



Title	Telemedicine in Dermatology: A Randomized Controlled Trial
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Aim

The project comprises two related, though distinct studies, with different objectives:

1. To assess the equivalence of store-and-forward tele-dermatology with conventional face-to-face consultation in setting a management plan for new, adult outpatient referrals.
2. To assess the equivalence of digital photography and dermoscopy with conventional face-to-face consultation in managing suspected cases of malignant melanoma (MM) or squamous cell carcinoma (SCC).

Conclusions and results

1. The study failed to recruit the number of patients required by the sample size calculations (208 recruited, number needed 892). The loss of control cases (26%) was greater than intervention cases (17%): difference 8% (95% CI: -3% to 19%, $p=0.18$). A statistically significant difference in ages between the two groups completing the study may have introduced a bias between the two groups. Another possible source of bias is the greater delay between the telemedicine opinion and the second opinion, whereas control cases usually received their second opinion on the same day as their outpatient appointment. In 55% (51/92) of telemedicine cases, and 78% (57/73) of control cases the diagnosis concurred (difference -23% 95% CI: -36% to -8%; $p=0.002$) with the second opinion. In 55% (51/92) of telemedicine cases, and 84% (61/73) of control cases, the management plan concurred with the second opinion (difference -28% 95% CI: -40 to -14%; $p=0.0001$). Of the 92 telemedicine cases, 53 (58% 95% CI: 47% to 67%) were judged also to require a face-to-face consultation, mainly to establish a diagnosis and treatment plan.
2. An unexpectedly high proportion (33%, 85/256) of referrals proved to have a malignancy or a severely dysplastic lesion, with almost 22% having MM or SCC, possibly reflecting the rise in incidence of skin

cancers reported elsewhere. When both standard and dermoscopic images were employed, diagnostic concordance was modest (68%). The approach was highly sensitive (98%, 95% CI: 92 to 99%), at the expense of specificity (43%, 95% CI: 36 to 51%). Overall, 30% of cases would not have needed to be seen face to face, but 2 SCCs would have been missed. If the highest thresholds of clinician confidence had been applied, no cancers would have been missed, but only 20% of patients would have avoided an outpatient appointment.

Recommendations

1. In view of the recruitment difficulties and the potential biases introduced by selective loss of patients and the delay in obtaining a valid second opinion in the study group, no valid conclusions can be drawn regarding the clinical performance of this model of store-and-forward telemedicine.
2. It is unlikely that digital photography with dermoscopy can dramatically reduce the need for conventional clinical consultations, while still maintaining clinical safety.

Methods

1. *Randomized controlled trial.* Patients in the telemedicine intervention group were referred to the consultant and managed, as far as possible, using one or more digital still images and a structured, electronic referral and reply. The control group was managed by conventional hospital outpatient consultation.
2. *Case series.* Patients referred under the Government's 2-week-wait for suspected skin cancer were photographed immediately prior to their outpatient appointment. Both standard and dermoscopic images were obtained if possible. A second opinion, based on photographs and referral forms was compared with the opinion of the consultant who saw the patient in clinic.