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Assessing the Potential for Patient-led Surveillance After Treatment of Localized Melanoma (MEL-SELF)
A Pilot Randomized Clinical Trial

Deonna M. Ackermann, MPH; Mbathio Dieng, PhD; Ellie Medcalf, MPH; Marisa C. Jenkins, MScMed; Cathelijne H. van Kemenade, MPH; Monika Janda, PhD; Robin M. Turner, PhD; Anne E. Cust, PhD; Rachael L. Morton, PhD; Les Irwig, PhD; Pascale Guitera, PhD; H. Peter Soyer, MD; Victoria Mar, MD; Jolyn K. Hersch, PhD; Donald Low; Cynthia Low, MLitt; Robyn P. M. Saw, MS; Richard A. Scolyer, MD; Dorothy Drabarek, MIPH; David Espinoza, MBiostat; Anthony Azzi, MD; Alister M. Lilleyman, MD; Amelia K. Smit, PhD; Peter Murchie, PhD; John F. Thompson, MD; Katy J. L. Bell, PhD

IMPORTANCE Patient-led surveillance is a promising new model of follow-up care following excision of localized melanoma.

OBJECTIVE To determine whether patient-led surveillance in patients with prior localized primary cutaneous melanoma is as safe, feasible, and acceptable as clinician-led surveillance.

DESIGN, SETTING, AND PARTICIPANTS This was a pilot for a randomized clinical trial at 2 specialist-led clinics in metropolitan Sydney, Australia, and a primary care skin cancer clinic managed by general practitioners in metropolitan Newcastle, Australia. The participants were 100 patients who had been treated for localized melanoma, owned a smartphone, had a partner to assist with skin self-examination (SSE), and had been routinely attending scheduled follow-up visits. The study was conducted from November 1, 2018, to January 17, 2020, with analysis performed from September 1, 2020, to November 15, 2020.

INTERVENTION Participants were randomized (1:1) to 6 months of patient-led surveillance (the intervention comprised usual care plus reminders to perform SSE, patient-performed dermoscopy, teledermatologist assessment, and fast-tracked unscheduled clinic visits) or clinician-led surveillance (the control was usual care).

MAIN OUTCOMES AND MEASURES The primary outcome was the proportion of eligible and contacted patients who were randomized. Secondary outcomes included patient-reported outcomes (eg, SSE knowledge, attitudes, and practices, psychological outcomes, other health care use) and clinical outcomes (eg, clinic visits, skin surgeries, subsequent new primary or recurrent melanoma).

RESULTS Of 326 patients who were eligible and contacted, 100 (31%) patients (mean [SD] age, 58.7 [12.0] years; 53 [53%] men) were randomized to patient-led (n = 49) or clinician-led (n = 51) surveillance. Data were available on patient-reported outcomes for 66 participants and on clinical outcomes for 100 participants. Compared with clinician-led surveillance, patient-led surveillance was associated with increased SSE frequency (odds ratio [OR], 3.5; 95% CI, 0.9 to 14.0) and thoroughness (OR, 2.2; 95% CI, 0.8 to 5.7), had no detectable adverse effect on psychological outcomes (fear of cancer recurrence subscale score; mean difference, −1.3; 95% CI, −3.1 to 0.5), and increased clinic visits (risk ratio [RR], 1.5; 95% CI, 1.1 to 2.1), skin lesion excisions (RR, 1.1; 95% CI, 0.6 to 2.0), and subsequent melanoma diagnoses and subsequent melanoma diagnoses (risk difference, 10%; 95% CI, −2% to 23%). New primary melanomas and 1 local recurrence were diagnosed in 8 (16%) of the participants in the intervention group, including 5 (10%) ahead of routinely scheduled visits; and in 3 (6%) of the participants in the control group, with none (0%) ahead of routinely scheduled visits (risk difference, 10%; 95% CI, 2% to 19%).

CONCLUSIONS AND RELEVANCE This pilot of a randomized clinical trial found that patient-led surveillance after treatment of localized melanoma appears to be safe, feasible, and acceptable. Experiences from this pilot study have prompted improvements to the trial processes for the larger trial of the same intervention.

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Supplemental content

Author Affiliations: Author affiliations are listed at the end of this article.

Corresponding Author: Katy J. L. Bell, PhD, Faculty of Medicine and Health, Sydney School of Public Health, Edward Ford Bldg, The University of Sydney, Sydney NSW 2006, Australia (katy.bell@sydney.edu.au).

Cutaneous melanoma is associated with high morbidity and mortality burden in populations of European ancestry.[1,2] In Australia, the incidence has been increasing since the 1980s, largely driven by increased diagnoses of localized melanoma before it has spread from the primary site on the skin (>95% of all new melanoma diagnoses in Australia in 2011).[3] After surgical excision of a localized melanoma, patients are recommended to undergo long-term follow-up at routinely scheduled clinic visits (clinician-led surveillance).[4] However, the frequency and duration of clinician surveillance varies widely, leading to substantial differences in health care utilization and costs and unclear clinical benefits for higher utilization patterns of care.[5] Some patients experience psychological harms (eg, anxiety) leading up to each visit,[6-8] and many do not adhere to follow-up schedules recommended by physicians.[9] Clinician-led surveillance can also incur considerable financial and opportunity costs to both the patient and the health care system, which may not be sustainable if melanoma incidence continues to rise.[10]

Patient-led surveillance is an alternative model of follow-up after treatment of localized melanoma, based on evidence that patients and their partners detect many subsequent new primary or recurrent melanomas ahead of a routinely scheduled clinic visit.[11,12] Although skin self-examination (SSE) by patients is universally recommended in clinical guidelines, it is often performed inadequately.[13,14] The patient-led model may include the following interventions: training in SSE (delivered face-to-face or via internet platform and/or smartphone applications), digital technologies to record and take images of concerning lesions (eg, smartphone applications, mobile dermatoscopes), online systems for submitting images for remote review by a dermatologist, and advice on whether urgent clinical review may be needed (teledermatology).[13] Previously, many physicians were reluctant to use telehealth methods, eg, teledermatology[15,16]; however, these methods have become more accepted during the COVID-19 pandemic as an alternative to traditional face-to-face consultations.[17] This model of care could address the current inequity of access to dermatologists and other melanoma specialists where populations are geographically dispersed, such as in Australia where 29% of residents live outside of major cities.[18]

To assess whether patient-led surveillance may be recommended as an alternative model of care in clinical practice, robust evidence is needed of its effects on health, psychological, and resource use outcomes compared with those of clinician-led surveillance. As a first step toward generating this evidence, we undertook a pilot trial to assess the feasibility, acceptability, and safety (including psychological effects) of patient-led surveillance compared with clinician-led surveillance.[19,20]

Key Points

Question What is the feasibility, acceptability, and safety of patient-led surveillance compared with clinician-led surveillance in patients who were previously treated for localized melanoma?

Findings This pilot randomized clinical trial including 100 patients found that patient-led surveillance was safe, feasible, and acceptable. Despite limited statistical power to detect effects on secondary outcomes, the intervention appears to improve skin self-examination practice and detection of subsequent new primary melanomas.

Meaning Patient-led surveillance is a promising new model of follow-up care after excision of localized melanoma; a larger randomized clinical trial will evaluate comparative effects on important health, psychological, and resource use outcomes.

Methods

Trial Design

The MELanoma SELF surveillance (MEL-SELF) pilot study was a randomized clinical trial (RCT) of patients previously treated for melanoma. Nine physicians from 2 melanoma specialty clinics and 1 primary care skin cancer clinic recruited participants in New South Wales, Australia. Of patients who were eligible and contacted, 100 were randomized to 6 months of patient-led surveillance plus usual care (ie, educational booklet[21] and routinely scheduled visits) or to clinician-led surveillance (usual care only).

The Sydney Local Health District Ethics Committee approved MEL-SELF, and the trial registered in the Australian and New Zealand Clinical Trials Registry. Written informed consent was obtained from each participant. The study is reported according to the Consolidated Standards of Reporting Trials (CONSORT) guidelines and was conducted from November 1, 2018, to January 17, 2020. The MEL-SELF trial protocol is available in Supplement 1.

Participants

Participants were recruited by their treating physician and were eligible if they had been treated for a stage 0, I, or II localized melanoma,[22] were attending routinely scheduled clinics, owned a compatible smartphone, were able to perform SSE (as determined by the recruiting physician), had a skin-check partner (ie, a family member or friend) who could assist them, were able to understand English, and had no history of cognitive impairment. There were no restrictions on how much time had passed since the diagnosis and treatment of their first primary melanoma. Details on participant enrollment and consent can be found in the study protocol (Supplement 1) and **Figure 1**.

Randomization

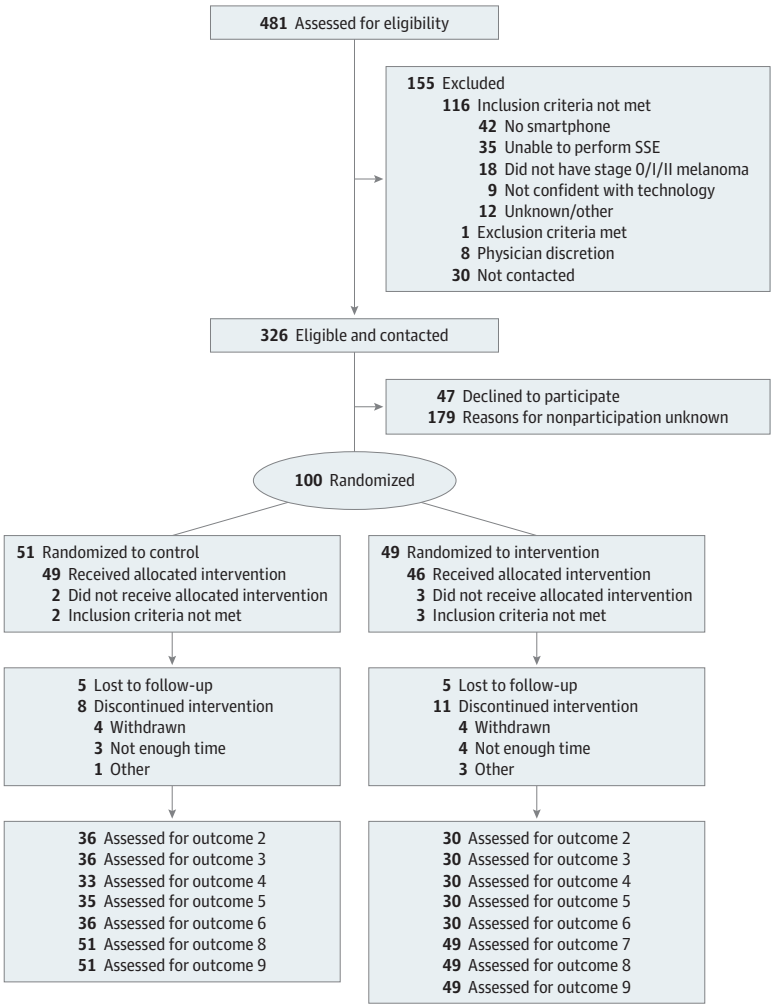
To ensure allocation concealment, participants were randomized 1:1 to either the intervention or the control group using an interactive voice recognition system provided by an offsite telephone randomization service. We accounted for the following stratification factors: age, group, sex, clinic type, and melanoma stage.[22] Owing to the nature of the research question, it was not possible to mask participants nor study coordinators to study group. The histopathologic findings for any new primary melanoma diagnoses were reviewed by the study dermatopathologist (R.A.S.), who was masked to study group.

Interventions

Patient-led Surveillance

The intervention group received usual care plus patient-led surveillance, which was composed of instructional videos on

Figure 1. Flowchart of Randomized Participants



All outcomes are reported in the Methods section and detailed in the eBox in Supplement 2. SSE denotes skin self-examination.

how to perform SSE, reminders to undertake SSE, a mobile dermatoscope attached to their smartphone, an application (app) that facilitated store-and-forward teledermatology, and fast-tracked unscheduled clinic visits. A schematic representation of patient-led surveillance is shown in **Figure 2**.

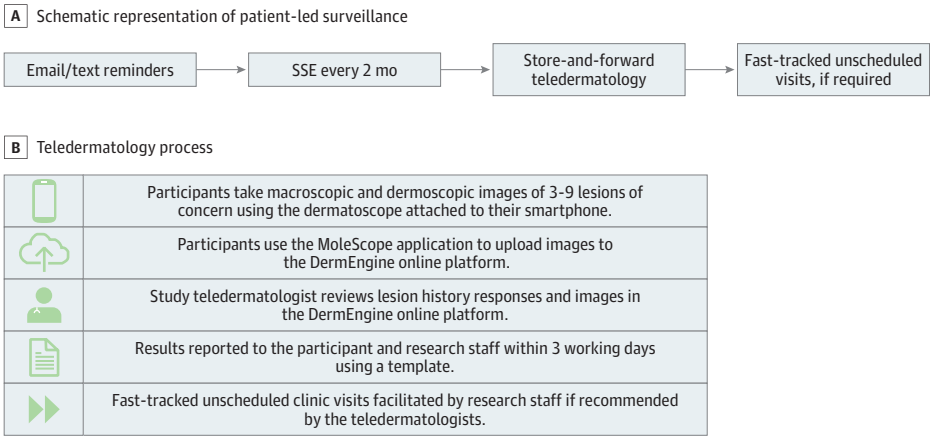
An internet-based version of the Achieving Self-directed Integrated Cancer Aftercare (ASICA) Skin-Checker app was used to guide total SSE (delivered via REDCap, Vanderbilt University).[23,24] The ASICA animated instructional videos—adapted for the Australian context—demonstrate how to conduct sequential SSE for each part of the body and provide guidance on identifying suspicious pigmented skin lesions and locoregional recurrence.[25,26] Reminders to complete SSE and upload images of suggestive lesions were sent every 2 months by short message service (text) and/or email, with further follow-up by telephone and email if tasks were overdue.

Skin self-examination was supported by a store-and-forward teledermatology process (Figure 2) with transmission of participant images and lesion history to a dermatologist for review. Participants received a mobile dermatoscope (MoleScope,™ MetaOptima) to attach to their smartphone, and they downloaded the device's app, which integrates it with a web-based teledermatology software system (DermEngine,™ MetaOptima). Participants were asked to take macroscopic and dermoscopic images of 3 to 9 different skin lesions that appeared most concerning and to include information on why the lesion was concerning to them. One of 3 trial teledermatologists (P.G., H.P.S., or V.J.M.) reviewed the information and digital images for each submission and provided results to the participant via the app within 3 working days. Research staff facilitated fast-tracked unscheduled clinic visits when needed. Detailed written and video instructions on how to use the dermatoscope and app were provided to participants. Research staff could be contacted via telephone or email by participants if they needed guidance or support with completing tasks.

Clinician-led Surveillance

Both randomized groups received usual care, that is, routinely scheduled or unscheduled clinic visits as determined by the treating physician(s) and an educational booklet. The booklet included instructions on how to conduct SSE and what signs to look for that might indicate a possible melanoma.[21]

Figure 2. Patient-led Melanoma Surveillance Model



A, Schematic summary of patient-led surveillance processes. B, Schematic summary of the teledermatology process. A template for sharing results of a dermatologic review with the patients is available in Supplement 2. SSE denotes skin self-examination.

Outcomes and Statistical Analysis

The trial outcomes are presented in the eBox in Supplement 2. A sample size of 100 participants with 1:1 allocation to intervention or control groups was calculated to ensure that the 95% CIs for the primary outcome had a margin of error of less than 10% (the trial protocol in Supplement 1 provides further details on sample size calculations). In accordance with the CONSORT guidelines for pilot trials,[20] no formal hypothesis testing was conducted. We calculated point estimates and 95% CIs for all outcomes. Analyses adhered to the intention-to-treat principle.

For the primary outcome, the proportion was estimated using the number of patients screened who were eligible and contacted as the denominator and the number of patients who were randomized as the numerator. The confidence interval was estimated using the Clopper-Pearson method.[27] We also estimated summary statistics of baseline characteristics for the population: screened, eligible and contacted, eligible and contacted but not randomized, randomized, and completed the 6-month questionnaire.

We selected the following secondary outcomes: (1) confidence in, knowledge of, and attitudes and beliefs about SSE; (2) adherence to recommended total body SSE practice; (3) level of fear of new subsequent primary or recurrent melanoma; (4) general anxiety, stress, and depression measured using the Depression Anxiety Stress Scales-21[28]; (5) acceptability of reducing the frequency of routinely scheduled clinic visits (to be reported separately); (6) successful submission of dermoscopic images for teledermatology (intervention group only); (7) number of skin clinic visits attended (scheduled and unscheduled); (8) number of skin lesions surgically excised and new subsequent primary or recurrent melanoma diagnoses; and (9) skin cancer-related health care resources use (to be reported separately). For the secondary outcomes, we estimated summary statistics at baseline and 6 months for randomized participants in intervention and control groups.

We estimated the effect of the intervention through logistic regression for binary outcomes, multiple linear regression for continuous outcomes, and Poisson regression for count outcomes. We used negative binomial regression for count outcomes where overdispersion was present. For noncontinuous outcomes, we estimated the effect of the intervention at 6 months using univariable models. For continuous outcomes, we included baseline measurement of the outcome in the models as a covariate to estimate between group difference in change from baseline.[29] For new melanoma diagnoses, we calculated the difference in proportions and confidence intervals using the χ^2 method without continuity correction. Sensitivity analyses removing outliers from linear regression analyses were also conducted. Analysis was performed from September 1, 2020, to November 15, 2020, using RStudio, version 1.2.5 (RStudio, PBC). We did not conduct hypothesis testing because it is not recommended for pilot studies.[20]

Results

A summary of recruitment into the trial is presented in Figure 1. Of the 481 patients screened from November 1, 2018, to May 24, 2019, for eligibility, 125 were ineligible and 30 could not be contacted, leaving 326 patients who were eligible and contacted. Of these, 100 patients (mean age [SD], 58.7 (12.0) years; 53 (54%) men) were randomized and enrolled in the trial (31% of 326 eligible/contacted patients; 95% CI, 26%-36%). Details on why screened patients were not randomized are provided in eTable 2 in Supplement 2. Of the 100 patients randomized, 49 were allocated to the intervention group and 51 to the control group. The clinical and demographic characteristics of the eligible and contacted and the patients randomized were similar (eTable 1 in Supplement 2).

Clinical and demographic characteristics were generally well balanced across the randomized intervention and control groups (**Table 1**). Of the 100 patients who were randomized, 30 in the intervention group (61% of 49) and 36 in the control group (71% of 51) completed the 6-month questionnaire and were included in the analyses of the patient-reported secondary outcomes (outcomes 2-5). Demographic and clinical characteristics were similar for participants who

Table 1. Baseline Characteristics of Randomized Participants

Characteristic	Frequencies, No. (%)[a]		
	Control	Intervention	Total
No.	51	49	100
Age, mean (SD), y	59.7 (11.6)	57.5 (12.3)	58.7 (12.0)
Sex			
Female	24 (47)	22 (45)	46 (46)
Male	27 (53)	27 (55)	54 (54)
No. of melanomas			
1	43 (84)	33 (67)	76 (76)
2	5 (10)	8 (16)	13 (13)
3 or more	3 (6)	8 (16)	11 (11)
Melanoma substage (highest substage if multiple primary melanomas)[b]			
0	18 (35)	18 (37)	36 (36)
IA	22 (43)	27 (55)	49 (49)
IB	6 (12)	3 (6)	9 (9)
IIA	1 (2)	0	1 (1)
IIB	2 (4)	0	2 (2)
III/IV	2 (4)	0	2 (2)
Unknown	0	1 (2)	1 (1)
Median time elapsed since diagnosis (IQR),[c]			
First melanoma diagnosis	5.9 (0.2-41.7)	5.5 (0.1-41.2)	5.6 (0.1-41.7)
Most recent melanoma diagnosis	5.6 (0.2-41.7)	4.3 (0.1-41.2)	4.7 (0.1-41.7)
Site			
Sydney	28 (55)	27 (55)	55 (55)
Newcastle	23 (45)	22 (45)	45 (45)
Indigenous status			
Neither Aboriginal nor Torres Strait Islander	33 (65)	41 (84)	74 (74)
Unknown	18 (35)	8 (16)	26 (26)
Main language spoken at home			
English	44 (86)	43 (88)	87 (87)
Other	7 (14)	6 (12)	13 (13)
Marital status			
Single, never married	2 (4)	2 (4)	4 (4)
Married	33 (65)	38 (78)	71 (71)
De facto/committed relationship	5 (10)	3 (6)	8 (8)
Separated/divorced	1 (2)	0	1 (1)
Widowed	3 (6)	0	3 (3)
Unknown	7 (14)	6 (12)	13 (13)
Level of education			
No formal	0	0	0
Primary school	1 (2)	0	1 (1)
High school diploma/certificate	9 (18)	11 (22)	20 (20)
Vocational diploma/certificate	7 (14)	9 (18)	16 (16)
Bachelor's degree	16 (31)	11 (22)	27 (27)
Postgraduate degree or higher	11 (22)	12 (25)	23 (23)
Unknown	7 (14)	6 (12)	13 (13)
Remoteness (based on postal code)[d]			
Metropolitan area/city	42 (82)	38 (78)	80 (80)
Inner regional/rural area	2 (4)	5 (10)	7 (7)
Unknown	7 (14)	6 (12)	13 (13)

[a] Percentages may not sum to 100 owing to rounding.

[b] According to guidelines from the American Joint Committee on Cancer.[22]

[c] Missing data for 4 control participants and 2 intervention participants.

[d] Per data from the Australian Bureau of Statistics, remoteness structure, July 2016.

did or did not complete the 6-month questionnaire (eTable 9 in Supplement 2). Of the 34 patients who did not complete it, 24 had withdrawn (14 from the intervention group, 10 from control) and 10 did not respond to repeated reminders from research staff (5 patients from each group). Reasons for withdrawal are provided in eTable 3 in Supplement 2. All 49 participants in the intervention group were included in the analysis of successful image submission (outcome 7), and all 100 randomized participants were included in the analysis of clinical outcomes (outcomes 8 and 9).

Table 2. Skin Self-examination Practices

Practice	Frequencies, No. (%)[a]				Effect, OR (95% CI)[b]
	Control (n = 51)		Intervention (n = 49)		
	Baseline	Follow-up	Baseline	Follow-up	
How many skin self-examinations performed per month?[c]					
<2	16 (36)	10 (28)	13 (30)	3 (10)	1 [Reference]
≥2	28 (64)	26 (72)	30 (70)	27 (90)	3.5 (0.9 to 14.0)
Area examined[d]					
Back of neck/scalp					
No	35 (80)	27 (75)	31 (72)	17 (55)	1 [Reference]
Yes	9 (20)	9 (25)	12 (28)	14 (45)	2.5 (0.9 to 7.0)
Torso					
No	31 (70)	30 (83)	31 (72)	20 (65)	1 [Reference]
Yes	13 (30)	6 (17)	12 (28)	11 (35)	2.8 (0.9 to 8.6)
Feet					
No	36 (82)	33 (92)	36 (84)	19 (61)	1 [Reference]
Yes	8 (18)	3 (8)	7 (16)	12 (39)	7.0 (1.7 to 27.8)
Buttocks					
No	42 (95)	33 (92)	39 (91)	22 (71)	1 [Reference]
Yes	2 (5)	3 (8)	4 (9)	9 (29)	4.5 (1.1 to 18.5)
Whole body skin surface examined?[e]					
No	38 (84)	23 (64)	36 (82)	14 (45)	1 [Reference]
Yes	7 (16)	13 (36)	8 (18)	17 (55)	2.2 (0.8 to 5.7)
Mirror used during your last skin check?[f]					
No/do not know	23 (68)	14 (56)	16 (48)	9 (33)	1 [Reference]
Yes	11 (32)	11 (44)	17 (52)	18 (67)	2.6 (0.8 to 7.8)
Did someone help you see difficult areas during your last skin check?[f]					
No/do not know	7 (21)	4 (16)	8 (24)	2 (7)	1 [Reference]
Yes	27 (79)	21 (84)	25 (76)	25 (93)	2.4 (0.4 to 14.3)

Abbreviation: OR, odds ratio.

[a] Percentages may not sum to 100 owing to rounding.

[b] Odds ratios report differences between groups at follow-up.

[c] Missing data at baseline for 7 (14%) participants in the control group and 6 (12%) in intervention group; and at follow-up for 15 (29%) in the control group and 19 (39%) in intervention group.

[d] Missing data at baseline for 7 (14%) participants in the control group and 6 (12%) in the intervention group; and at follow-up for 15 (29%) in the control group and 18 (37%) in intervention group.

[e] Missing data at baseline for 6 (12%) participants in the control group and 5 (10%) in intervention group; and at follow-up for 15 (29%) in the control and 18 (37%) in the intervention group.

[f] Missing data at baseline for 17 (33%) participants in the control group and 16 (33%) in intervention group; and at follow-up for 26 (51%) in the control and 22 (45%) in the intervention group.

At the 6-month follow-up, the intervention group had higher levels of confidence and knowledge of SSE, more positive attitudes and beliefs toward SSE, and were more likely to engage in SSE compared with the control group (eTable 4 in Supplement 2). Patients in the intervention group were more likely to perform SSE at least every 2 months (odds ratio [OR], 3.5; 95% CI, 0.9-14.0) and examine all body areas (OR, 2.2; 95% CI, 0.8-5.7), including neck/scalp (OR, 2.5; 95% CI, 0.9-7.0), buttocks (OR, 4.5; 95% CI, 1.1-18.5), and feet (OR, 7.0; 95% CI, 1.7-27.8). They were also more likely to use a mirror to check difficult-to-see areas, such as the back (OR, 2.6; 95% CI, 0.8-7.8) and to do SSE with their skin-check partner (OR, 2.4; 95% CI, 0.4-14.3; **Table 2**; eTable 5 in Supplement 2).

There was no evidence of a difference in psychological outcomes between the randomized groups. The between-group mean score difference for change in Fear of Cancer Recurrence Inventory severity subscale (intervention relative to control) was −1.3 (95% CI, −3.1 to 0.5), and for change in total Depression Anxiety and Stress Scales, −1.4 (95% CI, −5.8 to 2.0). The between-group difference for change in the anxiety subscale score was −0.1 (95% CI, −1.3 to 1.1); in the depression subscale score, −1.4 (95% CI, −3.2 to 0.4); and in the stress subscale score, 0.2 (95% CI, −2.2 to 2.6; eTable 6 in Supplement 2). Sensitivity analyses excluding outliers yielded similar results.

During the 6-month period, 26 of the 49 intervention participants (53%) successfully submitted dermoscopic images and received teledermatology reports on 1 or more occasions, and 14 (29%) successfully submitted images on 2 or more occasions (eTable 7 in Supplement 2). A total of 353 images were submitted by 26 participants; the number (median) per participant ranged from 1 to 35 (11) images. In the intervention group, 29 (59%) participants used the ASICA skin checker internet-based app at least 1 time (eTable 7 in Supplement 2). Of the 23 intervention participants who did not submit an image, 14 withdrew from the trial citing a variety of reasons (eTable 3 in Supplement 2).

Participants in the intervention group attended more clinic visits compared with those in the control group (risk ratio [RR], 1.5; 95% CI, 1.1-2.1; **Table 3**). Of the 195 total clinic visits, 115 (59%) were attended by the intervention group and 80 (41%) by the control group. Of 147 routinely scheduled visits (76% of total 195 visits), 81 (55%) were by the intervention group and 66 (45%), by the control. Of 48 fast-tracked unscheduled visits (25% of total 195 visits), 34 (71%) were by the intervention group (22 prompted by teledermatology) and 14 (29%) by the control.

Intervention and control participants were equally likely to have lesions surgically excised (RR, 1.1; 95% CI, 0.6-2.0). Of the 103 lesions surgically excised during the trial period, 53 (52%) were in the intervention group (8 prompted by teledermatology) and 50 (49%) in the control group. eTable 10 in Supplement 2 provides a detailed account of the clinic visits for 5 participants (10%) in the intervention group and 1 par-

Table 3. Number of Clinic Visits Attended, Lesions Surgically Excised, and New Melanoma Diagnoses During the 12 Months After Randomization

Clinical outcome	No. (%)[a]		
	Control	Intervention	Effect, risk ratio (95% CI)
No. of patients	51	49	NA
No. of clinic visits, median (IQR)	1 (0 to 6)	2 (0 to 9)	1.5 (1.1 to 2.1)
No. of skin lesions surgically excised, median (IQR)	0 (0 to 10)	1 (0 to 5)	1.1 (0.6 to 2.0)
			Effect, difference in proportions (95% CI)
Participants with ≥1 surgical excision of skin lesion	21 (41)	28 (57)	16 (−3 to 35)
Participants with new keratinocyte cancer diagnoses			
Squamous cell carcinoma	7 (14)	3 (6)	NA
Basal cell carcinoma	8 (16)	9 (18)	NA
Total[b]	11 (22)	12 (25)	1 (−18 to 15)
Participants with new melanoma diagnoses, stage[c]			
0	1 (2)	6 (12)	NA
IA	1 (2)	2 (4)	NA
IB	0	0	NA
IIA	0	0	NA
IIB	0	0	NA
IIC[d]	1 (2)	0	NA
Total[e,f]	3 (6)	8 (16)	10 (−2 to 23)
New melanoma diagnoses prompted by visit type			
Unscheduled visit	0	5 (10)	10 (2 to 19)
Scheduled visit	3 (6)	3 (6)	0 (−9 to 10)

Abbreviation: NA, not applicable.

[a] All values reported are frequencies (column percentages) unless otherwise indicated. Percentages may not sum to 100 owing to rounding.

[b] In the intervention group, 2 participants had 2 keratinocyte diagnoses and 1 participant had 3; and in the control group, 4 participants had 2 keratinocyte diagnoses, 1 participant had 3, and 1 participant had 9.

[c] According to guidelines from the American Joint Committee on Cancer.[22]

[d] The stage IIC melanoma was a desmoplastic melanoma with a Breslow thickness of 4.5 mm diagnosed at a routinely scheduled 6-month follow-up visit.

[e] Among the 11 participants diagnosed with new melanomas, there were a total of 13 melanoma diagnosed because 1 participant in the intervention group and 1 in the control had 2 melanoma diagnoses each. At the patient level, the unadjusted odds ratio for a new melanoma diagnosis (intervention vs control) was 3.1 (95% CI, 0.8 to 12.5). After accounting for the number of prior melanomas (<2 vs ≥ 2 prior melanomas), the adjusted odds ratio (intervention vs control) was 2.6 (95% CI, 0.6 to 10.7).

[f] One participant with melanoma had a local recurrence of lentigo maligna initially diagnosed in 2017 that required re-excision because margins were involved. The patient detected recurrence at the site of the scar in 2019 and the teledermatologist recommended urgent review. Pathology revealed lentigo maligna (evidence of the previous scar was seen in the superficial dermis).

ticipant (2%) in the control group who attended more than 4 visits during the 12-month period (intervention range, 5-10 visits; control, 6 visits).

During the trial, 11 participants were diagnosed with a subsequent new primary melanoma or recurrence, including 8 in the intervention group and 3 in the control group (Table 3). The between-group difference in diagnosis with a subsequent new primary melanoma or recurrence was 10% (95% CI, −2% to 23%). Of 8 intervention group participants diagnosed with a subsequent new primary melanoma or recurrence, 5 had a new primary melanoma in situ (stage 0 melanoma), 1 had a locally recurrent melanoma in situ, and 2 had stage IA melanoma[22]; 5 had melanoma diagnoses at fast-tracked unscheduled clinic visits (4 prompted by teledermatology and 1 by patient concerns). The between-group difference in diagnosis at an unscheduled visit was 10% (95% CI, 2%-19%). The 3 intervention group participants who were diagnosed with melanoma at a routinely scheduled visit did not submit any images in the 2 months before the diagnosis of the subsequent primary melanoma (1 had withdrawn from the study, 1 did not submit any images, and 1 submitted images only after removal of the new primary melanoma). Of the 3 control group participants diagnosed with a subsequent melanoma, there was 1 each of stage 0, stage IA, and stage IIC; all 3 diagnoses were made at routinely scheduled visits. The median time between randomization and surgical removal of a new melanoma was 6 months (range, 5-11 months) for the 5 participants diagnosed at an unscheduled visit and 7 months (range, 5-11 months) for the 6 participants diagnosed at a routinely scheduled visit. Twenty-three participants had new keratinocyte cancer diagnoses, 11 in the control group and 12 in the intervention.

Discussion

In this RCT of patient-led melanoma surveillance, 31% of eligible and contacted patients were randomized, supporting the feasibility of conducting a larger trial of the same intervention. In addition, the intervention was associated with improvements in SSE knowledge, attitudes, and practices without any adverse psychological outcomes. Although only one-half of the intervention group submitted images for teledermoscopy (owing to withdrawals and nonresponse), the intervention increased attendance of clinic visits and diagnosis of new melanoma cases. The increased clinic

attendance may be partly because the intervention was implemented as an add-on feature rather than a replacement of routinely scheduled visits in the intervention group. Despite this, there were similar numbers of lesions excised and new keratinocyte cancer diagnoses across the randomized groups.

Most (5 of the 8) new melanoma diagnoses in the patient-led surveillance group were made at fast-tracked unscheduled visits. All 3 new diagnoses in the control group were made at routinely scheduled visits, including a stage IIC melanoma clinically assessed as likely to be a basal cell carcinoma; however, histologic examination revealed it to be a 4.5-mm thick desmoplastic melanoma.

Two sequential RCTs[31,32] conducted to support patients and their skin-check partners in performing SSE reported increases in the frequency and thoroughness of SSE and self-identified melanoma. The present study adds to those findings by showing that patient-performed teledermoscopy could be used to triage suggestive lesions and prompt further evaluation in the clinic. Another RCT found that patient-performed teledermoscopy was feasible and could achieve moderately high diagnostic accuracy in identifying suggestive lesions.[33] Two RCTs in The Netherlands and the UK support the safety and cost-effectiveness of a reduction in routinely scheduled clinic visits (MelFo trials).[34,35] We previously found that patients would be receptive to reducing routinely scheduled visits with physicians provided they were adequately supported to perform SSE.[13,36] Overall, this suggests that patient-led surveillance may be a useful complement or alternative to clinician-led surveillance for localized melanoma.

Recruitment in the current trial was just under one-third of eligible and contacted patients, which is within the range of equivalent estimates from other melanoma surveillance trials.[34-38] This proportion reflects both the trial-specific context (burden of trial procedures) and the challenges of introducing a novel intervention. We included 179 patients in our calculations who were missing information on why they were not recruited, although some may have been ineligible or not contacted. We are collecting more detailed information on recruitment processes in a larger ongoing trial of the same intervention.[39]

The increased detection of melanoma observed in the intervention group raises the possibility of overdiagnosis, that is, the detection of indolent lesions that would not cause harm if left untreated.[40,41] Melanoma overdiagnosis may produce substantial financial and opportunity costs to the health care system,[4,10,42] as well as psychological distress.[7,8] We note that, unlike increased detection associated with screening asymptomatic people at lower risk for melanoma,[43,44] the patients in the present study population were clinically considered to be at high risk of a melanoma. All had a history of at least 1 melanoma and were in long-term regular clinical surveillance (at intervals ranging from every 3 months to every 12 months). Evidence of their high-risk status is shown by the 6% annual incidence rate observed in the control arm. Also, recognizing the potential for overcalling owing to histopathologic disagreement about borderline lesions,[45] all melanomas diagnosed in the study period were reviewed centrally by an expert dermatopathologist (R.A.S.). A final consideration is a defining feature of patient-led surveillance: that patients will recognize suggestive changes in moles and skin lesions; this could arguably be seen as detection of a "symptomatic" lesion in contrast to abnormalities detected by physicians during a total body skin examination in the clinic. Nevertheless, long-term follow-up after the pilot trial and after the larger ongoing trial are needed to better determine the extent of overdiagnosis associated with patient-led surveillance.[46-48]

The difficulties that were encountered have provided important information for refining the design and conduct of a larger ongoing RCT of patient-led surveillance.[39] Improvements to address the patient burden include the introduction of an active run-in phase prior to randomization to ensure participants are able to adhere to the protocol and use of a "target lesion" (chosen by the treating physician) that the patient will monitor via teledermoscopy along with any other suggestive lesions they identify. We are providing more 1-on-1 training on the intervention technologies to patients, and we are training the skin-check partners as well. The frequency of SSE and teledermatology has been reduced from every 2 months to every 3 months in response to participant feedback from the pilot trial. This is also the recommended minimum interval for monitoring with sequential digital dermoscopic imaging.[49,50]

Improvements to reduce the potential for medical overuse[51] and support the provision of right care[52] include requesting a more detailed clinical history from the patient when submitting images and, to facilitate sequential monitoring of lesions, allocating a single teledermatologist to all of the images submitted by a single patient. Patients are asked to only submit images of lesions that are concerning or suggestive; patients may choose not to submit any images other than that of the target lesion. Lastly, to help teledermatologists adjust the threshold for recommending urgent clinical review, we implemented a system that provides feedback to teledermatologists on their patients' clinical outcomes as well as the option to request a second opinion when uncertain.

The larger ongoing RCT of patient-led surveillance aims to assess comparative effects on health, psychological, and resource use outcomes in patients with localized melanoma.[39] If the intervention is found to be beneficial, it may then be tested in other clinical populations at higher risk of new primary or recurrent melanoma, including patients with stage III disease[12,53] and organ transplant recipients.[54] This evidence may transform melanoma surveillance models of care for diverse patient populations.

Limitations

This study had some limitations. The interpretation of possible intervention effects on secondary outcomes was limited by the small sample size, with confidence intervals that were generally wide and often crossed null effect. There was a relatively high withdrawal and nonresponse rate and suboptimal adherence to the intervention. In addition to the reasons for withdrawal listed in eTable 3 in Supplement 2, we gained further understanding of the difficulties experienced

through interviews with participants in the intervention group. These difficulties included insufficient time for the intervention, trouble choosing which skin lesions to image, and the skin-check partner's stress, lack of confidence, and unwillingness to assist the participant. The findings of a detailed qualitative assessment of the predictors and influences of adherence to patient-led surveillance will be published separately.

Conclusions

This pilot randomized clinical trial found that patient-led surveillance of melanoma appears to be safe, feasible, and acceptable. A larger RCT will generate more robust evidence of comparative effects on patient outcomes.

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Author Affiliations: School of Public Health, The University of Sydney, Sydney, New South Wales, Australia (Ackermann, Medcalf, Jenkins, van Kemenade, Cust, Irwig, Hersch, Drabarek, Smit, Bell); National Health and Medical Research Council (NHMRC) Clinical Trials Centre, The University of Sydney, Sydney, New South Wales, Australia (Dieng, Morton, Espinoza); Centre for Health Services Research, The University of Queensland, Brisbane, Queensland, Australia (Janda); Biostatistics Centre, University of Otago, Dunedin, Otago, New Zealand (Turner); Melanoma Institute Australia, The University of Sydney, Sydney, New South Wales, Australia (Cust, Guitera, Saw, Scolyer, Thompson); The Daffodil Centre, The University of Sydney, Sydney, New South Wales, Australia (Cust, Smit); Royal Prince Alfred Hospital, Sydney, New South Wales, Australia (Guitera, Scolyer, Thompson); Faculty of Medicine and Health, Sydney Medical School, The University of Sydney, Sydney, New South Wales, Australia (Guitera, Scolyer); Dermatology Research Centre, The University of Queensland Diamantina Institute, The University of Queensland, Brisbane, Australia (Soyer); School of Public Health and Preventive Medicine, Monash University, Melbourne, Victoria, Australia (Mar); Cancer Voices New South Wales, Sydney, New South Wales, Australia (D. Low, C. Low); Faculty of Medicine and Health, Sydney Medical School, The University of Sydney, Sydney, New South Wales, Australia (Saw); New South Wales Health Pathology, Sydney, New South Wales, Australia (Scolyer); Charles Perkins Centre, The University of Sydney, Sydney, New South Wales, Australia (Scolyer); Newcastle Skin Check, Newcastle, New South Wales, Australia (Azzi, Lilleyman); Academic Primary Care Research Group, Division of Applied Health Sciences, University of Aberdeen, Aberdeen, Scotland, United Kingdom (Murchie).

Author Contributions: Dr Bell had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Ms Ackermann and Dr Dieng contributed equally to this work as co-first authors.
Concept and design: Dieng, van Kemenade, Turner, Cust, Morton, Irwig, Mar, Hersch, D. Low, C. Low, Smit, Murchie, Thompson, Bell.
Acquisition, analysis, or interpretation of data: Ackermann, Dieng, Medcalf, van Kemenade, Jenkins, Janda, Turner, Cust, Morton, Guitera, Soyer, Mar, Hersch, Saw, Scolyer, Drabarek, Espinoza, Azzi, Lilleyman, Thompson, Bell.
Drafting of the manuscript: Ackermann, Dieng, van Kemenade, Jenkins, Turner, Drabarek, Espinoza, Smit.
Critical revision of the manuscript for important intellectual content: All authors.
Statistical analysis: Medcalf, Turner, Espinoza, Bell.
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Supervision: Morton, Soyer, Hersch, Saw, Bell.
*Other–*Irwig.
Other–Qualitative results (Discussion): Drabarek.
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