INFORMATION SHEET
For Healthcare Providers

MELANOMA SURVEILLANCE PHOTOGRAPHY TO IMPROVE EARLY DETECTION OF MELANOMA

BACKGROUND

Patients with a history of melanoma are at increased risk of subsequent primary melanomas. High risk patients often have multiple excisions of suspicious lesions 'just in case'. Melanoma surveillance photography (MSP) is a comprehensive surveillance method that combines 2D or 3D total body photography (images of the whole skin surface) with digital dermoscopy (close-up photos of individual skin lesions) to closely monitor lesions, and is performed at set intervals. MSP may reduce the number of benign lesions removed by providing objective evidence of change (or lack thereof), however, to date, there is insufficient evidence that MSP improves outcomes. MSP is therefore not currently reimbursed by Medicare and is often costly. This trial, sponsored by Monash University, coordinated by Melanoma and Skin Cancer Trials and approved by the Alfred Hospital Ethics Committee, will help provide the information needed by the Medical Services Advisory Committee to decide if MSP should be covered by Medicare.

Inclusion Criteria

Patients may be included if they meet ALL of the following criteria:

1. Aged 18 years or more at date of diagnosis
2. WITHIN 24 MONTHS OF HISTOLOGICALLY CONFIRMED PRIMARY CUTANEOUS MELANOMA (IN SITU OR INVASIVE)
3. Able to provide informed consent, complete questionnaires and attend a trial site for MSP
4. Appropriate for TBP referral, able to stand unassisted
5. High or very high risk of subsequent primary melanoma according to risk assessment tool*
6. 'Some' or 'Many' naevi (see figure 1)
7. Not previously under surveillance with TBP**
8. Living in Australia and not planning to move overseas within the next 3 years

Patients who have previously undergone dermoscopic imaging of ***individual*** lesions **ARE ELIGIBLE**.

**You are not required to calculate risk prior to referring your patient.*

***Patients that meet all eligibility criteria ***except* for #7** i.e. have previously been under surveillance with TBP **ARE ELIGIBLE** for IMAGE **Sub-study 1** (see page 2).

Exclusion Criteria

Patients will be excluded from the study for ANY of the following reasons:

1. Stage IV metastatic melanoma
2. Ocular melanoma, mucosal melanoma
3. Participation in another study involving MSP

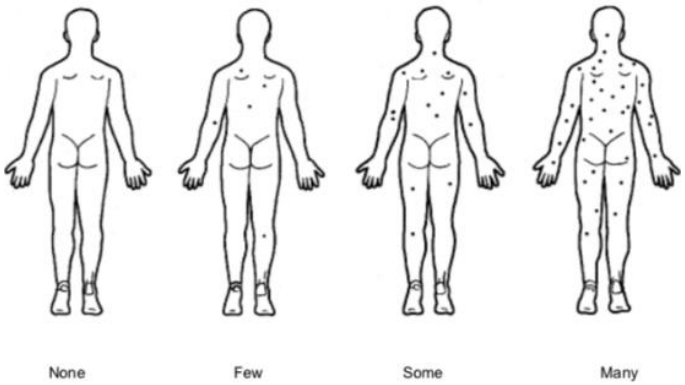


Figure 1: PICTOGRAM USED IN THE AUSTRALIAN MELANOMA FAMILY STUDY JAMA DERMATOLOGY 2016

Referral to your nearest IMAGE Research Team is encouraged, visit https://www.masc.org.au/image/ for more information

DESIGN:

A multicentre registry based randomised control trial.

PARTICIPANTS:

Adults with a diagnosis of primary melanoma (insitu or invasive) within the last 24 months (2 years).

CONTROL GROUP:

Continue 'standard care' routine clinical surveillance without MSP with their usual treating doctor and complete questionnaires at baseline, 12 and 24 months. Upon completion, participants will be invited to receive 3D total body photography (at no cost).

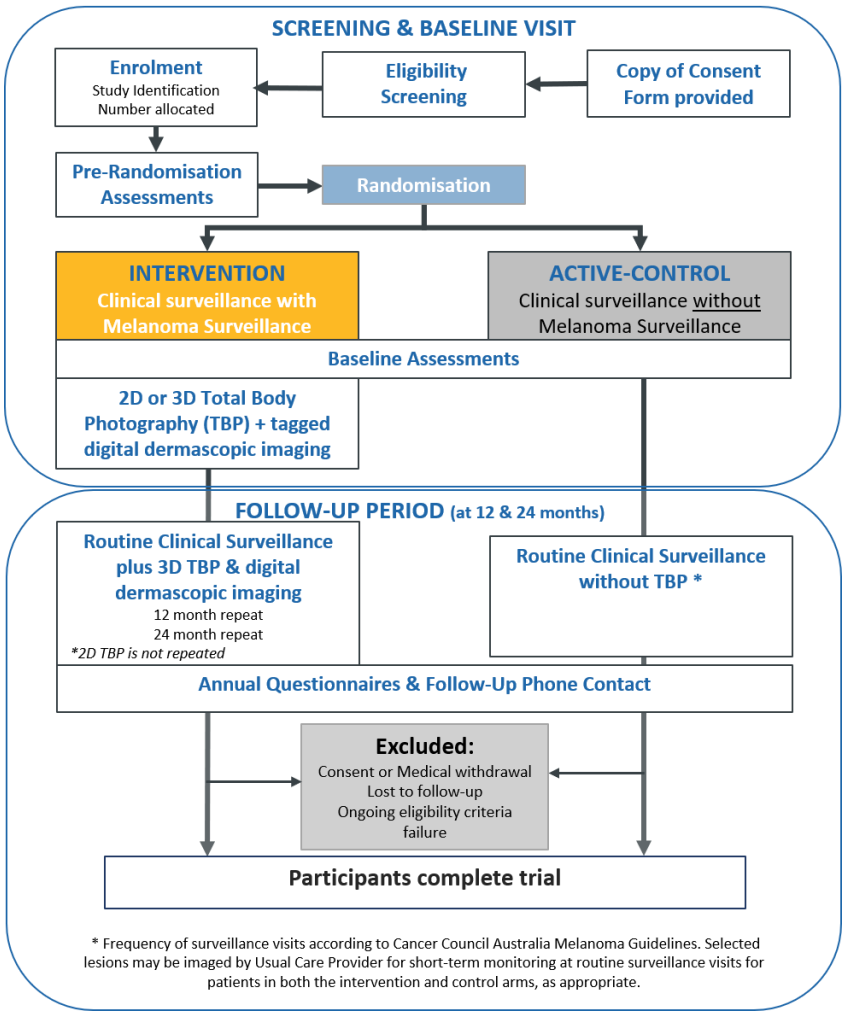
MAIN AIM:

To test whether surveillance with MSP compared to surveillance without MSP will lead to better patient outcomes in high and ultra-high risk patients. The primary outcome is diagnostic performance measured by the number of unnecessary biopsies (i.e. lesions biopsied to diagnose melanoma which are confirmed on pathology as benign).

INTERVENTION GROUP:

MSP (2D or 3D total body photography and digital dermoscopy) taken at trial site. A copy of images on USB is provided for routine clinical surveillance visits with their usual treating doctor. Participants attend trial site for repeat digital dermoscopy and complete questionnaires at 12 and 24 months.

Figure 2 TRIAL SCHEMA AND DESIGN



SUB-STUDY 1:

To assess benefit of MSP in high-risk patients who have not yet had a melanoma, this trial will compare Breslow thickness of the primary melanoma and biopsy rates prior to diagnosis amongst participants who were under surveillance with MSP to those under surveillance without MSP prior to their melanoma diagnosis.

This will involve linkage with MBS data over a 4.5-year timeframe prior to trial enrolment.