# A pilot randomised controlled trial examining the feasibility, acceptability and impact of giving information on personalised genomic risk of melanoma to the public, for motivating preventive behaviours

**Anne Cust**
Cancer Epidemiology and Prevention Research Group
Sydney School of Public Health & Melanoma Institute Australia
The University of Sydney, Australia

SYDNEY MEDICAL SCHOOL

THE UNIVERSITY OF SYDNEY

# Background

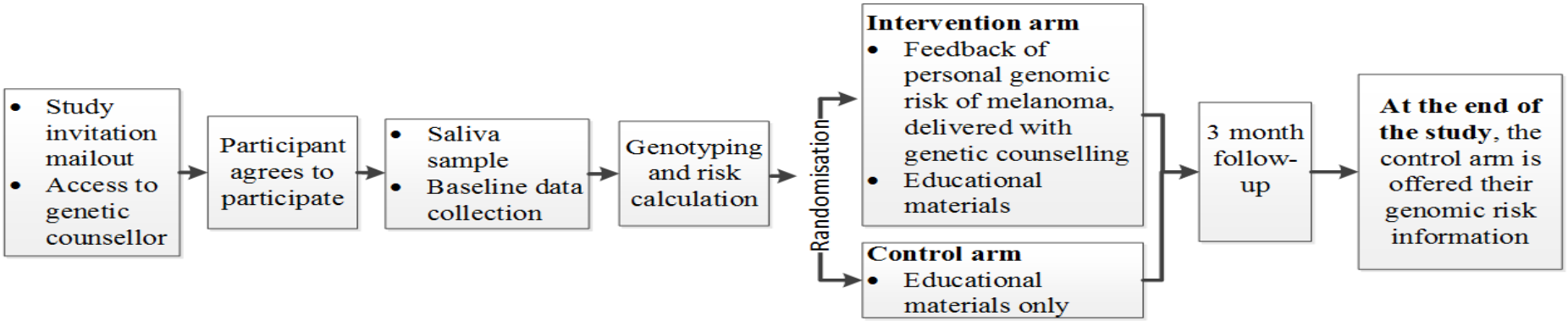
- A role for genomic risk information in *cancer prevention* has not yet been established outside rare familial syndromes
- Highly personalised nature of providing genomic risk information may be a more powerful motivator of behaviour change than standard approaches
- Can genomic risk information be used as a new strategy for primary prevention and early detection of cancer in the general population?

# Research questions

**Does knowledge of personal genomic risk of melanoma motivate behaviour change among the general population?**

**What are the broader ethical, psychological, social & economic implications?**

# Pilot RCT design




**Eligibility:** Aged 18-69 years, living in NSW

**Recruitment and follow-up**:

- 41% consent, 118 randomised
- 92% completion of 3-month follow-up questionnaires
- 87% elected to have a copy of their risk information sent to their doctor

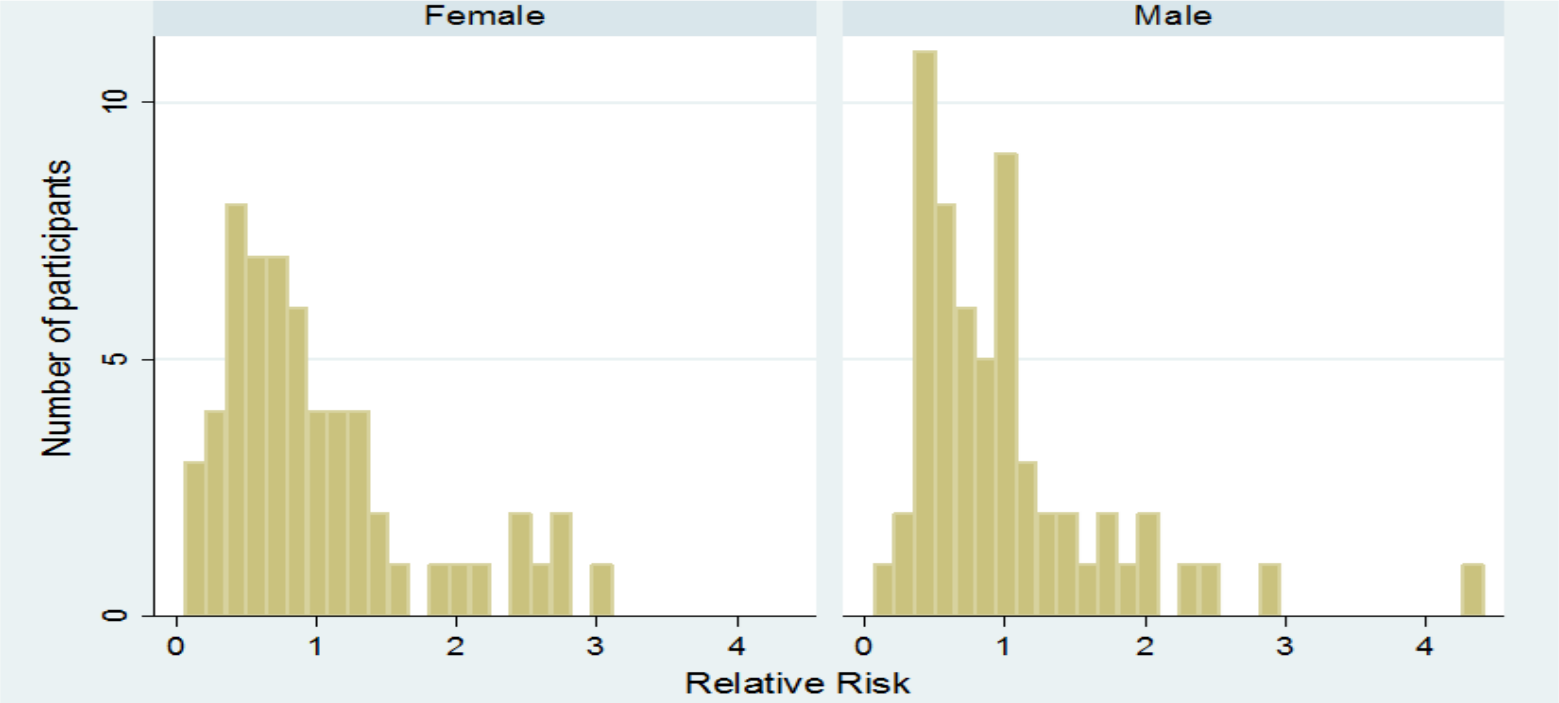
# Estimation of genomic risk

- 42 SNPs from 21 genes involved in pigmentation, nevus, telomere and other (unknown) pathways

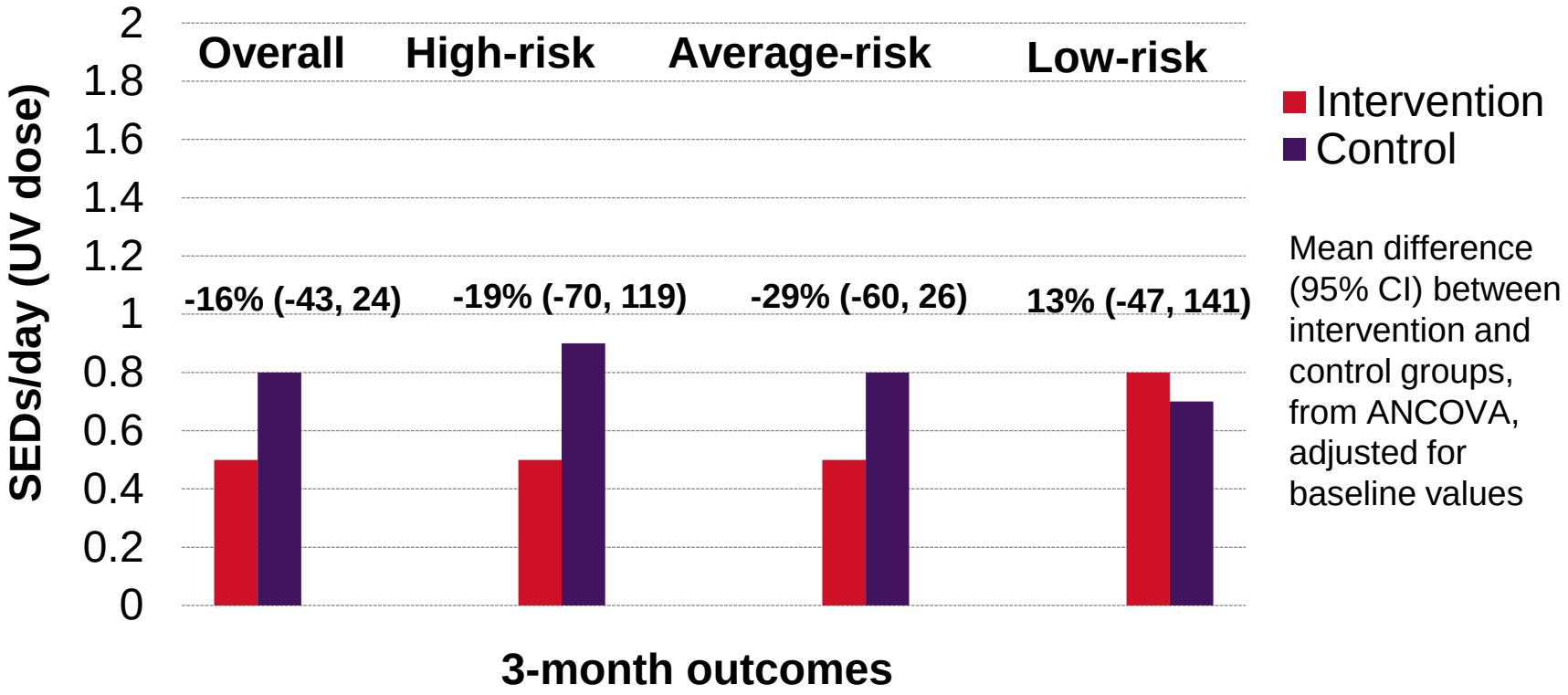
- Risks estimated (all SNPs combined) presented as:
  - 1) an **absolute-risk** estimate of the participant's remaining lifetime risk of developing melanoma
  - 2) a **relative risk -** compared to people their age & sex
  - 2) a **risk level** – high, average, low risk

# Distribution of relative risk estimates

Mean relative risk = 1, Median = 0.8



# Objective UV measure at 3-months




Mean difference (95% CI) between intervention and control groups, from ANCOVA, adjusted for baseline values

# Self-reported behaviours at 3-months

Compared to controls, the intervention group reported:

- Reduced intentional tanning ($p=0.06$)
- More likely to limit time in the sun during midday hours ($p=0.06$)
- Increased shade-seeking behaviour ($p=0.13$)
- Increased confidence identifying melanoma ($p=0.008$)
- Effect sizes appeared stronger for the average-risk group (and $p<0.05$ for all measures above)

# Psychological measures at 3-months

Compared to controls, the intervention group reported:

- **No difference in skin-cancer related worry**
  - Overall mean difference: -0.1, 95% CI -0.3, 0.1 (on a scale of 1-5)
  - High-risk group: 0.1 , 95% CI -0.2, 0.5

- **No difference in psychological distress and well-being** (MHI-5)
  - Overall mean difference: -0.4, 95% CI -4.7, 4.0 (on a scale of 0-100)
  - High-risk group: -0.1, 95% CI -8.3, 8.2

# Participant feedback

- …genuinely surprised by the result …and as a result of the risk info his wife has now booked him into the GP next week to have his first skin check
- Participant [with very fair skin, lots of moles and 3 x BCCs] could understand why she would receive a high risk result. She said her high risk result reinforces her need to be vigilant about sun protection and screening
- Participant felt it was very valuable to receive this information so he was aware he was at higher risk and could undergo appropriate checks

# Participant feedback

- “I appreciated that you sent the info about my genetic risk of melanoma to my GP. That prompted a conversation and a whole body skin check :) we're going to schedule that in biannually with my pap smear from now on.”

- “I have just renegotiated my life insurance and I ticked the box around have you had any genetic tests as "No“ I did not want to cause reason for them requesting my medical records unduly, and did not want my premiums affected.”

# Conclusions

- Results from this pilot study demonstrate the strong interest, feasibility and acceptability of giving information on personalised genomic risk of melanoma to the public.
- These preliminary results suggested some beneficial changes to preventive behaviours
- There was no evidence of adverse impacts on general distress or worry

# Acknowledgements

**Collaborators**

- Amelia Smit, Ainsley Newson, David Espinoza, Georgina Fenton, Lucinda Freeman, Louise Keogh, Phyllis Butow, Graham Mann, Michael Kimlin, Matthew Law, Rachael Morton, Judy Kirk, Suzanne Dobbinson, Peter Kanetsky, Kate Dunlop.

**Funding**

- Career Development Fellowships from the NHMRC and Cancer Institute NSW
- Sydney Catalyst Translational Cancer Centre pilot & seed grant
- University of Sydney Cancer SPARC grant