# Pilot RCT of decreased scheduled visits and digitally supported self-examination compared to usual care in people treated for localised melanoma

**Aim:** To conduct a pilot RCT among 100 adult patients treated for localised melanoma to assess the impact of decreased scheduled visits coupled with digitally supported self-examination compared to usual care. We will examine effects on patients’ adherence with self-examination, confidence in performing self-examination, level of fear of new or recurrent melanoma, number of clinic visits attended by patients (scheduled and un-scheduled), who first detected lesions, number of lesions biopsied or removed and number of melanoma and non-melanoma skin cancers discovered.

**Study Design:** Figure 1 shows the design of the trial. We will recruit 100 adult patients (18+ years old) who have been treated for a first primary localised melanoma (stage 0-II), between one and three years previously and who are undergoing follow-up with participating clinicians at Melanoma Institute Australia (MIA) and two General Practices and randomise in a ratio of 3:2 to intervention or control.

The intervention comprises: (i) decreased frequency of scheduled clinics (annual review for stage 0/I; six monthly review for stage IIa and 4 monthly review for stage IIb/c) (ii) a computer tablet App. (with instructional videos and electronic reporting of text and photos of lesions discovered on self-examination(8)), participant performed teledermoscopy, email/SMS reminders to do total skin self-examination every 2 months and an educational booklet. Controls will have (i) scheduled clinics as per guideline recommendations (annual clinic for stage 0, six monthly review for stage I, 4 monthly review for stage IIa and and 3 monthly review for stage IIb/c); (ii) email/SMS reminders to do total skin self-examination every 2 months and an educational booklet.

The project manager will use (i) administrative data from the MIA database and GP databases (ii) patient information on booking and attendance at MIA or GP clinics to identify potential participants who are due to attend for a routine clinic visit in the near future. The RA will then check this against their medical record (including clinician letters) to identify potential participants who appear to not meet exclusion criteria: no partner or friend to help with self-examination, non-English speaking, cognitive impairment, unable to perform self-examination, do not have access to WiFi/email, 1+ “high risk” criteria which makes them at very high risk of melanoma or non-melanoma skin cancer: dysplastic nevus syndrome (DNS); .a family history of at least 3 first-degree or second-degree relatives with a confirmed history of malignant melanoma; personal history of > 1 primary invasive melanoma; confirmed CDKN2A (OMIM 600160) or CDK4 (OMIM 123829) gene mutation (the highest-penetrance susceptibility gene mutations for melanoma); 2+ non-melanoma skin cancer in the last 5 years; 10+ cryotherapy treatments at the last clinic visit.

Potential participants will be sent study materials and invited to participate in the trial. Those that return a signed consent form will then be sent a questionnaire in the mail and online to measure demographics and their baseline level of fear of new or recurrent melanoma (using a melanoma specific version of the FCRI). The final decision on the eligibility of potential participants will be made by their clinician using standardised forms to apply the exclusion criteria. Consenting patients who finally meet all inclusion/exclusion criteria will be given the educational booklet at the clinic visit and randomised to intervention or control. They will be booked in for follow-up visits as per the intervention or control schedule. The project manager will deliver the tablet (loaded with ASICA and dermoscopy Apps) + mobile dermoscope to participants in the intervention group by one of the following methods: in person at clinic, by car, or courier. We aim to finish recruitment after six months.

We will measure outcomes at six months and 12 months follow-up. Outcomes will be measured through phone interview, online/postal questionnaire, data collected through computer tablets (in the intervention group), patient diaries on costs and resource use, review of MIA and GP data on clinic visits, surgical procedures and pathology reports and melanoma follow-up details from clinics outside of MIA/participating GPs where possible.

**Primary outcome:** Proportion of potential participants invited to participate who are recruited into the trial. **Secondary outcomes:** Adherence with recommended skin self-examination practice (total body self-examination conducted two- monthly); confidence, knowledge and attitudes to self-examination; whether adherence differs between tablet/Smartphone naive users compared to experienced users in the intervention group, level of fear of new or recurrent melanoma, number of lesions surgically evaluated, number and stage of new or recurrent melanoma and non-melanoma skin cancer detected; number of clinic visits attended (both scheduled and unscheduled) and resource use and costs.

**Statistical considerations:** A sample size of 100 participants will ensure that the 95% CI for the proportion of eligible patients who are recruited has a margin of error of less than 10%. Difference in secondary outcomes between randomised groups will be analysed with t-tests for continuous variables, chi-square tests for categorical variables and Poisson regression for count data.

**Expected Outcomes:** This will be the first randomised comparison to evaluate the impact of decreased scheduled follow-up coupled with digitally supported skin self-examination, compared to usual practice, on patient adherence with recommended skin self-examination practice, patient confidence, number of clinic visits attended, costs and other patient relevant outcomes. These results will be reported in high impact general medical, oncology or dermatology journal(s) and/or presented at international conferences. The data from this study will also be used to establish feasibility, and inform the planning, for a large randomised controlled trial of the same intervention, for which we will apply for funding from NHMRC, Cancer Australia and Cancer Council NSW.

**Budget considerations:**

**Figure: Design of a pilot randomised trial of an intervention to decrease scheduled visits and increase patient expertise in skin self-examination after treatment for localised melanoma.**

