis and Moderator Analysis', *Annals of Behavioral Medicine*, 45(2), pp. 224-238.

Rogers, R.W. (1975) 'A Protection Motivation Theory of Fear Appeals and Attitude Change<sup>1</sup>', *The Journal of Psychology: Interdisciplinary and Applied*, 91(1), pp. 93 - 114.

Rosenstock, I.M., Strecher, V.J. and Becker, M.H. (1988) 'Social learning theory and the health belief model', *Health Education & Behavior*, 15(2), pp. 175-183.

Sandberg, T. and Conner, M. (2009) 'A mere measurement effect for anticipated regret: impacts on cervical screening attendance', *British Journal of Social Psychology*, 48(Pt 2), pp. 221-36.

Sandberg, T. and Conner, M. (2011) 'Using self-generated validity to promote exercise behaviour', *British Journal of Social Psychology*, 50(4), pp. 769-783.

Saraiya, M., Glanz, K., Briss, P.A., Nichols, P., White, C., Das, D., Smith, S.J., Tannor, B., Hutchinson, A.B., Wilson, K.M., Gandhi, N., Lee, N.C., Rimer, B., Coates, R.C., Kerner, J.F., Hiatt, R.A., Buffler, P. and Rochester, P. (2004) 'Interventions to prevent skin cancer by reducing exposure to ultraviolet radiation: a systematic review', *American Journal of Preventive Medicine*, 27(5), pp. 422-66.

Saravanan, D. (2007) 'UV protection textile materials', *AUTEX Research Journal*, 7(1), pp. 53-62.

Saunders, R.P., Evans, M.H. and Joshi, P. (2005) 'Developing a Process-Evaluation Plan for Assessing Health Promotion Program Implementation: A How-To Guide', *Health Promotion Practice*, 6(2), pp. 134-147.

Schulz, K.F., Altman, D.G. and Moher, D. (2010) 'CONSORT 2010 Statement: Updated Guidelines for Reporting Parallel Group Randomized Trials', *Annals of internal medicine*, 152(11), pp. 726-732.

Schulz, K.F., Altman, D.G. and Moher, D. (2011) 'CONSORT 2010 Statement: Updated Guidelines for Reporting Parallel Group Randomized Trials', *Annals of Internal Medicine*, 154(4), pp. 291-292.

Segan, C.J., Borland, R. and Hill, D.J. (1999) 'Development and evaluation of a brochure on sun protection and sun exposure for tourists', *Health Education Journal*, 58(2), pp. 177-191.

Shack, L., Jordan, C., Thomson, C.S., Mak, V. and Møller, H. (2008) 'Variation in incidence of breast, lung and cervical cancer and malignant melanoma of skin by socioeconomic group in England', *BMC cancer*, 8(1), p. 271.

Sherman, S.J. (1980) 'On the self-erasing nature of errors of prediction', *Journal of Personality and Social Psychology*, 39(2), p. 211.

Silva, I.S., Higgins, C.D., Abramsky, T., Swanwick, M.A., Frazer, J., Whitaker, L.M., Blanshard, M.E., Bradshaw, J., Apps, J.M., Bishop, D.T., Newton-Bishop, J.A. and Swerdlow, A.J. (2009) 'Overseas sun exposure, nevus counts, and premature skin aging in young English women: a population-based survey', *The Journal of investigative dermatology*, 129 (1), pp. 50-59.

Sniehotta, F.F., Scholz, U. and Schwarzer, R. (2006) 'Action plans and coping plans for physical exercise: A longitudinal intervention study in cardiac rehabilitation', *British Journal of Health Psychology*, 11(1), pp. 23-37.

Sniehotta, F.F., Schwarzer, R., Scholz, U. and Schüz, B. (2005) 'Action planning and coping planning for long-term lifestyle change: theory and assessment', *European Journal of Social Psychology*, 35(4), pp. 565-576.

Spangenberg, E. (1997) 'Increasing Health Club Attendance Through Self-Prophecy', *Marketing Letters*, 8(1), pp. 23-31.

Spangenberg, E., Sprott, D.E., Grohmann, B. and Smith, R.J. (2003) 'Mass-Communicated Prediction Requests: Practical Application and a Cognitive Dissonance Explanation for Self-Prophecy', *Journal of Marketing*, 67(3), pp. 47-62.

Spence, J.C., Burgess, J., Rodgers, W. and Murray, T. (2009) 'Effect of pretesting on intentions and behaviour: a pedometer and walking intervention', *Psychology & health*, 24(7), pp. 777-89.

Sprott, D.E., Smith, R.J., Spangenberg, E.R. and Freson, T.S. (2004) 'Specificity of Prediction Requests: Evidence for the Differential Effects of Self-Prophecy on Commitment to a Health Assessment', *Journal of Applied Social Psychology*, 34(6), pp. 1176-1190.

Sprott, D.E., Spangenberg, E.R. and Fisher, R. (2003) 'The importance of normative beliefs to the self-prophecy effect', *Journal of Applied Psychology*, 88(3), p. 423.

Sprott, D.E., Spangenberg, E.R., Knuff, D.C. and Devezer, B. (2006) 'Self-prediction and patient health: Influencing health-related behaviors through self-prophecy', *Medical science monitor*, 12(5).

Stapleton, J., Turrisi, R., Hillhouse, J., Robinson, J. and Abar, B. (2010) 'A comparison of the efficacy of an appearance-focused skin cancer intervention within indoor tanner subgroups identified by latent profile analysis', *Journal of Behavioral Medicine*, 33(3), pp. 181-190.

Steckler, A.E. and Linnan, L.E. (2002) *Process evaluation for public health interventions and research*. Jossey-Bass.

Stone, A.A. and Broderick, J.E. (2007) 'Real-Time Data Collection for Pain: Appraisal and Current Status', *Pain Medicine*, 8(s3), pp. S85-S93.

Stone, A.A., Shiffman, S., Schwartz, J.E., Broderick, J.E. and Hufford, M.R. (2003) 'Patient compliance with paper and electronic diaries', *Controlled clinical trials*, 24(2), pp. 182-199.

The British Association of Dermatologists (2013) *Sunscreen factsheet*. Available at: <http://www.bad.org.uk/desktopDefault.aspx?TabId=734>.

The British Skin Foundation (2011) *Responde to NICE about Skin cancer Guidance* [Letter]. Available at: <http://www.bad.org.uk/site/734/default.aspx> (Accessed: 1 April 2011).

The Chartered Institute of Environmental Health (2005) *Saving our Skins Toolkit. Raising Awareness of the Risk of Skin Cancer*. Health, T.C.I.o.E.

Thomson, C.S., Woolnough, S., Wickenden, M., Hiom, S. and Twelves, C., J. (2010) 'Sunbed use in children aged 11-17 in England: face to face quota sampling surveys in the National Prevalence Study and Six Cities Study', *BMJ*, 340.

Todd, J. and Mullan, B. (2011) 'Using the theory of planned behaviour and prototype willingness model to target binge drinking in female undergraduate university students', *Addictive behaviors*, 36(10), pp. 980-986.

Tulah, A.S. and Birch-Machin, M.A. (2013) 'Stressed out mitochondria: The role of mitochondria in ageing and cancer focussing on strategies and opportunities in human skin', *Mitochondrion*, 13(5), pp. 444-453.

Turner-McGrievy, G. and Tate, D. (2013) 'Weight loss social support in 140 characters or less: use of an online social network in a remotely delivered weight loss intervention', *Translational Behavioral Medicine*, 3(3), pp. 287-294.

Turrisi, R., Hillhouse, J. and Gebert, C. (1998) 'Examination of cognitive variables relevant to sunbathing', *Journal of Behavioral Medicine*, 21(3), pp. 299-313.

U.S. Cancer Statistics Working Group (2010) 'United States Cancer Statistics: 1999–2007 Incidence and Mortality Web-based Report.'. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute. Available at: <http://apps.nccd.cdc.gov/uscs/>.

U.S. Cancer Statistics Working Group (2013) 'United States Cancer Statistics: 1999–2010 Incidence and Mortality Web-based Report.'. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute. Available at: <http://apps.nccd.cdc.gov/uscs/>.

van Dongen, A., Abraham, C., Ruiter, R.C. and Veldhuizen, I.T. (2012) 'Does Questionnaire Distribution Promote Blood Donation? An Investigation of Question–Behavior Effects', *Annals of Behavioral Medicine*, pp. 1-10.

van Sluijs, E.M.F., van Poppel, M.N.M., Twisk, J.W.R. and van Mechelen, W. (2006) 'Physical activity measurements affected participants' behavior in a randomized controlled trial', *Journal of clinical epidemiology*, 59(4), pp. 404-11.

van Valkengoed, I.G.M., Morr , S.A., Meijer, C.J.L.M., van den Brule, A.J.C. and Boeke, A.J.P. (2002) 'Do questions on sexual behaviour and the method of sample collection affect participation in a screening programme for asymptomatic Chlamydia trachomatis infections in primary care?', *International journal of STD & AIDS*, 13(1), pp. 36-38.

Waddington, D. (2004) 'Participant observation', *Essential guide to qualitative methods in organizational research*, pp. 154-164.

Walkosz, B., Voeks, J., Andersen, P., Scott, M., Buller, D., Cutter, G. and Dignan, M. (2007) 'Randomized trial on sun safety education at ski and snowboard schools in western North America', *Pediatric dermatology*, (3), pp. 222-9 [Online]. Available at: <http://www.mrw.interscience.wiley.com/cochrane/clcentral/articles/080/CN-00705080/frame.html>.

Walkosz, B.J., Buller, D.B., Andersen, P.A., Scott, M.D., Dignan, M.B., Cutter, G.R. and Maloy, J.A. (2008) 'Increasing sun protection in winter outdoor recreation a theory-based health communication program', *American Journal of Preventive Medicine*, 34(6), pp. 502-9.

Wallingford, S.C., Alston, R.D., Birch, J.M. and Green, A.C. (2013) 'Regional melanoma incidence in England, 1996–2006: reversal of north–south latitude trends among the young female population', *British Journal of Dermatology*, 169(4), pp. 880-888.

Walsh, A., Harris, S., Bowtell, N. and Verne, J. (2009) *Sunbed outlets and area deprivation in the UK*. Available at: [www.swpho.nhs.uk/skincancerhub/resource/item.aspx?RID=48408](http://www.swpho.nhs.uk/skincancerhub/resource/item.aspx?RID=48408) (Accessed: May 2014).

Walters, S.T., Vader, A.M., Harris, T.R. and Jouriles, E.N. (2009) 'Reactivity to alcohol assessment measures: an experimental test', *Addiction*, 104(8), pp. 1305-10.



Webb, T.L. and Sheeran, P. (2007) 'How do implementation intentions promote goal attainment? A test of component processes', *Journal of Experimental Social Psychology*, 43(2), pp. 295-302.

Weinstock, M.A. (1992) 'Assessment of sun sensitivity by questionnaire: validity of items and formulation of a prediction rule', *Journal of clinical epidemiology*, 45(5), pp. 547-552.

Weinstock, M.A., Rossi, J.S., Redding, C.A. and Maddock, J.E. (2002) 'Randomized controlled community trial of the efficacy of a multicomponent stage-matched intervention to increase sun protection among beachgoers', *Preventive Medicine*, 35(6), pp. 584-592.

Welsh Cancer Intelligence and Surveillance Unit (2011) ' Cancer in Wales, 1995-2009: A Comprehensive Report'. May 2014. Cardiff: WCISU.

WIDER (2007) *WIDER Recommendations to Improve Reporting of the Content of Behaviour*

*Change Interventions*. Available at: <http://interventiondesign.co.uk/wp-content/uploads/2009/02/wider-recommendations.pdf> (Accessed: 18 October 2009).

Williams, A.L., Grogan, S., Buckley, E. and Clark-Carter, D. (2012) 'A qualitative study examining women's experiences of an appearance-focussed facial-ageing sun protection intervention', *Body Image*, 9(3), pp. 417-420.

Williams, A.L., Grogan, S., Clark-Carter, D. and Buckley, E. (2013) 'Appearance-based interventions to reduce ultraviolet exposure and/or increase sun protection intentions and behaviours: A systematic review and meta-analyses', *British Journal of Health Psychology*, 18(1), pp. 182-217.

Winett, R.A., Cleaveland, B.L., Tate, D.F., Lombard, D.N., Lombard, T.N., Russ, C.R. and Galper, D. (1997) 'The Effects of the Safe-sun Program on Patrons' and Lifeguards' Skin Cancer Risk-reduction Behaviors at Swimming Pools', *Journal of Health Psychology*, 2(1), pp. 85-95.

World Health Organisation (2002) 'Sun Protection: An Essential Element of Health-Promoting Schools', *WHO INFORMATION SERIES ON SCHOOL HEALTH*, 7,

World Health Organisation [Online]. Available at: <http://www.who.int/hpr/gshi/>  
(Accessed: 10 November 2009).

World Health Organisation (2011a) *INTERSUN Programme* [Web page].  
Available at: <http://www.who.int/uv/intersunprogramme/en/> (Accessed: 29 April 2011).

World Health Organisation (2011b) *Sun Protection* [web page]. Available at:  
[http://www.who.int/uv/sun\\_protection/en/](http://www.who.int/uv/sun_protection/en/) (Accessed: 29 April 2011).

Yardley, L., Miller, S., Schlotz, W. and Little, P. (2011) 'Evaluation of a Web-based intervention to promote hand hygiene: exploratory randomized controlled trial', *Journal of Medical Internet Research*, 13(4), p. e107.