SWAT 174: Comparing health technologies for participant adherence and trial outcome data collection

Objective of this SWAT
Primary Objective:
To determine the effect of using a higher cost, mobile dermatoscope (with polarised light source), compared to a lower cost mobile dermatoscope (with no external light source), on ability of teledermatologists assess images and consequently recommend management in a randomised trial of patient-led surveillance in people with previously excised localised melanoma (MEL-SELF).

Secondary Objectives:
To determine the effect of using a higher cost mobile dermatoscope, compared to a lower cost mobile dermatoscope, on participant adherence (submission of images by participants) in a patient-led surveillance trial in people with early-stage melanoma.
To evaluate the use of an adaptive randomisation approach to optimise health outcome data.
To demonstrate that robust comparative clinical effectiveness data may be generated in a trial setting, supporting the transition of trial evidence into clinical practice.

Study area: Intervention adherence, Data Quality, Randomisation
Sample type: Participants
Estimated funding level needed: Low

Background
Reliance on a single model of health technology (e.g. medical device or test) for collecting data in a trial may expose trials to operational risk (including failure to complete the trial if the technology is no longer produced, participants do not adhere because of device deficiencies or if the technology is too difficult for patients to use), and the risk of producing incomplete data or data of insufficient quality for accurate assessment. Having at least two alternative devices for data collection may protect against these risks. More broadly, health technologies are frequently modified after they are introduced into clinical practice, and competitors might introduce alternatives with varying modifications. Adoption of these new modifications and versions of a technology after regulatory approval often occurs without critical evaluation of comparative effectiveness.(1) This SWAT will determine if robust comparative clinical effectiveness data may be generated in a trial setting, supporting the transition of trial evidence into clinical practice.

The SWAT will run in the intervention group of the MEL-SELF randomised trial of patient-led surveillance compared to clinician-led surveillance in people treated for early-stage melanoma (stage 0/I/II).(2) The host trial will assess whether patient-led surveillance (comprising: smartphone supported skin self-examination, teledermatology, fast-tracked unscheduled clinic visits in addition to routinely scheduled clinic visits) compared to clinician-led surveillance (usual care using treating doctors usual processes for fast-tracked unscheduled and for routinely scheduled clinic visits) increases the proportion of participants who are diagnosed with a subsequent new primary or recurrent melanoma at a fast-tracked unscheduled clinic visit.

MEL-SELF will provide a mobile dermatoscope to participants randomised to the intervention group. This digital device clips onto a smart phone and allows patients to take magnified images of concerning skin lesions for remote review by a dermatologist. Within the intervention group, participants will be randomised to either a lower cost non-polarised device or a higher cost polarised device.

Interventions and comparators
Intervention 1: Lower cost non-polarised dermatoscope
Intervention 2: Higher cost polarised dermatoscope

Index Type: Intervention: technology alternatives, Method of data collection,

Method for allocating to intervention or comparator
Adaptive randomisation. Randomisation to type of device will use permuted blocks of varying size, stratified by key variables that might influence use of the device (Specialist vs GP-led treatment

centre, age, and gender). The combination of adherence with the technology and quality of images will also be used for adaptive randomisation to protect against poor performance of one dermatoscope. The ratio will be adapted depending on adherence with submission of images that are of sufficient quality for teledermatology reporting. After 60 participants have been randomised into the intervention group, we will measure the proportion of intervention participants who have had an image reported on at one month after their baseline images were due. If there is >30% absolute difference in the proportion of intervention participants who have had an image reported on, subsequent participants will be randomised 2:1 to the dermatoscope model where more participants had an image reported on. If there is >50% absolute difference in the proportion of intervention participants who have had an image reported on, then all subsequent participants will be randomised to dermatoscope model where more participants had an image that was reported on.

Outcome measures
Primary: Proportion of participants who have a teledermatologist recommendation for management in response to a submitted image at one month after their baseline images were due.
Secondary: 1. Proportion of participants who have a teledermatologist recommendation for management in response to a submitted image at one month after their 3-month and 6-month images were due.
2. Proportion of participants who submit images of their target lesion at one month after their baseline, 3-month and 6-month images were due.
3. Proportion of all images submitted that are successfully reported on up to the 6-month timepoint.
4. Qualitative assessment of dermatologist comments on submitted images.
5. Quality of sequential images of the target lesion taken by the participant using the device and submitted for teledermatologist assessment at baseline, 3-month and 6-month time point (measured using a validated quality scale modified for use in the MEL-SELF trial) (3)
6. Device deficiencies reported by the 6-month timepoint.
7. Participant ease of use (assessed with a 5-point Likert scale question and an open-ended question in the 6-month questionnaire and qualitative assessment in interview) and analytical data from the online platform and app.

Analysis plans
Descriptive statistics (counts and percentages) will be used to report successful teledermatology assessments at baseline, 3, and 6 months. We will report the absolute difference in proportions and estimate the 95% confidence intervals. Quality of images will be measured using a checklist adapted from tool developed to assess the quality of images acquired by consumers and tested in another teledermatology study and reported using appropriate descriptive statistics.(3) Device deficiencies will be summarised with the counts reported per randomised group. Participant reported ease of use will be summarised using descriptive statistics for the quantitative responses. Qualitative methods will be used to analyse the open-ended questions, participant interviews and clinician comments.

Possible problems in implementing this SWAT
Using two devices may require additional staff time for administrative tasks and additional training. There is a risk of poor performance of one device. We are protecting against this with a pre-planned interim analysis with pre-defined stopping rules.

References
1. Bell KJL, Bossuyt P, Glasziou P, Irwig L. Assessment of changes to screening programmes: why randomisation is important. BMJ 2015;350:h1566.
2. Ackermann DM, Smit AK, Janda M, van Kemenade CH, Dieng M, Morton RL, et al. Can patient-led surveillance detect subsequent new primary or recurrent melanomas and reduce the need for routinely scheduled follow-up? A protocol for the MEL-SELF randomised controlled trial. Trials 2021;22(1):324.
3. Koh U, Betz-Stablein B, O'Hara M, Horsham C, Curiel-Lewandrowski C, Soyer HP, et al. Development of a Checklist Tool to Assess the Quality of Skin Lesion Images Acquired by Consumers Using Sequential Mobile Teledermoscopy. Dermatology 2021.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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