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Telemedicine in dermatology: a randomised controlled trial

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Abstract

Telemedicine in dermatology: a randomised controlled trial

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Objectives: To compare the clinical equivalence, patient and clinician opinion of store-and-forward (SF) teledermatology with conventional face-to-face consultation in setting a management plan for new, adult outpatient referrals. To assess the equivalence of digital photography and dermoscopy with conventional face-to-face consultation in the management of suspected cases of malignant melanoma or squamous cell carcinoma.
Design: For the SF teledermatology aspect of the study, a prospective randomised controlled trial was carried out.
Setting: Eight general practices and a hospital dermatology department in Sheffield, England.
Participants: For the SF teledermatology part of the study, adults (aged 16 years and over) requiring a new (not seen by a hospital dermatologist within the past year) consultant opinion. For the digital photography element of the study, adults (aged 16 years and over) requiring a consultant opinion due to suspicion of malignant melanoma or squamous cell carcinoma.
Interventions: 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. Patients referred to the 2-week wait clinic were invited to have a series of digital photographs, with and without dermoscopy, immediately before their face-to-face consultation. A second consultant viewed these and outlined a diagnosis and management plan which was compared with the actual management. Both were compared with the definitive diagnosis (either the final clinical or histological diagnosis, where undertaken).
Main outcome measure: The concordance between the consultant who had managed the case and an independent consultant who gave a second face-to-face opinion.
Results: A total of 208 patients were recruited. There was also a greater loss of control cases (26%) than intervention cases (17%). A statistically significant difference in ages between the two groups completing the study (mean age of intervention group 43.6 years, control group 49.7 years, $p = 0.039$) indicates that this may have introduced a bias between the two groups. A further possible source of bias is the delay (mean difference of 54 days, $p = 0.0001$) between the SF opinion and the second opinion in the SF group, whereas control patients 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, 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. Of the 92 telemedicine cases, 53 were judged also to require a face-to-face consultation, mainly to establish a diagnosis and treatment plan. With the digital photography for suspected skin cancer aspect of the study, it was found that an unexpectedly high proportion (33%, 85/256) of referrals proved to have a malignancy or a severely dysplastic lesion, with almost 22% having a malignant melanoma or squamous cell carcinoma, 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, though two squamous cell carcinomas would have been missed (a number-needed-to-harm of 153). If the highest level of clinician confidence had been applied, no cancers would have been missed, but only 20% of patients would have avoided an outpatient appointment.

Conclusions: In view of the difficulties in recruitment 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 SF telemedicine. With regard to digital photography in suspected skin cancer, it is unlikely that this approach can dramatically reduce the need for conventional clinical consultations, whilst still maintaining clinical safety. Additional research on the assessment of diagnostic and management agreement between clinicians would be valuable in this and other fields of research.

Contents

List of abbreviations

CI	confidence interval	PSQ	patient satisfaction questionnaire
FTF	face-to-face	RCT	randomised controlled trial
ITT	intention-to-treat	SF	store-and-forward
PC	personal computer	TD	teledermatology

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.

Executive summary

Introduction

The wider availability of broadband telecommunications and the implementation of the NHS-wide network will allow healthcare providers and commercial organisations to offer a range of telemedicine services to GPs as a way of obtaining a specialist opinion.

At the start of this study, there had been few rigorous studies of the cost-effectiveness of these approaches, most published papers being descriptive. There are many feasibility studies, often in inaccessible settings: for the military, in rural areas, in nursing homes or developing countries. Others were technical or methodological studies, with only one cost-minimisation study, in the field of radiology. Reviews have also been published, indicating promise, but with little evidence.

The use of real-time teleconference technology in healthcare has developed most rapidly in non-clinical use (e.g. administrative and educational activities), orthopaedics/emergency/disaster medicine, dermatology and psychiatry. These technologies appear to have potential in dermatology, where a visual examination of the skin is often the key part of the consultant's physical examination. However, clinicians are concerned that a purely visual examination may not always be adequate (e.g. for potentially malignant lesions and some rashes), and this will be one important aspect of the evaluation. The clinical effectiveness and cost-effectiveness of these services remain largely untested. Their potential impact is considerable, not simply on the use of technology, but mainly through the consequences for the use of staff time and the impact upon clinical practice.

This study aimed to conduct a rigorous scientific comparison of two competing approaches, which the study team believed would have different profiles of cost and benefit, with the current 'gold standard' – the outpatient consultation. It was important that such a comparison was undertaken before there is widespread implementation of these technologies.

There are two possible telemedicine applications that might be considered as potential substitutes for the conventional referral of a new dermatological patient by a GP for a consultant opinion.

The first of these approaches is variously called asynchronous or 'store-and-forward' (SF), where text and digital images are prepared by the referrer and forwarded electronically to the consultant, who considers these at his/her convenience (i.e. asynchronously), and returns a diagnostic and management opinion by a similar mechanism. This approach had been the subject of descriptive studies, and appeared feasible. However, there remained concerns that the inability of the specialist to take a direct history from the patient, palpate lesions or communicate the purposes of management to the patient and referrer may lead to suboptimal care. More positively, however, this approach showed the greatest potential to reduce patient waiting (by reducing the professional time needed and allowing consultants to offer opinions on more patients), costs and inconvenience. If this technology were tested for clinical equivalence and cost reduction, considerable gains might be realised if these aspirations were confirmed.

The second approach was the use of high-quality videoconferencing, in a synchronous manner, comprising a real-time teleconsultation between patient, consultant and, importantly, GP. This technology appeared, *a priori*, to have fewer clinical drawbacks, as a three-way discussion could be held, although it still precludes the palpation of lesions by the specialist. The greatest concern with this technology was cost, not simply the cost of the equipment and telecommunications, but the frequently ignored cost of clinical time, as such teleconsultations appeared significantly slower than routine, new outpatient consultations, and because GPs would be present during the consultation. Although the unit costs of a service can vary greatly with volume, synchronous communication is likely to be the most costly alternative. However, it also had potential for some less tangible benefits, such as the greater transfer of knowledge from consultant to GP,

factors which are more difficult to evaluate. Any technology that increases service accessibility, in itself a potential benefit, may run the risk of supply-induced demand.

In 1997, as the main SF component of this study was starting, the Department of Health introduced the '2-week wait' initiative for cancer. In principle, this policy sought to ensure that any patient suspected by their GP of having cancer had to be seen by an appropriate specialist within 2-weeks of the initial referral. Although this excluded basal cell carcinomas, other dermatological malignancies were covered. As the need for patients to be seen within this relatively (at that time) short period precluded their inclusion in the main study, a complementary study was established to examine the potential of SF telemedicine for this particular service.

Although on-line photographic libraries have been used to train clinicians in the recognition of skin cancers, and SF techniques have been applied to small numbers of suspected cancers, the performance of such approaches is highly dependent upon the nature of the patient population. A previous analysis of 52 audits and databases showed that, up to 2003, only 12% of referrals had subsequently been confirmed to have cancer (although this excluded basal cell carcinomas), and 58% of skin cancers reached hospital by other routes. There was, therefore, a strong case to consider alternative approaches to triage such referrals.

Objectives

The two key objectives of this study were:

- to compare the clinical equivalence, patient and clinician opinion of SF teledermatology with conventional face-to-face consultation in setting a management plan for new, adult outpatient referrals
- to assess the equivalence of digital photography and dermoscopy with conventional face-to-face consultation in the management of suspected cases of malignant melanoma or squamous cell carcinoma.

Design

For the SF teledermatology aspect of the study, a prospective randomised controlled trial (RCT) was carried out.

Setting

Eight general practices and a hospital dermatology department in Sheffield, England.

Participants

For the SF teledermatology part of the study, adults (aged 16 years and over) requiring a new (not seen by a hospital dermatologist within the past year) consultant opinion.

For the digital photography element of the study, adults (aged 16 years and over) requiring a consultant opinion due to suspicion of malignant melanoma or squamous cell carcinoma.

Interventions

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 were managed by conventional hospital outpatient consultation.

Patients referred to the 2-week wait clinic were invited to have a series of digital photographs, with and without dermoscopy, immediately before their face-to-face consultation. A second consultant viewed these and outlined a diagnosis and management plan. This was compared with the actual management. Both were compared with the definitive diagnosis (either the final clinical or histological diagnosis), where undertaken.

Main outcome measures

For diagnosis and management, the outcome measure was the concordance between the consultant who had managed the case and an independent consultant who gave a second face-to-face opinion.

Results

Store-and-forward teledermatology

The study failed to achieve the recruitment target of 446 in each group. A total of 208 patients were recruited. There was also a greater loss of control cases (26%) than intervention cases (17%): difference 8% [95% confidence interval (CI): –3 to

19%, $p = 0.18$]. A statistically significant difference in ages between the two groups completing the study (mean age of intervention group 43.6 years, control group 49.7 years, $p = 0.039$) indicates that this may have introduced a bias between the two groups. A further possible source of bias is the delay (mean difference of 54 days, $p = 0.0001$) between the SF opinion and the second opinion in the SF group, whereas control patients 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.

Digital photography

An unexpectedly high proportion (33%, 85/256) of referrals proved to have a malignancy or a severely dysplastic lesion, with almost 22% having a malignant melanoma or squamous cell carcinoma, 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, although two squamous cell carcinomas would have been missed (a number-needed-to-harm of 153). If the highest level of clinician confidence had been applied, no cancers would have been missed, but only 20% of patients would have avoided an outpatient appointment.

Conclusions

Store-and-forward teledermatology

In view of the difficulties in recruitment 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 SF telemedicine.

Digital photography in suspected skin cancer

It is unlikely that this approach can dramatically reduce the need for conventional clinical consultations whilst still maintaining clinical safety.

Research priorities

It should not be a high priority for research funding bodies to undertake similar studies of this approach to teledermatology. The RCT is particularly difficult to conduct in this area, particularly if the results are to retain any wider validity. Further study should be undertaken with more pragmatic study designs (e.g. cluster randomisation or non-RCTs). Descriptive study of past teledermatology projects would be valuable, and systematic comparative data should be collected on any future teledermatology initiatives commissioned by the NHS, possibly as a national audit project. Additional research on the assessment of diagnostic and management agreement between clinicians would be valuable in this and other fields of research.

Chapter 1
Introduction

The wider availability of broadband telecommunications and the implementation of the NHS-wide network will allow healthcare providers and commercial organisations to offer a range of telemedicine services to GPs as a way of obtaining a specialist opinion.

At the start of this study, there had been few rigorous studies of the cost-effectiveness of these approaches, most published papers being descriptive. There are many feasibility studies, often in inaccessible settings: for the military, in rural areas, in nursing homes or developing countries. Others were technical or methodological studies, with only one cost-minimisation study, in the field of radiology. Reviews have also been published, indicating promise, but with little evidence.

The use of real-time teleconference technology in healthcare has developed most rapidly in non-clinical use (e.g. administrative and educational activities), orthopaedics/emergency/disaster medicine, dermatology and psychiatry. These technologies appear to have potential in dermatology, where a visual examination of the skin is often the key part of the consultant's physical examination. However, clinicians are concerned that a purely visual examination may not always be adequate (e.g. for potentially malignant lesions and some rashes), and this will be one important aspect of the evaluation. The clinical effectiveness and cost-effectiveness of these services remain largely untested. Their potential impact is considerable, not simply on the use of technology, but mainly through the consequences for the use of staff time and the impact upon clinical practice.

This first element of this study, which is covered in Chapter 2, aimed to conduct a rigorous scientific comparison of two competing approaches, which the study team believed would have different profiles of cost and benefit, with the current 'gold standard' – the outpatient consultation. It was important that such a comparison was undertaken before there is widespread implementation of these technologies.

There are two possible telemedicine applications that might be considered as potential substitutes for the conventional referral of a new dermatological patient by a GP for a consultant opinion.

The first of these approaches is variously called asynchronous or 'store-and-forward' (SF); where text and digital images are prepared by the referrer and forwarded electronically to the consultant, who considers these at his/her convenience (i.e. asynchronously), and returns a diagnostic and management opinion by a similar mechanism. This approach had been the subject of descriptive studies, and appeared feasible. However, there remained concerns that the inability of the specialist to take a direct history from the patient, palpate lesions or communicate the purposes of management to the patient and referrer may lead to suboptimal care. More positively, however, this approach showed the greatest potential to reduce patient waiting (by reducing the professional time needed and allowing consultants to offer opinions on more patients), costs and inconvenience. If this technology were tested for clinical equivalence and cost reduction, considerable gains might be realised if these aspirations were confirmed.

The second approach was the use of high-quality videoconferencing, in a synchronous manner, comprising a real-time teleconsultation between patient, consultant and, importantly, GP. This technology appeared, *a priori*, to have fewer clinical drawbacks, as a three-way discussion could be held, although it still precludes the palpation of lesions by the specialist. The greatest concern with this technology was cost, not simply the cost of the equipment and telecommunications, but the frequently ignored cost of clinical time, as such teleconsultations appeared significantly slower than routine, new outpatient consultations, and because GPs would be present during the consultation. Although the unit costs of a service can vary greatly with volume, synchronous communication is likely to be the most costly alternative. However, it also had potential for some less tangible benefits, such as the greater

transfer of knowledge from consultant to GP; factors which are more difficult to evaluate. Any technology that increases service accessibility, in itself a potential benefit, may run the risk of supply-induced demand.

In 1997, as the main SF component of this study was starting, the Department of Health introduced the '2-week wait' initiative for cancer. In principle, this policy sought to ensure that any patient suspected by their GP of having cancer had to be seen by an appropriate specialist within 2 weeks of the initial referral. Although this excluded basal cell carcinomas, other dermatological malignancies were covered. As the need for patients to be seen within this relatively (at that time) short period precluded their inclusion in the main study, a complementary study was established to examine the potential of SF telemedicine for this particular service. This additional element is covered in Chapter 3.

Although on-line photographic libraries have been used to train clinicians in the recognition of skin cancers, and SF techniques have been applied to small numbers of suspected cancers, the performance of such approaches is highly dependent upon the nature of the patient population. A previous analysis of 52 audits and databases showed that, up to 2003, only 12% of referrals had subsequently been confirmed to have cancer (although this excluded basal cell carcinomas), and 58% of skin cancers reached hospital by other routes. There was, therefore, a strong case to consider alternative approaches to triage such referrals.

Chapter 2

Randomised controlled trial of store-and-forward telemedicine in general dermatology: clinical outcomes

Introduction

Telemedicine in dermatology

The advent of broadband telecommunications, capable of carrying high-quality, real-time moving images and sound, and the implementation of the NHS-wide network, will allow healthcare providers and commercial organisations to offer a range of telemedicine services to GPs as a way of obtaining a specialist opinion. Indeed, in the UK the feasibility of these methods had shown the potential for patients (and their GP) to consult a dermatologist from a distance, with perceived benefits for patients (reduced travel, loss of earnings, etc.) and the service (reduced costs for 'outreach' clinics, improved education of GPs, etc.) as early as 1996.[1]

As this study commenced, there had been few rigorous studies of the cost-effectiveness of these approaches, most published papers being descriptive.[2] There are many feasibility studies,[3–5] often in inaccessible settings: for the military,[6] in rural areas,[7] in nursing homes[8] or developing countries.[9] Others were technical or methodological studies,[10–15] with only one cost-minimisation study,[16] in the field of radiology. Reviews have also been published, indicating promise, but with little evidence.[17–19] A survey of telemedicine in rural areas of the USA[20] concluded that:

> "Most telemedicine programs have not handled enough cases of any one type to be able to draw conclusions about clinical efficacy. In addition, few are collecting data adequate for studies of clinical efficacy; most concentrate on acceptability instead. Few have collected data on comparison cases and few have randomly assigned patients to telemedicine vs. conventional care; there is consequently little published literature on this topic. It seems that the nature of current telemedicine programs will not alter this dynamic very quickly, due to low volume of cases and inadequate data collection plans."

and that:

> "High costs, combined with low utilization in the early years of operation, yielded high unit costs."

The use of real-time teleconference technology in healthcare has developed most rapidly in non-clinical use (e.g. administrative and educational activities), orthopaedics/emergency/disaster medicine, dermatology and psychiatry. These technologies appear to have potential in dermatology, where a visual examination of the skin is often the key part of the consultant's physical examination. However, clinicians are concerned that a purely visual examination may not always be adequate (e.g. for potentially malignant lesions and some rashes), and this will be one important aspect of the evaluation. The clinical effectiveness and cost-effectiveness of these services remain largely untested. Their potential impact is considerable, not simply on the use of technology, but mainly through the consequences for the use of staff time and the impact upon clinical practice.

A search of the Cochrane Library as this trial commenced yielded no randomised controlled trials (RCTs), reviews or trials under way. The study team believed, however, that there were two similar studies under way; one at Stanford and the other a UK trial involving two practices, funded by the Research and Development Directorate under it's 'Primary and Secondary Care Interface Programme'.

This study aimed to conduct a rigorous scientific comparison of two competing approaches, which the study team believed would have different profiles of cost and benefit, with the current 'gold standard' – the outpatient consultation. It was important that such a comparison was undertaken before there is widespread implementation of these technologies.

Telemedicine modalities

There are two possible telemedicine applications that might be considered as potential substitutes for the conventional referral of a new dermatological patient by a general practitioner for a consultant opinion. The first of these is variously called asynchronous or 'store-and-

forward' (SF), where text and digital images are prepared by the referrer and forwarded electronically to the consultant, who considers these at his/her convenience (i.e. asynchronously), and returns a diagnostic and management opinion by a similar mechanism.[21] This approach had been the subject of descriptive studies, and appeared feasible. However, there remained concerns that the inability of the specialist to take a direct history from the patient, palpate lesions or communicate the purposes of management to the patient and referrer may lead to suboptimal care. More positively, however, this approach showed the greatest potential to reduce patient waiting (by reducing the professional time needed and allowing consultants to offer opinions on more patients), costs and inconvenience. If this technology were tested for clinical equivalence and cost reduction, considerable gains might be realised if these aspirations were confirmed.

The second approach was the use of high-quality videoconferencing, in a synchronous manner, comprising a real-time teleconsultation between patient, consultant and, importantly, GP. This technology appeared, *a priori*, to have fewer clinical drawbacks, as a three-way discussion could be held, although it still precludes the palpation of lesions by the specialist. The greatest concern with this technology was cost, not simply the cost of the equipment and telecommunications, but the frequently ignored cost of clinical time, as such teleconsultations appeared significantly slower than routine, new outpatient consultations, and because GPs would be present during the consultation. Although the unit costs of a service can vary greatly with volume, synchronous communication is likely to be the most costly alternative. However, it also had potential for some less tangible benefits, such as the greater transfer of knowledge from consultant to GP, factors which are more difficult to evaluate.[22] Any technology that increases service accessibility, in itself a potential benefit, may run the risk of supply-induced demand.

There also appeared to be drawbacks shared by both telemedicine approaches. In particular, there would probably be a number of cases where, even after some form of teleconsultation (either synchronous or asynchronous), patients will still need to see the specialist in person (e.g. for palpation of lesions, for particular tests or treatment). This may be partly counteracted by the tendency for some of these treatments to be carried out at second or subsequent outpatient attendances in conventional referral systems.

Service models

In addition to the two main forms of telemedicine under consideration for dermatology, there were a variety of models for their implementation. For example, there were commercial services becoming available, where the GP, upon deciding to refer to a consultant, contacts the service, who then arranges an appointment between the patient and a nurse, trained to elicit a dermatological history and take suitable photographs. These would then be forwarded to a dermatologist, who sends an opinion, electronically, back to the GP. Alternatively, as in this study, a nominated member of the practice could take the history and photographs, forwarding them to a consultant and awaiting a reply. Each model may have different characteristics and performance, depending on the training and expertise of the photographer, the number of photographs taken and hence the maintenance of expertise, the detail and format of the clinical history and the technical capabilities of the particular camera and information system.

Study rationale and model

The study questions were posed in stages. In order to satisfy clinical quality standards, teledermatology (TD) applications would first need to demonstrate broad clinical equivalence with conventional outpatient consultation, at least for a significant, identifiable group of patients. We proposed to assess these outcomes in terms of diagnostic and management comparability with conventional management. The actual measures related to the concordance of two independent dermatological opinions, one of which must be face-to-face (FTF): evidence from descriptive studies suggested that agreement could be high and were used as the basis for our sample size calculations. The second group of outcomes related to patient, GP and dermatologist satisfaction with the three approaches. Third, we aimed to assess the costs to patients, the NHS and more widely. In addition, descriptive material would be gathered about the mechanics of both introducing and running such technologies in 'green-field' sites.

The evaluation of such technologies is complex. The outcome of consultation with a specialist can be varied and is often mixed (reassurance of patient or GP, an opinion of treatment, or actual management of the case, specialist treatment such as surgery). Economic aspects can be difficult to identify (e.g. staff time involved) and value (e.g. the value of GP and patient education). The study team believed at the outset that an RCT was both preferable and feasible in this setting.

Methods

Study aims and null hypotheses

The main objective of the study was to assess the equivalence of SF TD in setting a management plan for new, adult outpatient referrals. Secondary objectives were to assess diagnostic equivalence, patient and professional preferences and views and economic consequences. The null research hypothesis was that the telemedicine approach was not inferior to routine outpatient consultation. In order to test this hypothesis statistically, however, we assumed a null statistical hypothesis that the two approaches are different and that routine outpatient consultation was superior to telemedicine.

Clinical efficacy

The study's primary measure of clinical efficacy is the adequacy of the initial treatment plan. The adequacy of this plan was assessed by an independent dermatologist, blinded to the nature of the original consultation group, who saw patients as soon after the intervention as possible and assessed the adequacy of the initial diagnosis and management.

Sample size

The study team believed that the assessment of clinical equivalence would determine the sample size; cost differences and qualitative differences were expected to be relatively large, and require a smaller sample to detect reliably. The requirement to detect any inferiority of telemedicine in this regard allowed us to employ a one-sided test of equivalence.[23] The best estimate was that between 75 and 90% of diagnoses and management plans would be concordant with an independent specialist diagnosis in the control group.

If the two methods were equivalent, then 446 subjects (892 in total, including the conventional treatment group) randomised to each of the SF telemedicine and standard outpatient consultation options would have provided 80% power to conclude that patient treatment plan concordance with an independent specialist from the SF telemedicine method was not more than 5% lower than standard outpatient treatment plan concordance with an independent specialist. These power calculations were based on a standard outpatient treatment plan concordance of 90% with an independent specialist, using a one-sided significance level of 0.05. Allowing a loss to follow-up of 10% of patients, a total of 500 patients per group needed to be recruited (*Table 1*).

TABLE 1 *Two group test of equivalence in proportions*

Test significance level (one-sided)	0.05	0.05	0.05	0.05	0.05	0.05
Control proportion$_{Control}$	0.90	0.90	0.90	0.90	0.90	0.90
Equivalence limit difference$_{Control\ -\ SF,\ 0}$	0.05	0.06	0.07	0.08	0.09	0.1
Test expected proportion$_{SF}$	0.90	0.90	0.90	0.90	0.90	0.90
Expected difference$_{Control\ -\ SF,\ 0}$	0.00	0.00	0.00	0.00	0.00	0.00
Power (%)	80	80	80	80	80	80
n per group	446	310	228	174	138	112
n per group with 10% withdrawals	496	344	253	193	153	124
Test significance level (one-sided)	0.025	0.025	0.025	0.025	0.025	0.025
Control proportion$_{Control}$	0.90	0.90	0.90	0.90	0.90	0.90
Equivalence limit difference$_{Control\ -\ SF,\ 0}$	0.05	0.06	0.07	0.08	0.09	0.10
Test expected proportion$_{SF}$	0.90	0.90	0.90	0.90	0.90	0.90
Expected difference$_{Control\ -\ SF,\ 0}$	0.00	0.00	0.00	0.00	0.00	0.00
Power (%)	80	80	80	80	80	80
n per group	566	393	289	221	175	142
n per group with 10% withdrawals	629	437	321	246	194	158
Test significance level (one-sided)	0.0125	0.0125	0.0125	0.0125	0.0125	0.0125
Control proportion$_{Control}$	0.90	0.90	0.90	0.90	0.90	0.90
Equivalence limit difference$_{Control\ -\ SF,\ 0}$	0.05	0.06	0.07	0.08	0.09	0.1
Test expected proportion$_{SF}$	0.90	0.90	0.90	0.90	0.90	0.90
Expected difference$_{Control\ -\ SF,\ 0}$	0.00	0.00	0.00	0.00	0.00	0.00
Power (%)	80	80	80	80	80	80
n per group	685	476	350	268	212	172
n per group with 10% withdrawals	761	529	389	298	236	191

The null and alternative hypotheses of interest are:

$$H_0: p_{control} - p_{SF} \geq 0.05 \text{ (inequivalence)}$$

and

$$H_A: p_{control} - p_{SF} < 0.05 \text{ (equivalence)},$$

where $p_{control}$ and p_{SF} represent the initial treatment plan concordance with an independent specialist within the control and SF groups, respectively.

The null hypothesis of inequivalence would be rejected if the upper one-sided 95% confidence interval (CI) for the difference $p_{control} - p_{SF}$ was wholly within the interval 0 to 0.05 (the range of clinical equivalence). If the CI covers at least some points outside the equivalence range, then differences of potential clinical importance remain a real possibility and equivalence cannot be safely concluded. The secondary outcome of accuracy of initial diagnosis was analysed in a similar way.

Therefore, at the interim analysis after 150 patients in each group had been recruited, the null hypothesis of inequivalence would be rejected if the upper one-sided 95% CI for the difference $p_{control} - p_{SF}$ was wholly within the interval 0 to 0.1 (the range of clinical equivalence). If the CI covers at least some points outside the equivalence range, then differences of potential clinical importance remain a real possibility and equivalence cannot be safely concluded.

Mean differences in resource use and costs between the groups were to be compared by the most appropriate parametric and non-parametric hypothesis test depending on the distributions of the data. CIs for the differences were calculated where appropriate.

Setting and GP recruitment

The study was conducted between a locality group of eight general practices in Sheffield (with around 20 GPs serving a total population of almost 38,000, and generating around 400 new, adult dermatological referrals each year), and a single teaching hospital, the Royal Hallamshire Hospital, part of the Central Sheffield University Hospitals NHS Trust, which provides the local dermatology referral service.

Patient recruitment

Patients comprised new (referred with a new problem or not seen by a hospital dermatologist in the last 12 months), adult (aged 16 years and over) patients for whom the GP felt there would normally be a need for a conventional outpatient consultation with an NHS consultant dermatologist.

We intended to minimise the proportion of cases excluded from the study, as the study team believed that this allowed the fullest appraisal of the potential of the technologies. For example, a high proportion of dermatology outpatients require some form of biopsy of an isolated lesion, although many of the biopsies are not carried out at the first outpatient visit. The study team believed, therefore, that such cases could reasonably be included. There were, however, two main reasons for exclusion: first, the nature of the dermatological problem (these will be rare and mainly related to the anatomical site, e.g. genital lesions); second, reasons unrelated to the skin problem, such as an inability to understand the nature of the study for reasons of language barrier, mental illness or handicap, wish to consult privately, refusal of consent and so on. The Local Research Ethics Committee refused permission for us to collect any data from patients who refused to participate. This meant that we were unable to quantify or describe the scale or reasons for refusal to participate, or the basic characteristics of this group, even where the patients might have been prepared for us to do so.

Allocation to treatment

Patients were randomised into two, equal groups. For the initial stages, a total of 300 study numbers (0–300) were randomly allocated to study or control groups, by drawing lots (150 pieces of paper labelled 'C' and a further 150 labelled 'S' drawn blindly from a sealed container). The study was discussed with the patient by the GP, who also obtained written, informed consent. The GP then telephoned the principal investigator who assigned the next available study number, which had already been randomised. The Local Research Ethics Committee approved the study protocol.

Data collection

Initial data were collected in the practice on a one-page proforma. These outlined personal details, recruitment details, symptoms, signs and initial diagnosis and treatment by the GP. Most of the data were in a structured format. For control cases, this formed the referral letter. For telemedicine cases, these data were entered on to a similar screen for transmission with the digital images.

Control cases

For control cases, upon receipt at the hospital, the patient was allocated adjacent appointments with two different consultants on the same session. The personal details were transcribed on to a form for

the consultant treating the case and a second form for the consultant giving the independent opinion. These forms were used to record the consultant's diagnosis, treatment recommendations and their level of certainty with these when the patient attended.

Telemedicine cases

For study cases, the principal investigator allocated the cases to a consultant, having first printed out the referral data for the doctor giving the second opinion. The personal details were again transferred on to a form for the consultant to complete when the patient attended the clinic.

When the consultant viewing the telemedicine referral data thought management by telemedicine unsafe, they were able to transfer the management of the case to the consultant seeing the patient FTF (for the original purpose of giving the second opinion).

Additional data were abstracted from the clinical records in the hospital by the principal investigator. Data collection procedures for satisfaction studies are described later.

Clinical equivalence

The principal success measures relate to clinical adequacy and cost. Clinical adequacy was assessed by the accuracy of the diagnosis and the appropriateness of the initial treatment plan; the main outcome measure (upon which sample size calculations have been based) being agreement between independent dermatologists on patient management rather than diagnosis. Such methods have been used in previous, descriptive studies. Both dermatologists will be required to determine their most likely diagnosis, their level of certainty with this 'primary' diagnosis, a number of alternative diagnoses and a series of management actions. Previous studies have found that the majority of diagnoses and actions will be concordant between two independent dermatologists in these settings, although there was little documented evidence on the frequency of agreement between specialists who are not using telemedicine. In addition, the literature indicated that management agreement will probably be slightly more common than diagnosis, as a number of different specific dermatological diagnoses have common treatments (e.g. topical steroid applications).

Statistical methods

As the trial is a parallel group RCT, data will be reported and presented according to the revised CONSORT statement.[24] The statistical analyses were performed on both an intention-to-treat (ITT) basis and a per protocol basis.[23] This is because in a comparative trial, where the aim is to decide if two treatments are different, an ITT analysis is generally conservative: the inclusion of protocol violators and withdrawals will usually make the results from the two treatment groups more similar. However, for an equivalence trial this effect is no longer conservative: any blurring of the difference between the treatment groups will increase the chance of declaring equivalence.

The primary endpoint was the agreement or concordance of the clinical management decision for the patient with an independent second opinion. The proportion of patients in each group having a management decision agreeing with the second opinion would be calculated. A 95% CI for the difference in this proportion between the two treatment groups would also be calculated using methods for calculating the CI for the difference in two independent proportions.[25]

Null hypothesis

Our statistical null hypothesis [see the section 'Sample size' (p. 5)] was that the clinical treatment and management decisions for patients in the control and telemedicine groups were not equivalent and therefore that FTF hospital outpatient contact would result in superior clinical treatment and management decisions. The two methods would be regarded as having clinically equivalent treatment management decisions if the lower 95% CI for the difference $p_{\text{intervention}} - p_{\text{control}}$ (the proportions in the two groups respectively agreeing with the independent second management opinion) is wholly within the interval 0 to –0.10 (the range of clinical equivalence). Therefore, the results of the analysis of the primary endpoint will be one of the following:

1. The CI for the difference between the two treatments lies entirely within the equivalence range, so that equivalence may be concluded with only a small probability of error.
2. The CI covers at least some points that lie outside the equivalence range, so that differences of potential clinical importance remain a real possibility and equivalence cannot safely be concluded.
3. The CI is wholly outside the equivalence range.

Descriptive studies indicate that the potential value of telemedicine varies among different types of dermatological cases, with particular problems observed in diagnosing malignant melanoma and pityriasis rosea, although many common

conditions, including basal cell carcinoma, proved more amenable to telemedical diagnosis. It is important, therefore, to record basic patient characteristics, particularly main diagnosis, level of certainty and alternative diagnoses. These data will be particularly important in drawing together the conclusions of the study. It is possible that neither approach was the most appropriate for all cases, and that the conclusions would try to describe the merits of different approaches for different patient groups and the requirements for each type of approach. In general, data are analysed on an ITT basis.

Technology

Following a formal appraisal against a limited number of objectives, the study group selected the Nikon CoolPix 900 digital camera, which was felt to give the highest quality close-up pictures of skin when used by a health professional with limited training. It was also judged as best for close-up work by a trade magazine, and had been used in one pilot teledermatology project elsewhere, with apparent success. A basically standard Pentium II standard personal computer (PC) was employed for viewing the pictures in general practice, although with an improved graphics card and the then unusual 17-inch monitor running at super VGA level. Images were transferred directly from the camera's memory card using a proprietary card reader (CardPort Swift) and viewed using Piccolo software. The dermatology department was supplied with two similar PCs, although this time with 19-inch monitors. Software was selected to manage the collection, maintenance and transmission of data (developed by Agora Health Care Systems from software used in another pilot project, using Lotus Domino), allowing user interaction via Microsoft Internet Explorer (version 4 and above). Similar, web-based technology has been used subsequently by others.[26]

Training

Training was carried out by the principal investigator. This addressed basic photographic techniques (including use of tripod, lighting, image transfer on to the local computer and the remote system, receipt of results, etc.). Brief written instructions were provided. The trainer was available during office hours by mobile phone to answer questions, and was prepared to attend first patient consultations to assist with the first referral. This offer was accepted by three practices.

Results

Clinical outcomes

Patient recruitment

One practice invited to participate declined. A further two practices, one recruited to replace the first, were recruited for a few months before also deciding that the workload associated with the study could not be sustained. The other six practices continued to recruit, but with very varying numbers of patients. Throughout the study, one practice recruited almost half of patients (*Figure 1*), and recruitment was very variable.

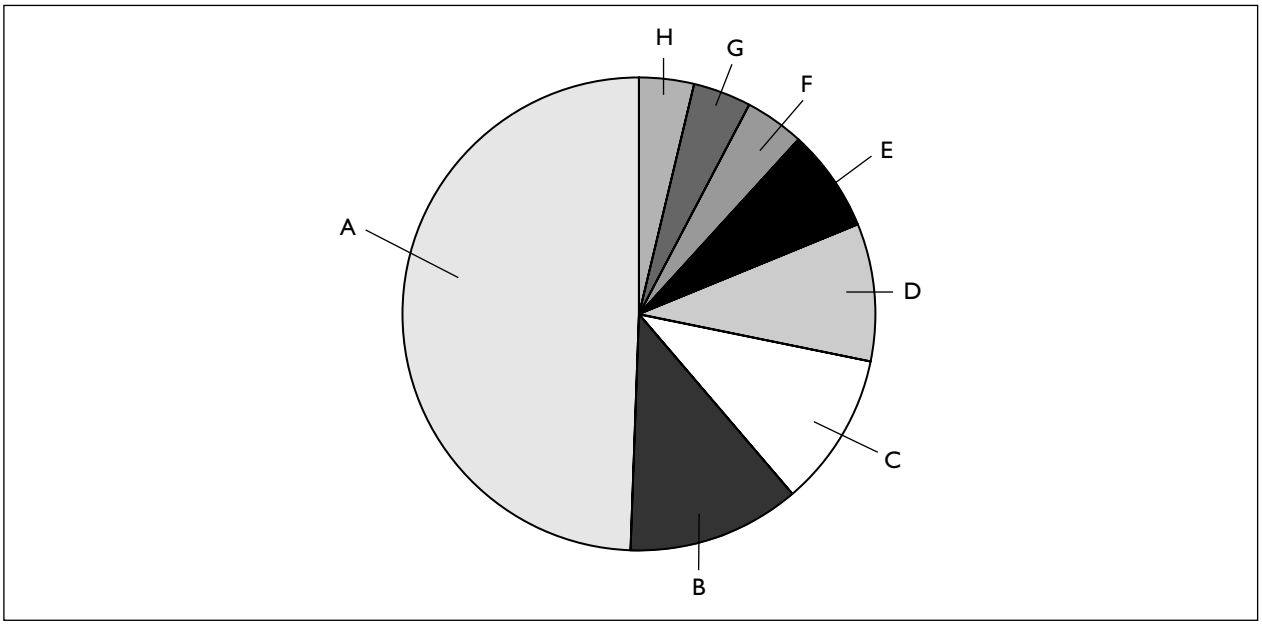

FIGURE 1 *Numbers of patients recruited by participating practices (A–H)*

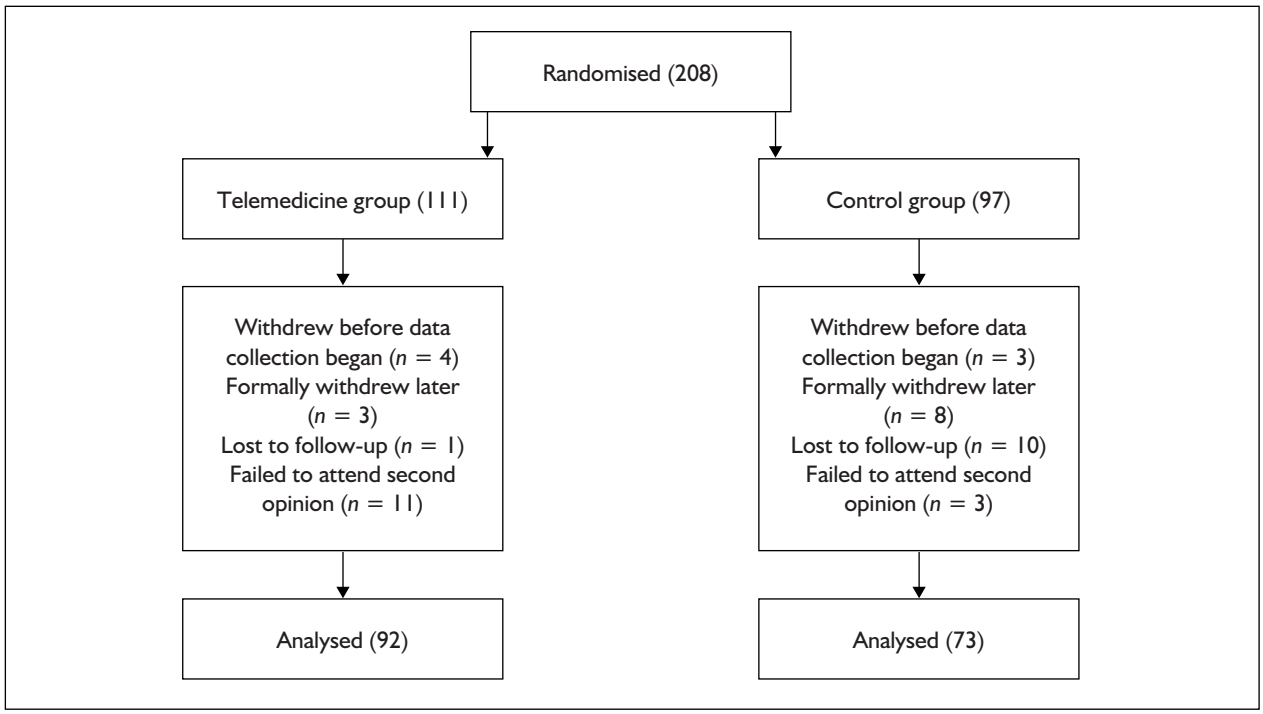

FIGURE 2 *CONSORT flowchart*

TABLE 2 *Baseline characteristics of intervention and control groups*

Characteristic		Intervention (n = 92)	Control (n = 73)	p^a
Age	Mean	43.6	49.7	0.039
	Standard deviation	17.8	19.8	
Gender	No. male	34	28	0.85
	% male	37	38	
	No. female	58	45	
	% female	63	62	

[a] p-Values from two independent samples, t-test and χ^2 test.

Participant flow and CONSORT Statement

Figure 2 shows the CONSORT Statement information available for the trial. This indicates that formal withdrawal following initial consent, failed attendance (despite two further invitations) and loss of follow-up were problems.

Initial characteristics of groups

The baseline characteristics of the two groups are shown in *Table 2*. These demonstrate that a significant difference in the average age of the groups arose, with the control group being older than the intervention group.

Numbers analysed

Compared with the intended recruitment for the interim analysis of 150 patients in each group and the final intention of 446 per group, the study was terminated when a total of 208 cases had been recruited, of whom 111 had initially been allocated to the intervention group and 97 to the control group. Of these, 92/111 (83%) of the intervention group and 73/97 (75%) of the control group had sufficient data for analysis of the main study outcomes: difference 8% (95% CI: –3 to 19%, p = 0.18).

Diagnostic equivalence

One of the main secondary outcome measures is diagnostic equivalence (*Table 3*). Our statistical null hypothesis [see the section 'Sample size' (p. 5)] was that the control and telemedicine groups were diagnostically not equivalent and therefore that FTF hospital outpatient diagnosis is

TABLE 3 *Diagnostic concordance*[a]

			Intervention	Control	Difference (%) (95% CI)	*p*
All cases	Number analysed		92	73	–23 (–36 to –8)[b]	0.002
	Same diagnosis	No.	51	57		
		%	55	78		
	Different diagnosis	No.	41	16		
		%	45	22		
Excluding patients whose management was transferred	Number analysed		39	73	–6 (–24 to 10)[c]	0.46
	Same diagnosis	No.	28	57		
		%	72	78		
	Different diagnosis	No.	11	16		
		%	28	22		

[a] Figures are numbers (percentage) of patients unless stated otherwise. *p*-Values are from a χ^2 test. Since the null hypothesis, analysis and sample size were based on the lower limit of one-sided 95% CI, which is statistically equivalent to a two-sided 90% CI.
[b] 90% CI: –34 to –11%.
[c] 90% CI: –21 to 7%.

superior. The two methods would be regarded as diagnostically equivalent if the lower 95% CI for the difference $p_{\text{intervention}} - p_{\text{control}}$ (the proportions in the two groups respectively agreeing with the independent second diagnostic opinion) is wholly within the interval 0 to –0.10 (the range of clinical equivalence). If the CI covers at least some points outside the equivalence range, then differences of potential clinical importance remain a real possibility and equivalence cannot be safely concluded.

For the study intervention group, diagnostic agreement was achieved in 55% (51/92) of cases. If those ($n = 53$) in the intervention group for whom management was transferred are excluded, for 72% (28/39) of the remaining intervention group the two consultants agreed on the diagnosis. In the control group, in 79% (57/72) of cases the diagnosis was agreed between the two consultants. No control cases had their management transferred. The differences in diagnostic concordance between study and control groups are highly statistically significant ($p = 0.002$), a difference of –23% (95% CI: –36 to –8%). Since the lower bound of the CI (–36%) is wholly outside our range of clinical equivalence (0 to –10%), we cannot reject our null statistical hypothesis that the two methods are not equivalent.

Similar results (*Table 3*) apply if those ($n = 53$) in the intervention group for whom management was transferred are excluded. The distribution of diagnosis between intervention and control groups shows a clear difference, mainly in the proportion of cases with no diagnosis (*Table 4*). Formal statistical analysis of these data is not appropriate, due to the small numbers in each cell.

TABLE 4 *Comparison of initial GP diagnoses between study groups*

Diagnosis	Intervention	Control
Acne vulgaris	7	4
Eczema/dermatitis	11	6
Malignant lesions	3	9
Melanocytic naevi	5	10
Other benign lesions	8	12
Hair/nail disorders	3	2
Psoriasis	8	3
Infections	4	3
Urticaria	5	3
Venous ulcer/eczema	2	1
Other	11	16
No diagnosis given	25	4
Total	**92**	**73**

Management equivalence

The main outcome measure is management equivalence (*Table 5*). Our statistical null hypothesis [see the section 'Sample size' (p. 5)] was that the clinical treatment and management decisions for patients in the control and telemedicine groups were not equivalent and therefore that FTF hospital outpatient contact would result in superior clinical treatment and management decisions. The two methods would

TABLE 5 *Management concordance*[a]

			Intervention	Control	Difference (%) (95% CI)	*p*
All cases	Number analysed		92	73	–28 (–40 to –14)[b]	0.0001
	Same management	No.	51	61		
		%	55	84		
	Different management	No.	41	12		
		%	45	16		
Excluding patients whose management was transferred	Number analysed		39	73	–17 (–34 to –1)[c]	0.041
	Same management	No.	26	61		
		%	67	84		
	Different management	No.	13	12		
		%	33	16		

[a] Figures are numbers (percentage) of patients unless stated otherwise. *p*-Values are from a chi-squared test. Since the null hypothesis, analysis and sample size were based on the lower limit of one-sided 95% CI, which is statistically equivalent to a two-sided 90% CI.
[b] 90% CI: –39 to –16%.
[c] 90% CI: –31 to –3%.

be regarded as having clinically equivalent treatment management decisions if the lower 95% CI for the difference $p_{\text{intervention}} - p_{\text{control}}$ (the proportions in the two groups respectively agreeing with the independent second management opinion) is wholly within the interval 0 to –0.10 (the range of clinical equivalence). If the CI covers at least some points outside the equivalence range, then differences of potential clinical importance remain a real possibility and equivalence cannot be safely concluded.

For the entire study group, management agreement was achieved in 68% (112/165) of cases. For the intervention group, management agreement was achieved in 55% (51/92) of cases. If those for whom management was transferred are excluded ($n = 53$), for 67% (26/39) of the remaining intervention group the two consultants agreed on the management. In the control group, in 84% (61/73) of cases the management plan was agreed between the two consultants. No control cases had their management transferred. The differences in management concordance between study and control groups are highly statistically significant ($p = 0.0001$), a difference of –28% (95% CI: –40 to –14%). Since the lower bound of the CI (–40%) is wholly outside our range of clinical equivalence (0 to –10%), then we cannot reject our null statistical hypothesis that the two methods are not equivalent. Similar results (*Table 5*) apply if those ($n = 53$) in the intervention group for whom management was transferred are excluded.

The results for both outcomes (*Figure 3*) and when the 53 patients in the intervention group for whom management was transferred are excluded show that the lower limits of the 95% CI for all four outcomes are clearly outside our *a priori* range of clinical equivalence (–0.10 to 0).

Care process measures

In total, 53 (58%) of telemedicine cases had their management transferred to the FTF consultation (*Table 6*). Most were for accurate diagnosis, although others required excision, for either diagnostic or cosmetic reasons, and a small number required a specific treatment which could only be provided in person, such as ultraviolet treatment.

One of the arguments in favour of telemedicine is that it can lead to a shorter waiting time for referrer and patient between the referral and receipt of a specialist opinion. In the study (*Table 7*), the time between referral and the delivery of an electronic opinion to the GP within the intervention group and between referral and the outpatient appointment (and hence an opinion to the patient) in the control group was very different. As intervention cases had to wait a similar amount of time for their second opinion (mean 59.6 days, median 57.5 days), there was a significant time difference between the photographs being taken and the second opinion being obtained.

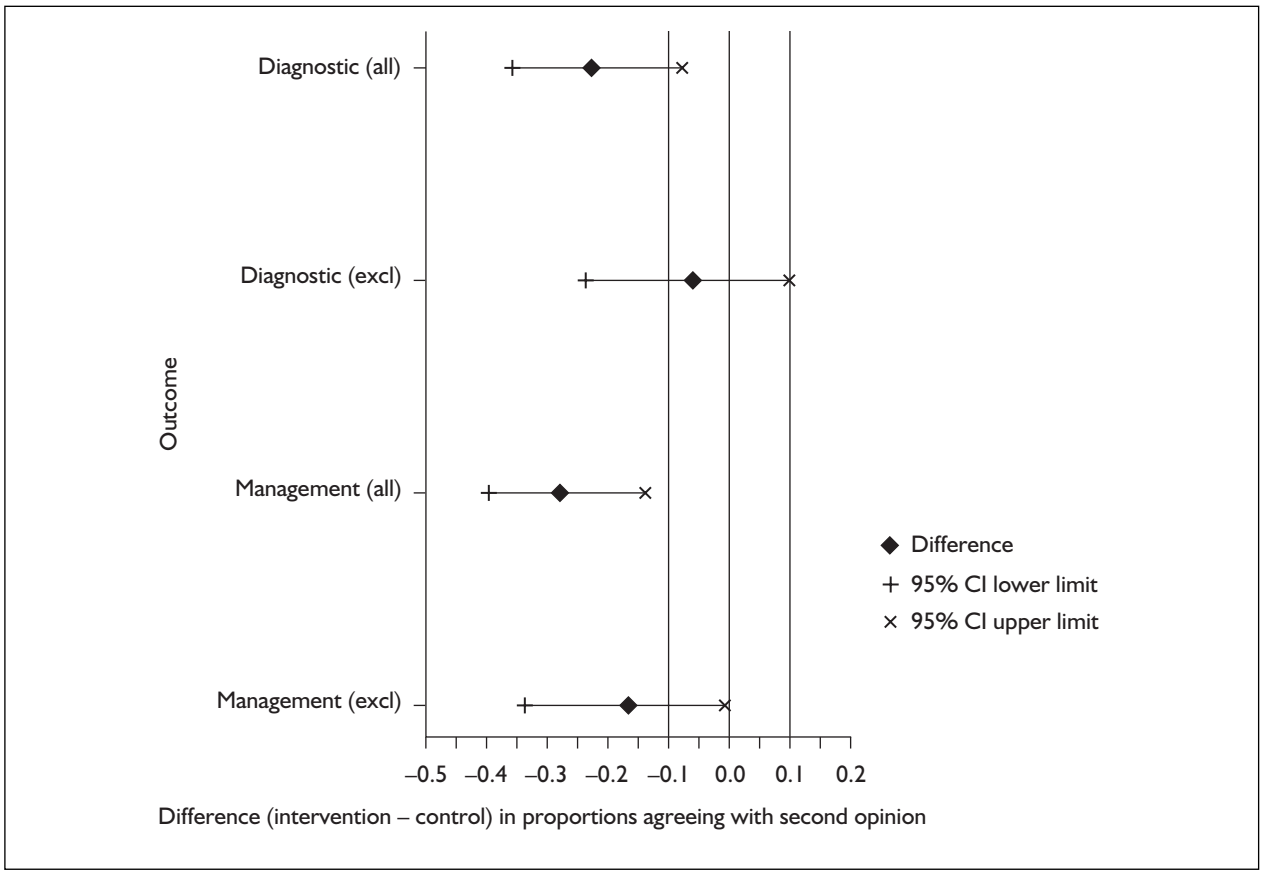

FIGURE 3 *Equivalence of diagnostic and management outcomes*

TABLE 6 *Reasons for management transfer of telemedicine cases*

Reason	Number	%
Diagnosis	33	35.9
Excise for diagnosis	9	9.8
Cosmetic excision	4	4.3
Treatment	7	7.6
Not transferred	39	42.4

TABLE 7 *Time between referral and opinion*

	Intervention	Control	*p*
Number analysed	85	72	
Mean time (days)	13	67	<0.0001
Standard deviation (days)	11.5	27.6	
Median time (days)	10	59	

A key determinant of cost is the number of subsequent visits made following the initial management. *Table 8* shows the proportion of patient having no follow-up after the initial diagnostic episode. The intervention group had a significantly lower proportion of patients requiring follow-up.

The median number of follow-up visits within the first 3 months among those who required follow-up and the rate of follow-up visits per 100 patients are shown in *Table 9*.

Patient satisfaction and perceptions

Patient survey

Methods

All patients who were recruited into the trial were asked to complete a self-administered patient satisfaction questionnaire (PSQ). A covering letter was attached to the questionnaire that began with a brief description of the study, its aims and objectives and how to complete the questionnaire. Confidentiality was assured. Contact details were also provided if the patient wished to discuss the PSQ further. Patients from the control group were

TABLE 8 *Proportion of patients with follow-up*

	Intervention (n = 92)		Control (n = 73)		Difference (%) (95% CI)	p
	No.	%	No.	%		
Follow-up	31	34	45	62	–28 (–42 to –13)	0.0003
No follow-up	61	66	28	38		

TABLE 9 *Mean numbers of follow-up visits*

		Intervention	Control	p
Number analysed		92	73	
Number of visits per patient referred	Mean	0.48	0.66	0.13
	Standard deviation	0.83	0.59	
Number analysed		31	45	
Number of visits per patient followed-up	Mean	1.42	1.09	0.0143
	Standard deviation	0.85	0.28	

TABLE 10 *Overall satisfaction with care received*

Satisfaction with care received	Patient group				Total	
	Control		Telemedicine			
	No.	%	No.	%	No.	%
Satisfied	60	89.6	65	81.3	125	85
Neither	6	9.0	9	11.3	15	10.2
Dissatisfied	1	1.5	6	7.5	7	4.8
Total	67	100	80	100	147	100

administered the questionnaire immediately following their traditional outpatient consultation at the hospital. Patients from the telemedicine group completed their questionnaire after they had returned to their GP for their telemedicine results. Patients were asked to complete the questionnaires as soon as possible and to return them in a Freepost envelope provided. A postcard reminder was mailed to patients 2 weeks after the first questionnaire. A second reminder, which included the original questionnaire, was forwarded 2 weeks after the first reminder.

The Patient Satisfaction Questionnaire III[27] was adapted for use within this study, as there was no suitable questionnaire available for use within this context. The questionnaire consisted of 51 items rated on a five-point Likert scale ranging from strongly agree to strongly disagree. The questions relate to aspects of satisfaction such as interpersonal aspects, time spent with the practitioner, communication, practitioner skills, access/availability, convenience of the medical appointment and financial aspects. Nine items were added from a questionnaire developed specifically for the asynchronous teledermatology consultation.[28]

The PSQ was piloted on a sample of 20 dermatology patients who had received a traditional consultation with a dermatologist at the hospital (and who were not part of the main trial). This pilot study was undertaken in March 1999. A covering letter asked patients to comment on the acceptability of the questionnaire, such as length to complete, questions that were unclear or difficult and for any other comments they had about the questionnaire. Patients' comments were favourable. The questionnaire was viewed as being quick and easy to complete, and questions were

TABLE 11 *Satisfaction with overall management*

Satisfaction with overall management	Patient group				Total	
	Control		Telemedicine			
	No.	%	No.	%	No.	%
Satisfied	59	86.8	66	83.5	125	85
Neither	7	10.3	7	8.9	14	9.5
Dissatisfied	2	2.9	6	7.6	8	5.4
Total	**68**	**100**	**79**	**100**	**147**	**100**

perceived as being clear and unambiguous. It was completed with few errors. As a result, no subsequent changes to the questionnaire were made.

Results

The PSQ was posted to 208 patients who were recruited into the trial and the final response rate was 71.2% (n = 148).

Overall levels of patient satisfaction were high in both groups and there was no statistical evidence to suggest that satisfaction varied between the groups.

About 90% (n = 60) of patients were satisfied with their overall care in the traditional group compared with 81% (n = 65) in the telemedicine group (*Table 10*), a difference of 8.3% (95% CI: –3 to 20%), χ^2 =1.97 on 1 df, p = 0.16.

About 87% (n = 59) of patients were satisfied with their overall management in the traditional group compared with 84% (n = 66) in the telemedicine group (*Table 11*), a difference of 3.2% (95% CI: –8.3 to 14.7%), χ^2 = 0.30 on 1 df, p = 0.59.

Satisfaction with other aspects of the patient consultation (such as interpersonal aspects, time spent with the practitioner, communication, practitioner skills, access/availability, convenience of the medical appointment) were also high, and there was no statistical evidence to suggest that satisfaction and attitudes varied between the telemedicine or traditional groups.

About 84% (n = 66) of patients from the telemedicine group reported being satisfied with their care and management and 85% (n = 66) said that they would be happy to use this system again. However, 38% (n = 30) agreed with the statement that they would prefer to discuss their skin problem with the dermatologist in person. Additionally, 40% (n = 31) said that they would feel something important was missing if they did not see the dermatologist in person. However, 76% (n = 60) of patients agreed with the statement that they would rather have their skin problem managed through telemedicine than have to wait a few weeks to see the dermatologist in person, suggesting that waiting time is an important factor in determining patients' satisfaction.

Patient interviews

Methods

The aim of the qualitative study was to explore the subjective perceptions and experiences of patients who received either an SF telemedicine consultation or a traditional referral for specialist opinion. This section provides an account of the patient interviews conducted as part of the study and explores two areas: participants' confidence in diagnosis and management and preferred future preferences.

All participants were asked within the PSQ to indicate whether they would be willing to be interviewed about their views and experiences of receiving either a traditional dermatology or TD. The final response rate to the questionnaire was 71.2% (n = 148). Of these, 60% (n = 89) of patients stated their willingness to be interviewed [55% (n = 49) from the telemedicine group, 45% (n = 40) from the control group]. About 40% (n = 59) of patients declined to be interviewed [42% (n = 25) from the telemedicine group, 58% (n = 34) from the control group]. The first 30 participants who had agreed to be part of the wider trial and to be interviewed subsequently were included in the sample. They comprised 12 men (six from the telemedicine group, six from the control group) and 18 women (13 from the telemedicine group, five from the control group). The age of participants ranged from 16 to

TABLE 12 *Age distribution of patients participating in interviews*

Age range (years)	Frequency	Control	Telemedicine	%
16–24	2	1	1	6.6
25–35	5	1	4	16.6
36–45	11	4	7	36.6
46–55	1	1	0	3.3
56–65	7	2	5	23.3
65>	4	2	2	13.3
Total	**30**	**11**	**19**	**100**

82 years (*Table 12*). Twenty-eight participants classed themselves as 'white' European, one as Afro-Caribbean and one as Asian. Participants from all the GP practices were represented, although the practice where access was negotiated first represented 33% (n = 10) of all the participants interviewed. The participants presented to their GPs with a range of dermatological problems. These included unspecified rashes that were itchy/painful or tender (16), gradual/sudden hair loss (two) and lesion(s) that were growing/ bleeding or painful (12).

Interviews were conducted, where possible, within 1 month of the individual's recent telemedicine or traditional FTF consultation. Each interview began by asking participants to describe their recent experiences of the care they had received. Responses to this were then followed up as a result of specific issues raised. This maintained the conversational flow, enabling the participants to tell their accounts in their own words, topics centring on satisfaction, future healthcare preferences and confidence with diagnosis. When all topics had been covered within the interview, participants were asked if there was anything else they considered important that had not been covered in the course of the interview. This often took the form of the participant recapping and expanding on the issues covered during the earlier part of the interview. The interview ended with contact details being exchanged in case the participant wished to discuss further the interview or any other aspects relating to the study. No patients did this.

The interviews varied in length, ranging between 30 minutes and 2 hours. Summary notes of each interview were made immediately following each interview and prior to verbatim transcription. Self-reflective notes were also kept by the researcher, which referred to any issues emerging during this data collection period that were considered relevant to understanding the meaning of satisfaction, the data analysis and/or the interview process.

Themes were identified from the transcripts, which described and exemplified the subjective perceptions and experiences of participants. The interview transcripts were analysed by the two researchers. They independently read and re-read the transcripts to identify important issues (that seemed important to the respondents and were important to the researchers in that they directly addressed the key questions raised for discussion). They were given a label (e.g. receiving a diagnosis). This process is called indexing. When this task had been completed for all of the transcripts, one researcher drafted a list of potential sub-themes by grouping some of these issues together. A similar process was used to group these into themes. Agreement on the labels/titles and content of the themes was then negotiated between the researchers. The presentations of the themes are illustrated with verbatim extracts from the accounts of participants chosen for their pertinence to the themes, and for being especially representative of all the participant accounts.[29] Finally, re-reading the original transcripts was undertaken by one of the researchers to ensure that interpretations made from the transcripts were grounded fully in what the participants had said.

Results

There was little difference in satisfaction between patients receiving telemedicine and those receiving traditional care. Patient satisfaction with care and management was high in both groups. Although each participant had their own perspective about what they had liked or disliked about the way in which they had been managed, a number of factors were common to both groups. From analysis of the interviews, five themes

emerged when participants described satisfaction with their care and management:

1. receiving a diagnosis, treatment and cure
2. receiving information and explanations
3. the need for participants to feel as though they were being taken seriously
4. the need for individualised personal care
5. the importance of minimal waiting for an appointment and treatment.

Thirteen of the 19 participants (68%) who received the telemedicine consultation said they felt confident with their diagnosis and management; six (32%) said that they were not confident with their management through telemedicine. The importance of FTF contact within a consultant consultation and having no health improvement following telemedicine treatment were the two factors that explained this lack of confidence. It is perhaps not surprising that those who said that they felt unconfident with their diagnosis and management through telemedicine also said that they would prefer to see a consultant FTF at any time in the future. Most participants who said that they were confident with their diagnosis and management attributed this to their trust and confidence in their own GP and their perception that their skin problem was not serious or 'life threatening'. Other factors were knowing that an expert had seen the telemedicine picture, being impressed by the quality of telemedicine photographs taken and having a match in diagnosis given by the consultant and GP. Age and gender did not appear to be associated with confidence in this group.

Eight of the 11 participants (73%) who received a traditional referral care said they felt confident with their diagnosis and management; two (18%) expressed little confidence with their management and one participant (9%) expressed no opinion. No improvement in condition was the factor that explained the lack of confidence for the two participants who said they had little confidence in telemedicine. The perception of having received a thorough consultation, where there had been an examination by the GP or consultant, and where there had been adequate explanations and information that had resulted in a subsequent improvement in their skin problem were the three main factors that explained this confidence. Other factors were having trust in the GP and being given the same diagnosis and management by both consultants. Age, gender or type of skin problem did not appear to be a factor that explained confidence in either group.

Staff perceptions

This section describes the methods, results and implications of the psychological evaluation of the perceptions and experiences of medical staff in primary and secondary care towards TD. First, it reports the findings of a survey that was carried out to elicit GPs' perceptions of TD 1 year following its introduction in their practices (a survey to elicit GPs' perceptions of telemedicine prior to its introduction into practices was also undertaken). Second, it reports the findings of in-depth semi-structured interviews carried out with the two consultant dermatologists who were part of the trial, in order to elicit their views and experiences of using teledermatology as part of the trial. Finally, it outlines the findings from interviews carried out with the two lead GPs from two practices that withdrew from the trial prior to its completion.

GPs' perceptions of teledermatology

Methods

The aim of this survey was to elicit the perceptions of GPs (n = 36) towards teledermatology 1 year following the introduction and implementation of teledermatology into their practices.

A questionnaire was posted to all GPs in the eight participating telemedicine practices in Sheffield (n = 42). The questionnaire was designed to identify the GPs' perceptions and views of TD, and also their views about being part of the clinical trial. The questionnaire comprised 15 precoded items and seven open-ended questions, which were generated through prior discussions with doctors, a review of the relevant literature and from the researchers' knowledge of the area and from the results of the questionnaire, circulated at the beginning of the study.[14] A preliminary paragraph pointed out that the questionnaire related specifically to the views of the GPs who had been actively recruiting patients as part of the study in addition to those who had chosen not to be actively involved.

The original intention had been to undertake in-depth qualitative interviews with all the participating GPs. However, due to a low response by the GPs to be interviewed, a pragmatic decision was taken to develop a postal questionnaire in order to obtain data that would yield a higher and more representative viewpoint. Responses were anonymous, to maximise response and encourage respondents to give open feedback.

TABLE 13 *GP response by practice*

Practice	Number of GP responses	%
1	4	11.4
2	4	11.4
3	6	17.1
4	2	5.7
5	4	11.4
6	4	11.4
7	4	11.4
8	7	20.0
Missing	1	
Total	**36**	**100**

Results

The questionnaire was posted to all GPs in the eight participating practices (n = 42) in September 2001. The response rate after 2 weeks was 52.3% (n = 22). Following a reminder, this increased to 85.7% (n = 36). Respondents were representative of the practices involved (*Table 13*).

Some 44.4% (n = 16) of the sample were women, 52.8% (n = 19) were men and this information was not available for one respondent (2.8%). Unlike the questionnaire circulated to GPs prior to the introduction of TD into their practices, gender was not found to be significant for any of the variables within the questionnaire, that is, responses to the questionnaire did not vary by gender. Over three-quarters (77.1%; n = 27) of respondents said that they had been actively involved in recruiting patients to the TD study and 22.9% (n = 8) said that they had not been involved in recruiting patients to the study (*Table 14*).

TABLE 14 *Respondents actively involved in recruiting patients to the study*

Practice	No. of GPs recruiting to study	No. of GPs not recruiting to study
1	2	2
2	2	2
3	3	3
4	2	0
5	4	0
6	3	1
7	4	0
8	7	0
Total	**27 (77.1%)**	**8 (22.9%)**

About 86% (n = 31; 95% CI: 71 to 94%) of the respondents said that they were very/fairly enthusiastic about being involved in the TD project compared with other categories (unsure/not enthusiastic/at all).

Only 21% (n = 7; 95% CI: 11 to 38%) of respondents felt that all or most of their expectations of TD had been met. One-third of respondents (33%; n = 11) felt that most expectations had not been met and 46% (n = 15) were unsure. As identified in the questionnaire completed by GPs prior to the introduction of TD within their practice, expectations of TD were of quicker access to specialist opinion, decreased referrals, effective means of obtaining a diagnosis, increased convenience for patients and an educational and teaching element for the GP.

Only 21% (n = 7; 95% CI: 10 to 37%) of respondents felt satisfied or very satisfied with TD in their practice, 47% (n = 16) said that they were dissatisfied or very dissatisfied with it and 32% (n = 11) were unsure. The respondents who reported being satisfied with TD in their practices were significantly more likely to feel confident about diagnosis and management through TD (Kendall's tau = 0.34, p = 0.020), to think that TD would make things better for them as GPs (Kendall's tau = 0.54, p = 0.001), that TD would make things better for their patients (Kendall's tau = 0.62, p = 0.001), perceive TD (Kendall's tau = 0.55, p = 0.001) and telemedicine (Kendall's tau = 0.39, p = 0.015) to have a useful role to play in GP practices, and say that their expectations of TD had been met than those who felt dissatisfied with TD in their practices (Kendall's tau = 0.49, p = 0.003). Furthermore, those who said they were satisfied with TD in their practice were significantly more likely to say that they would consider using the TD system in the future (Kendall's tau = 0.64, p = 0.001) than those who felt dissatisfied. Interestingly, those who reported being satisfied with TD in their practice were more likely to say that they had concerns relating to TD than those who were dissatisfied (Kendall's tau = –0.28, p = 0.039).

Some 31% (n = 10; 95% CI: 18 to 49%) of respondents said that they felt confident about diagnosis and management of care through TD, 28% (n = 9) said that they were unconfident and 41% (n = 13) remained unsure.

Only 23% (n = 8; 95% CI: 12 to 39%) of respondents said that they would consider using a telemedicine system in the future, 34% (n = 12)

said they would probably or definitely not and 43% (n = 15) were unsure.

Although there was no association between practice and overall satisfaction with telemedicine, there was a weak association between practice and views that they would use TD again in the future (p = 0.026), confidence about diagnosis and management of care through the TD system (p = 0.014), the perception that TD will make healthcare better for patients (p = 0.001) and the extent to which they felt that TD has a useful role to play in GP practices (p = 0.030).

In order to compare individual responses over time, GP responses were paired pre- and post-TD. There were 16 matched/paired responses (i.e. individual GPs who had completed both the pre- and post-TD questionnaires). Again, there were no significant findings to suggest that GPs' perceptions changed over time. However, there was some evidence, although not statistically reliable, that GPs' opinions had become more negative over time. Of the 16 paired responses, the four GPs who said they were confident with diagnosis and management pre-telemedicine, post-telemedicine two remained confident and two of them said they were not confident. Of the 10 GPs who said they were unsure pre-telemedicine, three said they were confident, two remained unsure and five said they were not confident post-telemedicine. Only one GP reported being unconfident pre-telemedicine and this GP remained unconfident post-telemedicine.

It was expected that the open-ended questions would provide more detailed information about some of the subjective perceptions and concerns of the GPs about TD. However, the respondents tended to write one-word responses, which did not help in understanding some of the responses given to the Likert-type questions. Nevertheless, these comments provided some insight into what seemed important to these GPs.

About 60% of respondents (n = 26) expressed aspects of telemedicine they had liked. Of these, 30.7% (n = 8) said they had liked nothing about teledermatology in their practice. The remaining respondents (69.2%; n = 18) said they had liked

- the improved access to experts (n = 12)
- receiving prompt feedback from consultants (n = 6)
- using the teledermatology technology and taking the photographs (n = 4).

About 91% of respondents (n = 33) responded to this question about aspects of telemedicine they had disliked. Two respondents (6%) said that there had been nothing they had disliked about using TD in their practice. The remaining respondents (93.9%; n = 31) identified thee factors:

- complex referral procedure (time consuming) (n = 11)
- increased workload (increased paperwork, taking photographs) (n = 18)
- TD system complicated (with problems establishing a connection between sites) (n = 9).

Some 60% of respondents (n = 22) suggested improvements to the telemedicine care system. Almost one-quarter of these (22.7%; n = 5) felt that nothing could have been better. However, most respondents (77.2%; n = 17) identified three factors:

- simplification of teledermatology software (n = 9)
- faster and more reliable connections (n = 6)
- less complex referral procedure (n = 6).

About 53% of respondents (n = 19) expressed their concerns about the impact of the system on their practice. Concerns related to:

- increased workload (n = 8)
- time consuming (n = 8)
- teledermatology system too complex (n = 3).

Some 58% of respondents (n = 21) suggested other factors that would help GPs in managing patients with telemedicine:

- shorter outpatient waiting list (n = 8)
- improved GP access to a specialist opinion (telephone access for information and advice) (n = 6)
- slots to see urgent patients (n = 4).

Consultants' perceptions

Methods

The aim of the interviews was to explore the subjective views and experiences of TD.

In-depth semi-structured interviews were carried out with the two consultant dermatologists who were part of the trial and who were actively involved in both the TD and traditional FTF consultations.

An interview guide was developed from a review of the relevant literature and from the researchers' knowledge of the area. Both participants were asked if they had any objections to the interview being tape-recorded, and neither objected. The interviews were conducted 1 year following the introduction and implementation of TD. The interviews with the first consultant lasted 45 minutes and the second interview lasted 60 minutes.

Results

Both participants reported having no previous involvement in any practical work or research relating to TD prior to being involved in the TD trial. Lack of strong evidence about telemedicine in dermatology and the opportunity to explore both its usefulness and effectiveness through the trial were the main motivating factors in taking part in the trial.

The impact of participating in the trial for both participants was viewed in terms of increased workload. For the first consultant this specifically related to the extra work involved in seeing extra trial patients as part of a normal clinic and participating in the teleconsultations. For the second consultant the impact of participating in the trial was the amount of time spent trying to get the software and communication systems working efficiently.

The type of skin problem presented to the consultants determined the extent to which they felt confident with TD. Where a diagnosis was viewed as clear with a well-established routine of management (such as eczema, psoriasis or acne), taken with a full and comprehensive account of a patient's history and existing management supplied by the GP, then the usefulness of using TD was highlighted.

With potentially more serious skin problems, such as diagnosis of potential skin cancers, the role of TD was viewed as being limited.

This lack of confidence with TD to diagnose potential skin cancers resulted in the first consultant requesting that most of the skin lesions needed to be seen FTF and questioning the practicality of using TD if it was only able to diagnose some conditions and not others.

The limitations of relying on photographs to diagnose and manage dermatological problems were evident. The second consultant, although recognising the limitations of using photographs to diagnose dermatological conditions, was more optimistic about the potential of good-quality photographs in the future.

Although the first consultant rated the quality of TD referrals as being good, both consultants questioned the value of a structured electronic referral letter.

For one consultant, other than the time it took to familiarise himself with the TD system, there had been no other organisational effects relating to the introduction of TD. The second consultant identified two problems. The first was related to the introduction of TD within a clinical trial, more specifically, the difficulties associated with trying to get patients seen by two different consultants in the same session. Second, although there were felt to be few problems with the teleconsultations themselves, there was a concern that if TD was being implemented on a larger scale, then interfacing the TD system with the other appointments would have been much more of an organisational issue.

Both consultants raised their concerns relating to the medico-legal issues of diagnosing and managing patients through TD. The result of these concerns was that both consultants would feel cautious about diagnosis and management using TD.

Neither consultant raised any significant concerns relating to the use of TD and confidentiality issues. One consultant viewed TD as potentially being more secure than current practices. The second consultant took a more cautious view.

Talking to the patient was viewed as an integral part of the consultant's role, and both consultants expressed some concern about the potential lack of patient contact.

Although acknowledging the role of TD in specific cases, both consultants were sceptical about the future use and role of TD. Both consultants agreed that a good-quality GP referral letter with a good-quality photograph is as good as a TD consultation.

The consultants were asked if there had been anything they had disliked about the introduction of TD. The first consultant identified two factors.

- lack of patient contact
- lack of feedback to patients.

The second consultant disliked the inability to ask the patient questions.

The first consultant saw the value in using a specialist nurse in order to improve the efficiency of using TD.

The second consultant identified two factors that he felt would improve future implementation of TD systems:

- The need for a reliable and configurable TD system. There was a perception that the software used as part of the trial had not come up to expectations.
- Established guidelines and protocols.

The TD system was perceived by both consultants as being relatively easy to use. However, both consultants emphasised the importance of the specialist needing to be trained in the same way as with conventional clinical practice in order to use TD safely and effectively. The second consultant also felt that a fair period of familiarisation and adjustment was needed when first taking TD referrals. A number of training aspects were identified.

Both consultants expressed caution and apprehension about using TD in the future. Where a diagnosis was clear and well defined with a well-established routine of management (such as eczema, psoriasis or acne), TD was viewed as potentially advantageous. However, more generally, the role and impact of TD were viewed as limited.

Practice withdrawal from the trial

Two of the original practices withdrew from the study; one prior to patients being recruited to the study (practice 1) and the other (practice 2) several months after recruitment started. In order to explore some of the issues that were considered instrumental in the decision to withdraw from the study, in-depth semi-structured interviews were carried out with the lead GP in both practices. The factors that emerged might also help to illuminate some of the views expressed by the GPs within the questionnaire.

Both GPs viewed telemedicine as a means to speeding up waiting times for dermatology patients. Three factors were viewed as significant by both GPs:

- time constraints
- lack of financial incentive/resources
- technology-related issues.

Discussion

Recruitment

The study suffered major problems with patient recruitment at both a practitioner level (a small number and proportion of the GPs recruited the majority of the cases) and individual patient level (only a small minority of eligible cases appear to have been recruited). Repeated visits to practices, discussions with practice teams and the eventual introduction of payment (with the agreement of the Research Ethics Committee) were all tried to increase recruitment, but all failed to make any significant impact. Consideration was given to recruiting additional practices, but it was considered that maintaining a position where only a minority of patients were recruited might threaten the external validity of the study and a strategy of trying to increase the proportion of patients recruited by participating practices was sustained. The study was terminated before even the numbers required for the interim analysis had been recruited.

The Local Research Ethics Committee rejected a request to invite patients who refused to volunteer basic, anonymised details (e.g. age and sex) and their reasons for refusing consent to participate in the trial. Unfortunately, therefore, we cannot examine any indicators, such as age or sex, of the representativeness of those recruited. Indeed, we do not even know how many patients were invited but refused although, anecdotally, GPs indicated that these were relatively few. The barrier to recruitment appeared to reside with the practitioners.

It is possible, therefore, that the patients actually recruited were not representative of routine adult dermatology referrals. It is likely that patients were recruited by the most enthusiastic doctors and probably represented the patients in whom the clinicians felt that TD stood the greatest chance of being beneficial. Counteracting this might have been the low level of expertise achieved by the GPs, due to the low workload.

The apparent 'failure' of randomisation, as indicated by differing age profiles, may reflect the low numbers finally recruited. It might, however, also indicate a failure within the randomisation process. Indeed, the fact that the intervention group had a mean age some 6 years higher than the control group might indicate that older patients were being selectively recruited into the intervention arm. Given, however, that the patients had already consented to treatment before the practitioner made the telephone call to

ascertain the allocation, this seems unlikely. The most likely explanation is by differential drop-out rates. The higher drop-out rate for the control group (*Figure 2*) could be explained by differential drop-out among younger patients.

Clinical outcomes

Although on analysis of the data available SF TD failed to achieve diagnostic and management equivalence, three factors suggest that these results may not represent a valid comparison.

The first concern relates to the numbers of cases recruited, which results in greater statistical uncertainty around any observed results. If, however, these results had been observed where no bias was possible, this would not invalidate the data.

One factor which brings the validity of the results into question is the differential loss between the two groups from initial recruitment to completion of the study. The difference in ages of the two groups suggests that this was not random.

Furthermore, the delay in obtaining the second opinion appointments for the intervention group (54 days longer than the control group) introduced a potentially serious bias between the intervention group (where there was a temporal difference between the photography and the FTF second opinion) and the control group (seen FTF by two consultants on the same day). This obviously allowed the potential for the condition to change, either as a result of spontaneous resolution or because of interim treatment by the GP. There was, however, rarely a report of the GP initiating additional treatment once the referral had been made, so this is less likely. We had initially considered ensuring an earlier appointment for all patients involved in the study, but this was rejected mainly because hospital management felt it would be unfair to other patients not involved in the study.

In conclusion, we believe that the difficulties in recruitment and the potential biases introduced by selective loss of patients and the delay in obtaining a valid second opinion in the study group mean that no valid conclusions can be drawn regarding the clinical performance on SF telemedicine in this study.

The levels of concordance observed are, however, statistically consistent with those of previous comparable studies (*Table 15*), as most studies are relatively small and share the wide CIs of our results.

Care process outcomes

In this study, as in others, patients who were able to receive a definitive opinion via telemedicine did

TABLE 15 *Comparison of key outcomes for published trials of store-and-forward teledermatology*

Lead author	Size	Diagnostic concordance	Other statistics
Bowns (this study)	92 in study group	55% overall; 72% if those transferred to normal care are excluded; (cf. 79% FTF)	55% management concordance; 67% if those transferred to normal care are excluded; (cf. 84% FTF); 42% of cases did not need to be seen FTF
Oztas, 2004[30]	125	<70%	
Eminovic, 2003[31]	96	Complete in 41%, partial in 10%, no agreement in 49%	23% of cases did not need to be seen FTF
Chao, 2003[32]	71	95%	
Lim, 2001[33]	53 images/49 patients	79% (range 73–85%); 86% if differential diagnosis included	
Taylor, 2001[34]	194	77%	31% of cases did not need to be seen FTF
Barnard, 2000[35]	50	73% (cf. 84% FTF)	
High, 2000[36]	106 conditions/96 patients	81–89%	
Loane, 2000[37]	96		69% of cases did not need to be seen FTF
Krupinski, 1999[38]	308	83%	62% good diagnostic confidence

so much more quickly than those awaiting a traditional appointment. This, however, is at least partly the result of the relative priority given to the two competing activities (viewing telemedicine referrals and conducting outpatient appointments) by the clinicians concerned. It is, however, a clear potential benefit, although this possible advantage is diminishing as NHS waiting times fall.

The higher number of visits per patient seen FTF suggests that, as might be expected, those telemedicine patients who need to be seen FTF probably have more severe conditions than the average traditional referral.

Satisfaction outcomes

Patient satisfaction

The findings from the patient survey suggest that patients from both groups were satisfied with their care and management, with no significant differences between the two groups. Similar findings have also been reported in other RCTs of patient satisfaction in telemedicine.[39–41] Despite these findings, over one-third of patients (38%, $n = 30$) who received the TD care and management reported that although they were satisfied they would prefer to be managed through a traditional FTF consultation than through telemedicine. Similar findings have been reported in other studies.[42–44] The findings from the qualitative data suggest that the perceived seriousness of the problem was the main factor that influenced this preference. Factors such as age, gender or GP practice were not significantly related to future preference. The fact that the local hospital within this study was less than 15 km from patients' GP surgeries, could also possibly explain this preference, and the inconvenience of travelling to see the consultant at the hospital may have been less significant than it might have been if patients had been living in remote or rural areas where telemedicine may be viewed as a convenient alternative to travelling long distances. Other qualitative findings suggest that patients were generally positive about their care and management, regardless of group. Receiving a diagnosis, treatment and cure, receiving adequate information and explanations, the need to be taken seriously, the need for individualised personal care and the importance of minimal waiting for an appointment and treatment were aspects to which patients frequently referred when discussing their overall experiences of care and management. The technological aspects of telemedicine did not appear to be significant to these patients. However, it was apparent that the patients' need to be managed quickly, with minimal waiting, resulted in them making 'trade-off' decisions between their confidence with diagnosis through telemedicine (as opposed to through a traditional FTF consultation), with perceived seriousness of skin problem and differences in waiting times offered by the two modes of healthcare delivery.

Findings from the patient survey and from the in-depth interviews suggest that patients were generally satisfied with most aspects of healthcare delivery. However, the satisfaction with telemedicine is not straightforward: it is confounded by factors such as future preferences, confidence in diagnosis and management, perceived seriousness of skin problem and waiting times.

Clinician satisfaction

Owing to the small sample size, it is difficult to generalise from the findings of the study. The GPs who completed the questionnaires had agreed to take part in the research trial and therefore may have been more accepting of telemedicine in comparison with the general GP population. There is also the potential for response bias: the non-responders may have been less satisfied with TD than those who responded and we have no information about the non-responders in this study.

Prior to the introduction of TD into their practices, GPs expressed clear views about what they viewed as its role. There was a general perception that TD in general practices would result in quicker diagnosis and treatment, decreased referral rates and improved medical education and training. There was an overwhelming view that a telemedicine system needed to be quick, easy to use, efficient and reliable. However, the follow-up questionnaire 1 year following the introduction of TD within the practices found that only 21% ($n = 7$) of GPs felt that their initial expectations had been met. This might well explain why only 21% ($n = 7$) of the GPs felt satisfied with TD and why 47% ($n = 16$) said that they were dissatisfied.

It was clear from the qualitative open-ended comments that GPs have concerns about the introduction of TD into their practices. Many GPs viewed the recruitment process as time consuming and complex and one that had increased their workload. The very fact that GPs were unwilling to be interviewed was perhaps evidence of their lack of time. There were also concerns about the quality of images transmitted and the reliability of the equipment. However, it is unclear from the findings of the questionnaire whether the GPs

were reacting specifically to telemedicine **or** to problems with the nature of the trial itself. In the light of this, it is suggested that future studies should observe practices that are currently using TD as part of their routine practice and that are not part of a clinical trial. The study reports less favourable GP responses to telemedicine than observed in previous studies, and suggests that GPs remain cautious, if not sceptical, about the introduction of TD into their practices.

The views of both the GPs and consultants are less favourable about TD than previous studies have reported. Only 21% (n = 7) of GPs were satisfied with teledermatology within their practice, with only 31% (n = 10) feeling confident about diagnosis and management of dermatological problems through TD, this being reflected in the finding that only 23% (n = 8) of GPs would consider using TD again in the future. Despite the GPs liking the improved access to experts, and receiving prompt feedback from the consultants, many disliked the complex referral procedure, increased workload and the time it took to use the TD system. However, as already discussed, it is unclear whether the GPs were reacting specifically to TD or to the problems of being part of a clinical trial. Although the consultants viewed TD as being potentially useful in managing specific dermatological problems, it was viewed as having a minor role in minimising the current issues facing dermatology.

The study recruited far fewer patients than planned. Therefore, the analysis may have been inadequately powered. However, although the low power and small sample sizes can explain the width of the CIs, it cannot explain the size of the observed effect. There was a 24% difference in diagnostic concordance and a 28% difference in management concordance between groups in the ITT sample. Similarly, there was a 7% difference in diagnostic concordance and a 17% difference in management concordance between groups when we exclude the 53 patients in the intervention group whose management was transferred. Overall, it is unlikely that the two methods are broadly clinically equivalent and that we failed to demonstrate this.

Economic outcomes

Data collection in this area by clinicians was particularly poor, leaving no scope for a direct comparison of the relative costs of the two consultation modalities. Furthermore, the low recruitment would have meant that the fixed costs of the care process would have been apportioned over a relatively small number of cases, resulting in an inflated unit cost. This is less important, as we were unable to demonstrate clinical equivalence for the TD approach.

Generalisability

There are a number of concerns regarding the generalisability of these findings. Foremost amongst these is the evidence that we were studying unrepresentative patient groups, recruited and managed by a highly selected subgroup of GPs. Furthermore, our findings should not be extrapolated to other models of SF TD.

It is important, however, to place these findings in the context of other published studies. Our findings are consistent with those of other studies[4,33,36,38,45,46] with lower indicators of clinical effectiveness and a significant proportion of patients still requiring an FTF consultation.[37] We also agree that "effective store-and-forward teledermatology requires very good images and comprehensive historical referral data".[47] The challenge remains to integrate TD appropriately within the overall dermatology service.[48]

Original study design

We initially proposed that these three technologies be compared in two stages. The first stage was to involve a comparison (by RCT) between traditional outpatient consultation and asynchronous, SF approaches. When approximately 150 patients [see the section 'Sample size' (p. 28)] had been recruited into each arm of this stage, a preliminary analysis would be undertaken to examine the clinical equivalence of the SF technology. This would have afforded an early opportunity to abandon study of SF should it have been evident that its clinical effectiveness fell significantly below that of the FTF consultation.

The descriptive studies available at the inception of the study indicated that we would have expected SF to be broadly equivalent at that stage. We would then proceed to the second stage, recruiting patients to the third arm of the trial – synchronous teleconsultation using videoconferencing technology. If SF did not prove equivalent to conventional outpatient consultation, the second stage would only compare synchronous teleconsultation with conventional outpatients.

The study team believed that this was the most practicable and cost-effective approach to compare these technologies. We had two broad reasons for proposing such an approach. First, SF

appeared to be feasible, acceptable and possibly the most cost-effective approach, based on the available descriptive studies. It also seemed the least dependent on developments in video and telecommunications technology and changes in this marketplace (where prices in telecommunications technology are generally falling and new products and standards are emerging rapidly). An early indication of the value of SF, based on a rigorous study design (i.e. an RCT) would have offered an immediate guide to the NHS. By deferring the study element that included synchronous technology, even if only by approximately 6 months, we would also have allowed the technology and market to mature for a period. Our second reasons were logistical. We felt that it would be much easier to introduce the two new technologies into the study practices sequentially, rather than simultaneously. It would simplify training and the technical implementations across several sites and would enable a large number of staff to become familiar with one approach before embarking on the most complex and demanding of the two technologies.

Stage 1 – RCT of SF or asynchronous teledermatology

This stage sought to compare the traditional outpatient consultation with asynchronous telemedicine. Here, the referring GP constructs a message, with structured data, free-text and digital images, which is then sent to the specialist, who deals with the information at his/her convenience, and offers an opinion as an electronic message in reply.

Before commencing the RCT, it was necessary to pilot a number of aspects of the systems and the methods of evaluation. Following a period of training for a range of staff in primary care and the relevant hospital, a number of tests were made of the asynchronous referral method. These confirmed both the technical operation of the electronic messaging and also the basic effectiveness of the training, in terms of image quality. We also needed to develop the administrative arrangements for the SF referral. In terms of evaluation, we intended to make maximum use of tools developed and validated elsewhere, to eliminate the unnecessary development and proliferation of such tools, and to enhance the capacity to make comparisons between different studies. However, data collection methods and instruments across all three major outcome categories (clinical, economic and satisfaction) needed to be piloted before recruitment commenced.

The control group of patients had their conventional outpatient appointment booked in the same way as appointments were booked for routine patients at the time. Waiting times for non-urgent outpatient appointments were of the order of 20 weeks. A range of consultants, who currently provided dermatological outpatient services for the participating practices, saw patients.

Stage 2

A decision on the nature of the second stage of the study was to have been taken following an interim analysis forming the stage 1 results, undertaken when approximately 150 patients had been recruited into each of the two arms. This analysis had an 80% power to establish if the SF option is achieving a level of agreement on the initial treatment plan which falls at least 10% below that of conventional consultation (*Table 1*), allowing the early rejection of SF if it is proved to be greatly inferior to FTF consultation.

If the SF option was judged to be clinically equivalent and broadly acceptable to patients, GPs and dermatologists, then recruitment to the second telemedicine option would have begun, forming a three-way RCT. If SF was judged not to be clinically equivalent, or proved grossly inadequate in some other way, asynchronous referral would have been abandoned, and only synchronous teleconsultation would have been compared with a conventional outpatient service.

Recruitment and consent would have proceeded broadly as in stage 1. However, the proportion of patients assigned to each group was to be amended to ensure that by the end of stage 2, approximately equal numbers (446) of patients would have been recruited to each modality.

Patients randomised into the synchronous telemedicine group would have an appointment booked before they left the surgery. However, they would attend their GP's surgery for that appointment, conducted by videoconference with the GP in attendance. In addition to the data on clinical equivalence, cost and acceptability, additional data would be collected to address the more complex issues (e.g. GP perception of the additional educational value of videoconferencing) which needed to be assessed for this particular option.

Second opinion

Control group. A second outpatient appointment was arranged with a second consultant, where

possible on the same day as the patient's normal outpatient attendance (this condition was met in all cases).

SF group. In addition to preparing the telemedicine referral message, an outpatient appointment with a second consultant was also arranged.

'Synchronous' telemedicine, videoconference group. For this group, an outpatient appointment with a second consultant would also be arranged.

The second appointment was identified to the consultant as a 'second opinion' for the purposes of the study, but the study arm allocated to the individual patients was not identified.

Changes to study design

A major change in the study design arose as a result of the publication of the results of another RCT. This indicated that, although asynchronous telemedicine appeared effective and cost-effective, synchronous telemedicine was effective, but significantly more costly than routine care.[49] This led the Steering Group for the study to seek the approval of the Health Technology Assessment Programme to abandon plans for the study of synchronous telemedicine. This was agreed.

Chapter 3

Digital photography in suspected skin cancer

Introduction

In 1997, as the main SF component of this study was starting, the Department of Health introduced the '2-week wait' initiative for cancer.[50] In principle, this policy sought to ensure that any patient suspected by their GP of having cancer had to be seen by an appropriate specialist within 2 weeks of the initial referral. Although this excluded basal cell carcinomas, other dermatological malignancies were covered. As the need for patients to be seen within this relatively (at that time) short period precluded their inclusion in the main study, we established a complementary study to examine the potential of SF telemedicine for this particular service.

Although on-line photographic libraries have been used to train clinicians in the recognition of skin cancers,[51] and SF techniques have been applied to small numbers of suspected cancers,[52,53] the performance of such approaches is highly dependent on the nature of the patient population.[54] A previous analysis of 52 audits and databases showed that, up to 2003, only 12% of referrals had subsequently been confirmed to have cancer (although this excluded basal cell carcinomas), and 58% of skin cancers reached hospital by other routes. There was, therefore, a strong case to consider alternative approaches to triage such referrals.

Methods

In many respects, this study is less complex than the main SF TD study. Rather than undertake a pragmatic RCT, with primary care staff (predominantly GPs) taking the photographs, we took advantage of the presence of a large Medical Photography Department, which already undertook a considerable volume of dermatological photographs, to take photographs immediately prior to the patients' attendance at outpatients. As photographs were, therefore, taken on the same day as an independent clinical opinion was being given, it avoided one of the emerging limitations of the main study, namely the significant delay between the photography and the clinical opinion. In addition, as all patients could be studied, acting in effect as their own controls, this was more statistically efficient in terms of its use of participating patients.

All patients who were either referred to the 2-week wait or 'target' clinics, or patients initially referred to the normal outpatient service but diverted by the consultant who read the letter to grade the urgency of the case, received a written invitation to participate, comprising a letter, consent form and patient information document. Specifically, they were invited to telephone the Medical Photography Department to make an appointment on the day of, and immediately preceding, their outpatient appointment, to discuss the study further with a photographer. If the patient agreed to participate, formal consent was obtained and photographs were taken, using both normal photographic methods and a dermoscope, which has been used previously in the telediagnosis of malignant melanoma.[55] This allowed us to study any additional discriminating power that the availability of dermoscopic images might add.

Outcome measures

In essence, we were trying to investigate the potential of photography to 'screen' referrals, identifying a subgroup of patients who could be advised and reassured about the benign nature of their lesion, without needing to be seen FTF by a dermatologist.

Information regarding the clinical management of the patients was extracted from the clinical records by the principal investigator. This included the diagnosis in clinic (if given), whether histology was obtained, management and whether the lesion was treated as malignant. Although, in the majority of cases of cancer, histology was undertaken, in a small number of cases, mainly of basal cell carcinoma, the consultant was so confident that the lesion was malignant and could be treated relatively simply (e.g. by cryotherapy) that no histology was obtained. A lesion was considered to be 'operationally' malignant if:

- malignancy was confirmed histologically or
- a definite clinical diagnosis of malignancy was made without histology.

TABLE 16 *Sensitivity and specificity defined*

Screening result	Gold standard malignant	Gold standard benign
Photographic screen positive	*A*: Either thought to be malignant, or recommended to be seen FTF, and were operationally malignant (i.e. clinically or histologically malignant)	*B*: Either thought to be malignant, or recommended to be seen FTF, and were operationally benign (i.e. clinically or histologically benign)
Photographic screen negative	*C*: Thought to be benign, and recommended not to be seen FTF, and were operationally malignant (i.e. clinically or histologically malignant)	*D*: Either thought to be benign, and recommended not to be seen FTF, and were operationally benign (i.e. clinically or histologically benign)

Sensitivity = $A/(A + C)$.
Specificity = $D/(B + D)$.
Positive predictive value = $A/(A + B)$.
Negative predictive value = $D/(C + D)$.

We included within this definition lesions where the pathologist assessed them as highly or extremely dysplastic.

The independent dermatologist who assessed the photographs was supplied with a copy of the initial referral forms or letter. They then gave their most likely diagnosis, their level of confidence in this diagnosis (on an analogue scale of 1, certain, to 5, highly uncertain), a clear opinion on whether they thought the lesion to be malignant and a recommendation on whether they would wish to see the patient. This enabled us to assess the equivalence of the management of patients, had they been managed according to the opinion and recommendation of the consultant examining the photographs. The level of certainty would be used to construct receiving operator characteristic curves.[10]

We can now define operationally the concepts of screen 'positive' and 'negative' (see below). In addition, we can also define the 'gold standard'. We can also define the sensitivity, specificity and positive and negative predictive values of the 'test' (*Table 16*).

The screening could be considered to have two stages: the first comprising clinical referral information and digital photographs and the second adding dermoscopic images.

The unit of analysis was the lesion, not the patient (as a number of patients were referred for more than one lesion, which were treated as independent for the purposes of the analysis).

Sample size

If we assume a prevalence of skin cancer of 100/500, that is, 20% per year, and a sensitivity of 67%, then with 500 patients screened the sample size is as in *Table 17*. With 500 patients screened with digital photography (and a disease prevalence of 20%), we should be able to estimate sensitivity within 10%, for example, 67% (95% CI: 57 to 77%).

TABLE 17 *Sample size for screening test (500 patients)*

	True disease status		
Test result	**Yes**	**No**	
Positive	67	*B*	*A* + *B*
Negative	33	*D*	*C* + *D*
	100	400	500

TABLE 18 *Sample size for screening test (250 patients)*

	True disease status		
Test result	**Yes**	**No**	
Positive	33	*B*	*A* + *B*
Negative	17	*D*	*C* + *D*
	50	200	250

Specificity can be estimated with greater precision because if we screen 500 (with a disease prevalence of 20%) then 400 will not have cancer. With a sample size of 500 we can estimate specificity to within 5% for a range of specificity estimates from 50 to 90%; for example, for a specificity estimate of 50% with 400 patients not having cancer the 95% CI is from 45 to 55%. We examined the consequences of reducing the numbers screened (and recruited) to 250 patients, still assuming a prevalence of 20% (*Table 18*). With 250 patients screened with digital photography, we should be

TABLE 19 *Age and gender distribution of eligible cases*

Age band (years)	Male		Female		Total	
	No.	%	No.	%	No.	%
≤24	1	0.8	14	10.3	15	5.9
25–34	9	7.5	15	11.0	24	9.4
35–44	7	5.8	22	16.2	29	11.3
45–54	14	11.7	18	13.2	32	12.5
55–64	35	29.2	28	20.6	63	24.6
65–74	25	20.8	21	15.4	46	18.0
75–84	25	20.8	15	11.0	40	15.6
≥85	4	3.3	3	2.2	7	2.7

TABLE 20 *Definitive diagnosis compared with referrer's referral diagnosis*[a]

Definitive diagnosis in clinic		Referrer's diagnosis			Total
		Malignant melanoma	Squamous cell carcinoma	Other	
Seborrhoeic wart/keratosis		50	13	7	70
Benign naevus	Benign	61	1	2	64
	Severely dysplastic	**3**	**0**	**0**	**3**
Basal cell carcinoma		**5**	**23**	**1**	**29**
Malignant melanoma	**Malignant melanoma**	**18**	**1**	**0**	**19**
	***In situ*, lentigo maligna, superficial spreading**	**5**	**0**	**0**	**5**
Squamous cell carcinoma	**Squamous cell carcinoma**	**2**	**14**	**0**	**16**
	Bowen's/*in situ*	**0**	**7**	**2**	**9**
Solar keratosis	Benign	2	8	2	12
	Severely dysplastic	**0**	**3**	**0**	**3**
Other	Benign	16	7	2	25
	Malignant	**0**	**0**	**1**	**1**
Total		**162**	**77**	**17**	**256**

[a] Cases of malignant or severely dysplastic disease are in bold type.

able to estimate sensitivity within 13%, for example, 67% (95% CI: 54 to 80%). We decided pragmatically that this reduction in power was acceptable.

Results

A total of 256 valid cases were recruited. Of these, 120 (46.9%) were male and 136 (53.1%) female. In addition, 11 cases were excluded following data collection. Most frequently (seven cases) this was because the wrong lesion had been photographed in an otherwise eligible patient who had multiple lesions. Such patients were not always clear which lesion had caused the referring clinician concern. In three cases the patient already had a definitive histological diagnosis following biopsy by the referrer. In three cases the image file had been lost.

The age and gender distribution of eligible cases is shown in *Table 19*.

Table 20 shows the broad categories of definitive diagnosis (clinical, with benefit of histology if undertaken) by the dermatologist against the referrer's diagnosis. Understandably, given the criteria and methods (a form is used, which asks the referrer to define the type of malignancy suspected) for referral, the majority were suspected of having a malignant melanoma or a squamous cell carcinoma. In total, 162 (63.3%) cases were referred as potential malignant

TABLE 21 *Number of patients seen by each consultant in clinic*

Consultant	No.	%
1	28	10.9
2	41	16.0
3	50	19.5
4	58	22.7
5	31	12.1
6	27	10.5
7	21	8.2
Total	**256**	**100**

TABLE 22 *Numbers of cases seen by each photographer*

Photographer	No.	%
1	93	36.3
2	74	28.9
3	44	17.2
4	22	8.6
5	12	4.7
6	11	4.3

melanomas, 77 (30.1%) were referred as potential squamous cell carcinomas, 15 (5.9%) had no certain diagnosis and two (0.8%) were referred for other clear reasons.

Table 21 shows the numbers of cases seen in clinic by each of the seven consultants who provided the service during the recruitment period.

Histology was undertaken in 164 cases (64.1%; 95% CI: 58 to 70%). As expected, most of those with a clear, clinical diagnosis of malignancy underwent biopsy or excision with histological examination of the lesion. Seven cases (2.7%; 95% CI: 1 to 6%) treated as malignant disease, mainly with diagnoses of basal cell carcinoma or Bowen's disease, underwent treatment without histological confirmation.

TABLE 23 *Reasons why dermoscopy was not undertaken*

Reason	Number	% of all cases
Anatomical site	1	0.4
Lesion too large	3	1.2
Technical reasons	3	1.2
Image files lost	1	0.4
Not obtained, but no reason given	12	4.7
Total	**20**	**7.8**

Table 22 shows the numbers of cases that each photographer attempted to photograph, including technical and other failures.

In 20 cases (7.8%; 95% CI: 5 to 12%), dermoscopic images were not available for review. *Table 23* indicates the reasons.

Three consultants gave an opinion on the photographs, and *Table 24* shows the numbers reviewed by each and the proportion they would have wanted to see FTF. There are clinically, operationally and statistically significant differences between the three consultants in the proportion they would have wished to see FTF.

Consultant identifiers are as in *Table 21*. Consultants did not review patients they had seen FTF in clinic.

There was little evidence of systematic variability in the level of certainty in respect of each primary diagnosis.

Table 25 shows the relationship between the operational diagnosis from the clinical encounter and the combined photographic and dermoscopic diagnoses.

Table 26 shows whether the lesion was treated operationally as malignant compared with the assessment based on photographs and dermoscope.

TABLE 24 *Number of photographic cases reviewed by each consultant and the proportion requiring review FTF*

Consultant	Numbers reviewed by each consultant				Total	
	Requiring FTF review		Not requiring FTF			
	No.	%	No.	%	No.	%
1	83	75.5	27	24.5	110	43.0
2	29	51.8	27	48.2	56	21.9
4	75	83.3	15	16.7	90	23.4
Total	**186**	**70.3**	**70**	**29.7**	**256**	**100**

TABLE 25 *Comparison of operational FTF diagnosis and dermoscopic diagnosis*

Dermoscopic diagnosis	Operational diagnosis							
	MM	SCC	BCC	BN	SW/K	Solar	Other	Total
MM	17	0	0	9	1	0	1	28
SCC	0	15	6	0	6	2	2	31
BCC	0	4	19	4	1	2	2	32
BN	5	0	0	49	6	1	0	61
SW/K	2	3	0	3	50	1	4	63
Solar	0	2	2	0	5	9	0	18
Other	0	1	2	2	1	0	17	23
Total	**24**	**25**	**29**	**67**	**70**	**15**	**26**	**256**

BCC, basal cell carcinoma, BN, benign naevus; MM, malignant melanoma; SCC, squamous cell carcinoma; Solar, solar keratosis; SW/K, seborrhoeic wart/keratosis.

TABLE 26 *Comparison of operational assessment of malignancy and dermoscopic assessment*

Dermoscopic assessment of malignancy	Operational assessment of malignancy		
	Malignant	Not malignant	Total
Malignant	63	24	87
Not malignant	17	130	147
Uncertain	5	17	22
Total	**85**	**171**	**256**

TABLE 27 *Comparison of operational diagnosis in clinic and decision to see FTF based on all clinical, photographic and dermoscopic information*

Decision based upon images	Operational diagnosis		
	Malignant	Non-malignant	Total
See FTF	83	97	180
Not see FTF	2	74	76
Total	**85**	**171**	**256**

Table 27 shows the relationship between the decision to see the patient FTF, based on all the information available, and the operational diagnosis of malignancy. This demonstrates a key finding that, had this been an operational service, two malignancies (both squamous cell carcinomas) would not have been called for an FTF consultation.

Tables 28 and *29* show the key outcome measures, relating whether or not the lesion was operationally malignant and the result of the screening.

TABLE 28 *Performance of photographic screening*

Photographic screening result	True disease status		
	Yes	No	
Positive	83	104	187
Negative	2	67	69
	85	171	

Sensitivity = 98% (95% CI: 92 to 99%).
Specificity = 39% (95% CI: 32 to 47%).
Positive predictive value = 44% (95% CI: 37 to 52%).
Negative predictive value = 97% (95% CI: 90 to 99%).

TABLE 29 *Performance of dermoscopic screening*

Dermoscopic screening result	True disease status		
	Yes	No	
Positive	83	97	180
Negative	2	74	76
	85	171	

Sensitivity = 98% (95% CI: 92 to 99%).
Specificity = 43% (95% CI: 36 to 51%).
Positive predictive value = 46% (95% CI: 39 to 53%).
Negative predictive value = 97% (95% CI: 91 to 99%).

To investigate the potential use of the level of certainty expressed by the consultant examining the photographic and dermoscopic evidence, we related the possible operation of screening using various levels of certainty as a cut-off. For example, if we take the highest level of certainty expressed (1 on the Likert scale), we find the consultants would have been content not to see 51 patients FTF (20%; 95% CI: 15 to 25%), and would have identified all the malignant lesions [i.e. a sensitivity of 100% (95% CI: 96 to 100%), with a specificity of 30% (95% CI: 23 to 37%)]. If, however, we use the next level of certainty, two malignant lesions would have been missed, and the sensitivity falls to 98% (95% CI: 92 to 99%), with a specificity of 36% (95% CI: 29 to 44%). As only two lesions would have been missed (the same cases for both photographic and dermoscopic images), the use of lower levels of certainty only results in a modest increase in specificity.

Discussion

Perceptions remain that the policy of ensuring that any patient with suspected skin cancer should be seen within 2 weeks by a specialist is misguided, with only 27% of consultant dermatologists believing that the system works well.[56]

Overall 85 (33.2%; 95% CI: 28 to 39%) of the lesions were frankly malignant or severely dysplastic. However, only 55 (21.5%; 95% CI: 17 to 27%) of these were malignant melanomas or squamous cell carcinomas (or severely dysplastic precursors to these tumours). This is still a relatively high figure, compared with a previous published analysis, which found 12% of patients seen in similar clinics to be suffering from malignant melanomas or squamous cell carcinomas. Another possible explanation is that there could have been some recruitment bias in favour of patients at higher risk of having a malignant lesion, perhaps because they were more concerned and more likely to volunteer for the study.

We identified similar trials in a literature search (*Table 30*). These are mainly restricted to pigmented lesions, and it is likely that diagnostic concordance would be higher with this more homogeneous group of lesion than those involved in this study.

A major concern for clinicians is that a number of malignancies will be missed if telemedicine is employed. This has been documented previously in a small case series,[61] and would have occurred had this not been a study but an implemented service. Taken together with the observation that this approach would only have resulted in 76 cases (30%) not requiring an FTF appointment, it is unlikely that this model would prove cost-effective for this particular group of patients. If, however, we had used a cut-off point related to the consultant's expressed level of confidence, we could have a system which would not have missed any malignant lesions, and would still have avoided outpatient appointments for one-fifth of the patients.

TABLE 30 *Summary of studies of digital photography on suspected skin cancer*

Lead author	Size	Diagnostic concordance	Other statistic
Bowns (this study)	256	68% concordance on whether or not the lesion was malignant, based on photography and dermoscopy	Sensitivity 98%; specificity 43%; 30% of cases would not need to be seen FTF
Shapiro, 2004[57]	49 pigmented lesions		Sensitivity 100%; specificity 100%; kappa 1.00
Jolliffe, 2001[58]	819 pigmented lesions		Sensitivity 81%; specificity 73%
Piccolo, 2000[59]	43 pigmented lesions	85%	
Piccolo, 1999[60]	66 pigmented lesions	91%	

Furthermore, if a slightly different model were employed, it might be more cost-effective, and carry less clinical risk, although there is clearly a trade-off between the two. Further training for the staff taking clinical photographs (e.g. to remove crusting from the surface of lesions), or in the interpretation of dermoscopic images,[62] might help improve the reliability of such methods for diagnosing skin cancer, but it is unlikely that their use will dramatically reduce the need for conventional clinical consultations.

Research priorities

It should not be a high priority for research funding bodies to undertake similar studies of this approach to TD. The RCT is particularly difficult to conduct in this area, particularly if the results are to retain any wider validity. Further study should be undertaken with more pragmatic study designs (e.g. cluster randomisation or non-RCTs). Descriptive study of past TD projects would be valuable, and systematic comparative data should be collected on any future TD initiatives commissioned by the NHS, possibly as a national audit project. Additional research on the assessment of diagnostic and management agreement between clinicians would be valuable in this and other fields of research.

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Contribution of authors

Ian Bowns (Honorary Senior Research Fellow, ScHARR) led the study, conceived the basic proposal and design, collected data, undertook basic descriptive analyses, drafted most of the report on behalf of the group and acts as guarantor of the study. Karen Collins (Research Fellow) designed the qualitative component of the study, undertook all interviews, analysed the data and drafted the sections on patient and clinician satisfaction. Stephen Walters (Statistician) contributed to the study design, undertook most of the tests of statistical significance and contributed to the report. Andrew McDonagh (Consultant Dermatologist) contributed to the study design, was one of the participating consultants and contributed to the report. All authors approved the final report.

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We look forward to hearing from you.

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