Melanoma in situ: Exploring Perceived Risk and Management Preferences

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This is to certify that the content of this thesis is my own work. This thesis has not been submitted for any other degree or purpose.

I certify that the intellectual content of this thesis is the product of my own work, and that all assistance received in preparing this thesis and all sources have been acknowledged.

Zhuohan Wu

21/12/2025

Abstract

Background:

Melanoma incidence and mortality trajectories in Australia and other countries show a classic epidemiologic signature of overdiagnosis. This appears to be largely driven by increased diagnosis of melanoma in situ (MIS), which in Australia is now diagnosed over twice as frequently as invasive melanoma.

Multiple evidence lines indicate that melanoma in situ is a risk factor for invasive melanoma rather than an obligate precursor. The existing terminology and the overdiagnosis of MIS could lead to patients' psychological harm, with many people not distinguishing between in situ and invasive melanoma. These harms can manifest as anxiety about being diagnosed, fear of cancer recurrence, and possible healthcare overuse.

Changing the diagnostic label for MIS has been proposed as one strategy to mitigate these harms. A new label without the word "melanoma" might help patients recognise the lower risk of this type of lesion compared to invasive melanomas and reduce potential psychological harms. It may also pave the way for the de-escalation of treatment and surveillance.

Aim: My MPhil aims to explore how the MIS diagnosis label may affect a potential patient's perceived risk of adverse outcomes, and how this may shape management decisions.

Methods:

My study uses data from a large online randomised experiment involving Australian adults without a history of melanoma. Participants were randomly assigned to receive one of three hypothetical diagnostic labels for the same low-risk melanocytic skin pathology: "melanoma in situ," "low-risk melanocytic neoplasm," or "low-risk melanocytic neoplasm, in situ."

I first aimed to assess how participants' perceived risk differed across the alternative diagnostic labels compared with the control "melanoma in situ". Participants completed a series of perceived risk measures and perceived risk of dying from melanoma. We also examined whether differences existed between participants' perceived risk and calculated estimates of invasive melanoma and melanoma-specific mortality, derived using a published risk model and Australian mortality statistics.

I then undertook an analysis of free-text survey data to explore the emotional reasoning behind participants' numerical ratings and choices. Participants provided optional free-text explanations for their perceived risk of dying from melanoma in the hypothetical scenario, as well as for their preferences for further surgery after a completely excised lesion with narrow margins (wide local excision or no further surgery), and choice of follow-up (routinely scheduled clinic visits or patient-led self-surveillance with clinical review as needed). These responses were analysed using qualitative content analysis to better understand the factors shaping participants' judgments.

Results:

Chapter 1 introduces the background to alternative labels for melanoma in situ and outlines published research on skin cancer risk perception. It also describes key risk perception constructs—including absolute and comparative risk, experiential risk, and vulnerability—to comprehensively capture the different dimensions of perceived risk.

Chapter 2 presents the study protocol of the large randomised experiment, including the co-primary outcomes of choice between no further surgery or further surgery to ensure clear histological margins greater than 0.5mm, and choice between patient-initiated clinical follow-up when needed (patient-led surveillance) and regular, routinely scheduled clinical follow-up (clinician-led surveillance).

Chapter 3 explores the perceived risk of invasive melanoma and of dying from melanoma across randomised label groups. Alternative labels reduced perceived risk across all four risk constructs (absolute and comparative risk, experiential risk, and vulnerability). While all participants substantially overestimated their risk of future invasive melanoma and melanoma-specific mortality compared with calculated risk estimates, overestimation was smaller in alternative label groups.

Chapter 4 presents the qualitative content analysis of the free-text responses. Elevated perceived risk was driven by intuitive associations with the word “melanoma,” limited understanding of disease progression, and strong emotional responses. While alternative labels attenuated some of these reactions, they did not fully correct misconceptions about prognosis. Participants’ existing habits of attending routinely scheduled skin check clinics and reliance on medical expertise played a more important role in shaping their follow-up decisions than diagnostic labels.

Conclusions:

Diagnostic terminology is important in shaping perceived risk, but alternative labels alone may not realign perceptions with actual clinical risk. Reducing the psychological harms of MIS overdiagnosis may require clearer communication about prognosis and help realign public perceptions with the actual risk profile.

List of included publications

Chapter	Status	Details
Chapter 1	Thesis	Introduction
Chapter 2	Published	*Impact of alternative diagnostic labels for melanoma in situ on management choices and psychological outcomes: protocol for an online randomised study.* Published in *BMJ Open.*
Chapter 3	Submitted	*Mind the Gap: Impact of new labels on public perceptions and calculated risk of adverse outcomes after a melanoma in situ diagnosis. A secondary analysis of an online randomised experiment.* Submitted to *Medical Decision Making*.
Chapter 4	Submitted	*Exploring how diagnostic labels for low-risk melanocytic pathology shape perceived risk and management preferences: A content analysis of free-text responses in a randomised online study.* Submitted to *Patient Education and Counseling.*
Chapter 5	Thesis	Discussion

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I would also like to thank my partner and my family for their love and continued support throughout this journey. I would not be here today without them.

Authorship attribution statement

I, Zhuohan Wu (ZW), carried out the research presented within this thesis during my Mphil candidature from 2024 to 2025 at the Sydney School of Public Health, The University of Sydney.

I conducted this research under the guidance of my supervisors Katy JL Bell (KB), Brooke Nickel (BN), and Farzaneh Boroumand (FB). Other authors included David Elder (DE), Peter M Ferguson (PMF), Richard A Scolyer (RAS), Blake O'Brien (BO), Raymond Barnhill (RB), Adewole S Adamson (ASA), Alexander C J van Akkooi (ACJvA), Jon Emery (JE), Lisa Parker (LP), Donald Low (DL), Cynthia Low (CL), Elspeth Davies (ED), Sherrie Liu (SL), Stacey Lewis (SL), Bella Spongberg-Ross (BSR).

I am the first author on all three papers in this thesis, reflecting my substantial contribution to all aspects of these studies, including but not limited to study design, obtaining ethics approval, obtaining and managing the data, analysis and interpretation of data, and writing and revising the manuscripts.

Chapter 1, ZW wrote the chapter, with critical feedback from the lead supervisor KB.
Chapter 2 of this thesis has been published as “Impact of alternative diagnostic labels for melanoma in situ on management choices and psychological outcomes: protocol for an online randomised study”. ZW co-led drafting of the manuscript, led drafting of the study questionnaire and application to the Human Research Ethics Committee, and assisted with the targeted literature review (full-text screening and data extraction). BN and KB conceptualised the research and provided methodological expertise. KB, who is the guarantor, led the targeted literature review and the Clinician and Consumer Investigator survey to decide the choice of alternative labels and co-led the drafting of the manuscript. FB

calculated the sample size. BN, FB, DE, PMF, RAS, BO'B, RB, ACJvA, ASA, JE, LP, DL, CL, ED, SLi, SLe, BS-R, and KB revised the manuscript. All authors read, contributed to and approved the final manuscript.

Chapter 3 has been submitted but has not yet published. Chapter 3 of this thesis has been submitted as “Mind the Gap: Impact of new labels on public perceptions and calculated risk of adverse outcomes after a melanoma in-situ diagnosis. A secondary analysis of an online randomised experiment”. ZW conducted the study and drafted the manuscript. KB and BN provided methodological guidance and administrative support. FB provided statistical support. ASA, LP, and ED contributed critical clinical and conceptual feedback during manuscript development.

Chapter 4 has been submitted but has not yet published. Chapter 4 of this thesis has been submitted as “Exploring how diagnostic labels for low-risk melanocytic pathology shape perceived risk and management preferences, A content analysis of free-text responses in a randomised online study”. ZW conducted the study and drafted the manuscript. KB and BN provided methodological guidance and administrative support. Farzaneh Boroumand provided statistical support. ASA, LP, and ED contributed critical clinical and conceptual feedback during manuscript development.

Chapter 5, ZW wrote the chapter, with critical feedback from the lead supervisor KB.

In addition to the authorship attribution statements above, in cases where I am not the corresponding author of a published item, permission to include the published material has been granted by the corresponding author.

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22/12/2025

As supervisor for the candidature upon which this thesis is based, I can confirm that the authorship attribution statements above are correct.

Professor Katy Bell

24 December 2025

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Generative AI Statement

During the preparation of the paper, the author used the University of Sydney's protected version of Microsoft Copilot for the purposes of text enhancement. The use of this generative AI tool includes sentence structure and spelling. The author confirms that where text was modified by generative AI, the content was reviewed for possible errors, inaccuracies, and bias. The author takes full responsibility for the submitted thesis and ensures the work is their own and has used generative AI within the parameters of use.

Ethics approval

The study is registered with the Australian New Zealand Clinical Trials Registry (ID 386943), and approval was received from The University of Sydney Human Research Ethics Committee (2024/HE000019) on 25/06/2025.

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Chapter 1. Introduction:

Rationale for considering a new diagnostic label for melanoma in situ

Melanoma incidence and mortality trajectories in Australia and other countries show a classic epidemiologic signature of overdiagnosis [1]: steeply increasing incidence curves coupled with largely flat mortality trends [1–3]. While aging populations may lead to a small real increase in melanoma incidence[4], much of the increase is likely due to overdiagnosis. The increased diagnosis of melanoma in situ (MIS)[6,7], has resulted in it being detected more than twice as often as invasive melanoma in Australia[8], with an estimated 71–76% of MIS cases overdiagnosed in 2021. The associated costs for short-term treatment for the approximately 20,000 MIS overdiagnoses in that year were estimated at $17.7–$18.6 million AUD[5].

Multiple evidence lines now indicate that MIS is a risk factor for invasive melanoma rather than an obligate precursor [8–11]. Overdiagnosis is partly driven by lowering the diagnostic threshold over the years, such that the same lesion that was called benign in years gone by would now be labelled MIS. Concerns about litigation may also be driving a tendency to interpret melanocytic lesions as a more severe diagnosis [12]. Harms from melanoma overdiagnosis include physical and psychological adverse effects, as well as the use of limited health resource costs [13]. Physical harms can result from overtreatment, repeated skin biopsies, scarring, pain, infection, and/or functional impairment. Psychological harms include anxiety and fear [14], with many people not distinguishing between melanoma in situ and invasive melanoma [15]. These psychological harms can manifest as anxiety about being outdoors, fear of cancer recurrence, or guilt for past UV exposure, causing melanoma [16]. Health resource costs include costs for management of the current lesion and of future long-term clinical surveillance, with substantial out-of-pocket costs to the patient, and opportunity costs caused by the use of clinician and patient time. There is also a possible denial of life insurance as the person is now a cancer survivor [3].

One potential solution is to consider a new label for MIS without the word "melanoma" [17]. This might help patients recognize the lower risk of this type of lesion compared to invasive melanomas and help to reduce potential psychological harms. It may also pave the way for the de-escalation of treatment and surveillance[14,16,18]. This study seeks to expand upon evidence from other cancer contexts, including thyroid, breast, and prostate lesions [19–21], which support the proposals to introduce new diagnostic labels and recalibrate diagnostic thresholds to alleviate the burden of overdiagnosis [17]. In the case of MIS, existing evidence supports the consideration of such an approach [11].

Literature review of perceived risk measures

Risk perception is considered a key influence on patients' health behaviour [22,23]. Many health behaviour models suggest that the perceived probability of an adverse event motivates individuals to engage in behaviours they believe will decrease their risk, including health protective behaviours[24–27,] medical interventions, including surgery[28], and follow-up clinical review[29]. Knowing how people perceive their risk helps to understand their decision-making processes. At present, no studies have examined perceived risk in relation to alternative diagnostic labels for MIS. To inform the measurement of risk perception in our study (Chapters 2-4), I undertook a targeted literature review to find publications related to the measurement of cancer risk perception instruments.

Literature search methods

Using eight "target" articles in breast and prostate cancer research settings known to my supervisors (see Appendix 1), I used the 'SpiderCite' tool from The Evidence Review Accelerator (TERA)[30] to conduct forward and backward citation searches to find relevant articles on risk perception of melanoma and skin cancer. Of 1,105 records retrieved by the search (7th July 2023), 472 full texts were reviewed, and 10 articles related to melanoma or

skin cancer were included. Figure 1 presents the PRISMA flow chart for the targeted literature search.

Literature search findings

Table 1 summarises the 10 articles published between 2011 and 2020. Researchers have increasingly moved beyond unidimensional measures, acknowledging the distinction between cognitive assessments and emotional responses. Several studies explicitly differentiate between cognitive risk (logical probability) and affective risk (cancer worry). "Feeling of vulnerability" has emerged as a distinct experiential variable from affective risk, often measured alongside traditional likelihood estimates utilising multi-item scales to capture these distinct constructs. Furthermore, the distinction between absolute and comparative risk within the cognitive risk is prominent. While absolute measures assess personal likelihood, comparative measures anchor the respondent's risk against a peer group (e.g., "compared to the average person"). This approach was utilised across diverse populations, including the general German population (Diehl, 2019), US general population samples (Kiviniemi, 2013; Buster, 2011), and high-risk melanoma families (Taber, 2020).

After extracting information on all skin cancer risk perception measurement instruments that were used in the 10 articles, I was able to group these into four categories: Absolute risk, Comparative risk (both cognitive measures), Cancer worry (affective measures), and experiential risk (vulnerability), described in detail below.

Cognitive risk perception

Cognitive risk perception, also known as deliberative risk perception, is typically measured using absolute and comparative risk perceptions.

Absolute risk perception is more widely used and typically asks the participant to evaluate their risk in numeric responses, such as percentages or categorical responses. However,

patient and public participants may have insufficient numeracy to accurately answer absolute risk perception questions.[31–33] Comparative risk perception questions, which assess one's perceived risk of developing an illness relative to others, may be easier to understand.[34] They show stronger correlations to actual risk than absolute risk estimates[35,36] and have been found to have a greater influence on behaviour[37,38].

Affective risk perception

It is also increasingly recognised that people may often think about health risks in an affective way rather than deliberately via cognitive risk perception[39]. Affective risk perception typically involves asking participants about their emotional reaction regarding an illness (cancer worry), and their intuitive sense of risk (experiential) [40]. This latter aspect seeks to capture the experiential dimension of risk perception, also referred to as "feeling-of-risk", often measured by asking participants about their feelings about vulnerability. [41].

Experiential risk perception is not commonly used in theories of health behaviour; however, studies have found that this measure was closely related to healthcare intentions and attitudes [42]. Some argue that intuition measures are distinct from both cognitive assessments and emotional responses[1]. Not only does it capture initial or developing emotional responses, but it also includes past experiences intuitively recalled from memory [40], supporting its use as a separate risk perception category to that of emotional risk perception.

Summary

Recent studies often use the tripartite risk perception (TRIRISK) model to analyse cognitive, affective (emotional reaction), and experiential (feeling of risk) perceptions in a triangular manner. [43]. Each is empirically distinguishable and explains unique variance in behavioural intentions[44]. Different measures may capture different domains of risk perception; relying on a single measure could lead to bias and affect correlations with health behaviour and intention

[45]. Since these measures are predictive in diverse ways, it is recommended to incorporate both absolute and comparative measures, along with affective and experiential ones[46].

Perceived risk measures selected for the study

For our online randomised study, we chose a 7-point scale for all verbal response questions and a numeric scale from 0 to 100% to assess absolute risk perception. Studies indicate that although differences among likelihood scales are minor, a seven-point, verbally labelled scale performs better. [47]. Each aspect of risk perception was assessed using a single-item measure. This approach was chosen to minimise respondent burden and survey length, while recognising evidence that single-item measures can provide efficient and acceptable assessment of well-defined constructs.[41].

The exact wording of all questions is provided below. In Chapter 3, we compare perceived risk outcomes across the different diagnostic labels. An additional question assessed participants' perceived risk of dying from melanoma following the hypothetical diagnosis, which enabled direct comparison between perceived and calculated risk. The qualitative questions were an extension of the main study survey and were designed to elicit participants' interpretations of the hypothetical diagnosis and its implications. In Chapter 4, content analysis of free-text responses explores whether diagnostic terminology influences participants' interpretations of their perceived risk, as well as their preferences for surgery and management.

Cognitive measure (absolute risk and comparative risk):

Given the diagnosis of (given label), on a scale of 0–100%, what do you think your chances are of developing an invasive melanoma sometime in your life?

Given the diagnosis of (given label), what do you think your chances are of developing an invasive melanoma, compared to others of your age, gender, and skin colour?

Answer from Much lower chance (0) to Much higher chance (6). (3) is the midpoint of the scale, indicating "being about as likely as others of the same age, gender, and skin colour to develop melanoma."

Given the diagnosis of (given label), on a scale of 0 –100%, what do you think your chances are of dying from melanoma?

Affective measure (cancer worry and experiential risk)

Given the diagnosis of (given label), how anxious do you feel?
Answer from Not at all anxious (0) to Extremely anxious (6). (3) is the midpoint of the scale, indicating moderately anxious.

Given the diagnosis of (given label), how vulnerable do you feel to developing invasive melanoma sometime in your life?
Answer from Not at all vulnerable (0) to Extremely vulnerable (6). (3) is the midpoint of the scale, indicating moderate vulnerability.

Qualitative study questions

Please explain your reasoning behind the percentage (Perceived risk of dying) you provided. [This question is optional]

Please tell us how you decided on that surgery management option. What were the important factors that helped you decide? [This question is optional]
Please tell us how you decided on that follow-up management option. What were the important factors that helped you decide? [This question is optional]

Thesis aim, objectives, and structure

The overall aim of this thesis is to investigate whether the use of alternative diagnostic labels "low-risk melanocytic neoplasm" and "low-risk melanocytic neoplasm, in situ"—for melanoma in situ influences patients' perceptions of risk and the reasoning underlying their management preferences. This is done through an online randomised study using hypothetical scenarios (protocol described in Chapter 2).

This MPhil addresses two specific objectives. First, it quantitatively examines how different diagnostic labels affect perceived risk of an invasive melanoma and of dying from melanoma (Chapter 3). Second, it qualitatively analyses participants' free-text explanations to explore how diagnostic terminology shapes their interpretations of disease severity, risk, and management preferences (Chapter 4). This work aims to contribute to the broader literature on risk communication and overdiagnosis by highlighting the potential role of diagnostic terminology in shaping risk perception and healthcare decisions for melanoma in situ.

Chapter 2 outlines the protocol for this study. The protocol specifies eligibility criteria and demographic quotas to ensure relevance to the Australian context and describes the development of alternative labels through co-design with clinicians and consumer investigators. Randomisation procedures, outcome measures, sample size, and analytic methods were pre-specified. Participants received identical clinical information, differing only in the diagnostic label. Primary outcomes were management preferences (further surgical and type of follow-up), with secondary outcomes assessing perceived risk and free-text responses. While the parent study examined the effect of diagnostic terminology on the co-primary outcomes on management decision preferences, this thesis focuses on the secondary outcomes using psychological measures and free text explanations. The findings from the parent study are presented in Appendix B.

Chapter 3 aims to quantitatively assess whether alternative diagnostic labels reduce overestimation of risk following a melanoma in situ diagnosis, with a focus on the relationship between calculated melanoma risk and perceived risk across diagnostic labels. Perceived risk is assessed using numeric and verbal measures across absolute, comparative, affective, and experiential dimensions.

Chapter 4 aims to qualitatively explore how diagnostic terminology shapes participants' interpretations of perceived risk and management decisions. Content analysis of free-text responses is used to explore how diagnostic labels shape participants' interpretations, emotions, and beliefs. These responses are systematically coded to identify common themes, allowing examination of how diagnostic labels influenced not only numerical risk judgments but also underlying interpretations, emotions, and beliefs.

Together, these chapters integrate quantitative and qualitative evidence to provide a nuanced assessment of how diagnostic language shapes perceived risk and the reasoning underlying treatment and clinical follow-up preferences, highlighting implications for risk communication and the management of overdiagnosis in melanoma in situ.

Figure 1. Flow diagram of the literature search

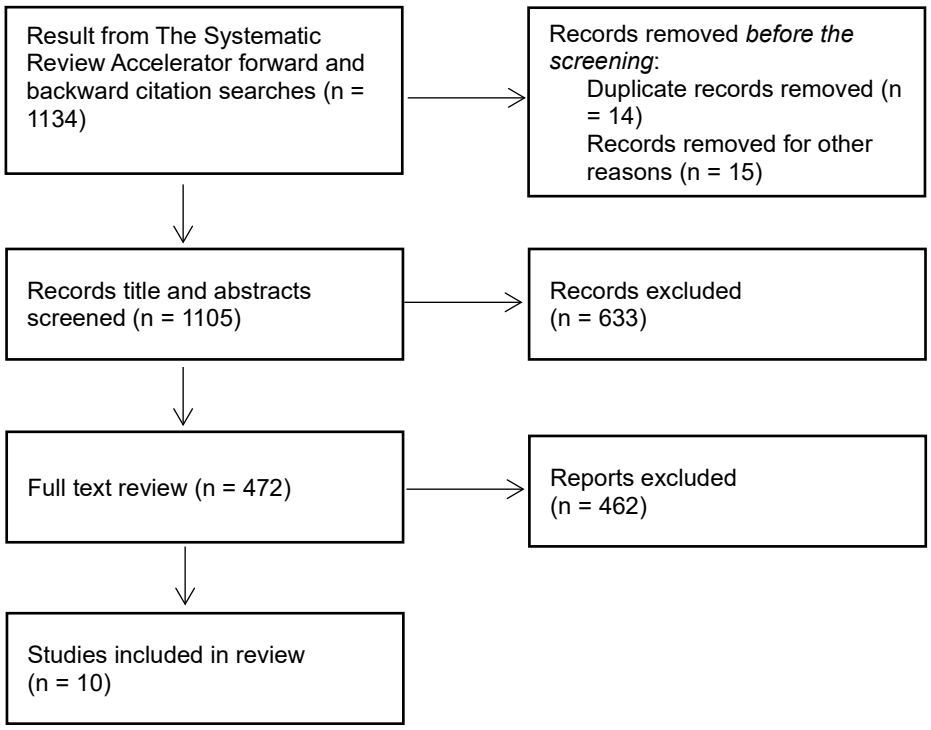

Table 1. Measurement of Risk Perception

Author, Date	Demographic	Measures	Type of Scale (Response Anchors)	Validity & Reliability
Diehl (2019)	3,000 individuals living in Germany and between 14 and 45 years of age	Comparative Measure	5-point verbal response (far below average to far above average)	
Nahar (2013)	Lit reviews of skin cancer risk perception papers (from 1990 to 2013), reviewed 20 papers.	Absolute and comparative measures.	Multiple scales	Concluded that risk perception measurements remain uncertain
Janssen (2012)	2 different study groups, (n1 = 491 and n2 = 277) of Dutch adults aged (31 and 36), 48% and 35% had a high level of education	Absolute (categorical) and Experiential measure. Cognitive (both 3 items) and Affective (3 items and 6 items).	Multiple items were assessed, and the mean was calculated. 5-point verbal respond (1=very low; 5=very high), (1=completely agree; 5=completely disagree)	Cognitive (α = 0.82 and α = 0.77), Affective (α = 0.91 and α = 0.84)

Kiviniemi (2013)	Data from the US National Cancer Institute's 2005 Health Information National Trends Survey (HINTS), (n=1476)	Absolute (categorical), Comparative and Worry measure	5-point verbal respond (1=very low; 5=very high).3-point verbal scale. 4-point verbal scale (1=rarely; 4=all the time)	
Janssen (2015)	2 different study groups in the Netherlands (n1=112 and n2=447), 113 participants were university students or employees, and 447 people from the general population	Absolute (categorical) and Experiential measure. Affective (6 items and 3 items) and Cognitive (4 items and 3 items).	Multiple items were assessed, and the mean was calculated. Rated on a 7-point scale	Previously used in other studies
Dillard (2017)	Women college students (n=115), Average age (M=18.8), mostly white (95%) and non-Hispanic (96%)	Absolute (numeric and categorical), Comparative and Experiential measure	Numeric scale (0 to 100%) and 11-point verbal scale (0=no chance; 10=certain to happen), 7-point scale (1=much lower; 7=much higher), 11-point scale (0=not at all; 10=extremely)	Been used in previous research
Tong (2019)	Participants (n=273) were recruited from Amazon's Mechanical Turk (Mturk) pool. Native English speakers, at least 18 years old and located in the US	Absolute measure and cancer worry	Did not specify	Pretested and previously used in other studies
Taber 2020	Participants (n=144) were unaffected members of melanoma-prone families	Experiential measure, Absolute, Comparative, cancer worry (3 items)	5-point scale (1=strongly disagree; 5=strongly agree), Numeric scale (0 to 100%) and 5-point scale (0=very unlikely; 5=very likely), 7-point scale (1=much below average; 7=much	Previously used in other studies (cognitive and experiential)

			above average), three 5-point scale (0=not at all; 7=very)	
Dillard (2015)	Women college students (n=138), average age 18.4, mostly white and non-Hispanic	Absolute (numeric and categorical), Comparative, Experiential measure, Cancer worry	Numeric scale (0 to 100%) and 11-point verbal scale (0=no chance; 10=certain to happen), 7-point scale (1=much lower; 7=much higher), 11-point scale (0=not at all; 10=extremely), five-point scale (From not at all to all the time)	Previously used in other studies (except worry) a=.36 and a=.81 (without absolute numeric scale)
Buster (2011)	HINTS survey of 1246 US adults, 77.5% were white, 12.9% Hispanic, and 9.6% black; 64.4% were female. Whites and blacks had higher education levels than Hispanics, with whites also having higher incomes.	Absolute (categorical), Comparative, Cancer worry	Multiple verbal scales and dichotomous scales (agree/disagree)	

Appendix 1. Articles used for forward and backward citation searches

Brown, R., Sillence, E., & Pepper, G. (2023). Perceptions of control over different causes of death and the accuracy of risk estimations. Journal of Public Health, 32(7), 1271–1284. https://doi.org/10.1007/s10389-023-01910-8

Dillard, A. J., Couper, M. P., & Zikmund-Fisher, B. J. (2010). Perceived Risk of Cancer and Patient Reports of Participation in Decisions about Screening: The DECISIONS Study. Medical Decision Making, 30(5_suppl), 96–105. https://doi.org/10.1177/0272989x10377660

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Chapter 2. Impact of alternative diagnostic labels for melanoma in situ on management choices and psychological outcomes: protocol for an online randomised study

Chapter 2 presents the protocol paper of my MPhil thesis. It detailed the survey used in the study. It was designed to capture a comprehensive range of psychosocial and behavioural outcomes. This included validated and commonly used measures across multiple dimensions of perceived risk (absolute, comparative, experiential, and vulnerability), including perceived risk of invasive melanoma and of dying from melanoma. In addition, the survey included items assessing skin and demographic characteristics to provide sufficient data to calculate participants' actual risk and enable comparisons with their perceived risk.

The development of this protocol involved an iterative process in consultation with clinicians, consumer representatives, and members of the public to ensure that the alternative diagnostic labels were both clinically plausible and easily understood by non-clinicians. The protocol paper also includes details of the survey platform, the randomisation procedure, the required sample size, trial database registration, and approval from a Human Research Ethics Committee.

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Impact of alternative diagnostic labels for melanoma in situ on management choices and psychological outcomes: protocol for an online randomised study

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ABSTRACT

Introduction A diagnosis of melanoma in situ presents negligible risk to a person's lifespan or physical well-being, but existing terminology makes it difficult for patients to distinguish these from higher risk invasive melanomas. This study aims to explore whether using an alternative label for melanoma in situ may influence patients' management choices and anxiety levels.

Methods and analysis This study is a between-subjects randomised online experiment, using hypothetical scenarios. Following consent, eligible participants will be randomised 1:1:1 to three labels: 'melanoma in situ' (control), 'low-risk melanocytic neoplasm' (intervention 1) and 'low-risk melanocytic neoplasm, in situ' (intervention 2). The required sample size is 1668 people. The co-primary outcomes are (1) choice between no further surgery or further surgery to ensure clear histological margins greater than 5 mm and (2) choice between patient-initiated clinical follow-up when needed (patient-led surveillance) and regular routinely scheduled clinical follow-up (clinician-led surveillance). Secondary outcomes include diagnosis anxiety, perceived risk of invasive melanoma and of dying from melanoma and management choice anxiety (after surgery choice and follow-up choice). We will make pairwise comparisons across the three diagnostic label groups using regression models (univariable and multivariable).

Ethics and dissemination The study has been registered with the Australian New Zealand Clinical Trials Registry (ACTRN12624000740594). Ethics approval has been received from The University of Sydney Human Research Ethics Committee (2024/HE000019). The results of the study will be published in a peer-reviewed medical journal, and a plain language summary of the findings will be shared on the Wiser Healthcare publication page (https://www.wiserhealthcare.org.au/category/publications/).

Trial registration number Australian New Zealand Clinical Trials Registry (ID 386943).

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The randomised design enables robust comparison of diagnostic labels on decision-making and psychological outcomes.
⇒ The study has been co-designed with patients, members of the public and clinicians to ensure that labels and evidence are relevant to end-users.
⇒ The large online randomised study is representative of adults in the Australian community.
⇒ The study's hypothetical nature limits its ability to capture real patients after an actual melanoma in situ diagnosis (or alternative label).
⇒ The study does not explore the potential for recalibration of diagnostic thresholds using existing labels, the impact of diagnostic labels on actual patient or clinician decisions or the impact of detailed risk information on diagnostic labels, all of which are areas for future research.

INTRODUCTION

Melanoma incidence and mortality trajectories in Australia and other countries show a classic epidemiological signature of overdiagnosis:[1] steeply increasing incidence curves coupled with flat mortality trends.[2–6] While ageing populations may lead to a small real increase in melanoma incidence,[7] much of the increase is likely overdiagnosis.[2–6] This appears to be largely driven by increased diagnosis of melanoma in situ,[2 4 8] which in Australia is now diagnosed over twice as frequently as invasive melanoma.[9] Similar findings have been found for melanoma in the USA (diagnosed at least as frequently as invasive melanoma)[3] and Denmark (diagnosed over half as frequently as invasive melanoma).[10]

Multiple evidence lines indicate that melanoma in situ is a risk factor for invasive melanoma rather than an obligate precursor.[3 9 11 12] Overdiagnosis is partly driven by lowering the diagnostic threshold over the years, such that the same lesion that was called benign in the past would now be labelled melanoma in situ.[12] Concerns about litigation may also be driving a tendency to interpret melanocytic lesions as a more severe diagnosis[13] particularly in partial biopsies or where the lesion extends to the surgical margins. Harms stemming from melanoma overdiagnosis include physical, psychosocial and economic dimensions.[14] Physical harms can include overtreatment, repeat skin biopsies,[15] scarring,[15] pain, infection and/or functional impairment. Psychological harms include anxiety and fear,[16 17] with many patients perceiving that they have a high risk of dying from melanoma, when their actual risk is much lower (and risk all-cause mortality is actually lower than the population average).[18] These psychological harms can manifest as anxiety about being outdoors, fear of cancer recurrence, or guilt for past ultraviolet (UV) radiation exposure causing melanoma.[5] Social harms include impacts of the diagnosis on loved ones, and on patients' social networks.[15] Economic harms include treatment costs for the immediate diagnosis and for future long-term clinical surveillance. These incur substantial financial costs to both the health system and patient (as out-of-pocket costs), as well as opportunity costs for both clinician time and patient time. There is also a possible denial of life insurance as the person is now identified as a cancer survivor by many insurance companies.[3]

One possible solution is to consider a new label for melanoma in situ without the word 'melanoma'.[12] This might help patients recognise the lower risk of this type of lesion[18] and help to reduce the potential psychological harm. It may also pave the way for the de-escalation of treatment[19] and surveillance.[20–22] Evidence from other cancer contexts, including thyroid,[23] breast[24] and prostate[25] lesions, suggests that new diagnostic labels may beneficially impact psychological outcomes and management decisions.[26] We seek to build on these findings by investigating the potential impacts of new labels for melanoma in situ. To ensure relevance of our findings to end-users, we will test alternative labels for melanoma in situ that were chosen by our co-investigators representing clinicians, patients and the public. Alternative label(s) need to be acceptable to both patients and clinicians, and convey the low, but not zero, risk of future invasive melanoma. This study aims to explore whether using an alternative diagnostic label to communicate a hypothetical melanoma in situ diagnosis influences management choice and level of anxiety among Australian adults.

METHODS AND ANALYSIS

Study design

An online randomised study of Australian community members will be run, with participants randomised to receive one of the three hypothetical scenarios about the diagnosis of a melanoma in situ. Each group will be presented with a different diagnostic label, and we will survey participants about their preferred choices of management for that diagnosis, their level of anxiety about that diagnosis and their level of anxiety about their management choices.

This study is a between-subjects randomised online experiment. Following consent, eligible participants will be randomised 1:1:1 to 'melanoma in situ' (control), 'low-risk melanocytic neoplasm' (intervention label 1) and 'low-risk melanocytic neoplasm, in situ' (intervention label 2). The co-primary outcomes and secondary outcomes will be compared across randomised groups.

There will be an equal probability of being assigned to each of the three groups, and we expect approximately equal numbers per group. We will use Qualtrics survey software to randomly allocate participants into groups, present the scenarios, survey questions and collect data on the outcomes.[27] Our participants' flow diagram presents a summary of the randomisation of participants into the allocated control and intervention arms (figure 1).

Eligibility criteria

Participants will be eligible if they are 40 years or older, understand written English and reside in Australia. Participants will be excluded if they have a history of melanoma (invasive or in situ).

Recruitment and data collection

Participants will be recruited from the general Australian public through an independent social research company (Dynata), which has a panel of 600 000 participants whose demographic characteristics align closely with those of the national population. Dynata has a point system in which participants receive points after completing surveys. The points can then be used to redeem vouchers, cash or other rewards. Stratified sampling will be used, with quotas in place for gender (50% male, 50% female or other), age (25% for each of 40–29 years, 50–59 years, 60–69 years, 70 years or older, ±15% allowed for first three age groups and ±30% for oldest age group),[28] education (50% high school or less, 50% more than high school, ±15% allowed) and State or Territory of residence (quotas proportionate to Australian population, ±5% allowed: New South Wales, 31.3%; Victoria, 25.6%; Queensland, 20.5%; South Australia, 6.9%; Western Australia, 10.9%; Tasmania, 2.1%; Northern Territory, 0.9%; and Australian Capital Territory 1.7%).[29]

Participants who agree to participate in the study will complete an online Qualtrics survey managed by the research team. Only eligible participants will proceed to the randomisation step. The survey will capture baseline data and characteristics of participants including sociodemographic details including their age, location, health literacy, and personal and family history of any cancer, and participant responses on outcome measures. The survey questions are presented in the online supplemental file.

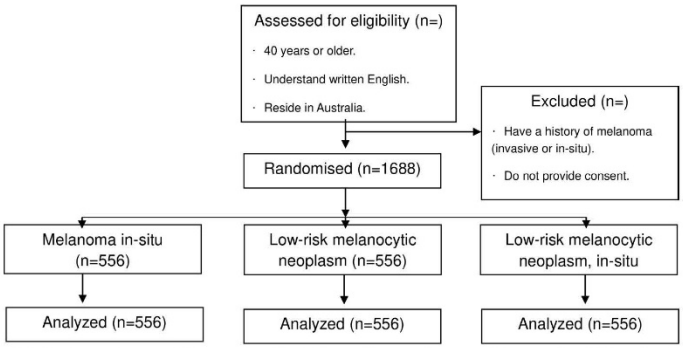

Figure 1 Study Consolidated Standards of Reporting Trials flow diagram for participants. Participants' selection inclusion criteria are age over 40 years, understanding written English and residing in Australia. Patients will be excluded if they have melanoma or do not provide consent.

All data will be collected via Qualtrics software and hosted on The University of Sydney secure server. Information will be de-identified, and we will not be able to link the survey back to participants. The non-identifiable data will be downloaded for analysis and stored within The University of Sydney's Research Data Store.

Determination of alternative labels to be tested

We undertook a targeted literature search in September 2023 by retrieving forward and backward citation searches of four key papers on the topic.[5 12 26 30] We used the automated tool 'Spider Cite'[31] to identify records and Covidence to screen title, abstract and full texts.[32] Of 593 unique records retrieved, we screened the full text of 27 and included seven papers describing nine alternative labels (see box 1).

Using short online questionnaires implemented in Qualtrics,[27] we then ran three rounds of surveys with the nine international clinician co-investigators (with expertise in dermatopathology, dermatology, surgical oncology, primary care and radiation oncology) and six patient/public co-investigators (two with lived experience of a melanoma diagnosis and four without a history of melanoma) to determine choice of alternative labels. This resulted in the final choice of two alternative labels that we will test in the online survey: *low-risk melanocytic neoplasm* and *low-risk melanocytic neoplasm, in situ.*

Interventions

Participants will be randomised using Qualtrics randomisation software to receive one of the three hypothetical scenarios. They will not be blinded. In each scenario, the participant will be told that the results of their recent skin surgery indicate a particular diagnosis. Group 1 (the control group) will be told they have a *melanoma in situ.* Group 2 will be told that they have a *low-risk melanocytic neoplasm.* Group 3 will be told that they have a *low-risk melanocytic neoplasm, in situ.* We will not provide further explanation of what low risk means.

Primary and secondary outcomes

Primary and secondary outcomes are described in table 1. The co-primary outcomes are (1) participant's choice of surgical management option: no further surgery versus further surgery (to achieve pathology margins greater than 5 mm) and (2) follow-up management option: patient-led surveillance (self-skin examination with patient-initiated clinic visits) versus clinician-led surveillance (6 monthly routinely scheduled clinic visits).

Box 1 Process to select alternative labels to melanoma in situ for testing

⇒ In the first-round surveys, clinician and patient/public co-investigators indicated their ranking the seven labels identified in the targeted literature search and two additional labels in order of preference. The potential alternative labels from the literature search were as follows: melanocytic neoplasm of low malignant potential (8, 24, 25), melanocytic neoplasm, atypical neoplasm (25), severe or high-grade melanocytic dysplasia, superficial atypical melanocytic proliferation of uncertain malignant significance (SAMPUS) (26–28), melanocytic tumour of uncertain malignant potential (MELTUMP) and melanocytoma (28). The two additional labels suggested by the research team were low-risk melanocytic neoplasm and low-risk melanocytic lesion.

⇒ In the second-round surveys, co-investigators indicated their preferred ranking of the top three choices from round 1 and two new labels suggested in round 1: low-risk melanocytic neoplasm, low-risk melanocytic lesion and melanocytic neoplasm of low malignant potential, melanocytic intraepithelial neoplasia and in situ melanocytic neoplasm.

⇒ In the third-round surveys, co-investigators indicated their preferred ranking of the top two choices from round 2 and three new labels suggested in round 2: in situ melanocytic neoplasm, low-risk melanocytic neoplasm, in situ melanocytic neoplasm, low risk, low-risk melanocytic neoplasm, in situ and dysplastic naevus.

The two highest ranked labels, chosen as the alternative labels to test in the online experiment, were '*low-risk melanocytic neoplasm*' and '*low-risk melanocytic neoplasm, in-situ*'.

Table 1 Participant characteristics and outcome measures

Variable	Measure
Participant characteristics	
Melanoma risk	Melanoma risk prediction-based self-assessed risk factors[38]
General mood and well-being	WHO (Five) Well-Being Questionnaire[39]
Medical minimiser/maximiser	Single-Item Maximiser/Minimiser Elicitation Question (MM1)[40]
Health literacy	Single Item Literacy Screener (SILS)[41]
Melanoma worry	Direct choice between specified options, one choice possible
Self-efficacy	Generalised Self-Efficacy Scale (GSE)[42]
Primary outcomes	
Co-primary outcomes are choices for two management decisions. 1. Choice of further surgery: – No further surgery – Further surgery to ensure margins>5mm from lesion on pathology 2. Choice of follow-up: – Patient-led surveillance: self-monitoring with patient-initiated clinic visits as needed – Clinician-led surveillance: 6monthly routinely scheduled clinic visits	Direct choice between two management approaches for each co-primary outcome Choice of further surgery and choice of follow-up
Secondary outcomes	
Diagnosis anxiety (feelings)	Single-question Visual Analogue Scale (0–6)[43 44]
Experiential perceived risk (vulnerability)	Single-question Visual Analogue Scale (0–6)[44]
Perceived lifetime absolute risk of invasive melanoma	Single-question Visual Analogue Scale (0–100)[44]
Perceived lifetime comparative risk of invasive melanoma	Single-question Visual Analogue Scale (0–6)[44]
Perceived lifetime risk of dying from melanoma	Single-question Visual Analogue Scale (0–100)
Management choice anxiety	Single-question Visual Analogue Scale (0–6)[43]
Open-text explanation of management choice	Free text (optional)

The first co-primary outcome on surgical management choice reflects recent retrospective analyses that have found that narrower margins are likely to be as safe as margins currently recommended in guidelines in small melanoma in situ.[33] Indeed, very narrow histological clearance (≥1 mm) appears to be safe for melanoma in situ of the trunk and limbs.[34] The new MPATH-Dx V2.0 melanocytic lesion classification scheme recommends that provided margins are not involved, and clinicians may consider not re-excising class II lesions—which includes melanoma in situ.[35] The second co-primary outcome on follow-up management choice centres around patient-led surveillance (also called patient-initiated follow-up) as an alternative model of follow-up for cancer survivors to routinely schedule clinic appointments.[36] Among people diagnosed and treated for early stage melanoma, patient-led surveillance is being evaluated in the MELanoma SELF surveillance (MEL-SELF) randomised controlled trial. Here, this model of care includes training in self-skin examination, digital technologies to record and take images of concerning lesions (using a mobile dermatoscope), online system for submitting images for remote review by a dermatologist and advice on whether urgent clinical review may be needed (teledermatology).[37]

Secondary outcomes are as follows: diagnosis anxiety, perceived lifetime risk of invasive melanoma, perceived lifetime risk of dying from melanoma, management choice anxiety and open-text explanation of management choices (free text input).

Sample size

We estimated a sample size of 1668 participants with 556 participants per group in the study, which would provide 80% power (1 - β) to detect a pairwise difference in the proportion of choosing no further surgery and 89% power to detect a pairwise difference in the proportion in choosing patient-led surveillance as small as 10%.

The assumptions are 50% would choose no further surgery (most conservative assumption) and 35%[22] would choose patient-led surveillance in the control label condition, a 5% dropout rate, α=0.05, the normal approximation to the binomial distribution and the standard formula for comparing proportions in independent equal-sized groups.

Analysis

The analysis will focus on assessing the impact of different diagnostic labels for melanoma in situ on participants' psychological responses and healthcare decisions. Data analysts will be blinded to intervention assignment. For both co-primary outcomes, we will compare the proportion chosen for each management option. For first four secondary outcomes, we will compare summary statistical measures (means or medians) across randomised groups. For the last outcome, we will use thematic framework methods of qualitative data.

The analysis will adhere to the intention-to-treat principle, and participant data will be analysed according to their randomly assigned diagnostic label group, regardless of adherence to the study protocol. The number of participant responses included in each analysis will be presented for each outcome. We will summarise categorical data for the randomised groups using counts and percentages, and continuous data using the minimum and maximum, mean and SD or median and IQR.

Statistical analyses will be conducted within a superiority framework to make pairwise comparisons across the three diagnostic label groups. Binary outcomes will be analysed using logistic regression. Continuous outcomes will be analysed using linear regression. For the cancer worry outcome, we will compare changes in worry across

randomised groups by including baseline scores as a covariate in the regression model. Effect estimates for all primary and secondary outcomes will be presented with associated 95% CI. All hypothesis tests will be two-sided with a significance level (α) of 5%. The potential for participants' health literacy to act as an effect modifier of intervention effects will be explored.

We will estimate unadjusted and adjusted effects using the relevant regression model. These will include variables used in sampling strata: age, education and geographic location (by state/territory). Prognostic factors will be measured through the baseline questionnaire and include baseline anxiety levels, sun exposure behaviour, prior diagnosis of melanoma and diagnosis of melanoma in a family member. The effects of participants' health literacy on intervention effects will also be explored as a potential confounder.

Planned start and end dates for the study

The anticipated date of first participant enrolment was 01 July 2024, and the anticipated date of last data collection completion was 01 August 2024 (see Australian New Zealand Clinical Trials Registry, ID: ACTRN12624000740594).

Patient and public involvement

Two authors have lived experience of a melanoma diagnosis (one had MIS and one had a thin stage I invasive melanoma), and four authors are members of the public. Two authors are affiliated with Cancer Voices New South Wales (NSW), one author is a patient researcher from Cambridge UK, and three authors are affiliated with Health Consumers NSW.

ETHICS AND DISSEMINATION

Ethics approval of this project was provided by The University of Sydney on 06 May 2024 (No. 2024/HE000019). The study is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12624000740594). Updates to the protocol will be uploaded to the registry and identified by version number.

As this study is an online randomised experiment which includes a hypothetical scenario, we do not anticipate significant adverse events because of the trial interventions or conduct. Participants are reminded at several points before and after the study as part of the participant information, consent and debrief processes that the nature of the study is hypothetical, that none of the information relates to their actual health or well-being and that researchers do not have access to their actual medical histories or information. The debriefing content also includes links to relevant resources for participants who wish to find out more.

Data availability statement

The research team will have access to the final dataset. Access may be granted to other researchers on reasonable request. No contractual agreements limit the disclosure of data to other investigators. The findings of the study will be published in a peer-reviewed medical journal. A lay summary of the findings will be published via permanent link at the Wiser Healthcare publications page.

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Contributors ZW co-led drafting of the manuscript, led drafting of the study questionnaire and application to the Human Research Ethics Committee and assisted with the targeted literature review (full-text screening and data extraction). BN and KB conceptualised the research and provided methodological expertise. KB, who is the guarantor, led the targeted literature review and the Clinician and Consumer Investigator survey to decide the choice of alternative labels and co-led drafting of the manuscript. FB calculated the sample size. BN, FB, DE, PMF, RAS, BO'B, RB, ACJvA, ASA, JE, LP, DL, CL, ED, SLi, SLe, BS-R and KB revised the manuscript. All authors read, contributed to and approved the final manuscript.

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Chapter 3. Mind the Gap: Impact of new labels on public perceptions and calculated risk of adverse outcomes after a melanoma in-situ diagnosis. A secondary analysis of an online randomised experiment

In chapter 3, we investigate whether alternative diagnostic labels shape perceptions of risk across multiple dimensions (absolute, comparative, experiential, and vulnerability) as well as the perceived risk of dying from melanoma. We paid particular attention to perceived likelihood of invasive melanoma (absolute risk) and melanoma-related mortality, and how these perceptions compare with calculated risk estimates. By highlighting the gap between perceived and calculated risk, this study aims to clarify the role of diagnostic language in risk overestimation and to support more accurate, evidence-based communication for low-risk melanocytic conditions.

Mind the Gap: Impact of new labels on public perceptions and calculated risk of adverse outcomes after a melanoma in-situ diagnosis. A secondary analysis of an online randomised experiment

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Abstract

Background:

Alternative diagnostic labels for melanoma in situ may better reflect its lower risk (15-year survival 98%) compared to invasive melanoma (10-year survival ranging from 98% for AJCC stage IA to 19% for stage IV).

Design:

Secondary analysis of online randomised experiment in Australian adults without melanoma. Participants were randomised to a hypothetical diagnosis of "melanoma in situ (MIS)" (control), "low-risk melanocytic neoplasm", or "low-risk melanocytic neoplasm, in situ" and completed a survey.

Outcomes:

Perceived risk measures: future invasive melanoma and mortality risk (0%–100%), comparative risk, affective risk, vulnerability (7-point Likert scales).

Calculated risk measures: lifetime invasive melanoma risk (from participants' risk factors); melanoma mortality probability (Australian sex-age specific mortality rates).

Analysis:

Intention-to-treat analysis across randomised groups, unadjusted and adjusted for covariates (linear regression models).

Results:

1,668 adults were recruited. Compared to "MIS," perceived melanoma mortality risk was lower for "low-risk melanocytic neoplasm" (−10.4%, 95% CI: −13.1% to −7.63%, $p < .001$) and for "low-risk melanocytic neoplasm, in situ" (−7.4%, 95% CI: −10.2% to −4.6%,

$p < .001$). Similar patterns were observed for perceived risk of invasive melanoma, comparative, affective risk, and vulnerability. Participants in all groups substantially overestimated their lifetime risk of invasive melanoma (by 48.7%) and of dying from melanoma (by 32.0%) compared to the calculated risk; overestimation was lower in alternative label groups.

Conclusions:

Diagnostic labels without the word “melanoma” reduced risk overestimation, supporting MIS relabelling to mitigate overdiagnosis harm by reflecting its largely indolent nature.

Trial registration: ANZCTR: 386943

Highlights:

- Alternative diagnostic labels for melanoma in situ that do not include the word "melanoma" significantly decreased perceived risk compared to melanoma in situ.
- Participants substantially overestimated their risk; alternative labels reduced this overestimation of perceived risk compared to calculated risk.
- A new label for melanoma in situ may better communicate the lower risk of adverse outcomes for this lesion compared with invasive melanoma. This may reduce patient anxiety and allow for management decisions that align with their values and preferences.

Introduction

Australia has the highest melanoma incidence in the world, reflecting a true burden from the disease, as well as probable substantial overdiagnosis: indolent lesions that meet melanoma diagnostic criteria but would not cause harm if left untreated [1-5]. This is especially likely for melanoma in situ (MIS, American Joint Committee on Cancer (AJCC) stage 0), which shows steeply rising incidence trends alongside stable mortality[1,6,7]. MIS is now diagnosed more than twice as often as invasive melanoma[8], and may be better conceptualised as a risk factor for invasive melanoma rather than an obligate precursor [2,8-10], as its natural history if left untreated remains uncertain[10].

Patients diagnosed with MIS have overall survival rates that are higher than age and sex matched rates for the general population, and melanoma mortality rates are only modestly increased[11]. However, they often report high perceived risks of new or recurrent melanoma and of dying from melanoma[12,13], with similar perceived risk estimates to patients diagnosed with invasive melanoma who have a higher actual risk of these events[14]. According to recent estimates, fifteen-year melanoma-specific survival for patients with MIS is 98%[11], while the ten-year melanoma-specific survival for patients with invasive melanoma ranges from 98% for AJCC stage IA to (at best) 23-52% for patients with stage IV melanoma (on immune checkpoint inhibitors in a trial setting)[15,16].

Melanoma localised to the skin (AJCC stage 0-II) are treated by surgical excision, with wider clinical margins recommended for invasive melanomas (1-2cm) than for melanoma in situ (5 mm margins)[15,17]. Research has shown that second excisions to achieve these margins (wide local excisions) do not appear to reduce the risk of recurrence[18], but can cause scarring, prolong recovery time, lead to additional procedures and increase healthcare costs [19].

Adoption of an alternative diagnostic label for MIS that omits the word "melanoma" has been proposed as a way to better communicate the low-risk nature of these lesions[10,11] and help to reduce adverse psychological effects, such as fear of melanoma recurrence[12]. Retention of the MIS label might be supported by health behaviour models that suggest a higher perceived probability of adverse events can beneficially motivate adoption of health protective behaviours[20,21]. On the other hand, recalibrating perceived risk to reflect empirical probabilities of adverse events, could allow for a more patient centred approach that includes shared decision making[22]. This might also facilitate appropriate de-escalation of surgical treatment [23] and routine surveillance[24-26]. Evidence from other cancer contexts, including thyroid[27], breast[28], and prostate[29] lesions, suggests that new diagnostic labels may beneficially impact psychological outcomes and management decisions[30], likely operating via a recalibration of the perceived risk of the lesion.

Risk perception is considered a key component in determining patients' health behaviour and treatment choices[31,32], but there is uncertainty about how it is best assessed[33,34]. A triangular framework that considers cognitive, affective, and experiential risk has been proposed to comprehensively evaluate health-related risk perceptions[35]. Improving the accuracy of patients' risk perceptions is also closely linked to the effectiveness of decision aids in supporting informed healthcare decisions [36].

In this study, we aimed to examine the impact of alternative diagnostic labels on Australian adults' perceived risk from MIS. We hypothesized that alternative labels would result in lower perceived risk than the "melanoma in situ" label.

Methods

We report this study in accordance with the Consolidated Standards of Reporting Trials (CONSORT)[37] reporting guideline and the Guideline for RepOrting Vignette Experiments (GROVE)[38].

Study design

This is a secondary analysis of an online study that randomised Australian adults 1:1:1 to hypothetical diagnostic labels for the same lesion: "melanoma in situ" (control), "low risk melanocytic neoplasm" (alternative 1), and "low risk melanocytic neoplasm, in situ" (alternative 2). We selected the two alternative labels used in the study through a process of co-design with 9 international clinicians and 6 patient/public co-investigators (see published protocol[39]). The primary outcomes (will be reported separately) assessed the effect of alternative melanoma in situ labels on preferences for further surgery and for type of follow-up[39]. The current analysis reports pre-specified secondary outcomes related to perceived risk of future adverse events. Participants were recruited from the general Australian public through an independent social research company (Dynata), which has a panel of 600,000 participants whose demographic characteristics align closely with those of the national population[40]. All data collected is de-identified.

Participant eligibility

Participants were eligible if they were: 40 years or older, could understand written English, and resided in Australia. Participants were excluded if they had a personal history of melanoma (invasive or in situ). Quotas were used to ensure adequate recruitment across gender (50% male, 50% female, or other) and age.[41] (25% for each of: 40-29 years, 50-59 years, 60-69 years, 70 years or older, +/- 15% allowed for the first three age groups and +/- 30% for the oldest age group), education (50% high school or less, 50% more than high

school, +/-15% allowed), and State or Territory of residence[42] (quotas proportionate to Australian population, +/-5% allowed: New South Wales 31.3%, Victoria 25.6%, Queensland 20.5%, South Australia 6.9%, Western Australia 10.9%, Tasmania 2.1%, Northern Territory 0.9%, and Australian Capital Territory 1.7%). We collected data on Indigenous status but no other ancestry, race and ethnicity data were directly collected (data on skin and hair colour were collected). The full survey is provided in the Supplement. No harm was anticipated, as the study was conducted in an online, hypothetical setting.

Randomization

We used Qualtrics survey software[43] to randomly allocate eligible participants into three groups with an allocation ratio of 1:1:1, present the scenarios, survey questions, and collect data on the outcomes. Questions were asked immediately after the randomization. Participants were blinded to the study aims and were unaware that alternative diagnostic labels were being compared.

Outcomes

Perceived risk

Participants estimated their perceived risk from their assigned hypothetical diagnosis using five single-item measures: two numeric scales and three Likert scales. We asked participants to provide an estimated lifetime risk of developing invasive melanoma and of lifetime risk of dying from melanoma, on 0–100% Visual Analogue Scales. We also assessed three additional dimensions of perceived risk using 7-point Likert-type scales (0–6): comparative risk (how participants perceived their risk for an invasive melanoma diagnosis compared with others of the same age and sex), affective risk (how anxious or worried they felt about developing melanoma), and vulnerability (their sense of personal susceptibility to developing melanoma). Detailed descriptions for the five perceived risk measures are provided in Box 1.

Calculated risk

We calculated two risk measures to estimate participants' actual risk of a future invasive melanoma and of dying from melanoma. We calculated lifetime risk of a first primary invasive melanoma using an externally validated Australian risk tool[44] (data for the tool's risk factors were collected via the survey: family history of melanoma, personal history of non-melanoma skin cancer, number of moles, natural hair colour, skin colour, and tendency to sunburn). To calculate their melanoma mortality risk, we used sex-age-specific rates of melanoma deaths in the Australian general population and multiplied this by the standardised mortality ratio (SMR) for dying from melanoma after a melanoma in situ diagnosis compared to the general population found in a USA study. For men, the Australian age-specific mortality rates per 100,000 were: 1.4 (40–49 years), 3.9 (50–59), 10.6 (60–69), 28.2 (70–79), and 83.7 (80+). For women, the rates were 1.1 (40–49 years), 1.7 (50–59), 3.6 (60–69), 11.9 (70–79), and 31.3 (80+)[45]. The SMRs from the USA study that we used to adjust Australian age-specific rates upwards after the hypothetical melanoma in situ diagnosis were: 1.8 for ages 40–49, 1.85 for 50–59, 1.41 for 60–69, 2.01 for 70–79, and 2.18 for 80+. [11] (There are no published estimates for increased melanoma mortality risk after a melanoma in situ diagnosis for the Australian population.)[45].

Covariates

Respondents provided information on the following sociodemographic and personal characteristics: age, gender, partner status and age, state or territory location, postcode (used to create remoteness of residence), health insurance status, education, employment status, household income, Indigenous status, country of birth, language spoken at home, personal history of cancer (non-melanoma), history of melanoma in family or other loved one, health literacy (Single Item Literacy Screener[46]), medical minimiser/maximiser (Single-Item

Maximiser/Minimiser Elicitation Question[47]), melanoma cancer worry, health status, wellbeing (WHO Well-Being Questionnaire[48]), self-efficacy (Generalized Self-Efficacy Scale[49]). The information on the risk factors described above (used to calculate risk of a first primary invasive melanoma) was also used to calculate their 10-year risk of a second primary melanoma (in situ or invasive) if they had just received a melanoma in situ diagnosis[50]. This summary risk measure was included as a covariate in the multivariable regression models (see below).

Sample size

The sample size of 1668 participants was determined for the primary outcomes of the main randomised study: management decisions on the need for wide local excision (surgery or no further surgery) and surveillance (routinely scheduled clinic visits or patient-led surveillance)[39]. The current secondary analysis may not have sufficient statistical power to detect small differences in perceived-risk outcomes.

Statistical methods

Using the intention-to-treat principle (data analysed according to randomised groups), we made pairwise comparisons across the three diagnostic label groups within a superiority framework. We present effect estimates for outcomes with associated 95% confidence intervals (CI). All hypothesis tests were two-sided with a significance level (α) of 5%.

For unadjusted effect estimates, we treated the outcomes as continuous and compared the differences between groups. For adjusted effect estimates, we used multiple linear regression models (treating the perceived risk measures as continuous outcomes), with adjustment for relevant covariates chosen from a pre-specified set of potential prognostic factors (covariates measured through the baseline questionnaire) and the sampling strata variables ("quotas": age, education, geographic location by state/territory). For each outcome, we included

potential prognostic factors that had $p<0.20$ in the multivariable model. The distribution for perceived risk of dying from melanoma was positively skewed, and so values were log-transformed before analysis. The differences between groups on the log scale correspond to ratios of geometric means on the original scale[51,52], which we report.

To assess participants' overestimation of the lifetime risk of an invasive melanoma and of dying from melanoma, we calculated the difference between their perceived risk estimate and the calculated risk estimate. We used Kruskal–Wallis tests for differences in the magnitude of overestimation across diagnostic labels.

All analyses were conducted using R statistical software version 4.4.1.

Registration and Ethics approval

The study is registered with the Australian New Zealand Clinical Trials Registry (ID 386943), and approval was received from the University of Sydney Human Research Ethics Committee (2024/HE000019) on 25/06/2025.

Result

A summary of recruitment, randomisation, and analysis populations is presented in Figure 1. Of the 1688 participants randomised, 562 were assigned to “melanoma in situ”, 563 to “low-risk melanocytic neoplasm”, and 563 to “low-risk melanocytic neoplasm, in situ”. Characteristics of the study population and randomised groups are shown in Table 1.

Perceived risk

Perceived risks are presented in Table 2, and Figures 2 and 3.

Perceived lifetime risk of invasive melanoma

Diagnostic labels had a statistically significant effect on perceived lifetime risk of invasive melanoma ($p < 0.001$). The mean perceived lifetime risk of invasive melanoma (scale 0-100%) after receiving a "melanoma in situ" diagnosis was 56.5%, a "low risk melanocytic neoplasm" diagnosis was 44.0% (adjusted mean difference -12.9%, 95% CI: -15.4 to –10.4; $p < 0.001$) and a "low risk melanocytic neoplasm, in situ" was 47.3% (adjusted mean difference -9.4%, 95% CI: -11.9 to –6.9; $p < 0.001$). (Figure 2 and Table 2)

Perceived risk of dying from melanoma

There was also a statistically significant effect of diagnostic labels on perceived risk of dying from melanoma ($p < 0.001$). The adjusted geometric mean (back-transformed from the log scale; scale 0-100%) for perceived median risk of dying from melanoma after receiving a "melanoma in situ" diagnosis was 43.0% (95% CI 35.4%, 52.1%), a "low-risk melanocytic neoplasm" diagnosis was 29.1% (95% CI 24.1%, 35.3%), and a "low-risk melanocytic neoplasm in situ" diagnosis was 32.8% (95% CI 27.0, 39.8%). (Figure 3 and Table 2)

Comparative risk

There was a statistically significant effect of diagnostic labels on the perceived risk of invasive melanoma when compared with others of the same age and sex ($p < 0.001$). The mean comparative risk after receiving a "melanoma in situ" diagnosis was 3.5 (scale 0-6, from "much lower" to "much higher" more likely; 3 indicates "being about as likely as others of the same age, gender, and skin colour to develop melanoma"), a "low-risk melanocytic neoplasm" diagnosis was 2.9 (adjusted mean differences = -0.6, 95% CI: -0.7–-0.5; $p < .001$) and a "low risk melanocytic neoplasm, in situ" diagnosis was 3.1 (adjusted mean differences = -0.4, 95% CI: -0.5–-0.3; $p <0.001$). (Table 2).

Affective risk (diagnostic anxiety)

There was a statistically significant effect of diagnostic labels on diagnostic anxiety ($p<0.001$). The mean anxiety level (scale 0 to 6, from "not at all" to "extremely" anxious; 3 representing the midpoint of the scale.) after receiving a "melanoma in situ" diagnosis was 3.5, a "low risk melanocytc neoplasm" diagnosis was 2.7 (adjusted mean difference -0.9 (95% CI: -1.0, -0.7), $p <0.001$), and a "low risk melanocytic neoplasm in situ" diagnosis was 2.8 (adjusted mean difference -0.7 (95% CI: -0.8, -0.5), $p<0.001$). (Table 2).

Perceived vulnerability

There was a statistically significant effect of diagnostic labels on perceived vulnerability to invasive melanoma ($p<0.001$). The mean perceived vulnerability (scale 0 to 6, from "not at all" to "extremely" vulnerable; 3 representing the midpoint of the scale.) for the group of participants receiving a "melanoma in situ" diagnosis was 3.7, for "low risk melanocytc neoplasm" diagnosis was 3.0 (adjusted mean difference -0.8 (95% CI: -0.9, -0.6), $p <0.001$), and a "low risk melanocytic neoplasm in situ" diagnosis was 3.1 (adjusted mean difference -0.5 (95% CI: -0.7, -0.4), $p<0.0001$) (Table 2, Table 3).

Calculated Risk

Across the full sample (n = 1,688), the distribution of calculated lifetime risks for an invasive melanoma was positively skewed, with an overall median of 1.8% (IQR: 1.1-3.1), for the three randomised groups: "melanoma in situ": 1.7% (1.1%–3.1%); "low-risk melanocytic neoplasm": 1.8% (1.1%–3.3%); "low-risk melanocytic neoplasm, in situ": 1.9% (1.1%–3.0%). (Figure 2). Using the Australian sex-specific mortality rates, the overall mortality rates were the same across groups: 3.9 deaths per 100,000 people, IQR (1.7-11.9 deaths per 100,000 people). After applying the upwards adjustment using the SMRs from the US study, the final distribution of calculated risks of dying from melanoma was positively skewed, with

a median melanoma mortality risk of 0.0072% (IQR: 0.0031%-0.0239%), or 7.2 deaths per 100,000 people. (Figure 3, Table 3).

Overestimation of risk

Perceived vs Calculated lifetime risk of invasive melanoma diagnosis

Participants greatly overestimated their risk of invasive melanoma, with a median perceived lifetime risk (50%; IQR: 30%-69%) that was much higher than the median calculated lifetime risk (1.8%; IQR: 1.1%-3.1%). Nearly all participants overestimated their risk by some amount: 98.9% in the "melanoma in situ" group, 97.9% in the "low-risk melanocytic neoplasm" group, and 98.2% in the "low-risk melanocytic neoplasm" in situ group. The magnitude of overestimation differed significantly by label ($p < 0.001$), with the difference in the median perceived and calculated lifetime risk of an invasive melanoma greater in the "melanoma in situ" group (55.9% difference) compared to the low-risk melanocytic neoplasm group (44.8% difference) and the "low-risk melanocytic neoplasm in situ" group (47.6% difference). (Figure 2, Table 3).

Perceived vs Calculated risk of dying from melanoma

Participants greatly overestimated their risk of dying from melanoma, with a median perceived risk (32%; IQR=13%-51%) that was much higher than the median calculated mortality (0.0072%; IQR: 0.0031%-0.0239%). Nearly all participants overestimated their risk of dying from melanoma: 97.0% in the "melanoma in situ" group, 98.0% for the "low-risk melanocytic neoplasm" group, and 97.5% in the "low-risk melanocytic neoplasm in situ" group. The magnitude of overestimation differed significantly by label ($p < 0.001$), with the difference in the median perceived and calculated risk of dying from melanoma substantially greater in the in the "melanoma in situ" group (46.0% difference) compared to the "low-risk

melanocytic neoplasm" group (28.9% difference) and the "low-risk melanocytic neoplasm in situ" group (31.0% difference). (Figure 3, Table 3).

Discussion

Across all risk measures - absolute, comparative, affective, and vulnerability - the label "melanoma in situ" was consistently perceived by members of the public as indicating higher risk of future adverse events than the alternative labels "low-risk melanocytic neoplasm" and "low-risk melanocytic neoplasm, in situ". Although all participants substantially overestimated both their likelihood of developing invasive melanoma and their risk of death following diagnosis, we observed the greatest overestimation in those assigned the "melanoma in situ" label compared to alternative labels. This was especially notable for the gap in perceived and calculated risk of dying from melanoma, with an absolute reduction in overestimation by 15% or more when the alternative labels were used. The current diagnostic label for these low-risk melanocytic skin lesions, "melanoma in situ" appears at least partly responsible for inflated risk perceptions and the harms arising from its (over)diagnosis.

Responses on the comparative, affective, and vulnerability scales also show label effects on intuitive or emotional judgments and not just probabilistic reasoning. The consistency of the "melanoma in situ" label effect across both numeric and verbal scales suggests that linguistic framing influences not only cognitive estimation but also emotional appraisal and perceived vulnerability. This aligns with prior research showing that diagnostic terms strongly influence patients' mental models of disease, perceived seriousness, and treatment preferences[53], and reinforces calls to reconsider diagnostic terminology for low-risk cancer [28,30] including melanoma in situ. Inaccurate perceptions are clinically important to understand, as they can drive anxiety, preference for aggressive treatment, and requests for increased surveillance—factors contributing to overdiagnosis and overtreatment burdens[29,54].

Using less alarming labels, such as low-risk melanocytic neoplasm, may help convey the true biological nature of the condition, promote more proportionate management, and allow for more informed decisions. While the two “low-risk” labels similarly lowered risk perceptions the best descriptor to differentiate a low-risk invasive melanoma (AJCC IA) from MIS requires further research. In our results, “low-risk melanocytic neoplasm in situ” was associated with a numerically higher perceived risk than “low-risk melanocytic neoplasm”, although the difference was small and not significant. Further, changing labels may represent only one element of a wider strategy that is needed. The underlying challenge may lie in how people interpret and respond to the concept of low-risk cancer. Over time, alternative terminology may also acquire similar emotional meanings as existing labels. Regardless of whether the label is changed, understanding the mechanisms that drive these reactions will therefore be important for developing communication strategies that accurately convey risk while minimising unnecessary psychological harm.

Our findings suggest that although new diagnostic labels may lower the perceived risk of future adverse events, this was still inflated compared to their actual calculated risk. It is possible that current communication strategies currently employed by clinicians and public health officials do not sufficiently contextualise the low risk nature of these lesions. Future research to develop and evaluate the effectiveness of verbal and written risk framing tools may identify strategies for reassuring patients, ensuring that the 'low risk' message is not only delivered but truly understood. The use of absolute risk estimates and graphical displays (e.g. icon arrays) may help patients more accurately interpret low-probability outcomes and distinguish the risk of in situ vs. invasive melanoma. This may improve patient understanding of the disease and allow them to make informed decisions about management options[55]. However, wide local excision and routine clinical follow-up are currently recommended by clinical guidelines for management of melanoma in situ, largely based on extrapolation from

evidence in invasive melanoma,[56] despite emerging data that such approaches may be unnecessary in most cases[57]. These recommendations imply the lesions are high risk of adverse events, which may undermine any efforts to communicate their low-risk nature.

Our study findings extend prior research on cancer labelling effects by providing experimental evidence that terminology for melanocytic pathology can alter public understanding of the disease severity and likelihood of adverse outcomes[27,28,30,54]. In other types of cancer, studies have found that the words used to describe a condition significantly affect how worried patients feel and the kinds of treatments they prefer. For example, using different terms for the diagnosis ductal carcinoma in situ (DCIS) can lead to different levels of anxiety and treatment choices[58]. Research in low-risk prostate and thyroid cancer has also found that alternative diagnostic labels changes how serious people think the condition is and whether they prefer less invasive treatment options [27,29].

This study has several strengths, including its randomised design, the use of multiple measures of perceived risk, and a large representative Australian sample. By comparing perceived and actual melanoma risks, we were also able to explore misperception and overestimation in a meaningful way. The most important limitation is that as participants were responding to a hypothetical, rather than real diagnosis, their perceptions may not reflect the affective and cognitive processes of actual patients. The numeric risk scales used in our survey may have been difficult for participants to interpret [59,60], and the patient-reported numerical risk perception in this experiment may not precisely reflect participants' underlying perceptions. The study sample size was calculated for co-primary outcomes. The current analysis of secondary perceived risk outcomes may have been underpowered to detect small but potentially meaningful differences. We did not conduct subgroup analyses of variables that may influence participants' perceived risk nor did we examine correlations between the different risk measures, both of which may be explored in future research in this

area. Relatedly, we recently reported that fear of melanoma recurrence is common among Australian patients treated for localised melanoma (92% MIS or AJCC IA), and that this varies by age, sex. The level of fear correlated with patients' perceived, but not their calculated, melanoma risk[61].

Some overestimation of risk may be unavoidable, and future research may also explore what level of difference between perceived risk and calculated risk is considered acceptable by clinicians and patients in risk communication. It is also important to understand how the individual words used in a diagnosis influence how people think and feel about their risk. A separate report presenting a qualitative content analysis of participants' free-text responses will provide insights into the effects of the descriptor "low-risk" vs. omitting the term "melanoma" from the diagnostic label to provide a further understanding of how people may estimate their risk of invasive melanoma. Future research to develop and evaluate the effectiveness of verbal and written risk framing tools may identify strategies for reassuring patients, ensuring that the 'low risk' message is not only delivered but truly understood.[62]

Conclusion

Alternative diagnostic labels for melanoma in situ without the word "melanoma" reduce overestimation of perceived risk of future adverse events. Combining alternative diagnostic labels with improved communication strategies could support more balanced decision-making and reduce the harms associated with "melanoma in situ" overdiagnosis and overtreatment.

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During the preparation of the paper, the author used the University of Sydney's protected version of Microsoft Copilot for the purposes of text enhancement. The use of this generative AI tool includes sentence structure and spelling. The author confirms that where text was modified by generative AI, the content was reviewed for possible errors, inaccuracies, and bias. The author takes full responsibility for the submitted thesis and ensures the work is their own and has used generative AI within the parameters of use.

Statements and Declarations

Ethical considerations

The study is registered with the Australian New Zealand Clinical Trials Registry (ID 386943), and approval was received from The University of Sydney Human Research Ethics Committee (2024/HE000019) on 25/06/2025.

Consent to participate

Informed consent to participate was obtained electronically from all participants prior to study commencement. No identifiable individual data are included in this manuscript.

Declaration of conflicting interests

The Authors declare(s) no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Data availability

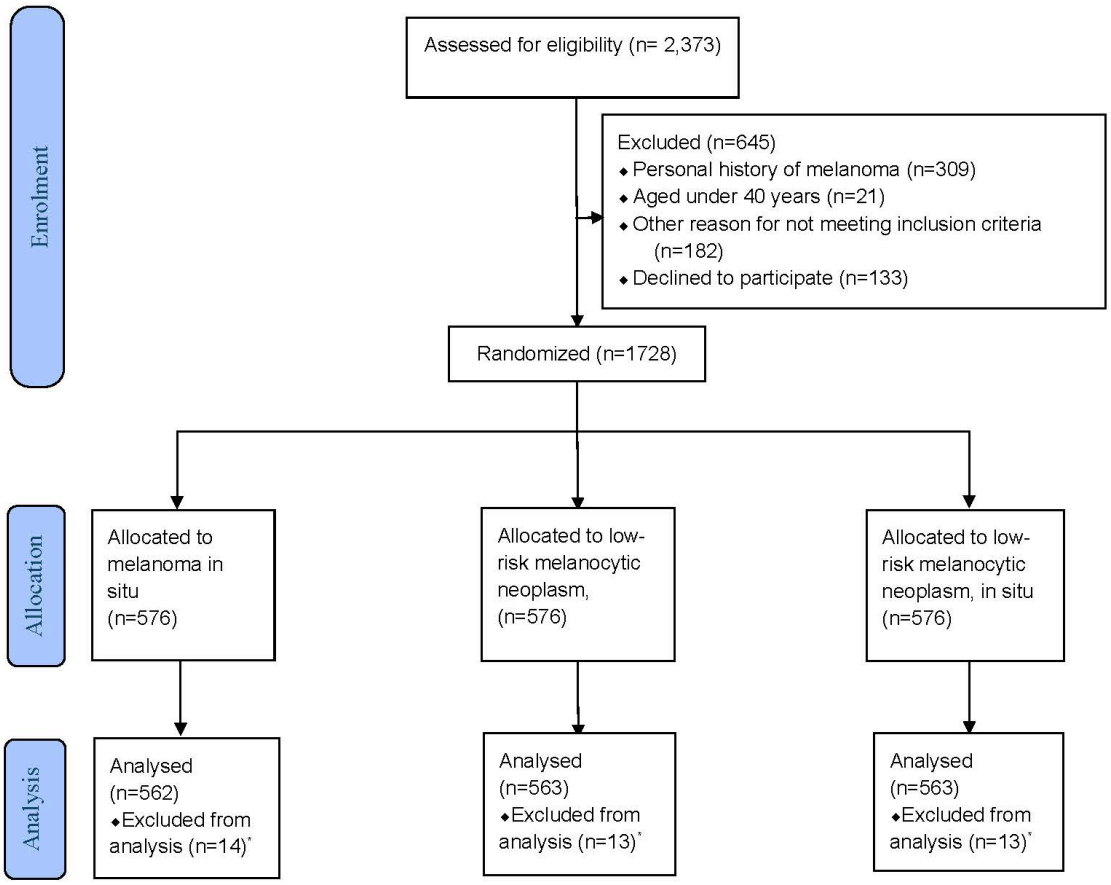
De-identified data will be made available upon reasonable request. The complete result used in this study is publicly available via the Open Science Framework (**10.17605/OSF.IO/6VHUW**).

Box 1. Summary of Perceived Risk Outcome Measures

Measure	Scale Range	Description / Interpretation
Perceived lifetime absolute risk	0 – 100 %	Question: "What do you think your chances are of developing an invasive melanoma sometime in your life?" Numeric estimate of absolute risk.
Perceived lifetime comparative risk	Much lower (0) to Much higher (6), (3) is the midpoint of the scale	Question: "What do you think your chances are of developing an invasive melanoma, compared to others of your age, gender, and skin colour?" Assesses perceived relative risk.
Diagnosis anxiety (affective risk)	Not at all (0) to (6) Extremely, (3) is the midpoint of the scale	Question: "Given the diagnosis of (the given label), how anxious do you feel? Assesses emotional response to the hypothetical diagnosis.
Experiential perceived risk (vulnerability)	Not at all (0) to (6) Extremely, (3) is the midpoint of the scale	Question: "How vulnerable do you feel to developing invasive melanoma sometime in your life?" Captures an intuitive or experiential sense of personal susceptibility.
Perceived risk of dying from melanoma	0 – 100 %	Question: "What do you think your chances are of dying from melanoma?" Numeric estimate of perceived mortality risk.

Tables and figures

Figure 1: Flow of participant



*N=40 excluded from analysis as did not finish survey

Figure 2: Perceived versus calculated lifetime risk of an invasive melanoma

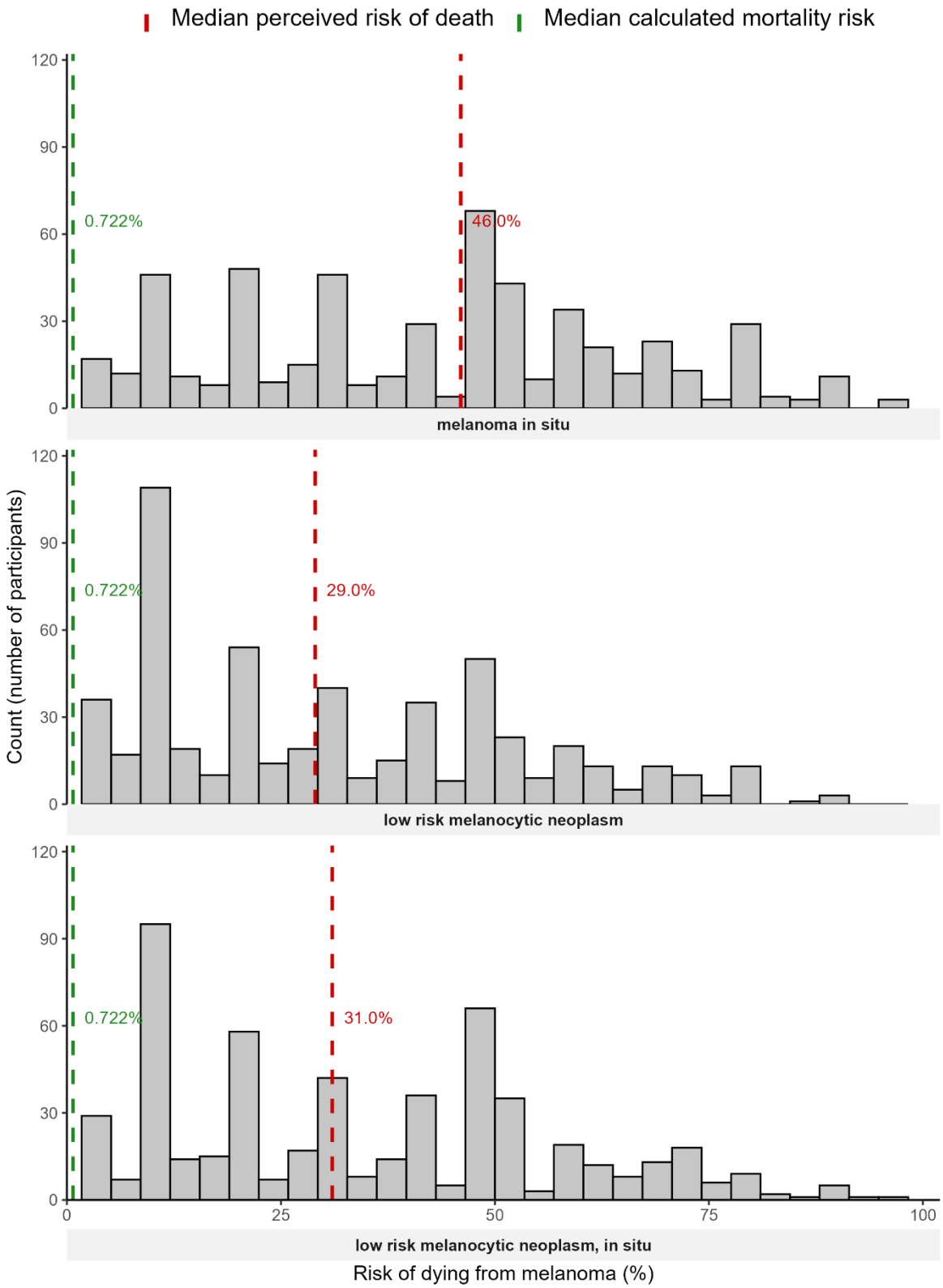


Figure 3: Perceived versus calculated risk of dying

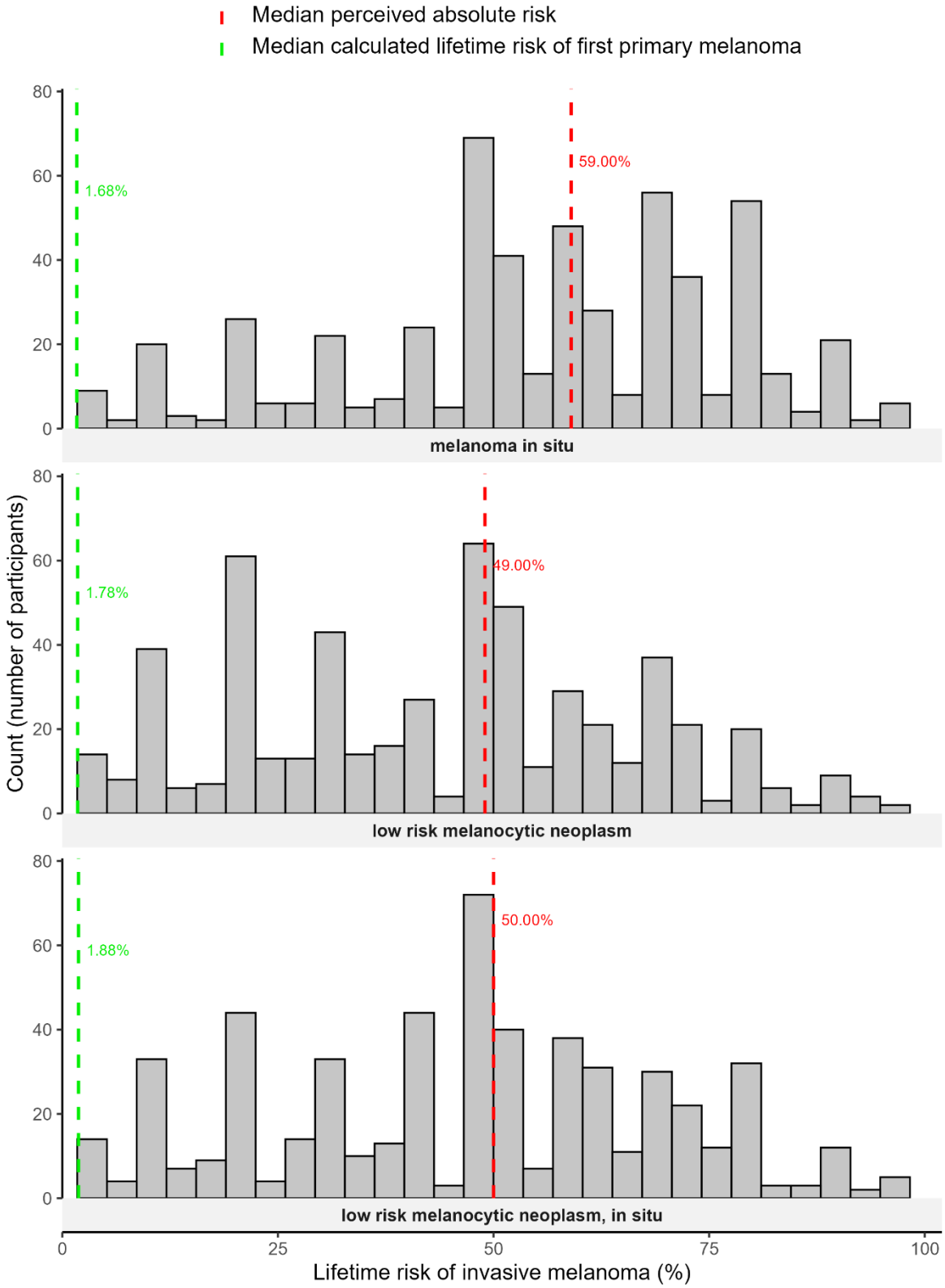


Table 1: Baseline characteristics of randomised groups: number (%)

Characteristic	Melanoma In situ (N=562)	Low risk melanocytic neoplasm (N=563)	Low risk melanocytic neoplasm, in situ (N=563)
Gender			
Women	287 (51%)	271 (48%)	285 (51%)
Male	275 (49%)	292 (52%)	278 (49%)
Age			
40-49	100 (18%)	119 (21%)	110 (20%)
50-59	123 (22%)	116 (21%)	108 (19%)
60-69	157 (28%)	154 (27%)	151 (27%)
70-79	151 (27%)	135 (24%)	162 (29%)
80 or over	31 (5.5%)	39 (6.9%)	32 (5.7%)
Indigenous	8 (1.4%)	19 (3.4%)	16 (2.8%)
Country of birth			
Australia	426 (76%)	410 (73%)	418 (74%)
English language spoken at home	535 (95%)	533 (95%)	541 (96%)
State or territory of residence			
Australian Capital Territory	8 (1.4%)	8 (1.4%)	11 (2.0%)
New South Wales	166 (30%)	175 (31%)	191 (34%)
Northern Territory	5 (0.9%)	2 (0.4%)	2 (0.4%)
Queensland	115 (20%)	116 (21%)	121 (21%)
South Australia	40 (7.1%)	41 (7.3%)	42 (7.5%)
Tasmania	15 (2.7%)	13 (2.3%)	11 (2.0%)
Victoria	159 (28%)	150 (27%)	127 (23%)
Western Australia	54 (9.6%)	58 (10%)	58 (10%)
Rurality[1]			
metropolitan	409 (73%)	412 (74%)	408 (73%)
rural	151 (27%)	147 (26%)	153 (27%)
Health insurance	294 (52%)	326 (58%)	312 (55%)
Education			
High school or less	240 (43%)	226 (40%)	256 (45%)
Non-University qualification	224 (40%)	208 (37%)	210 (38%)
University degree	98 (17%)	129 (23%)	97 (17%)
Employment[2]			
Employed	217 (39%)	261 (46%)	225 (40%)
Not in workforce	300 (53%)	263 (47%)	290 (52%)
Unemployed	44 (7.8%)	38 (6.8%)	47 (8.4%)
Income			
less than $100,000	384 (68%)	376 (67%)	373 (66%)
$100-200,000	99 (18%)	119 (21%)	119 (21%)
>$200,000	30 (5.3%)	30 (5.3%)	33 (5.9%)

Prefer not to say	49 (8.7%)	38 (6.7%)	38 (6.7%)
Health literacy			
Adequate	490 (87%)	471 (84%)	481 (85%)
Limited	72 (13%)	92 (16%)	82 (15%)
Perceived Health status			
Healthy	415 (74%)	400 (71%)	411 (73%)
Personal cancer diagnosis	127 (23%)	126 (23%)	131 (23%)
Non-melanoma skin cancer history	55 (9.8%)	56 (9.9%)	62 (11%)
Melanoma in family or other loved one	79 (14%)	73 (13%)	76 (13%)
Melanoma worry			
Not worried at all	179 (32%)	164 (29%)	171 (30%)
A bit worried	295 (52%)	312 (55%)	306 (54%)
Very/quite worried	88 (16%)	87 (15%)	86 (15%)
Hair			
Black	93 (17%)	108 (19%)	90 (16%)
Brown	292 (52%)	300 (53%)	301 (53%)
Blond/fair	155 (28%)	132 (23%)	138 (25%)
Red/auburn	22 (3.9%)	23 (4.1%)	34 (6.0%)
Moles (self reported)[3]			
None	204 (36%)	207 (37%)	209 (37%)
Few	291 (52%)	283 (50%)	289 (51%)
Some	57 (10%)	65 (12%)	62 (11%)
Many	10 (1.8%)	8 (1.4%)	3 (0.5%)
Sunbed use ever	73 (13%)	59 (10%)	70 (12%)
Maximiser (on minimiser-maximiser scale)[4]	347 (62%)	341 (61%)	324 (58%)
Wellbeing (rescaled to 0 to 100) (median, Q1, Q3)[5]	56 (36, 76)	60 (36, 76)	60 (36, 76)
Self-efficacy (rescaled to 0 to 100) (median, Q1, Q3)[6]	58 (38, 68)	58 (38, 68)	58 (30, 68)

1. Remoteness of residence missing for 4 participants in the melanocytic neoplasm group, and 2 participants in the other two randomised groups.
2. Employment status unknown for 1 participant in each randomised group.
3. Participants estimated their mole density by selecting one of four body images showing increasing numbers of moles, ranging from none/few to many.
4. Single-Item Maximiser/Minimiser Elicitation Question (MM1), higher scores indicate a maximising orientation, reflecting a preference for proactive medical action.
5. Higher scores indicate more wellbeing.
6. Higher scores indicate more self-efficacy

Table 2: Perceived Absolute and Comparative Risk, Diagnostic Anxiety, Perceived Vulnerability and Estimated Perceived Risk of Dying Across Randomised Diagnostic Label Groups

Outcome	Melanoma In situ (N=562)	Low risk melanocytic neoplasm (N=563)	Unadjusted Mean Difference (95% CI)	Adjusted Mean Difference	P value	Low risk melanocytic neoplasm, in situ (N=563)	Unadjusted Mean Difference	Adjusted Mean Difference	P value
Perceived lifetime absolute risk (scale 1 to 100 %) (mean, SD)	56.5% (22.9%)	44.0% (23.2)	-12.5% (-15.2%, -9.84%)	-12.9% (-15.4%, -10.4%)[1]	<0.0001	47.3% (1.5%)	-9.3% (-12.0%, -6.6%)	-9.4% (-11.9%, -6.9%)[1]	<0.0001
Perceived lifetime comparative risk (scale 0 to 6) (mean, SD)	3.5 (1.3)	2.9 (1.3)	-0.7 (-0.9, -0.5)	-0.6 (-0.7, -0.5)[2]	<0.0001	3.1 (1.4)	-0.5 (-0.7, -0.4)[2]	-0.4 (-0.7, -0.4)[2]	<0.0001
Diagnostic anxiety (scale 0 to 6) (mean, SD)	3.5(1.5)	2.7 (1.6)	-0.8 (-1.0, -0.6)	-0.9 (-1.0, -0.7)[3]	<0.0001	2.8 (1.5)	-0.6 (-0.8, -0.5)	-0.7 (-0.8, -0.5)[3]	<0.0001
Perceived vulnerability (scale 0 to 6) (mean, SD)	3.7 (1.4)	3.0 (1.5)	-0.7 (-0.9, -0.5)	-0.7 (-0.9, -0.6)[4]	<0.0001	3.1 (1.5)	-0.5 (-0.7, -0.4)[2]	-0.5 (-0.7, -0.4)[4]	<0.0001
Perceived dying risk (scale 1 to 100 %) (medium, IQR)	46% (39%)	(29%)39%	-10.4% (-13.1%, -7.6%)	Geometric means[5]: 32.8%, (27.0%%, 39.8)[5]	<0.0001	31%(38%)	-7.4% (-10.2%, -4.6%)	Geometric means[5]:29.1 %, (24.1%, 35.3%)[5]	<0.0001

1. Adjusted for age, partner status, Indigenous status, wellbeing, minimiser-maximiser tendencies, and melanoma worry.
2. Adjusted for age, gender identity, state or territory, partner status, health insurance, cancer diagnosis, wellbeing, minimiser-maximiser tendencies, melanoma worry, and perceived health status.

3. Adjusted for age, gender identity, state or territory, partner status, health insurance, cancer diagnosis, wellbeing, minimiser-maximiser tendencies, melanoma worry, and perceived health status.
4. Adjusted for age, gender identity, state or territory, income, partner status, country of birth, language spoken at home, Indigenous status, health insurance, wellbeing, health literacy, minimiser-maximiser tendencies, and melanoma worry.
5. Adjusted for age, state or territory, Indigenous status, melanoma cancer in partner, wellbeing, self-efficacy, health literacy, and melanoma worry. The analysis was conducted on log-transformed data. Pairwise comparisons on the back-transformed scale shows both alternative labels have ratios below 1 indicate proportionally lower perceived risk: low-risk melanocytic neoplasm (ratio = 0.68) and low-risk melanocytic neoplasm, in situ (ratio = 0.76).

Table 3. Comparison between calculated and perceived melanoma risk by diagnostic label

Outcome	Comparison (Label)	Median calculated (Median, IQR)	Median perceived (Median, IQR)	Gap (Perceived – Calculated)	Gap difference between groups	p-value[3]
First primary invasive melanoma risk (1-100%)[1]	Melanoma in situ	1.68% (1.06%-3.13%)	59% (47.2%-71.8%)	+57.3%	Ref	
	Low risk melanocytic neoplasm	1.78% (1.1%-3.26%)	49% (23%-60.5%)	+47.2%	-10.1%	<0.001
	Low risk melanocytic neoplasm, in situ	1.88% (1.1%-3.26%)	50% (30%-62%)	+48.1%	-9.2%	<0.001
Risk of dying from melanoma (1-100%)[2]	Melanoma in situ	0.0072% (0.00314-0.0239%)	46 (21%-59.9%)	+41.9%	Ref	
	Low risk melanocytic neoplasm	0.0072% (0.00314-0.0239%)	28.9 (11%-50%)	+31.6%	-10.3%	<0.001
	Low risk melanocytic neoplasm, in situ	0.0072% (0.00314-0.0239%)	31 (11%-50%)	+34.5%	-7.4%	<0.001

1. Perceived lifetime absolute risk of developing invasive melanoma – Actual lifetime risk of developing a first primary invasive melanoma.
2. Perceived risk of dying from melanoma – Actual risk of dying from melanoma (estimated by multiplying the standardized mortality ratio (SMR) for melanoma in the U.S. population by the melanoma mortality rate in the Australian population).
3. Based on the result of the Kruskal-Wallis rank sum test

The complete result used in this study is publicly available via the Open Science Framework (**10.17605/OSF.IO/6VHUW**)

Chapter 4. Exploring how diagnostic labels for low-risk melanocytic pathology shape perceived risk and management preferences

A content analysis of free-text responses in a randomised online study

In chapter 4, this study undertook a qualitative content analysis of participants' free-text responses explaining their perceived risk estimates and management preferences following a hypothetical diagnosis. While quantitative measures in the previous chapter capture the magnitude of perceived risk, free-text responses provide insight into how individuals interpret, justify, and emotionally process that risk and decision. Analysing these explanations allows examination of the reasoning underlying numerical judgments and treatment preferences, and how alternative diagnostic labels influence these.

Exploring how diagnostic labels for low-risk melanocytic pathology shape perceived risk and management preferences

A content analysis of free-text responses in a randomised online study

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Abstract

Background:

This qualitative content analysis of free-text responses from an online randomised experiment aimed to understand how alternative labels for "melanoma in situ" influence public perceptions of risk and preferences for surgery and follow-up.

Methods:

Australian adults aged ⩾40 years with no personal history of melanoma were randomised 1:1:1 to "melanoma in situ", "low-risk melanocytic neoplasm", or "low-risk melanocytic neoplasm, in situ". They estimated their lifetime risk of dying from melanoma, indicated preferences for wide local excision, and type of follow-up, and provided free text explanations of these. We analysed free text responses using inductive and deductive methods.

Results:

Of 1,668 randomised, 1,439 provided at least one free-text explanation. Participants assigned to "melanoma in situ" were less likely to perceive this label as indicating a low risk of dying from melanoma: (n=84,17.8%) vs "low-risk melanocytic neoplasm" (n=127, 26.0%) and "low-risk melanocytic neoplasm in situ" (n=121, 24.7%). They were also more likely to express fear of melanoma (14.4% vs 12.1% and 10.4% respectively) and that additional surgery was necessary to minimise the risk of recurrence (37.6% vs 33.9% and 33.3% respectively). Across all groups, most participants (n=962, 74.9%) preferred routinely scheduled clinic visits for follow-up, commonly explaining that this was the safest option (n = 758, 59.0%). Many indicated they already attended routine skin checks, reflecting the commonness of this behaviour amongst Australians.

Conclusions:

Labels that omitted the term “melanoma” resulted in some shift in perceptions toward lower risk and reduced perceived need for additional treatment. Personal experience and context were often more dominant drivers.

Practice Implications:

Future research should examine how clearer communication about prognosis and risk of melanoma in situ by clinicians can more effectively align patient perceptions with their true level of risk.

Keywords:

Melanoma in situ, Diagnostic terminology, Risk perception, Decision making, Patient-clinician communication

1. Introduction

Overdiagnosis[1-5] of MIS is recognised as a significant and growing problem in Australia [1,6-8]. Although patients with melanoma in situ (MIS) generally have long-term survival rates higher than those of age- and sex-matched population averages[9], many still perceive themselves as having a high risk of recurrence or death[10,11]. Alternative diagnostic labels that remove the word melanoma that better communicate the low-risk nature of MIS[12] may reduce psychosocial harms[11] from (over)diagnosis and allow for management choices informed by patient preferences and values rather than driven by emotive responses. It may also pave the way for the de-escalation of treatment[13] and surveillance[14-16].

This study presents a qualitative content analysis of free-text explanations collected in an online randomised experiment evaluating the effects of alternative MIS labels on perceived risk, and preferences for surgery and surveillance[17]. We aimed to deepen understanding of the interpretative processes that shape patients' reactions to different diagnostic labels, and to identify communication challenges and opportunities to improve MIS risk communication and management decisions in clinical practice[18].

2. Methods

2.1 Study design

The study was conducted within an online, randomised experiment involving Australian community members who were randomly allocated to one of three hypothetical scenarios. Each group received a different diagnostic label for the same underlying low risk melanocytic skin pathology: group 1 (Control): "melanoma in situ"; group 2: "low-risk melanocytic neoplasm"; and group 3: "low-risk melanocytic neoplasm, in situ". The choice of alternative labels was decided using a process of co-design with 9 international clinicians and 6

patient/public co-investigators (see published protocol for details[19]). Participants were recruited from the general Australian public through an independent social research company (Dynata), which has a panel of 600,000 participants whose demographic characteristics align closely with those of the national population. We excluded participants aged younger than 40 years as melanoma in situ is unlikely to diagnosed in that age agroup[20].

After reading the hypothetical scenario which included their assigned diagnosis, participants were asked to explain the reasoning behind their perceived mortality risk estimate and management preferences (Box 1). Specifically, they provided optional free-text responses to explain their answers for: perceived risk of dying from melanoma in this scenario; preference for further wide local excision (WLE) of a completely excised lesion (WLE vs no WLE); and preference for type follow-up (routinely scheduled skin checks with a doctor vs patient-led surveillance with clinical review as needed). A detailed description of the full online study is provided in the prespecified study protocol[19]. The study was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12624000740594). Ethics approval was received from The University of Sydney Human Research Ethics Committee (2024/HE000019) on 25 June 2025. Results are reported according to the Standards for reporting qualitative research[21].

2.2 Participants eligibility

Participants were eligible if they were: 40 years or older, understood written English, and resided in Australia. Participants were excluded if they had a personal history of melanoma (invasive or in-situ). Quotas were in place to ensure adequate recruitment across levels of gender, age [22], education, and state or territory of residence[23], and we randomised within strata of these participant characteristics.

2.3 Data analysis

This content analysis[24] employed a combination of inductive and deductive analytical approaches. The inductive analysis enabled unanticipated themes to emerge directly from participants' free-text responses, while the deductive component ensured systematic exploration of findings from the main study (e.g. how participants' interpretations differed quantitatively across diagnostic labels) and existing knowledge on management preferences (e.g., the common behaviour among Australians to attend clinics for routine skin checks[25]).

An initial coding framework was developed by the research team after reviewing a subset of participant responses. One researcher conducted the first round of coding and grouped responses into preliminary themes (ZW). These early themes were then reviewed by two independent researchers (KB and BN), and refinements were made through iterative discussion until consensus was achieved.

One researcher then applied the thematic coding framework to all responses (ZW). To assess the consistency of coding, 20% of responses were independently coded by two additional researchers (KB and BN). Intercoder agreement was evaluated using Cohen's kappa[26], calculated per code and then summarised using the mean kappa across all codes. After the 20% double-coding check, only minor refinements were made to the coding, and no further changes were made to existing themes or the addition of new themes.

3. Results

A total of 1,668 adults participated in the experiment, with 1,439 providing at least one free-text explanation. Of these, 1,310 respondents explained their perceived lifetime risk of death after the diagnosis (control: 426, label 1: 439, label 2: 442), 1,243 their rationale for choice of surgery (control: 410, label 1: 412, label 2: 420), and 1,226 their rationale for choice of follow-up (control: 402, label 1: 409, label 2: 412) (Figure 1). Participant characteristics were balanced across randomised groups (Table 1). Intercoder agreement was high across all

coding domains[27]. The mean Kappa coefficient indicated high reliability for perceived risk of dying (κ= 0.85), surveillance preference (κ= 0.81), and follow-up preference (κ= 0.79).

Below we present the main findings of the content analysis for each of the three questions, with themes and sub-themes. Tables 2-4 present the frequency of each theme and sub-theme by diagnostic label.

3.1 Perceived risk of dying (n=1,310)

We categorised participants' explanations for their perceived risk of dying from melanoma from the scenario into three broad themes: responses indicating a low chance of dying, a high chance of dying, or neither low nor high (other). Overall, many perceived their risk of dying from melanoma was low (n=885, 61.1%), but fewer assigned to "melanoma in situ" perceived this (n=258, 54.7%) than assigned to "low-risk melanocytic neoplasm" (n=317, 64.8%) or "low-risk melanocytic neoplasm, in situ" (n=310, 63.3%).

Explanations that the diagnostic label itself indicated a low risk of dying from melanoma were less frequent in those assigned to "melanoma in situ" (n=84, 17.8%) than to "low-risk melanocytic neoplasm" (n=127, 26.0%), or "low-risk melanocytic neoplasm, in situ" (n=121, 24.7%). The descriptor of "low-risk" often seemed to be driving these effects, for example: *"Being in the low risk category gives me confidence"* (Male, age 70- 79, 'low-risk melanocytic neoplasm, in situ') and *"It's low risk, so I don't believe my chance of dying from this would be very high"* (Male, age 40- 49, 'low-risk melanocytic neoplasm').

Others expressed a low perceived risk based on their personal behaviours or experiences - such as attending for regular skin checks, sun protection, or previous reassurance from clinicians (n=288, 19.9%); this explanation frequency was more similar across the three randomised groups: "melanoma in situ" (n=85, 18.0%), "low-risk melanocytic neoplasm" (n=101, 20.7%), "low-risk melanocytic neoplasm, in situ" (n=102, 20.8%). Personal

characteristics were more important than the hypothetical diagnosis for these participants, for example: *"I don't think I have enough moles to worry about"* (Female, age 40 - 49, 'melanoma in situ') and *"I do not go out in the sun [as] I am very aware of the damage it can do"* (Male, age 60- 69, 'low-risk melanocytic neoplasm, in situ').

Some pointed to competing health risks, noting they were more likely to die from old age or other illnesses (n=123, 8.5%). This response was less frequent among those assigned "melanoma in situ" (n=28, 5.9%), than to "low-risk melanocytic neoplasm" (n = 54, 11.0%) or "low-risk melanocytic neoplasm, in situ" (n=41, 8.5%). One participant explained: *"I think another cancer might take me earlier"* (Female, age 80+, 'low-risk melanocytic neoplasm').

A smaller group believed melanoma is generally curable when detected early, contributing to their low perceived likelihood of death (n=142, 9.8%). This explanation was more frequent in those assigned to "melanoma in situ" (n = 61, 12.9%), than to "low-risk melanocytic neoplasm" (n = 35, 7.2%) or "low-risk melanocytic neoplasm, in situ" (n = 46, 9.4%). For example: *"I think skin cancer is highly curable and low risk of death."* (Female, age 60 - 69, 'melanoma in situ').

In contrast, a significant minority of participants indicated a high risk of dying from melanoma (n=314, 21.6%). Fear-based reasoning was the most common explanation (n=178, 12.3%), with responses indicating beliefs that melanoma was inherently dangerous. This was more frequent in those assigned to "melanoma in situ" (n=68, 14.4%) than the two low-risk labels (n=59, 12.1%, and n=51, 10.4% respectively). The word "melanoma" in the diagnostic label appeared to driving this difference: *"Cancer, although disappearing for a while, always comes back and kills you, it's just a matter of time"* (Male, age 40- 49, 'melanoma in situ').

Explanations explicitly referring to the diagnosis as indicating a high-risk also were also more frequent in those assigned to "melanoma in situ" (n = 26, 5.5%), than to "low-risk

melanocytic neoplasm" label (n = 18, 3.7%), or "low-risk melanocytic neoplasm, in situ" (n = 19, 3.9%). For example: *"Melanoma diagnosis would make me think this sort of problem might happen again."* (Male, age 60- 69, "melanoma in situ").

References to high personal risk included factors such as older age or other health conditions that reduced their ability to cope with the disease. This rationale was more frequent in those assigned to "melanoma in situ" (n = 31, 6.6%), than to "low-risk melanocytic neoplasm" (n = 18, 3.7%), or "low-risk melanocytic neoplasm, in situ" (n = 24, 4.9%).

Finally, a subset of responses did not neatly align with low or high risk (n=252, 17.3%). The frequency of responses that did not engage with the scenario—either providing average / 50–50 estimates or offering no explanation—were relatively similar across labels.

3.2 Preference for surgery (n=1243)

We identified three broad themes in participants' explanations for their surgery preferences: preferred additional surgery (wide local excision, WLE), preferred no additional surgery (no WLE), and other explanations. Many participants provided explanations reflecting a preference for WLE (n=646, 49.0%); this was more frequent in those assigned to "melanoma in situ" (n=250, 56.7%) than to "low-risk melanocytic neoplasm" (n=196, 44.9%) or "low-risk melanocytic neoplasm, in situ" (n=200, 45.4%).

The most common reason provided was a desire to reduce risk or prevent recurrence, which was more frequent in those assigned to "melanoma in situ" (n=166, 37.6%), than to "low-risk melanocytic neoplasm" (n=148, 33.9%) or "low-risk melanocytic neoplasm, in situ" (n=147, 33.3%). Participants explained: *"Reduce the risk of spread"* (Female, age 50-59, 'Low-risk melanocytic neoplasm, in situ').

Others expressed a preference for complete removal of the lesion, expressing a wish to "make sure it's all gone"; this was also more frequent in those assigned to "melanoma in situ" (n=49, 11.1%) than to "low-risk melanocytic neoplasm" (n=32, 7.3%) or "low-risk melanocytic neoplasm, in situ" (n=34, 7.7%). For example: "*It's a no brainer. Make sure it's all gone".* (Female participant age 50-59, from 'melanoma in situ' group).

A few preferred WLE due to personal health conditions that made them favour a more aggressive approach (n=24, 1.8%), or linked their preference directly to high-risk perceptions, including concerns about "melanoma," "cancer spread" (n=46, 3.5%), with similar frequencies across diagnostic labels for these subthemes.

In contrast, a significant minority indicated they would forgo WLE (n=503, 38.2%). Participants expressed that the lesion posed minimal threat and did not warrant additional surgery; this explanation was less frequent in those assigned to "melanoma in situ" (n=78, 17.7%) than to "low-risk melanocytic neoplasm" (n=102, 23.3%) or "low-risk melanocytic neoplasm, in situ" (n=115, 26.1%). *Participants explained: "Seems like the extra surgery not worth it based on the risk of [diagnostic label]"* (Male, age 70-79, 'low risk melanocytic neoplasm, in situ').

Others preferred to avoid unnecessary medical procedures in general, expressing a preference for conservative or less invasive management approaches; this explanation was also less frequent in those assigned to "melanoma in situ" (n=25, 5.7%), than to "low-risk melanocytic neoplasm" (n=52, 11.9%) or "low-risk melanocytic neoplasm, in situ" group (n=36, 8.2%). For example: *"Traditionally I tend to avoid invasive procedures if at all possible"* (Female, age 70-79, 'low risk melanocytic neoplasm').

Smaller numbers cited the harms or burdens of surgery - such as scarring, pain, inconvenience, or recovery difficulties (n=52, 3.9%) or indicated that their personal health conditions made further surgery undesirable (n=43, 3.3%).

Finally, a subset of responses did not clearly align with either invasive or conservative preferences participants (n=170, 12.9%). Some participants expressed uncertainty or an intention to defer to clinician advice (n=133, 10.1%), often stating they would "*Discuss with my doctor*" (Female, age 70-79, 'melanoma in situ') rather than rely on their own judgment.

3.3 Follow-up management preference (n=1226)

In the last question, we categorised participants' explanations for their preferred type of follow-up into three overarching themes: preference for professional medical care, preference for self-examination, and preference for both/other explanations. The preference for routinely scheduled clinic visits was high across all groups (n=962, 74.9%). Across all diagnostic labels, the most common explanation was a desire for safety assurance and confidence in doctor expertise (n=758, 59.0%). This explanation was more frequent in those assigned to "melanoma in situ" (266, 62.4%), than to "low-risk melanocytic neoplasm" (242, 55.9%), or "low-risk melanocytic neoplasm, in situ" (250, 58.7%). A participant explained: *"I would prefer an expert check as I consider I would be high risk of developing another tumor"* (Female, age 40-49, 'melanoma in situ').

Participants often described clinicians as more capable of detecting concerning changes or felt reassured by professional oversight. Some people directly referenced their personal experience with attending routinely scheduled skin check clinics (n=64, 5.0%) a behaviour that is relatively common in the general Australian population. Others indicated limited ability to self-check due to difficulty seeing certain body areas (n=84, 6.5%), or a preference

for professional follow-up because of the convenience of doctor visits (n=37, 2.9%), or because they believed they had a high personal risk of melanoma (n=19, 1.5%).

Only a minority of participants provided explanations aligning with a preference for self-examination (n=214, 16.6%). These responses, indicating a proactive approach to monitoring their own skin, were less frequent among those assigned to “melanoma in situ” (n=22, 5.2%), than to “low-risk melanocytic neoplasm” (n=34, 7.9%) or to “low-risk melanocytic neoplasm, in situ" (n=28, 6.6%). A participant explained: *“Prefer to check myself and if I find anything, will return to the doctor.”* (Female, age 40- 49, ‘low-risk melanocytic neoplasm’).

Others described the efficiency of self-monitoring in terms of time, cost, or convenience (n=58, 4.5%), or cited low perceived risk in the hypothetical scenario (n=46, 3.6%) or believed their personal health characteristics meant they did not need professional follow-up (n=26, 2.0%).

Lastly, a subset of responses did not clearly indicate a preference for either option (n=109, 8.5%). Some expressed uncertainty or the desire for further medical advice before deciding (n=40, 3.1%), while others explicitly wanted both self-examination and professional care (n=20, 1.6%).

4. Discussion and conclusion

4.1 Discussion

Across all diagnostic labels, many participants perceived a high risk of dying from melanoma, with alternative labels prompting more benign interpretations and less fear than the “melanoma in situ” label. Participants assigned to “melanoma in situ” were more likely

to perceive that WLE was needed – with explanations that this would minimise the risk of a recurrence, remove "all of it", and manage the inherent danger posed by the lesion. Across all groups, most participants preferred routinely scheduled clinic visits for follow-up, with many indicating this was the safest option for early melanoma detection. There was a suggestion that alternative labels may have resulted in a small shift towards self-monitoring, but differences were small.

Overall, this content analysis demonstrates that diagnostic terminology influences participants' interpretations of the condition and their management preferences, consistent with findings from studies of low-risk thyroid cancer[28,29] and ductal carcinoma in situ of the breast[30]. Fear of cancer and reliance on doctor expertise remained dominant themes in our study for explanations of surgery and follow-up preferences, which were also found in the studies of other low-risk cancers[29,30]. Across all three questions in our study, many participants drew on their own preventive behaviours, medical history, and general attitudes toward cancer rather than relying solely on the hypothetical diagnostic information provided. This agrees with others' findings that factors such as personal beliefs and lived experiences consistently play a central role in shaping perceived risk and management preferences[31].

Changes in diagnostic terminology can frame risk differently but may not be sufficient to improve risk understanding or drive treatment de-escalation. This highlights a critical disconnect: even with more accurate labelling, the default assumption of high risk in the Australian context may make it difficult to address the underlying fear driving the preference for more health care. These findings highlight the need for clearer communication about the low risk of future adverse events after a melanoma in situ diagnosis, and to include discussions that more healthcare is not always better or necessary[32]. Communication strategies currently used by clinicians and public health officials may not sufficiently contextualise the low risk of these lesions. This may be especially pertinent in the Australian

context, where public awareness campaigns, high incidence rates, and widespread engagement in routine skin checks contribute to heightened fear of melanoma and stronger default assumptions that any melanocytic lesion carries meaningful cancer risk[25].

To help clinicians better explain what they mean by low risk to patients, risk communication tools and decision aids designed according to best practice principles may be beneficial[33-35]. Communication strategies incorporating cultural context, personal health histories[36], and supportive decision aids may reduce confusion, alleviate cancer anxiety, and promote informed decision-making[37]. Future research could explore how diagnostic terminology, risk communication, and decision support tools may be best integrated, in order to strengthen public understanding and empower patients to make management choices aligned with their values and clinical risk[18,38].

This study has several strengths, including its randomised design and a large representative Australian sample. However, our findings should be interpreted within the context of study limitations. As participants were responding to a hypothetical scenario rather than a real diagnosis, their perceptions may not reflect the emotion of real-world decision-making following an actual diagnosis. In particular, they were told that their doctor advised that they recommended either surgery option and either follow-up option as suitable. While this allowed us to elicit participants' management preferences, most clinicians will follow current clinical guidelines and recommend wide local excision and clinical surveillance. The Australian context may also limit the generalisability of findings to other settings with lower melanoma incidence, mortality, and public awareness, and where prevention campaigns have been less prominent[25]. While general themes were identifiable, not all reasoning could be confidently categorised, and some responses were brief or lacked detail, limiting the ability to capture the full nuance of participants' thought processes. More in-depth qualitative analysis (e.g., through interviews) may help to explore these perspectives further.

4.2 Conclusion

Alternative diagnostic labels to MIS shifted participants' risk perceptions and influenced their management preferences; however, label effects were often outweighed by broader contextual influences.

4.3 Practice implication

The causes and potential solutions for melanoma overdiagnosis are complex, multifactorial, and interrelated[39], and adopting an alternative label could be one part of the solution. It is essential to consider carefully how low-risk melanocytic lesions are both labelled and explained. Clearer, more proportionate terminology may help explain the non-invasive nature of melanoma in situ, which helps reduce unnecessary anxiety and support rational decision-making. Clinicians also may benefit from how the diagnostic terms themselves frame patient understanding before any treatment is discussed. Regardless of whether labels are revised, enhancements in risk communication are still needed, and changes in terminology alone are unlikely to resolve the broader challenges of overdiagnosis. Effective risk communication strategies are needed to clearly convey the low biological risk of these lesions and support informed decision-making, regardless of whether the diagnostic label itself is modified.

The findings may also have implications for clinical guidelines and patient education materials. If terminology evolves to better reflect biological behaviour, treatment and follow-up recommendations must remain consistent with this framing to avoid mixed messages. Decision aids and other resources should be reviewed to ensure that language accurately conveys low risk without minimising the need for appropriate follow-up. Aligning terminology, risk communication, and management guidance may help reduce overtreatment while maintaining patient safety.

Data availability

De-identified data will be made available upon reasonable request. The complete result used in this study is publicly available via the Open Science Framework (10.17605/OSF.IO/6VHUW).

Declaration of generative AI and AI-assisted technologies in the manuscript preparation process.

During the preparation of the paper, the author used the University of Sydney protected version of Microsoft Copilot for the purposes of text enhancement. The use of this generative AI tool includes sentence structure and spelling. The author confirms that where text was modified by generative AI, the content was reviewed for possible errors, inaccuracies, and bias. The author takes full responsibility for the submitted thesis and ensures the work is their own and has used generative AI within the parameters of use.

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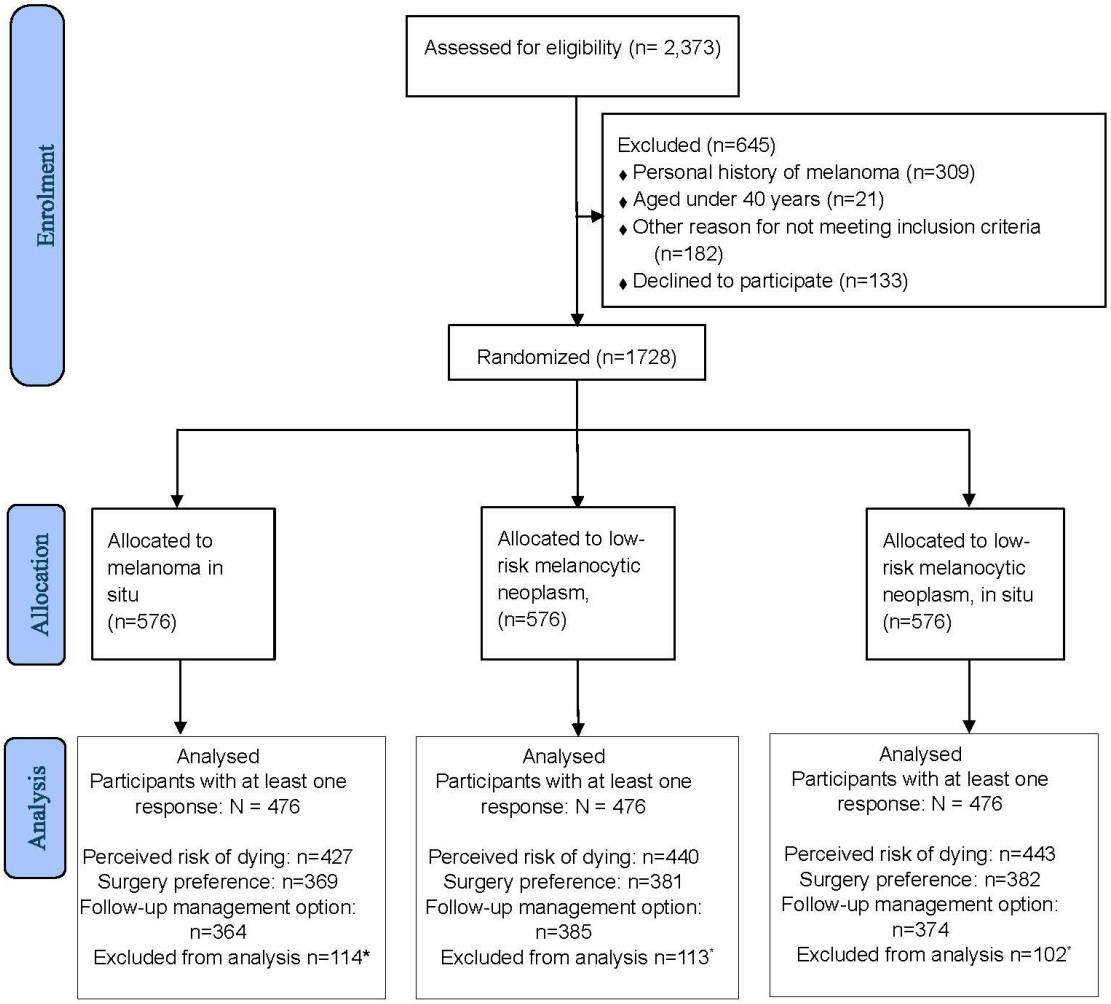
Tables and figures

Figure 1: Flow of participant



*N=40 excluded from analysis as did not finish survey

Table 1: Baseline characteristics of randomised groups: number (%)

Characteristic	melanoma in situ (N = 476)	low risk melanocytic neoplasm (N = 476)	low risk melanocytic neoplasm, in situ (N = 487)
Age			
40-49	79 (17%)	92 (19%)	91 (19%)
50-59	100 (21%)	99 (21%)	90 (18%)
60-69	138 (29%)	129 (27%)	135 (28%)
70-79	130 (27%)	119 (25%)	144 (30%)
80+	29 (6.1%)	37 (7.8%)	27 (5.5%)
Gender			
Female	241 (51%)	233 (49%)	238 (49%)
Male	235 (49%)	243 (51%)	249 (51%)
Education			
High school or less	203 (43%)	196 (41%)	211 (43%)
Non-University	85 (18%)	72 (15%)	79 (16%)
Other	103 (22%)	101 (21%)	110 (23%)
University degree	85 (18%)	107 (22%)	87 (18%)
Employment[1]			
Employed	187 (39%)	219 (46%)	192 (40%)
Not in workforce	252 (53%)	226 (48%)	256 (53%)
Unemployed	36 (7.6%)	30 (6.3%)	38 (7.8%)
Income			
$100-200,000	88 (18%)	99 (21%)	99 (20%)
>$200,000	23 (4.8%)	25 (5.3%)	30 (6.2%)
less than $100,000	325 (68%)	322 (68%)	329 (68%)
Prefer not to say	40 (8.4%)	30 (6.3%)	29 (6.0%)
Partner status			
No Partner	102 (21%)	91 (19%)	78 (16%)
Partnered	293 (62%)	299 (63%)	321 (66%)
Previously Partnered	81 (17%)	86 (18%)	88 (18%)
Birth country			
Australia	363 (76%)	352 (74%)	359 (74%)
New Zealand	15 (3.2%)	15 (3.2%)	14 (2.9%)
Other	53 (11%)	68 (14%)	55 (11%)
UK	45 (9.5%)	41 (8.6%)	59 (12%)
Language at home			
English	454 (95%)	457 (96%)	469 (96%)
Non-English	22 (4.6%)	19 (4.0%)	18 (3.7%)
Indigenous			
No	460 (97%)	449 (94%)	468 (96%)
Prefer not to say	9 (1.9%)	13 (2.7%)	8 (1.6%)
Yes	7 (1.5%)	14 (2.9%)	11 (2.3%)
Health insurance	250 (53%)	272 (57%)	270 (55%)
Rurality[2]			
Metro	343 (72%)	346 (73%)	352 (73%)
Non-Metro	132 (28%)	126 (27%)	133 (27%)
Personal cancer diagnosis[3]	115 (24%)	109 (23%)	120 (25%)

Non-melanoma skin cancer history	53 (11%)	52 (11%)	59 (12%)
Melanoma history in family or partner	69 (14%)	66 (14%)	70 (14%)
Wellbeing (rescaled to 0 to 100) (median, Q1, Q3)[4]	55 (25) 60 (36, 76)	56 (24) 60 (36, 76)	55 (25) 60 (36, 76)
Self-efficacy (rescaled to 0 to 100) (median, Q1, Q3)[5]	50 (21) 58 (38, 68)	50 (22) 58 (38, 68)	48 (23) 55 (30, 68)
Health literacy			
Adequate health	417 (88%)	407 (86%)	422 (87%)
Limited health	59 (12%)	69 (14%)	65 (13%)
Maximiser (on minimiser-maximiser scale)[6]			
Maximiser	298 (63%)	297 (62%)	279 (57%)
Melanoma worry			
A bit worried	250 (53%)	264 (55%)	258 (53%)
Not worried at all	145 (30%)	137 (29%)	147 (30%)
Very/Quite worried	81 (17%)	75 (16%)	82 (17%)

Notes

1. Employment status unknown for 1 participant in each randomised group
2. Remoteness of residence was missing for 4 participants in the melanocytic neoplasm group, and 3 participants in the other two randomised groups.
3. Personal cancer history missing for 4 participants in the melanocytic neoplasm group, and 4 participants in the other two randomised groups.
4. Higher scores indicate more wellbeing.
5. Higher scores indicate more self-efficacy
6. Single-Item Maximiser/Minimiser Elicitation Question (MM1), higher scores indicate a maximising orientation, reflecting a preference for proactive medical action.

Table 2. Themes in explanations provided for perceived risk of dying from melanoma

Themes and subthemes	Explanation of themes	Melanoma in situ (n = 472)	Low-risk melanocytic neoplasm (n = 489)	Low-risk melanocytic neoplasm, in situ (n = 490)	Total (N = 1451)
Lower risk of dying					
Low-risk diagnosis perception from the diagnostic label	Participants interpreted the diagnostic label and accompanying scenario as indicating a low-risk situation.	84 (17.8%)	127 (26.0%)	121 (24.7%)	**332 (22.9%)**
Low personal risk	These participants drew on aspects of their own lifestyle, health behaviours, or past experiences to justify a low perceived risk	85 (18.0%)	101 (20.7%)	102 (20.8%)	**288 (19.9%)**
Competing medical risks	They described pre-existing conditions or age-related vulnerabilities that they felt were more likely to cause death than melanoma.	28 (5.9%)	54 (11.0%)	41 (8.4%)	**123 (8.5%)**
Melanoma is curable	They believed treatments available made death from melanoma unlikely.	61 (12.9%)	35 (7.2%)	46 (9.4%)	**142 (9.8%)**
		258 (54.7%)	317 (64.8%)	310 (63.3%)	**885 (61.0%)**
Higher risk of dying					
High-risk diagnosis from the diagnostic label	Participants' interpretation of the diagnostic wording, or the scenario triggered concerns about cancer.	26 (5.5%)	18 (3.7%)	19 (3.9%)	**63 (4.3%)**

High personal risk	Participants mentioned factors such as older age, a history of skin cancer, or other health conditions that weakened their ability to cope with the disease.	31 (6.6%)	18 (3.7%)	24 (4.9%)	**73 (5.0%)**
Fear of melanoma	Some participants expressed general fear-based beliefs about melanoma being inherently dangerous, aggressive, or incurable.	68 (14.4%)	59 (12.1%)	51 (10.4%)	**178 (12.3%)**
		125 (26.5%)	95 (19.4%)	94 (19.2%)	**314 (21.6%)**
Other					
Average	Participants provided mid-range estimates or described themselves as having an "average" risk.	32 (6.8%)	31 (6.3%)	39 (8.0%)	**102 (7.0%)**
No explanation	Nonsensical responses or stated a number without justification.	57 (12.1%)	46 (9.4%)	47 (9.6%)	**150 (10.3%)**
Total responses		**472 (100%)**	**489 (100%)**	**490 (100%)**	**1451 (100%)**

Table 3. Themes in explanations provided surgery preference

Themes and subthemes	Explanation of themes	Melanoma in situ (n = 441)	Low-risk melanocytic neoplasm (n = 437	Low-risk melanocytic neoplasm, in situ (n = 441)	Total (N = 1319)
Additional surgery preference					
Risk reduction / prevent recurrence	Participants believed it would better ensure complete removal of the lesion and minimise any possibility of the cancer returning.	166 (37.6%)	148 (33.9%)	147 (33.3%)	**461 (35.0%)**
Personal health conditions favouring more surgery	Some participants felt that their existing health issues placed them at greater vulnerability.	14 (3.2%)	5 (1.1%)	5 (1.1%)	**24 (1.8%)**
General preference for complete removal	Participants expressed a broad preference for removing "all of it" without stating the specific reason. This view was less about the specific scenario and more about personal attitudes toward cancer management.	49 (11.1%)	32 (7.3%)	34 (7.7%)	**115 (8.7%)**
High risk perception (melanoma / cancer concerns)	These participants believed that melanoma or cancer is inherently dangerous, wanting more extensive treatment regardless of the lesion's described risk level.	21 (4.8%)	11 (2.5%)	14 (3.2%)	**46 (3.5%)**
		250 (56.7%)	196 (44.8%)	200 (45.4%)	646 (49.0%)
No additional surgery preference					

Harms / burden of surgery	Participants under this sub-theme emphasised the physical, emotional, or logistical burdens of surgery—including pain, scarring, recovery time, cost, and impact on daily life.	16 (3.6%)	19 (4.3%)	17 (3.9%)	**52 (3.9%)**
Personal health conditions favouring less surgery	Some participants' existing medical issues or physical limitations made surgery undesirable or riskier.	14 (3.2%)	18 (4.1%)	11 (2.5%)	**43 (3.3%)**
Preference for conservative / less invasive management	Participants in this category preferred monitoring, minimal intervention, or stepwise treatment rather than immediate aggressive action.	25 (5.7%)	52 (11.9%)	36 (8.2%)	**113 (8.6%)**
Low risk perception / perceived unnecessity	Participants felt that the described lesion did not pose enough risk to justify further surgery.	78 (17.7%)	102 (23.3%)	115 (26.1%)	**295 (22.4%)**
		133 (30.2%)	191 (43.7%)	179 (40.6%)	**503 (38.1%)**
Other					
Uncertainty / follow doctor recommendation	These participants expressed indecision or indicated they would rely on their doctor's expertise to guide the choice.	44 (10.0%)	40 (9.2%)	49 (11.1%)	**133 (10.1%)**
Other	These responses were vague, unrelated to the decision, or too unclear to interpret.	14 (3.2%)	10 (2.3%)	13 (2.9%)	**37 (2.8%)**
Total		**441 (100%)**	**437 (100%)**	**441 (100%)**	1319 (100%)

Table 4. Themes in explanations provided for follow-up preference

Themes and subthemes	Explanation of themes	Melanoma in situ (n = 426)	Low-risk melanocytic neoplasm (n = 433)	Low-risk melanocytic neoplasm, in situ (n = 426)	Total (N = 1285)
Preference for professional medical care					
Safety assurance / reliance on doctor expertise	Participants commonly preferred doctor-led follow-up because they believed professionals were more skilled at detecting early signs of recurrence or new lesions.	266 (62.4%)	242 (55.9%)	250 (58.7%)	**758 (59.0%)**
Personal experience with skin checks	Participants referred to their prior experiences with regular skin examinations or previous diagnoses.	16 (3.8%)	29 (6.7%)	19 (4.5%)	**64 (5.0%)**
Limited ability to self-check	Participants mentioned difficulty seeing or assessing parts of their body.	30 (7.0%)	27 (6.2%)	27 (6.3%)	**84 (6.5%)**
Preference due to convenience of doctor visits	For some, attending scheduled appointments was easier or more structured than self-monitoring.	12 (2.8%)	17 (3.9%)	8 (1.9%)	**37 (2.9%)**
Perceived high personal risk	A smaller group believed they were personally at higher risk due to age, skin type, medical history, or previous skin cancer.	7 (1.6%)	7 (1.6%)	5 (1.2%)	**19 (1.5%)**
		331 (77.7%)	322 (74.4%)	309 (72.5%)	**962 (74.9%)**
Preference for self-examination					

Self-efficacy / proactive stance	These participants felt capable of monitoring their own skin changes and valued taking responsibility for their health.	22 (5.2%)	34 (7.9%)	28 (6.6%)	**84 (6.5%)**
Efficiency (time/cost/convenience)	Participants cited practical benefits such as avoiding travel, appointments, waiting times, or medical costs.	14 (3.3%)	21 (4.8%)	23 (5.4%)	**58 (4.5%)**
Low risk perception from scenario	Some participants interpreted the hypothetical diagnosis as low risk, leading them to believe professional oversight was unnecessary.	15 (3.5%)	15 (3.5%)	16 (3.8%)	**46 (3.6%)**
Low personal risk (personal condition/history)	Participants grounded their reasoning in personal factors such as few moles, minimal sun exposure, young age, or a history of good skin health.	6 (1.4%)	7 (1.6%)	13 (3.1%)	**26 (2.0%)**
		57 (13.4%)	77 (17.8%)	80 (18.8%)	**214 (16.6%)**
Code for both / Other					
Uncertainty / wanting further medical advice	These participants lacked confidence in choosing between professional care and self-examination.	12 (2.8%)	16 (3.7%)	12 (2.8%)	**40 (3.1%)**
Wanting both options	Some participants felt that a combination of self-examination and periodic professional review would be more suitable.	10 (2.3%)	6 (1.4%)	4 (0.9%)	**20 (1.6%)**
Other	These responses were too vague, unrelated, or unclear to interpret meaningfully.	16 (3.8%)	12 (2.8%)	21 (4.9%)	**49 (3.8%)**
Total		**426 (100%)**	**433 (100%)**	**426 (100%)**	**1285 (100%)**

Box 1. Free-text prompt questions and clinical scenarios presented to participants

Outcome	Prompt / Scenario	Response Options	Free-text component
Outcome 1: Perceived risk of dying	"Given the diagnosis of 'assigned label', on a scale from 0–100%, what do you think your chances are of dying from melanoma?"	Numeric scale: 0–100%	Participants provided a free-text explanation
Outcome 2: Surgery preference	A doctor asks: "Would you like us to perform additional surgery to remove more normal skin around the scar, or would you prefer no further surgery at this time? Both options are reasonable, and we will arrange whichever you choose."	No further surgery (scar already excised with 3-mm margins); or Further surgery (additional excision to increase margins to 5 mm)	Participants provided a free-text explanation
Outcome 3: Follow-up management preference	"Your doctor explains that you may choose regular 6-month skin checks, or learn to check your skin yourself (with tele-dermatologist support) and book appointments only if needed. Both options are reasonable."	Patient-led surveillance (self-checks with tele-support); or Regular 6-month doctor visits	Participants provided a free-text explanation

Chapter 6. Discussion

Principal Findings

This thesis aimed to (i) assess the effects of alternative labels for melanoma in situ on perceived risk of an invasive melanoma diagnosis and of dying from melanoma, and (ii) understand possible mechanisms for label effects on risk perception and management preferences. This was addressed through three papers prepared for publication in peer-reviewed medical journals (one published and two submitted).

In Chapter 2, I presented the study protocol for the online randomised study, which laid the foundation for the entire MPhil project. The protocol's primary outcomes are to assess whether alternative labels of melanoma in situ influence: surgery preference (no further surgery versus additional surgery to achieve clear margins greater than 0.5 mm) and follow-up preference (patient-led surveillance with clinical review when needed versus routinely scheduled clinical review). The protocol includes secondary outcomes that are the focus of this MPhil thesis: perceived risk of invasive melanoma and of dying from melanoma, and free-text explanations for risk of dying, surgery preference, and follow-up preference. For context, the report of label effects on the primary outcomes is included in the appendix (see Appendix B).

In Chapter 3, I described the impact of the new diagnostic labels on perceived vs calculated risk of invasive melanoma and of dying from melanoma as a pre-specified secondary analysis of the online randomised experiment. In this study, I found that the label "melanoma in situ" was consistently perceived as indicating higher risk than the alternative labels "low-risk melanocytic neoplasm" and "low-risk melanocytic neoplasm, in situ". Removing the word "melanoma" significantly lowered participants' perceived risk of invasive melanoma and of dying from melanoma. This labelling effect resulted in reductions in perceived lifetime risk

of these events of up to 12% (0%–100% scales). The influence of terminology extended beyond numerical estimates to a broader psychological construct of risk, incorporating affective and experiential dimensions such as experiential risk (anxiety) and perceived vulnerability. Across outcomes, including numerical estimates for perceived lifetime risk of invasive melanoma or dying from melanoma, verbal likelihood descriptors (e.g., 0 = 'not at all' to 6 = 'extremely') for comparative risk, experiential risk, and felt vulnerability questions, the pattern remained consistent - 'melanoma in situ' was perceived as indicating higher risk than the two alternative labels. This suggests that the alternative diagnostic labels influenced not only cognitive estimation but also emotional appraisal. Both alternative labels decreased perceptions of risk; however, inclusion of 'in situ' in the label did not result in additional effects to 'low-risk melanocytic neoplasm' alone and was numerically less effective. The reason for this is unclear, with one possibility being that the added words introduced complexity or lacked sufficient clarity for lay understanding. Our results suggest that the combination of the absence of the "low-risk" descriptor and the presence of the word "melanoma" both drives increased perceived threat. There was a profound disconnect between the risk perceived by the individual and their actual calculated risk of developing invasive melanoma and their risk of death following diagnosis. While we observed the greatest overestimation in those assigned the "melanoma in situ" label, nearly all participants in all groups overestimated their risk, and many substantially did so.

In Chapter 4, I explored how the alternative diagnostic labels shaped perceived risk and management preferences in a content analysis of free text responses provided in the online randomised experiment. The qualitative findings aligned closely with quantitative results from Chapter 3 and the main study findings (see Appendix B). The alternative diagnostic labels were interpreted as lower risk and resulted in less fear than the "melanoma in situ" label. In addition, participants assigned to "melanoma in situ" were more likely to perceive

that additional surgery was needed to minimise the risk of a recurrence, even though the lesion had been completely excised. The content analysis demonstrates that diagnostic terminology influences participants' interpretations of the condition and their management preferences. The labels had less effect on participant preference for the type of follow-up, with a large majority preferring routinely scheduled clinic visits across all label groups. There was some signal of greater willingness to self-monitor in those assigned to the alternative labels, other factors, such as personal beliefs and lived experiences were more dominant in shaping their follow-up preferences[1]. The free-text responses to the perceived risk of dying question indicated that the numerical overestimation of risk (perceived vs actual calculated risk) found in Chapter 3 may have been partly due to inadequate understanding of probability among participants. Many explanations that indicated reassurance or confidence that their risk was minimal (e.g., “I’m not worried,” and “it is treatable”) matched to numerical estimates that were higher than would be expected for someone who genuinely felt low risk (48% and 50% risk of dying for the explanations above). Other participants used language indicating they were concerned (e.g., “sounds worrying,” and “it’s scary”) while choosing relatively low numerical probabilities (27% and 30% risk, respectively). The comparative risk appeared to show closer agreement with the tone and direction of participants’ qualitative reasoning. This suggests that comparative risk judgments may better capture participants’ intuitive interpretations of diagnostic labels, particularly when absolute percentage estimates were inflated or internally inconsistent. This is in keeping with other findings on the general poor understanding of probabilities and numerical risk in the community[2,3].

This suggests that comparative risk judgments may better capture participants’ intuitive interpretations of diagnostic labels, particularly when absolute percentage estimates were inflated or internally inconsistent.

Significance of Findings

Together, this thesis provides robust experimental evidence that the two alternative diagnostic labels" low-risk melanocytic neoplasm" and "low-risk melanocytic neoplasm, in situ" meaningfully reduce perceived disease severity and preference for escalated treatment compared to "melanoma in situ". These findings extend prior literature on cancer labelling effects[4-7], by demonstrating the impacts of diagnostic labels for low-risk melanocytic pathology on risk perception and management preferences. Our findings also highlight the importance of best-practice risk communication to help people interpret probabilistic information about low-risk cancers[2,3]. Developing and evaluating implementation strategies for this, including decision support tools, are likely to be synergistic with the adoption of alternative diagnostic labels in correcting risk overestimation and de-escalating care. Inflated perceptions of risk are clinically significant as they can drive anxiety, preference for aggressive treatment, and requests for increased surveillance - factors contributing to health care overuse, including overdiagnosis and overtreatment[4,8]. When "melanoma in situ" was used, participants were more likely to perceive that additional surgery was needed to manage inherent danger. The qualitative content analysis illuminates why this label effect might occur. The term "melanoma" appears to trigger more fear-based reasoning and the assumption of lethality, with the "low-risk" descriptor lessening this perceived threat. Participants assigned the "melanoma in situ" label were more likely to believe that other conditions were less likely to cause death than their skin lesion, and more frequently cited fear-driven reasoning for aggressive treatment.

The impact of terminology was consistently moderated by participants' lived experiences, emotional responses, and general attitudes toward cancer. As observed in other qualitative studies of low-risk cancer[9,10], fear of cancer and reliance on doctor expertise remained dominant themes. Many participants drew on their own preventive behaviours and medical

history rather than relying solely on the hypothetical diagnostic information provided. This indicates that while diagnostic labels are powerful, they may also compete with deeply ingrained cultural narratives about cancer. We believe this may explain why more than 75% of our participants preferred routinely scheduled clinic visits in all label groups. These findings may be somewhat specific to the Australian context of the study, where high incidence rates, public awareness campaigns, and widespread engagement in skin checks[11] likely contribute to a heightened fear of melanoma and a default assumption that any melanocytic lesion carries meaningful cancer risk.

There is debate in the dermatopathology community about proposals to reconsider terminology for low-risk melanocytic lesions, with recognition that clearer, more standardised, and risk-aligned terminology is needed [12]. Recent evidence highlights both the variability in current diagnostic practice and the momentum toward revising classification systems[13,14], suggesting a favourable environment for adopting terminology that more accurately reflects biological risk[15]. Questions have also been raised about whether the term "melanoma" may overstate the clinical threat, leading to unnecessary wide local excision [16].

In October 2024, the Australian Government announced funding to develop a National Targeted Skin Cancer Screening Program Roadmap in the country[17]. If implemented, a national targeted screening program is likely to further increase the detection of MIS. While this may beneficially increase the early detection and treatment of potentially lethal melanomas, it will also increase harms from overdiagnosis, overtreatment, and the associated costs of MIS. Adoption of more accurate, risk-aligned terminology could reduce patient harm and health resource use associated with increased MIS diagnosis.

Strengths and limitations

Strengths include the randomised study design, which enabled robust comparison of diagnostic labels on risk perception and management preferences. The study was co-designed with consumers and clinicians to ensure labels and evidence were relevant to end-users. The large online randomised study was broadly representative of adults in the Australian community. Limitations include the hypothetical nature of the study, which meant it could not capture actual experiences of patients after a melanoma in situ diagnosis (or alternative label) diagnosis, although this is a relatable scenario for most Australians (given the high rate of melanoma in situ diagnosis in Australia). Less realistic was the framing that the doctor had advised that either management choice was reasonable for decisions on wide local excision and the type of follow-up. While this allowed us to elicit participant management preference, most clinicians will follow current clinical guidelines and recommend wide local excision and clinical surveillance.

Future Research

Our findings suggest that while revising diagnostic terminology is an important first step to convey the true biological nature of the condition, labels alone may not be sufficient to fully align patient perception with clinical reality. Future research should investigate how terminology can be paired with risk communication tools and decision aids to improve patient understanding[18]. Clearer communication strategies must account for the cultural context and the emotional weight of cancer language to reduce anxiety and support evidence-based, proportionate management choices[19]. Providing clearer, more understandable information may improve patient knowledge and increase willingness to undertake recommended treatments[20]. Investigating how new diagnostic labels may impact clinician risk perception and management decisions is also critically important, given that many

patients rely on their doctor's advice for management, and indeed this may not often be presented as a decision that is shared with the patient.

Conclusion

Alternative diagnostic labels to MIS shifted participants' perceptions and affected their management preferences. Adopting clearer, less alarming terminology for low-risk melanocytic pathology may support more proportionate decision-making and reduce unnecessary overtreatment. With or without alternative labels, clearer communication about the prognosis and risk is needed to support patients in understanding the low probability of adverse outcomes and to better align perceptions with actual clinical risk. In addition, updates to clinical management guidelines for melanoma in situ are also needed to ensure clinician recommendations are consistent with the evolving evidence base.

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Appendix A. Ethics approval

THE UNIVERSITY OF SYDNEY

RESEARCH INTEGRITY
& ETHICS ADMINISTRATION

HUMAN RESEARCH ETHICS APPROVAL

The University of Sydney confirms that this project meets the requirements of the National Statement on Ethical Conduct in Human Research.

Project identifier:	2024/HE000019
Project title:	The potential impact of alternative diagnostic labels for Melanoma in-situ (MIS) on psychological outcomes and health care use: An online randomized study
Version:	0.01
Chief Investigator:	Katy (Catherine) Bell
Authorised project team:	Kirsten McCaffery Brooke Nickel Zhuohan Wu
Date of approval:	Monday, 6 May, 2024
Project end date:	05 May 2028

Project summary

This study explores whether an alternative label used to communicate a hypothetical melanoma in-situ diagnosis influences management choice and level of anxiety among members of the Australian community. Participants will be presented with a hypothetical scenario where they are randomly given a diagnosis of melanoma in-situ (control label) or one of two alternative labels (e.g. melanocytic lesion, melanocytic neoplasm). They will then be asked to choose between different management options, such as whether they would have additional surgical removal of skin around the scar site or not, and whether they would prefer six monthly clinic review by a melanoma doctor, or to be taught to undertake skin self-examination themselves.

Documents approved

Document type	File name	Document version	Application version
Survey or questionnaire	Qualtrics survey - melanocytic skin lesion experiment 17 April.pdf		.01
Survey or questionnaire	questionnaire_4.16.docx		
Procedure or other study tools	StudyDebriefing_4.16.docx		
Procedure or other study tools	StudyLandingPage_4.16.docx		
Participant Information Statement (PIS)	StudyPIS_4.16.docx		

Conditions of Approval

- Research must be conducted according to the approved proposal.

- An annual progress report must be submitted on or before the anniversary of approval and a final report on completion of the project.
- You must report as soon as practicable anything that might warrant review of ethical approval of the project including:
  - Serious or unexpected adverse events (which should be reported within 72 hours).
  - Unforeseen events that might affect continued ethical acceptability of the project.
- Any changes to the proposal must be approved prior to their implementation (except where an amendment is undertaken to eliminate *immediate* risk to participants).
- Researchers working on this project must be sufficiently qualified by education, training, and experience for their role, or adequately supervised. Changes to the project team must be reported and approved.
- Researchers must disclose any actual, potential of perceived conflicts of interest, including any financial or other interest or affiliation, as relevant to this project.
- Research data and primary materials must be retained and stored in accordance with relevant legislation and University guidelines.
- Ethics approval is dependent upon ongoing compliance of the research with the *National Statement on Ethical Conduct in Human Research*, the *Australian Code for the Responsible Conduct of Research*, applicable legal requirements, and with University policies, procedures, and governance requirements.
- If your research project is a clinical trial and is being sponsored by the University or is to be conducted on a University of Sydney site, you must comply with additional University governance requirements prior to commencing your Clinical Trial.
- The University may conduct audits on approved projects.
- The Chief Investigator has ultimate responsibility for the conduct of the research and is responsible for ensuring all others involved will conduct the research in accordance with the above.

Ethics Committee Representative

Associate Professor Syeda Zakia Hossain
Chair
Health Review Committee (Low Risk)

The University of Sydney HRECs are constituted and operate in accordance with the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research (NHMRC). All personnel named on the project should be acquainted with these documents.

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Appendix B. Supplementary Materials for Chapter 1

Impact of alternative diagnostic labels for melanoma in-situ: an online randomized study.

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Word Count: 3000 words

42 **ABSTRACT**

43 **Introduction**

44 We aimed to explore whether alternative labels for melanoma in-situ influenced
45 patients' management preferences and anxiety levels.

46 **Methods**

47 In this between-subjects online experiment using hypothetical scenarios, Australian
48 adults were randomized 1:1:1 to: "melanoma in-situ" (control), "low-risk melanocytic
49 neoplasm" (intervention 1) and "low-risk melanocytic neoplasm, in-situ"
50 (intervention 2). Participants were Australian residents aged 40 years or older, without
51 a personal history of melanoma, who could understand written English. The co-
52 primary outcomes were (i) preference for no wide local excision (WLE) vs WLE to
53 and (ii) preference for patient initiated clinical follow-up when needed vs routinely
54 scheduled clinical follow-up.

55 **Results**: Between 2 September - 4 October 2024, 1688 people were randomized and
56 included in the analysis. 57.5% (323/562) preferred WLE after a completely excised
57 "melanoma in-situ". Alternative labels reduced preference for this, with 47.6%
58 preferring WLE after a completely excised "low risk melanocytic neoplasm" (risk
59 difference: -9.9%; 95% CI: -15.7%, -4.1%, p=0.0001) and 48.7% preferring WLE
60 after a completely excised "low risk melanocytic lesion in-situ" (risk difference: -
61 8.8%; 95% CI: -14.6%, -3.0%, p=0.005). The proportions who preferred routinely
62 scheduled clinical surveillance visits were >75% across all randomized groups and
63 were not significantly different. Alternative labels also reduced anxiety about the

diagnosis and management.

Conclusions: Labels including the term “low-risk” and without the term “melanoma” reduced preference for WLE after a completely excised lesion, and anxiety, but not preference for routinely scheduled clinical follow-up.

Limitations: Hypothetical scenarios may not be realistic.

Trial registration: ACTRN12624000740594 (14 June 2024)

INTRODUCTION

Multiple lines of evidence now indicate that melanoma in-situ (MIS) is better conceptualized as a risk factor for invasive melanoma rather than an obligate precursor[1-4]. Labeling the risk factor "melanoma" may cause anxiety and fear[5,6], with many patients perceiving they have a high risk of dying from melanoma, when their actual risk is low[7]. These psychological harms can manifest as anxiety about being outdoors, fear of cancer recurrence, or guilt for past UV exposure causing melanoma[8].

Beyond psychological effects, social harms include impacts of the diagnosis on loved ones, and on patients' social networks[9]. The associated overtreatment may cause physical harms including repeat skin biopsies[9], scarring[9], pain, infection, and/or functional impairment. Economic harms include treatment costs for the immediate diagnosis[10], and for future long term clinical surveillance[11]. These incur substantial financial costs to both the health system and patient (as out-of-pocket costs)[12], as well as opportunity costs for both clinician time[13] and patient time[14]. There is also a possible denial of life insurance as the person is now identified as a cancer survivor by many insurance companies[1].

Related issues stem from (i) problems with the reproducibility of the MIS pathology diagnosis[15], and (ii) the expansion of its definition over time[16,17]. Together these all present a strong rationale for considering the adoption of diagnostic labels that do not include the word "melanoma"[4]. A new label might help patients recognize the lower

93 risk of this type of lesion[7] compared to invasive melanoma (particularly those that are
94 not AJCC IA[18]), and help to reduce the potential psychological and other types of
95 harm. It may also pave the way for the de-escalation of surgical treatment [19] and
96 clinical surveillance for subsequent new primary or recurrent melanoma[20-22].
97
98 Evidence from other cancer contexts, including those of the thyroid[23], breast[24], and
99 prostate[25], suggests that new diagnostic labels may beneficially impact psychological
100 outcomes and management decisions[26]. We sought to explore whether using
101 alternative labels to communicate a hypothetical melanoma in-situ diagnosis
102 influenced management preference and level of anxiety.
103
104 ## METHODS
105 We followed the CONSORT guideline for reporting randomized trials[27] and the
106 Guideline for RepOrting Vignette Experiments (GROVE)[28] in writing this report. A
107 detailed description of the study protocol was published[29].
108 **Study design**
109 We designed an online randomized study of Australian community members with
110 participants randomized to receive one of three hypothetical scenarios communicating
111 the diagnosis of a low-risk melanocytic skin lesion that would currently be labeled
112 "melanoma in-situ". Each group was presented with a different diagnostic label, and
113 participants were surveyed about their preferred management for that diagnosis (co-
114 primary outcomes) and their anxiety about the diagnosis and their choice of

115 management. Following consent, eligible participants were randomized 1:1:1 to
116 "melanoma in-situ" (control), "low risk melanocytic neoplasm" (intervention label 1),
117 and "low risk melanocytic neoplasm, in-situ" (intervention label 2). Qualtrics survey
118 software was used to randomly allocate participants into groups, present the scenarios,
119 and the survey questions to collect data on covariates and outcomes[30].

120 **Participants**

121 People were eligible if they were: 40 years or older, understood written English, and
122 resided in Australia. Participants were excluded if they had a personal history of
123 melanoma (invasive or in-situ).

124 **Setting and location**

125 Participants were recruited from the general Australian public through an independent
126 social research company (Dynata), which has a panel of 600,000 participants whose
127 demographic characteristics align closely with those of the national population.
128 Dynata has a points system in which participants receive points after completing
129 surveys. The points can then be used to redeem vouchers, cash, or other rewards.
130 Those who agreed to participate were assessed for eligibility and randomized through
131 the Qualtrics survey software (Qualtrics, Provo, UT, 2020). The survey captured
132 baseline data and characteristics of participants including socio-demographic details
133 including their age, location, health literacy, and personal and family history of any
134 cancer, and participant responses on outcome measures (See Supplementary Material,
135 Supplement 2).

136 **Interventions**

In all three randomized scenarios the participants were told that they were attending their general practitioner (GP) after recent skin surgery, and that the pathology report indicated a particular diagnosis, that had been completely excised, with pathology margins of 3 mm. They were given information about management options and told that their GP recommended all options as being clinically appropriate. The two alternative diagnostic labels were chosen by the clinician, patient, and public co-Investigators through an iterative process using online surveys as described in the published protocol[29]. The three levels for the diagnostic label intervention were: "melanoma in-situ" (control), "low-risk melanocytic neoplasm" (intervention label 1) and "low-risk melanocytic neoplasm, in-situ" (intervention label 2).

Outcomes and covariates

Supplement 1 in the Supplementary Materials provides an overview of the pre-specified primary and secondary outcomes and covariates[29]. The co-primary outcomes were (i) participant's preferred surgical management option: no further surgery vs wide local excision (WLE, to achieve pathology margins greater than 5 mm), and (ii) preferred follow-up management option: patient led surveillance (self-skin examination with patient-initiated clinic visits) vs clinician led surveillance (six monthly routinely scheduled clinic visits).

The first co-primary outcome, preferred surgical management option, reflects recent retrospective analyses that have found that even very narrow histological clearance ($\geq$1mm) appears to be safe for melanoma in-situ of the trunk and limbs[31-33]. The MPATH-Dx V2.0 melanocytic lesion classification scheme recommends that provided

159 margins are not involved, clinicians may consider not re-excising class II lesions,
160 including melanoma in-situ[34]. The second co-primary outcome, preferred follow-up
161 management option, centers around patient-led surveillance (also called patient-
162 initiated follow-up) as an alternative model of follow-up for cancer survivors to the
163 current usual practice of routinely scheduled clinic appointments[35]. The MEL-SELF
164 randomized controlled trial (RCT)[36] is evaluating patient-led surveillance that
165 includes training in self-skin examination, digital technologies to record and take
166 images of concerning lesions (using a mobile dermatoscope), online system for
167 submitting images for remote review by a dermatologist, and advice on whether
168 urgent clinical review may be needed (teledermatology)[37].
169 Secondary outcomes included diagnosis and management anxiety as well as multiple
170 perceived risk measures. A comparison of perceived vs calculated risk, and a
171 qualitative content analysis will be reported separately.
172 **Sample size**
173 We estimated a sample size of 1668 participants with 556 participants per group in the
174 study would allow us to detect pairwise differences in proportions of 10% or greater
175 for the surgery and follow-up preference outcomes, with 80% and 89% power,
176 respectively. The assumptions were: 50% would prefer no further surgery and 35%[22]
177 patient-led surveillance in the "melanoma in-situ" (control) group, a 5% dropout rate,
178 $\alpha = 0.05$, the normal approximation to the binomial distribution, and the standard
179 formula for comparing proportions in independent equal-sized groups.
180 **Randomisation, allocation concealment, implementation and blinding**

We used the Qualtrics survey software to randomly allocate participants into three groups with allocation ratio, 1:1:1 (Qualtrics, Provo, UT, 2020). Qualtrics uses the Mersenne Twister pseudorandom number generator to randomise participants. Quotas were used during recruitment to ensure that approximately 50% of respondents were male, 50% of respondents were without tertiary education, the sample included people from all Australian states and territories, and from all age groups (50-60, 60-70, 70-80, 80+ years), with participants randomised within strata of these variables. The online survey study design meant that allocation sequence was concealed to participants and researchers. Participants were unblinded after assignment to interventions. Researchers remained blinded until after data analysis was complete.

Statistical methods

The analysis adhered to the intention-to-treat principle with participant data analyzed according to their randomly assigned diagnostic label group. Analyses were conducted within a superiority framework to make pairwise comparisons across the three diagnostic label groups. Effect estimates for all primary and secondary outcomes are presented with associated 95% confidence intervals (CI). All hypothesis tests were two-sided with a significance level (α) of 5%. We estimated unadjusted absolute effect measures and adjusted relative effects using the relevant multivariable regression model (logistic regression for binary outcomes and linear regression for continuous outcomes). These models included variables used in sampling strata: age, education, geographic location (by state/territory), and covariates measured through the baseline questionnaire (pre-specified as potential prognostic factors[29]). For each outcome we

included potential prognostic factors that had $p<0.20$ in the multivariable model. Finally, we undertook subgroup analysis of the co-primary outcomes to investigate potential effect modification by health literacy status (prespecified in our protocol[29]).

Patient and public involvement

Two authors have lived experience of a melanoma diagnosis (one had MIS and one had a thin stage I invasive melanoma), and one author is members of the public. Two authors are affiliated with Cancer Voices NSW, one author is a patient advocate and senior researcher from Oxford UK.

Ethics and trial registration.

Ethics approval of this project was provided by the University of Sydney on 6 May 2024 (No. 2024/HE000019). The study is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12624000740594).

RESULTS

Between 2 September - 4 October 2024, 2373 people were assessed for eligibility and 1728 people were recruited and randomized (Figure 1). Of these, we excluded 40 people did not finish the survey, leaving 1688 people included in the analysis ("melanoma in-situ" n=562, "low-risk melanocytic neoplasm" n=563, "low-risk melanocytic neoplasm, in situ" n=563). The baseline demographic and clinical characteristics were similar across randomized groups.

Outcomes and estimation

Diagnostic anxiety

There was evidence of label effects on diagnostic anxiety ($p<0.0001$). Compared to a

mean anxiety level of 3.5 (scale 0 to 6) in those assigned "melanoma ", mean anxiety level was 2.7 in those assigned "low risk melanocytic neoplasm" (adjusted mean difference -0.9 [95% CI: -1.0, -0.7], p <0.0001), and 2.8 in those assigned "low risk melanocytic neoplasm" (adjusted mean difference -0.7 [95% CI: -0.8, -0.5], p<0.0001). (Table 2)

Co-Primary Outcome: choice of Wide Local Excision

There was evidence of label effects on preference for wide local excision of a completely excised lesion (p=0.0004, Figure 2: panel A). Compared to 57.5% (323/562) of those assigned "melanoma in-situ", 47.6% (268/563) assigned "low risk melanocytic neoplasm" (risk difference -9.9% [95% CI: -15.7%, -4.1%]; OR: 0.64 [95% CI: 0.50, 0.82] p=0.0003), and 48.7%, (274/563) assigned "low risk melanocytic lesion, in-situ" (risk difference -8.8% [95% CI: -14.6%, -3.0%]; OR: 0.69 [95% CI: 0.54, 0.89] p=0.003) preferred to have a wide local excision (Table 3).

Anxiety after choice of Wide Local Excision

There was evidence of label effects on anxiety after choice for wide local excision (p<0.0001). Compared to a mean anxiety level of 3.0 (scale 0 to 6) in those assigned "melanoma in-situ", mean anxiety level was 2.4 in those assigned "low risk melanocytic neoplasm" (adjusted mean difference -0.7 [95% CI: -0.8, -0.5], p <0.0001), and 2.7 in those assigned "low risk melanocytic neoplasm, in-situ" (adjusted mean difference -0.4 [95% CI: -0.6, -0.3] p<0.0001) (Table 3).

Co-Primary Outcome: choice of follow-up

There was no evidence of label effects on preference for routinely scheduled clinical

follow-up for melanoma surveillance (p=0.72, Figure 2: panel B). Compared to 78.8% (443/562) of those assigned "melanoma in-situ", 75.8% (427/563) assigned "low risk melanocytic neoplasm" (risk difference -3% [95% CI: -7.9%, 1.9%]; OR: 0.88 [95% CI: 0.66, 1.19], p=0.41), and 76.9% (433/563) assigned "low risk melanocytic lesion " (risk difference -1.9% [95% CI: -6.8%, 3.0%]; OR: 0.94 [95% CI: 0.70, 1.27], p=0.69) preferred routinely scheduled clinical follow-up visits rather than patient-led surveillance (Table 3).

Anxiety after choice of follow-up

Despite the lack of label effects on preference for type of follow up, there was evidence of an effect on anxiety after making their choice (p<0.0001). Compared to a mean anxiety level of 2.6 (scale 0 to 6) in those assigned "melanoma in-situ", mean anxiety level was 2.1 in those assigned "low risk melanocytic neoplasm" (adjusted mean difference -0.6 [95% CI: -0.8, -0.4], p <0.0001), and 2.3 in those assigned "low risk melanocytic neoplasm in-situ" (adjusted mean difference -0.3 [95% CI: -0.5, -0.2], p=0.0001) (Table 3).

Subgroup analyses

Health literacy (pre-specified)

There was no statistically significant evidence that health literacy modified the effect of diagnostic label on preference for wide local excision (p=0.39) or for routinely scheduled follow up (p=0.95), although small numbers in the inadequate health literacy subgroups limited our power to detect differences in effects. Point estimates indicated that the effect of "low risk melanocytic neoplasm" on preference for wide local excision was larger in those with inadequate health literacy (risk difference -

15.9% [-31.1%, -0.7%]; OR 0.49 [0.26, 0.95]) than in those with adequate health literacy (risk difference -8.7% [-15.0%, -2.4%]; OR 0.65 [0.50, 0.85]), although confidence intervals were wide and overlapping. The effect sizes were more similar for "low risk melanocytic neoplasm, in-situ", with point estimates indicating a smaller effect in those with inadequate health literacy than those with adequate health literacy, but with wide confidence intervals that overlapped (Table 4). Point estimates for effects on preference for routinely scheduled follow-up visits indicated no difference in the effects of either alternative diagnostic label for people with inadequate vs adequate health literacy.

DISCUSSION

In this hypothetical study where the doctor did not make management recommendations but instead asked the patient to state their preference, 58% of the participants said they would prefer a wide local excision after a completely excised "melanoma in-situ" with close margins (3 mm). When "low risk melanocytic neoplasm" was used to describe the same lesion, 48% said they would prefer a wide local excision - an absolute difference of 10%. Adding in-situ to the label ("low risk melanocytic neoplasm, in-situ) did not appear to have any additional effect, with 49% of participants in this group saying that they would prefer a wide local excision. In contrast, both alternative diagnostic labels had minimal effect on preference for type of follow-up, with all groups showing a strong preference for routinely scheduled visits with their doctor for melanoma surveillance (>75% of participants preferred this in all groups) rather than patient-led surveillance supported by teledermatology. Both

alternative labels decreased diagnostic and management choice anxiety.

Our findings are likely to be generally applicable to Australians and other populations with high rates of melanoma. However, most of our study population had adequate health literacy, was not ethnically or culturally diverse, and tended to live in major cities (with access to tertiary health care facilities). Our results may not apply to other populations such as those living in rural areas or with inadequate health literacy. The pre-specified subgroup analysis indicated that the effect of "low risk melanocytic neoplasm" on preference for wide local excision may be greater for those with inadequate health literacy, although the small numbers in this group limited our statistical power for this analysis. The hypothetical nature of the experiment limits the extrapolation to effects on management choices made in real life.

If the pathology community were to adopt a new label for MIS, this might also mitigate or even negate the need for the category of severe atypia / dysplasia. These terms may also provoke anxiety in patients[4], and they are already grouped together with MIS in the MPATH-Dx classification schema (class II) [38]. Adding "in-situ" to the label appears to have no additional effect to "low-risk melanocytic lesion", and further research is needed to understand labels that best differentiate melanoma in-situ from low risk subsets of thin invasive melanomas (MPATH-Dx class III)[39].

Wide local excision is universally recommended by clinical management guidelines,

317 which is based on extrapolation of studies performed for invasive melanomas. Despite
318 emerging evidence that it is likely to be unnecessary in most cases where there is
319 complete excision of the low-risk melanocytic lesion, it is still common practice[33].
320 Routinely scheduled clinical follow up of MIS after WLE is currently recommended
321 by Australian[40] and US[40] guidelines (at least a single annual clinic visit), but not by
322 UK[41] and European[42] guidelines. Large RCTs that provide evidence on the safety of
323 forgoing wide local excision and routinely scheduled clinical follow up may be
324 needed to drive clinical guidelines and practice change towards de-escalation of
325 follow-up care. The Swedish WoW[43] and Dutch NORMA 2[19] trials, currently
326 recruiting patients, are studying the safety of foregoing a WLE for invasive melanoma
327 with clear margins, but there are no ongoing trials yet for MIS.
328
329 The Dutch and UK MELFO study found a reduction in follow-up schedule was safe
330 for patients after treatment for invasive melanoma[44], but there are no trials yet for
331 MIS. The MEL-SELF trial is studying patient-led surveillance offered in addition to
332 routinely scheduled clinical surveillance, with the acceptability of reducing routine
333 clinic frequency included as a secondary outcome[36]. Suggestions on reducing visit
334 frequency were also provided by patients[22] and clinicians[45] who participated in the
335 pilot trial.
336
337 Strengths of this study include the multidisciplinary research team, robust study
338 design and analysis, and large sample size. We tested alternative labels that were

chosen by our co-investigators who are practicing clinicians (both those who treat patients with low-risk melanocytic lesions and pathologists who make the diagnosis) and patient and public representatives (with and without lived experience of low-risk melanoma)[29]. This ensured that the labels that were tested were acceptable to all end-users, and conveyed the low, but not zero, risk of subsequent invasive melanoma. Inclusion of patients and public co-Investigators ensured that less medicalized terms were chosen, which tend to be associated with a preference for less invasive management[46].

There are important limitations to this study that are already noted above, most notably the hypothetical nature of the experiment. Participants were told that their doctor recommended either option for both management decisions as a reasonable choice and would organize whichever the patient preferred. This is an unlikely scenario in practice currently, as most clinicians would simply make a strong recommendation for both management decisions. Based on current clinical guidelines, these recommendations would be for a wide local excision, and (in Australia and US) routinely scheduled clinical follow-up. Our measures of anxiety after the diagnosis and each management decision are also based on participants imagining hypothetical scenarios. Anxiety after an actual diagnosis is likely to be higher, and our estimated reduction in anxiety levels with the alternative labels may be conservative.

Conclusion

These results inform the ongoing discussion about change in diagnostic labels within

the pathology community, and the potential for de-escalation of surgery and clinical surveillance after excision of a low-risk melanocytic lesion.

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Author Contributions

Katy JL Bell (Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing - review and editing), Zhuohan Wu (Data curation, Formal analysis, Validation, Visualization, Writing – original draft,

Writing - review and editing), Farzaneh Boroumand (Methodology, Supervision, Validation, Visualization, Writing - review and editing), Lisa Parker (Investigation, Methodology, Writing - review and editing), David Elder (Methodology, Writing - review and editing), Peter Ferguson (Methodology, Writing - review and editing), Blake O'Brien (Methodology, Writing - review and editing), Adewole S Adamson (Methodology, Writing - review and editing), Elspeth Davies (Methodology, Writing - review and editing), Alexander C.J. van Akkooi (Methodology, Writing - review and editing), Richard A. Scolyer (Methodology, Writing - review and editing), Raymond Barnhill (Methodology, Writing - review and editing), Jon Emery (Methodology, Writing - review and editing), Donald Low (Methodology, Writing - review and editing), Cynthia Low Methodology, Writing - review and editing), Brooke Nickel (Conceptualization, Investigation, Methodology, Supervision, Writing - review and editing).

Conflict of Interest

RAS has received fees for professional services from SkylineDx BV, IO Biotech ApS, MetaOptima Technology Inc., F. Hoffmann-La Roche Ltd, Evaxion, Provectus Biopharmaceuticals Australia, Qbiotics, Novartis, Merck Sharp & Dohme, NeraCare, AMGEN Inc., Bristol-Myers Squibb, Myriad Genetics, GlaxoSmithKline.

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Data availability statement

The data underlying this article are available in the Open Science Framework: https://doi.org/10.17605/OSF.IO/6VHUW

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Figure Legends

Figure 1: Flow of participants

Figure 2: Primary outcomes across randomized diagnostic label groups

A: Probability of choosing wide local excision (rather than no further surgery)

B: Probability of choosing routinely scheduled clinic visits (rather than patient-led surveillance)

Table 1: Baseline characteristics of randomised groups: number (%)

Characteristic	Melanoma In situ (N=562)	Low risk melanocytic neoplasm (N=563)	Low risk melanocytic neoplasm, in situ (N=563)
Gender			
Women	287 (51%)	271 (48%)	285 (51%)
Male	275 (49%)	292 (52%)	278 (49%)
Age			
40-49	100 (18%)	119 (21%)	110 (20%)
50-59	123 (22%)	116 (21%)	108 (19%)
60-69	157 (28%)	154 (27%)	151 (27%)
70-79	151 (27%)	135 (24%)	162 (29%)
80 or over	31 (5.5%)	39 (6.9%)	32 (5.7%)
Indigenous	8 (1.4%)	19 (3.4%)	16 (2.8%)
Country of birth			
Australia	426 (76%)	410 (73%)	418 (74%)
English language spoken at home	535 (95%)	533 (95%)	541 (96%)
State or territory of residence			
Australian Capital Territory	8 (1.4%)	8 (1.4%)	11 (2.0%)
New South Wales	166 (30%)	175 (31%)	191 (34%)
Northern Territory	5 (0.9%)	2 (0.4%)	2 (0.4%)
Queensland	115 (20%)	116 (21%)	121 (21%)
South Australia	40 (7.1%)	41 (7.3%)	42 (7.5%)
Tasmania	15 (2.7%)	13 (2.3%)	11 (2.0%)
Victoria	159 (28%)	150 (27%)	127 (23%)
Western Australia	54 (9.6%)	58 (10%)	58 (10%)
Rurality[1]			
metropolitan	409 (73%)	412 (74%)	408 (73%)
rural	151 (27%)	147 (26%)	153 (27%)
Health insurance	294 (52%)	326 (58%)	312 (55%)
Education			
High school or less	240 (43%)	226 (40%)	256 (45%)
Non-University qualification	224 (40%)	208 (37%)	210 (38%)
University degree	98 (17%)	129 (23%)	97 (17%)
Employment[2]			
Employed	217 (39%)	261 (46%)	225 (40%)

Not in workforce	300 (53%)	263 (47%)	290 (52%)
Unemployed	44 (7.8%)	38 (6.8%)	47 (8.4%)
Income			
less than $100,000	384 (68%)	376 (67%)	373 (66%)
$100-200,000	99 (18%)	119 (21%)	119 (21%)
>$200,000	30 (5.3%)	30 (5.3%)	33 (5.9%)
Prefer not to say	49 (8.7%)	38 (6.7%)	38 (6.7%)
Health literacy			
Adequate	490 (87%)	471 (84%)	481 (85%)
Limited	72 (13%)	92 (16%)	82 (15%)
Perceived Health status			
Healthy	415 (74%)	400 (71%)	411 (73%)
Personal cancer diagnosis	127 (23%)	126 (23%)	131 (23%)
Melanoma in family member	47 (8.4%)	44 (7.8%)	45 (8.0%)
Melanoma in family or other loved one	79 (14%)	73 (13%)	76 (13%)
Melanoma worry			
Not worried at all	179 (32%)	164 (29%)	171 (30%)
A bit worried	295 (52%)	312 (55%)	306 (54%)
Very/quite worried	88 (16%)	87 (15%)	86 (15%)
Hair			
Black	93 (17%)	108 (19%)	90 (16%)
Brown	292 (52%)	300 (53%)	301 (53%)
Blond/fair	155 (28%)	132 (23%)	138 (25%)
Red/auburn	22 (3.9%)	23 (4.1%)	34 (6.0%)
Moles			
None	204 (36%)	207 (37%)	209 (37%)
Few	291 (52%)	283 (50%)	289 (51%)
Some	57 (10%)	65 (12%)	62 (11%)
Many	10 (1.8%)	8 (1.4%)	3 (0.5%)
Sunbed use ever	73 (13%)	59 (10%)	70 (12%)
Maximiser (on minimiser-maximiser scale)	347 (62%)	341 (61%)	324 (58%)
Wellbeing (rescaled to 0 to 100) (median, Q1, Q3)[3]	56 (36, 76)	60 (36, 76)	60 (36, 76)
Self-efficacy (rescaled to 0 to 100) (median, Q1, Q3)[4]	58 (38, 68)	58 (38, 68)	58 (30, 68)

1. Remoteness of residence missing for 4 participants in the melanocytic neoplasm group, and 2 participants in the other two randomised groups
2. Employment status unknown for 1 participant in each randomised group,
3. Higher scores indicate more wellbeing.
4. Higher scores indicate more self-efficacy

Table 2: Diagnostic anxiety and perceived vulnerability across randomised diagnostic label groups

Outcome	Melanoma In situ (N=562)	Low risk melanocytic neoplasm (N=563)	Unadjusted Mean Difference (95% CI)	Adjusted Mean Difference	P value	Low risk melanocytic neoplasm, in situ (N=563)	Unadjusted Mean Difference	Adjusted Mean Difference	P value
Diagnostic anxiety (visual analogue scale 0 to 6) (mean, SD)	3.5 (1.5)	2.7 (1.6)	-0.8 (-1.0, -0.6)	-0.9 (-1.0, -0.7)[1]	<0.0001	2.8 (1.5)	-0.6 (-0.8, -0.5)	-0.7 (-0.8, -0.5)[1]	<0.0001
Perceived vulnerability (visual analogue scale 0 to 6) (mean, SD)	3.7 (1.4)	3.0 (1.5)	-0.7 (-0.9, -0.5)	-0.8 (-0.9, -0.6)[2]	<0.0001	3.1 (1.5)	-0.5 (-0.7, -0.4)[2]	-0.5 (-0.7, -0.4)	<0.0001

1. Adjusted for age, sex, state or territory, education, employment status, household income, partner status, country of birth, Indigenous status, hair colour, health insurance, rurality of residence, personal history of cancer (any type), self-efficacy, health literacy, minimiser-maximiser, melanoma worry, calculated risk of new primary melanoma
2. Adjusted for age, sex, state or territory, education, household income, partner status, country of birth, English spoken at home, Indigenous status, health insurance, personal history of cancer (any type), personal history of keratinocyte skin cancer, wellbeing, health literacy, minimiser-maximiser, melanoma worry, perceived health status, calculated risk of new primary melanoma

Table 3: Surgery and surveillance choices and management choice anxiety across randomised diagnostic label groups

Outcome	Melanoma In situ (N=562)	Low risk melanocytic neoplasm (N=563)	Absolute Difference	Adjusted Effect Measure	P value	Low risk melanocytic neoplasm, in situ (N=563)	Absolute Difference	Adjusted Effect Measure	P value
Prefer wide local excision	323 (57.5%)	268 (47.6%)	-9.9% (-15.7%, -4.1%)	OR[1]: 0.64 (0.50, 0.82)[2]	0.0003	274 (48.7%)	-8.8% (-14.6%, -3.0%)	OR[1]: 0.69 (0.54, 0.89)[2]	0.0032
Surgery choice anxiety (visual analogue scale 0 to 6) (mean, SD)	3.0 (1.5)	2.4 (1.5)	-0.6 (-0.8, -0.4)	MD[3]: -0.7 (-0.8, -0.5)[4]	<0.0001	2.7 (1.5)	-0.4 (-0.6, -0.2)	MD[3]: -0.4 (-0.6, -0.3)[4]	<0.0001
Prefer routinely scheduled clinic visits	443 (78.8%)	427 (75.8%)	-3% (-7.9%, 1.9%)	OR[1]: 0.88 (0.66, 1.19)[5]	0.41	433 (76.9%)	-1.9% (-6.8%, 3.0%)	OR[1]: 0.94 (0.70, 1.27)[5]	0.69
Surveillance choice anxiety (visual analogue scale 0 to 6) (mean, SD)	2.6 (1.5)	2.1 (1.4)	-0.5 (-0.7, -0.4)	MD[3]: -0.6 (-0.8, -0.4)[6]	<0.0001	2.3 (1.5)	-0.3 (-0.5, -0.1)	MD[3]: -0.3 (-0.5, -0.2)[6]	0.0001

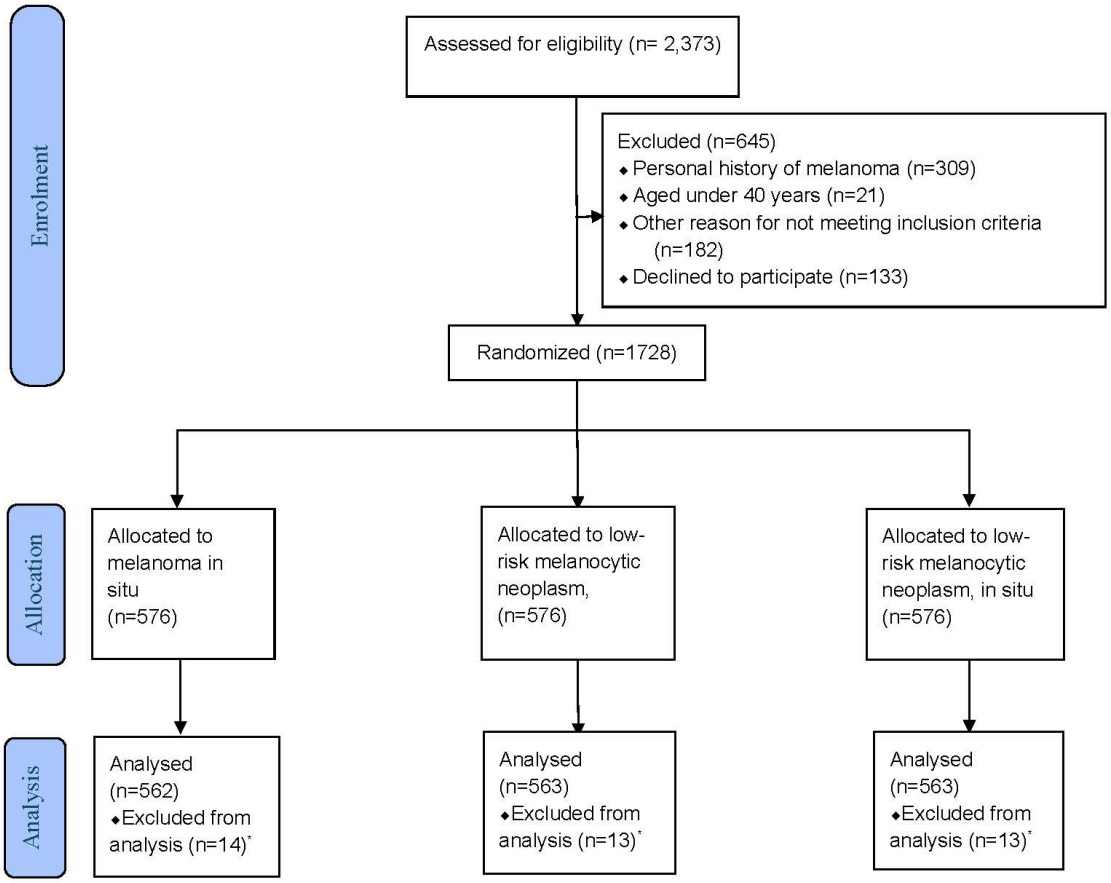
1. OR: Odds Ratio
2. Adjusted for age, sex, state or territory, education, partner status, country of birth, Indigenous status, hair colour, health insurance, melanoma in a loved one, self-efficacy, minimiser-maximiser, melanoma worry, perceived health status, calculated risk of new primary melanoma
3. MD: Mean Difference
4. Adjusted for: age, sex, state or territory, education, household income, partner status, Indigenous status, hair colour, personal cancer diagnosis, wellbeing, self-efficacy, health literacy, minimiser-maximiser, melanoma worry, calculated risk of new primary melanoma
5. Adjusted for age, sex, state or territory, education, employment status, partner status, English spoken at home, Indigenous status, health insurance, rurality of residence, history of melanoma in a loved one, self-efficacy, minimiser-maximiser, calculated risk of new primary melanoma
6. Adjusted for: age, sex, state or territory, education, household income, partner status, country of birth, Indigenous status, hair colour, wellbeing, self-efficacy, health literacy, melanoma worry, calculated risk of new primary melanoma

Table 4: Subgroup analyses of surgery and surveillance choices by health literacy status

Outcome	Melanoma in-situ (N=562)	Low risk melanocytic neoplasm (N=563)	Risk Difference	Adjusted Odds Ratio	Low risk melanocytic neoplasm, in-situ (N=563)	Risk Difference	Adjusted Odds Ratio	P value[1]
Prefer wide local excision								
Adequate health literacy	281 (57.3%)	229 (48.6%)	-8.7% (-15.0%, -2.4%)	OR: 0.65 (0.50, 0.85)	231 (48.0%)	-9.3% (-15.6%, -3.0%)	OR: 0.68 (0.52, 0.89)	
Inadequate health literacy	42 (58.3%)	39 (42.4%)	-15.9% (-31.1%, -0.7%)	OR: 0.49 (0.26, 0.95)	43 (52.4%)	-5.9% (-21.6%, 9.8%)	OR: 0.83 (0.42, 1.62)	
Overall	323 (57.5%)	268 (47.6%)	-9.9% (-15.7%, -4.1%)	OR: 0.64 (050, 0.82)	274 (48.7%)	-8.8% (-14.6%, -3.0%)	OR: 0.69 (0.54, 0.88)	0..39
Prefer routinely scheduled follow up clinic visits								
Adequate health literacy	395 (80.6%)	368 (78.1%)	-2.5% (-7.6%, 2.6%)	OR: 0.87 (0.63, 1.21)	382 (79.4%)	-1.2% (-6.2%, 3.8%)	OR: 0.95 (0.68, 1.32)	
Inadequate health literacy	48 (66.7%)	59 (64.1%)	-2.6% (-17.2%, 12.0%)	OR: 0.92 (0.46, 1.85)	51 (62.2%)	-4.5% (-19.6%, 10.6%)	OR: 0.89 (0.44, 1.82)	
Overall	443 (78.8%)	427 (75.8%)	-3% (-7.9%, 1.9%)	OR: 0.88 (0.66, 1.19)	433 (76.9%)	-1.9% (-6.8%, 3.0%)	OR: 0.94 (0.70, 1.27)	0.95

1. P value for interaction between label and health literacy

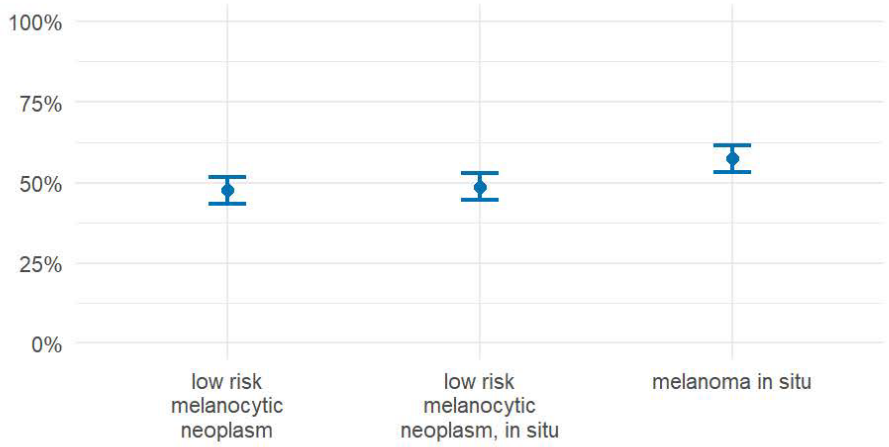
Figure 1: Flow of participants



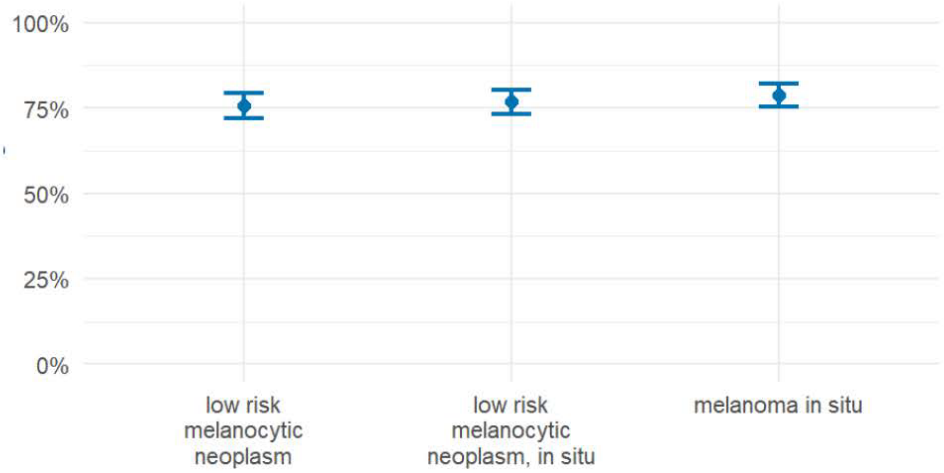
*N=40 excluded from analysis as did not finish survey

Figure 2: Primary outcomes across randomized diagnostic label groups

A: Probability of choosing wide local excision (rather than no further surgery)



B: Probability of choosing routinely scheduled clinic visits (rather than patient-led surveillance)



Appendix C. Supplementary Materials for Chapter 2

The SPIRIT guideline checklist of Chapter 2.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	ItemNo	Description	Page
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	4
	2b	All items from the World Health Organization Trial Registration Data Set	NR
Protocol version	3	Date and version identifier	NR
Funding	4	Sources and types of financial, material, and other support	16
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1-2
	5b	Name and contact information for the trial sponsor	15
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	15-16
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	NR

Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5-7
	6b	Explanation for choice of comparators	NR
Objectives	7	Specific objectives or hypotheses	6-7
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7-8

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	10
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	NR
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	NR

	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NR
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10-11 and Table 1
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	NR
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	12
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	8-9
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8-9

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	8-9
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8-9
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12-13
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NR
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8-9
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NR
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	9

Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	12-14
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	13-14
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	10-13
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NR
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NR
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	14
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NR
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	14

Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	14
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	8
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NR
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	9
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	16
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	4-15
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	14-15
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	14-15
	31b	Authorship eligibility guidelines and any intended use of professional writers	NR

	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NR
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplement
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NR

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

Landing Page ✓

Effect of the label for a low risk melanocytic lesion on preferred management strategy: a randomised experiment.

Thank you for your interest in our study about low-risk melanocytic lesion.

In this study, you will be randomised to be shown one of three hypothetical scenarios following surgery on a mole, which will be followed by questions about management options and anxiety.

The study is being conducted by a team of researchers from The University of Sydney School of Public Health. The team members are:

- Professor Katy Bell (School of Public Health at the University of Sydney)
- Dr Brooke Nickel (School of Public Health at the University of Sydney)
- Mr Zhuohan Wu (School of Public Health at the University of Sydney)

Taking part in the study involves completing one online questionnaire which will take approximately 10 minutes to complete.

Being in this study is completely voluntary and you do not have to take part. Your decision on whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney.

Please take the time to read through the Participant Information Statement below.

If you are interested in taking part in this study, you will be asked to consent to take part by ticking the 'yes' box at the beginning of the questionnaire. By giving your consent to take part in this study, you are telling us that you:

✓ Understand what you have read in the Participant Information Statement.
✓ Agree to take part in the research study as outlined in Participant Information Statement.
✓ Agree to the use of your personal information as described.

When you have consented, you will fill out an online questionnaire that asks a series of questions, such as:

- Demographic questions, such as age, education, income level and relationship status.
- General health and cancer related questions.
- Melanoma and other cancer history related questions.

You will be randomised to read one of three HYPOTHETICAL EXAMPLES (these are made up examples) in which different labels are used to explain a low-risk melanocytic skin lesion result. **Please note that you WILL NOT be receiving information or advice on any real mole check results or information about your actual health status**.

The hypothetical examples will be followed by questions about choice of management strategy and personal perspective.

Pre-Survey PIS ✓

Effect of the label for a low-risk melanocytic lesion on management strategy: a randomised experiment

PARTICIPANT INFORMATION STATEMENT

(1) What is the study about?

You are invited to participate in a study that assesses how different labels given to an atypical mole (low-risk melanocytic skin lesion) affect a person's anxiety and cancer concern, and their intention to undergo different treatment options. We are interested in a range of views and experiences.

(2) Who is running the study?

The study is being conducted by a team of researchers and clinicians.

The team members are:

• Professor Katy Bell (School of Public Health at the University of Sydney).

• Dr Brooke Nickel (School of Public Health at The University of Sydney).

• Mr Zhuohan Wu (School of Public Health at the University of Sydney).

Professor Katy Bell is leading the study.

(3) What will the study involve for me?

If you agree to participate, you will complete an online questionnaire asking for some background information about yourself and your medical history. You will be randomised to be shown one of three hypothetical scenarios about low-risk melanocytic lesion results, which will be followed by questions about treatment choice, anxiety and cancer concern. After completing and submitting this questionnaire, there will be no further contact anticipated between yourself and the research team.

(4) How much time will the study take?

The study involves one online questionnaire which will take approximately 10 minutes to complete.

(5) Who can take part in the study?

Eligible participants will be people living in Australia aged 40 years or older with no prior history of melanoma. Participants must read and speak adequate English to be eligible.

(6) Do I have to be in the study? Can I withdraw from the study once I've started?

Being in this study is completely voluntary and you do not have to take part. Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney. Submitting your completed questionnaire is an indication of your consent to participate in the study. You can withdraw your responses any time before you have submitted the questionnaire without giving a reason. Once you have submitted it, we will not be able to withdraw your responses due to their anonymous nature, and therefore we will not be able to tell which one is yours.

(7) Are there any risks or costs associated with being in the study?

There are no foreseeable risks involved if you participate in this study; however some participants may feel emotional. Participants who express or experience distress during the survey are not obligated to continue and can contact the Cancer Council helpline for support on 13 11 20 or info@cancer.org.au. Please contact researchers via email katy.bell@sydney.edu.au if you require further information or support. Aside from giving up your time, we do not expect that there will be any costs associated with taking part in this study.

(8) Are there any benefits associated with being in the study?

Findings from this study will provide much needed Australian-first data on the impact of different labels for a low-risk melanocytic skin lesion. That said, we cannot guarantee that you will receive any direct benefits from being in the study.

(9) What will happen to the information about me that is collected during the study?

By providing your consent, you are agreeing to us collecting personal information that you provide in your answers to the survey for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise. Your information will be stored securely and your identity/information will be kept strictly confidential, except as required by law. Study findings will be published as articles in academic journals, and presented at conferences, but you will not be individually identifiable in these publications. The research team will have access to the final trial dataset. Access may be granted to other researchers on reasonable request. Sharing research data is important for advancing knowledge and innovation. A de-identified set of the data collected in this study may be made

available for use in future research.

(10) Can I tell other people about the study?

Yes, you are welcome to tell other people about the study.

(11) What if I would like further information about the study?

When you have read this information, Professor Katy Bell will be available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage during the study, please feel free to contact Prof Katy Bell on katy.bell@sydney.edu.au.

(12) Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. The results of the study and a plain language summary of the findings will be published on the permanent web page wiserhealthcare.org.au/category/publications after the study has been published in a medical journal.

(13) What if I have a complaint or any concerns about the study?

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney. As part of this process, we have agreed to carry out the study according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect people who agree to take part in research studies. If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number xx.

The Manager, Ethics Administration, University of Sydney:

- Telephone: +61 2 8627 8176
- Email: human.ethics@sydney.edu.au
- Fax: +61 2 8627 8177 (Facsimile)

(14) Has this study received funding?

The study is funded by an NHMRC Centre Research Excellence Grant (2006545, CIA McCaffery) and an NHMRC Investigator Grant (1174523, CIA Bell)

Pre-Survey Consent Form ✓

Do you consent to take part in this study as described in the Participant Information Sheet and Consent Form?

- ◯ Yes
- ◯ No

Section 1: Screening and Socio-Demographic ✓

Which of the following best describes your current gender identity?

- ◯ Male
- ◯ Female
- ◯ Non-binary / gender fluid
- ◯ Different identity

Have you been previously diagnosed with a melanoma?

- ◯ Yes
- ◯ No

Do you have a partner?

- ◯ Spouse

- ◯ De-facto partner
- ◯ Partner who does not reside with you
- ◯ No partner
- ◯ Widowed
- ◯ Divorced or separated
- ◯ [ ] Other - please list:

What is your age?

[ ]

Section 1.5: Screening and Socio-Demographic Part 2

Which Australian state or territory do you currently live in?

- ◯ New South Wales
- ◯ Victoria
- ◯ Australian Capital Territory
- ◯ Queensland
- ◯ South Australia
- ◯ Western Australia
- ◯ Northern Territory
- ◯ Tasmania

Where are you located? (please enter your post code)

[ ]

What is your highest level of education?

- ◯ Year 10 or below
- ◯ Year 11
- ◯ Year 12
- ◯ Certificate I/II
- ◯ Certficate III/IV
- ◯ Advanced diploma/diploma
- ◯ Bachelor's degree
- ◯ Graduate diploma/graduate certificate
- ◯ Postgraduate degree (Master's or Doctorate)
- ◯ Level not determined

What is your current employment status?

- ◯ Permanent or ongoing
- ◯ Fixed-term contract
- ◯ Casual/temporary (no paid sick leave or annual leave)
- ◯ Self-employed
- ◯ On paid leave (e.g. maternity leave)
- ◯ Unemployed
- ◯ Not working/not in the labour force (e.g. student, home duties, retired)

What was your total household income before taxes during the past 12 months?

- ◯ Less than AUD $30,000
- ◯ Between AUD $30,000 - $49,999
- ◯ Between AUD $50,000 - $79,999
- ◯ Between AUD $80,000 - $99,999
- ◯ Between AUD $100,000 - $149,999
- ◯ Between AUD $150,000 - $199,999
- ◯ AUD $200,000 or more
- ◯ Prefer not to say

Do you have children?

- ◯ Yes
- ◯ No
- ◯ Prefer not to say

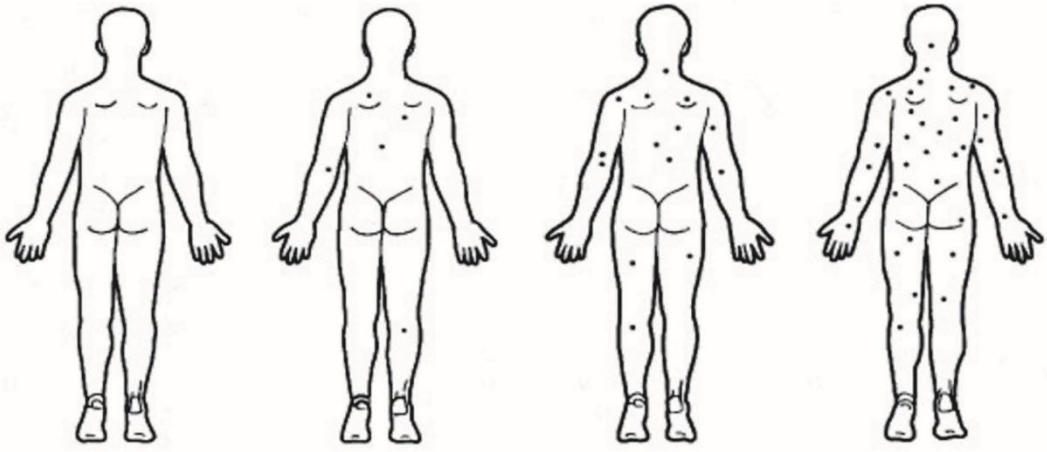
Are you of Aboriginal or Torres Strait Islander origin?

- ◯ Aboriginal
- ◯ Torres Strait Islander
- ◯ Both Aboriginal and Torres Strait Islander
- ◯ Neither Aboriginal or Torres Strait Islander
- ◯ Prefer not to say

What was your natural hair colour when you were 18 years of age

- ◯ Black
- ◯ Brown
- ◯ Fair or Blond
- ◯ Red or Auburn

Looking at the image below, please select the option that most closely resembles the number of moles on your body when you were 18 years of age.



None | Few moles | Some moles | Many moles

- ◯ None
- ◯ Few moles
- ◯ Some moles
- ◯ Many moles

Have you ever used a sunbed or sunlamp?

- ◯ No
- ◯ Yes

Were you born in Australia?

- ◯ Yes
- ◯ No

What is your country of birth?

- ◯ UK
- ◯ India
- ◯ China
- ◯ New Zealand
- ◯ The Philippines
- ◯ [ ] Other - please list:

In which year did you move to Australia?

[ ]

What language do you mostly speak at home?

- ◯ English
- ◯ Mandarin
- ◯ Arabic
- ◯ Cantonese
- ◯ Vietnamese
- ◯ [ ] Other - please list:

Do you have private health insurance?

- ◯ Yes
- ◯ No
- ◯ Don't know

Section 2: General Health ✓

In general, would you say your health is ...

- ◯ Excellent
- ◯ Very good
- ◯ Good
- ◯ Fair
- ◯ Poor

Have you ever been diagnosed with cancer?

- ◯ Yes
- ◯ No
- ◯ Don't know

Which type of cancer?

- ☐ Melanoma
- ☐ Skin (not melanoma)
- ☐ Prostate
- ☐ Breast
- ☐ Bowel
- ☐ Lung
- ☐ Lymphoma
- ☐ _____ Other - please list:
- ☐ Don't know

Has a current or former partner ever been diagnosed with cancer?

- ◯ Yes
- ◯ No

Which type of cancer?

- [ ] Melanoma
- [ ] Skin (not melanoma)
- [ ] Prostate
- [ ] Breast
- [ ] Bowel
- [ ] Lung
- [ ] Lymphoma
- [ ] Other - please list:
- [ ] Don't know

Has anyone in your immediate family (parents, siblings or children) ever been diagnosed with cancer?

- ◯ Yes
- ◯ No
- ◯ Don't know

Which type of cancer? Please tick all that apply

- [ ] melanoma
- [ ] Skin (not melanoma)
- [ ] Prostate
- [ ] Breast
- [ ] Bowel
- [ ] Lung
- [ ] Lymphoma
- [ ] Other - please list:
- [ ] Don't know

Who was this? Please tick all that apply

- ◯ Mother
- ◯ Father
- ◯ Sister
- ◯ Brother
- ◯ Daughter
- ◯ Son
- ◯ [ ] Other - please list:

How worried are you about developing melanoma?

- ◯ Not worried at all
- ◯ A bit worried
- ◯ Quite worried
- ◯ Very worried

Sometimes, medical action is clearly necessary and sometimes it is clearly not necessary. Other times, reasonable people differ in their beliefs about whether medical action is needed.
In situations where it's not clear, do you tend to lean towards taking action or do you prefer to wait and see if action is needed?
Importantly, there is no right way to be.

I strongly lean towards wait and see.	I lean towards wait and see.	I somewhat lean towards wait and see.	I somewhat lean towards taking action.	I lean towards taking action.	I strongly lean towards taking action.
◯	◯	◯	◯	◯	◯

The following questions are related to how you have been feeling over the past two weeks. Please read each statement and then choose the most appropriate

option regarding how you felt in the last two weeks.

	At no time	Some of the time	Less than half of the time	More than half of the time	Most of the time	All of the time
I have felt cheerful and in good spirits.	○	○	○	○	○	○
I have felt calm and relaxed.	○	○	○	○	○	○
I have felt active and vigorous.	○	○	○	○	○	○
I woke up feeling fresh and rested.	○	○	○	○	○	○
My daily life has been filled with things that interest me.	○	○	○	○	○	○

Please respond to the following statements.

	Not at all true	Hardly true	Moderately true	Exactly true
I can always manage to solve difficult problems if I try hard enough.	○	○	○	○
If someone opposes me, I can find the means and ways to get what I want.	○	○	○	○
It is easy for me to stick to my aims and accomplish my goals.	○	○	○	○
I am confident that I could deal efficiently with unexpected events.	○	○	○	○

	Not at all true	Hardly true	Moderately true	Exactly true
Thanks to my resourcefulness, I know how to handle unforeseen situations.	○	○	○	○
I can solve most problems if I invest the necessary effort.	○	○	○	○
I can remain calm when facing difficulties because I can rely on my coping abilities.	○	○	○	○
When I am confronted with a problem, I can usually find several solutions.	○	○	○	○
If I am in trouble, I can usually think of a solution.	○	○	○	○
I can usually handle whatever comes my way.	○	○	○	○

Section 3: Health Literacy ✓

How often do you need to have someone help you when you read instructions, pamphlets or other written material from your doctor or pharmacy?

- ○ Always
- ○ Often
- ○ Sometimes
- ○ Occasionally
- ○ Never

Hypothetical - Control

Please read the hypothetical information below and answer the questions that follow. You are asked to imagine as if the following information is true. Please answer how you would feel or react if you were in this situation, to the best of your ability.

You are at the doctor (GP) after you recently had a small surgery done to remove one of your moles.

The doctor has the test results and says: “We found a melanoma in situ. We removed it all, with at least 3mm of normal skin around the melanoma in situ. You can decide whether or not you want us to remove more normal skin from around the scar. And you can also decide whether you would like to book in for regular skin checks with me every 6 months, or whether you would like us to teach you how to check your skin yourself and only book in to see us if you're worried about another mole. I recommend any of these options as a reasonable choice, and I will organise which ever ones you prefer."

Hypothetical - Label 1

Please read the information below and answer the questions that follow. Please note that you will be asked to imagine as if the following information is true. Please answer how you would feel or react if you were in this situation, to the best of your ability.

You are at the doctor (GP) after you recently had a small surgery done to remove one of your moles.

The doctor has the test results and says: “We found a low risk melanocytic neoplasm. We removed it all, with at least 3mm of normal skin around the low risk melanocytic neoplasm. You can decide whether or not you want us to remove more normal skin from around the scar. And you can also decide whether you would like to book in for regular skin checks with me every 6 months, or whether you would like us to teach you how to check your skin yourself and only book in to see us if you're worried about another mole. I recommend any of these options as a reasonable choice, and I will organise which ever ones you prefer."

Hypothetical - Label 2

Please read the information below and answer the questions that follow. Please note that you will be asked to imagine as if the following information is true. Please answer how you would feel or react if you were in this situation, to the best of your ability.

You are at the doctor (GP) after you recently had a small surgery done to remove one of your moles.

The doctor has the test results and says: “We found a low-risk melanocytic neoplasm, in situ. We removed it all, with at least 3mm of normal skin around the low-risk melanocytic neoplasm, in situ. You can decide whether or not you want us to remove more normal skin from around the scar. And you can also decide whether you would like to book in for regular skin checks with me every 6 months, or whether you would like us to teach you how to check your skin yourself and only book in to see us if you're worried about another mole. I recommend any of these options as a reasonable choice, and I will organise which ever ones you prefer."

Section 5: Primary and Secondary Outcome Measures ✓

After learning of your pathology result, how anxious do you feel?

	Not anxious at all									Extemely anxious
	0	1	2	3	4	5	6	7	8	9	10
How anxious											

After learning of your pathology result, what percentage risk do you think you have of developing an invasive melanoma in your lifetime?

	Low risk										High risk
	0	10	20	30	40	50	60	70	80	90	100
How anxious											

After learning of your pathology result, what percentage risk do you think you have of dying from melanoma?

	Low risk										High risk
	0	10	20	30	40	50	60	70	80	90	100
How anxious											

After learning of your pathology result, which of these surgery management options would you choose?

- ◯ No further surgery
- ◯ Further surgery to remove more skin around the scar (so that the distance from the margins to the melanoma in situ are greater than 5 mm)

Please tell us how you decided on that surgery management option. What were

the important factors that helped you decide? [This question is optional].

After making that surgery management choice, how anxious do you feel?

	Not anxious at all									Extemely anxious
	0	1	2	3	4	5	6	7	8	9	10
How anxious											

After learning of your pathology result, which of these follow up management options would you choose?

- ◯ I do my own skin checks with help from my partner/friend/relative. I am taught how to examine my total body and am given a special imaging device that clips on my phone. I have access to videos and online support to help me do skin checks and to use the imaging device. I can take images of any moles that concern me and send these to a dermatologist. If they are also concerned, then I am booked into clinic with my doctor for a skin check.
- ◯ My doctor does my skin check at regular 6 monthly appointments

Please tell us how you decided on that follow up management option. What were the important factors that helped you decide? [This question is optional].

After making that follow up management choice, how anxious do you feel?

	Not anxious at all									Extemely anxious
	0	1	2	3	4	5	6	7	8	9	10
How anxious											

Section 6: Debrief Statement ✓

You were a participant in this study which aimed to investigate how people would react to different information provision on diagnosis of a low-risk prostate lesion results by the label given to the prostate lesion.

During the study, you were asked to imagine a hypothetical scenario in which you or your partner are given a diagnosis result after having gone to a routine screening. You were then asked to complete a series of survey questions.

You were randomised to receive one of three different hypothetical scenarios.

These three diagnosis scenarios were:

1. Diagnosis of a melanoma in situ.
2. Diagnosis of a low-risk melanocytic neoplasm.
3. Diagnosis of a low-risk melanocytic neoplasm, in situ.

The purpose of this study was to examine the impact of these different labels/diagnoses on preferred management strategy and psychological outcomes such as worry and health seeking intentions.

It is important to remember that this study was entirely hypothetical (made up). The study team does not have access to any of your medical history.

If you have any further questions regarding the study, feel free to contact Prof Katy Bell (katy.bell@sydney.edu.au)

For more information on melanoma and skin checks, please visit the following websites:

Melanoma Institute Australia

Cancer Council - Melanoma

Section 7: Feedback ✓

Thank you for your participation in the survey. Your time and contribution is greatly appreciated. If you are interested in the results of the study, the results and a lay summary of the results will be published at the following permanent web page: Wiser Healthcare publications

Appendix D. Supplementary Materials for Chapter 3

The study CONSORT checklist

Section/topic	No	CONSORT 2025 checklist item description	Reported on page no.
Title and abstract			
Title and structured abstract	1a	Identification as a randomised trial	2
	1b	Structured summary of the trial design, methods, results, and conclusions	2
Open science			
Trial registration	2	Name of trial registry, identifying number (with URL) and date of registration	3
Protocol and statistical analysis plan	3	Where the trial protocol and statistical analysis plan can be accessed	6
Data sharing	4	Where and how the individual de-identified participant data (including data dictionary), statistical code and any other materials can be accessed	6
Funding and conflicts of interest	5a	Sources of funding and other support (eg, supply of drugs), and role of funders in the design, conduct, analysis and reporting of the trial	10
	5b	Financial and other conflicts of interest of the manuscript authors	10-11
Introduction			
Background and rationale	6	Scientific background and rationale	5-6
Objectives	7	Specific objectives related to benefits and harms	5-6
Methods			
Patient and public involvement	8	Details of patient or public involvement in the design, conduct and reporting of the trial	7
Trial design	9	Description of trial design including type of trial (eg, parallel group, crossover), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	7
Changes to trial protocol	10	Important changes to the trial after it commenced including any outcomes or analyses that were not prespecified, with reason	8
Trial setting	11	Settings (eg, community, hospital) and locations (eg, countries, sites) where the trial was conducted	8
Eligibility criteria	12a	Eligibility criteria for participants	9
	12b	If applicable, eligibility criteria for sites and for individuals delivering the interventions (eg, surgeons, physiotherapists)	NA
Intervention and comparator	13	Intervention and comparator with sufficient details to allow replication. If relevant, where additional materials describing the intervention and comparator (eg, intervention manual) can be accessed	7-8

Outcomes	14	Prespecified primary and secondary outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome	7-8
Harms	15	How harms were defined and assessed (eg, systematically, non-systematically)	NA
Sample size	16a	How sample size was determined, including all assumptions supporting the sample size calculation	9
	16b	Explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	17a	Who generated the random allocation sequence and the method used	7
	17b	Type of randomisation and details of any restriction (eg, stratification, blocking and block size)	7
			Reported on page no.
Allocation concealment mechanism	18	Mechanism used to implement the random allocation sequence (eg, central computer/telephone; sequentially numbered, opaque, sealed containers), describing any steps to conceal the sequence until interventions were assigned	7
Implementation	19	Whether the personnel who enrolled and those who assigned participants to the interventions had access to the random allocation sequence	7
Blinding	20a	Who was blinded after assignment to interventions (eg, participants, care providers, outcome assessors, data analysts)	7
	20b	If blinded, how blinding was achieved and description of the similarity of interventions	7-8
Statistical methods	21a	Statistical methods used to compare groups for primary and secondary outcomes, including harms	9-10
	21b	Definition of who is included in each analysis (eg, all randomised participants), and in which group	9-10
	21c	How missing data were handled in the analysis	NA
	21d	Methods for any additional analyses (eg, subgroup and sensitivity analyses), distinguishing prespecified from post hoc	11-14
Results			
Participant flow, including flow diagram	22a	For each group, the numbers of participants who were randomly assigned, received intended intervention, and were analysed for the primary outcome	11-14
	22b	For each group, losses and exclusions after randomisation, together with reasons	In Supplement
Recruitment	23a	Dates defining the periods of recruitment and follow-up for outcomes of benefits and harms	7
	23b	If relevant, why the trial ended or was stopped	NA
Intervention and comparator delivery	24a	Intervention and comparator as they were actually administered (eg, where appropriate, who delivered the intervention/comparator, how participants adhered, whether they were delivered as intended (fidelity))	11-14
	24b	Concomitant care received during the trial for each group	In supplement
Baseline data	25	A table showing baseline demographic and clinical characteristics for each group	In supplement
Numbers analysed, outcomes and estimation	26	For each primary and secondary outcome, by group: ● the number of participants included in the analysis	

		● the number of participants with available data at the outcome time point ● result for each group, and the estimated effect size and its precision (such as 95% confidence interval) ● for binary outcomes, presentation of both absolute and relative effect size	
Harms	27	All harms or unintended events in each group	7
Ancillary analyses	28	Any other analyses performed, including subgroup and sensitivity analyses, distinguishing pre-specified from post hoc	NA
Discussion			14-17
Interpretation	29	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	17
Limitations	30	Trial limitations, addressing sources of potential bias, imprecision, generalisability, and, if relevant, multiplicity of analyses	

Citation: Hopewell S, Chan AW, Collins GS, Hróbjartsson A, Moher D, Schulz KF, et al. CONSORT 2025 Statement: updated guideline for reporting randomised trials. BMJ. 2025; 388:e081123. https://dx.doi.org/10.1136/bmj-2024-081123

*We strongly recommend reading this statement in conjunction with the CONSORT 2025 Explanation and Elaboration and/or the CONSORT 2025 Expanded Checklist for important clarifications on all the items. We also recommend reading relevant CONSORT extensions. See www.consort-spirit.org.

Appendix E. Supplementary Materials for Chapter 4

Appendix for Exploring how diagnostic labels for low-risk melanocytic pathology shape perceived risk and management preferences

Table 1. Example explanations for perceived risk of dying from melanoma

Theme	Subtheme	Example quotes (label)
Lower chance of dying	Low-risk diagnosis perception from the diagnostic label	"I would not worry unless they gave me a bad result." (*Melanoma in situ*) "It is really low risk and they removed the whole mole." (*Low-risk melanocytic neoplasm*) "It's low risk, so I don't believe my chance of dying from this would be very high" (*Low-risk melanocytic neoplasm*) "It's low risk." (*Low-risk melanocytic neoplasm, in situ*) "Being in the low risk category gives me confidence" (*Low-risk melanocytic neoplasm, in situ*)
	Low personal risk	"I get annual skin checks at a cancer clinic so hopefully would catch it early." (*Melanoma in situ*) "I don't think I have enough moles to worry about" (*Melanoma in situ*) "I've always used sun protection." (*Low-risk melanocytic neoplasm*) "I do not go out in the sun [as] I am very aware of the damage it can do" (*Low-risk melanocytic neoplasm, in situ*) "I don't go out into the sun as much." (*Low-risk melanocytic neoplasm, in situ*)
	Competing medical risks	"Lots of other things I am more likely to die from." (*Melanoma in situ*) "I think another cancer might take me earlier." (*Low-risk melanocytic neoplasm*) "I am 90 so it wouldn't have time." (*Low-risk melanocytic neoplasm, in situ*)
	Melanoma is curable	"I think skin cancer is highly curable and low risk of death." (*Melanoma in situ*) "Think there is lots of medical advances now to help" (*Melanoma in situ*) "There are treatments that work if caught soon enough." (*Low-risk melanocytic neoplasm*) "If caught early enough, it should all be removed successfully." (*Low-risk melanocytic neoplasm, in situ*)
Higher chance of dying	High-risk diagnosis from the diagnostic label	"Melanoma diagnosis would make me think this sort of problem might happen again." (*Melanoma in situ*) "It's still a melanoma." (*Low-risk melanocytic neoplasm*)

		"Although 'low risk', an insufficient area surrounding it has been removed." (*Low-risk melanocytic neoplasm, in situ*)
	High personal risk	"Family history of melanoma." (*Melanoma in situ*)
		"I have a fair complexion and spend quite a lot of time outside." (*Low-risk melanocytic neoplasm*)
		"I have had it once before so my chances are high of getting it again." (*Low-risk melanocytic neoplasm, in situ*)
	Fear of melanoma	"Cancer… always comes back and kills you." (*Melanoma in situ*)
		"Cancer, although disappearing for a while, always comes back and kills you, it's just a matter of time" (*Melanoma in situ*)
		"People I know died from melanoma." (*Low-risk melanocytic neoplasm*)
		"Very dangerous." (*Low-risk melanocytic neoplasm, in situ*)
Other	Average	"I just think it would be each way." (*Melanoma in situ*)
		"Anything is possible." (*Low-risk melanocytic neoplasm*)
		"Life is 50/50." (*Low-risk melanocytic neoplasm, in situ*)

The SRQR study checklist

Standards for Reporting Qualitative Research (SRQR)*

http://www.equator-network.org/reporting-guidelines/srqr/

	Page/line no(s).
Title and abstract	
Title - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	1
Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	2-3
Introduction	
Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	4
Purpose or research question - Purpose of the study and specific objectives or questions	4
Methods	
Qualitative approach and research paradigm - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**	4-5
Researcher characteristics and reflexivity - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	6
Context - Setting/site and salient contextual factors; rationale**	4-5
Sampling strategy - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**	5
Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	5
Data collection methods - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**	4-5

Data collection instruments and technologies - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	4-5
Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	6
Data processing - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	4-6
Data analysis - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	6
Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	6

Results/findings

Synthesis and interpretation - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	6-12
Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	6-12

Discussion

Integration with prior work, implications, transferability, and contribution(s) to the field - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	12-14
Limitations - Trustworthiness and limitations of findings	14

Other

Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	Declare on submission
Funding - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	Declare on submission

*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

**The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

Reference:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative research: a synthesis of recommendations.** *Academic Medicine*, Vol. 89, No. 9 / Sept 2014

DOI: 10.1097/ACM.0000000000000388