


Impact of a store-and-forward teledermatology intervention versus usual care on delay before beginning treatment: A pragmatic cluster-randomized trial in ambulatory care

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Abstract

Introduction: In France, 66% of patients forego getting specialized care by dermatologists because of difficulty obtaining appointments. Store-and-forward teledermatology could improve how promptly treatment begins by reducing the delay in obtaining a specialist's opinion. In this study, we compared the delay before care between general practitioners (GPs) using a store-and-forward teledermatology intervention and GPs addressing their patients with a standard referral letter.

Methods: We performed an open-label, pragmatic cluster-randomized controlled trial with two parallel arms. GP clinics in Paris (France) were randomly assigned to use either teledermatology referral (use of electronics to send clinical images taken using a mobile phone) or conventional referral (using standard letters) to care for patients for whom a dermatologist's advice was needed for the diagnosis or treatment of skin lesions. Dermatologists integrated responses to teledermatology requests in their usual schedule. Patients were followed up for three months. Primary outcome was the delay, in days, between the GP's consultation and a reply by the specialist allowing treatment to begin. Analyses were adjusted for clustering of GPs and identities of dermatologists.

Results: Between February and June 2014, 103 patients were included in the study (53 patients of 20 GPs in the intervention group). The median delay between the initial GP's consultation and the reply allowing for treatment to begin was four days in the intervention group and 40 days in the control group (adjusted hazard ratio = 2.55; $p < 0.011$).

Discussion: We showed that a simple store-and-forward teledermatology intervention significantly reduced the delay before beginning care (ClinicalTrials.gov identifier: NCT02122432).

Keywords

Teledermatology, teleconsulting

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Introduction

Skin diseases represent about 2.5% to 5.5% of primary care consultations in France,¹ and general practitioners (GPs) require a dermatologist's opinion in approximately 25% of these consultations.² Traditionally, when such an opinion is needed, the GP sends the patient for a formal face-to-face consultation with the specialist. However, approximately 66% of patients do not obtain the dermatologist's opinion for various reasons, including the lack of specialists' availability and the distance needed to travel to see the specialist. There is an average delay of 41 days to get a dermatological consultation.³

Asynchronous store-and-forward teledermatology enables a GP to get a dermatologists' opinion by sending

them photographs of their patient's skin along with a clinical description, using a simple camera and a secured messaging device. The diagnosis and management of skin problems using asynchronous store-and-forward

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teledermatology with mobile phones showed good concordance with face-to-face consultations for diagnosis and following clinical course.⁴⁻⁹

In France, teledermatology is not yet regulated. Some experiments have been conducted, but involved complex protocols with expensive technologies.^{7,10} Nevertheless, many GPs are already using unsecured systems to get dermatologists' opinions for their patients. Thus, there is a need to develop and evaluate a simple, secure, and convenient intervention for teledermatology in ambulatory care in France.

The objective of this study was to assess the impact of a simple teledermatology intervention on the delay of obtaining a dermatologist's opinion in order to begin treatment. We compared GPs using a store-and-forward teledermatology protocol to those using a standard referral letter for a dermatologist.

Methods

Trial design

This study was a cluster-randomized controlled trial with two parallel arms evaluating the impact of teledermatology on treatment delay. Clusters were groups of GPs in Paris, France, working in the same medical facility with a median group size of five clinicians (range 4-6). The randomization list was computer generated by an investigator (VT-T) who did not have contact with either physicians or patients. Patients, physicians, and evaluators were not blinded from the intervention.

Participants

Patients were eligible to participate if they: 1) were over 18 years old and; and 2) had a skin condition for which the GP needed a dermatologist's opinion for diagnosis or treatment.

Patients were excluded if: 1) the physician considered that the patient required urgent medical care (e.g. immediate referral to the dermatologist or advice via telephone); 2) patients were not able to attend the dermatologists' consultation (e.g. unable to travel by ambulance, residents in nursing home, etc.); 3) patients presented a diagnosed skin condition for which they only needed a technical procedure (e.g. plantar wart which need to be burned, suspected skin cancer referred for biopsy consideration, etc.) or follow-up; and 4) GPs could not obtain informed consent.

All patients gave informed consent before participating in the study. Our study was approved by the Institutional Review Board of Hospital Cochin (IRB 00001072).

Study procedures

Teledermatology group. The store-and-forward teledermatology intervention was inspired by the intervention described by Whited et al.¹¹ For the intervention group, GPs took pictures of the patient's skin lesion and then sent them by

secured email along with a written message to dermatologists. GPs had to take at least three pictures of a skin lesion with a camera with a resolution of at least 3 Megapixels (mobile phone or digital camera). All photographs were taken according to the American Telemedicine Association's recommendations.¹² GPs received two hours of training by an investigator (EP) who taught the GPs how to take photographs, and provided GPs with a workbook summarizing the detailed procedure for taking adequate photographs.

GPs sent photographs to the dermatologist using MS-Santé, a free secured email inbox, created by ASIP Santé, a French national organization that develops tools for health professionals' communications. All physicians in France have an MS-Santé account.

Pictures were sent along with a standardized email message containing the patient's contact information, medical history and ongoing treatments, the reason for consultation, symptoms (including starting date and evolution), and descriptions of the skin lesions. Investigators designed this standardized email with the help of dermatologists and GPs.

Three dermatologists responded to the teledermatology requests. They worked in a private practice, a community health centre, and a hospital's dermatology department, respectively.

Whenever they received a teledermatology request, they replied with a diagnosis, possible differential diagnoses, and/or a management plan. In the latter case, the referring GP was responsible for implementing the recommendations and relaying this information to the patient. If necessary, the dermatologists scheduled the patient for a clinical visit. Dermatologists were instructed to answer the requests whenever they wished, in order to integrate the intervention in their usual practice.

Control group. Patients in the control group were given a standardized referral letter on paper from the GP and were instructed to get an appointment with the dermatologist of their choice. This corresponds to the usual procedure to obtain a specialist's opinion in France. The standardized referral letter contained similar information to the one in the intervention group.

Outcomes

The primary outcome was the delay, in days, between the initial GP's consultation and the dermatologist's reply allowing the patient or the GP to begin treatment, whether it was medication, preventive, or watchful waiting. An algorithm was built before the study began to determine this date. For example, if the dermatologist responded to a teledermatology request by stating that they could not ascertain the diagnosis and/or treatment from photographs alone and needed to see the patient face-to-face, we considered the delay between the initial consultation and the date of the face-to-face consultation (see Appendix 1). Whenever patients visited the dermatologist, we always

considered the date of the consultation as the date the patient could begin care. If the patient did not get a consultation from the dermatologist, the delay was arbitrarily set at 90 days (the mean delay to get a dermatology consultation in the area of the study was six weeks). An investigator (EP) phoned the patient 90 days after inclusion to assess dates of consultations with the dermatologist.

Secondary outcomes were: 1) the number of dermatology consultations that were prevented (i.e. every teledermatology request for which the dermatologist did not need to see the patient in consultation); 2) the proportion of satisfied patients assessed via two questions using a Likert scale with 4 items (1: very satisfied to 4: very unsatisfied), about global and time-to-treatment satisfaction; 3) the proportion of satisfied GPs assessed via two questions using a Likert scale with 4 items (1: very satisfied to 4: very unsatisfied), also about global and time-to-treatment satisfaction; and 4) the number of unusable photographs, defined as photographs the dermatologist considered insufficiently clear to perform an assessment.

Sample size and statistical analysis

Sample size. As accurate sample size calculation involved the specification of exact values for inputs not accurately measurable, we used the maximum sample size that was reasonably feasible¹³ and calculated a power curve, using the formula by Xie and Waksman, to estimate the power of the analysis as a function of the estimated hazard ratio (HR), taking into account: 1) the total number of events in each arm; 2) the ratio of randomization allocation; and 3) the intra-cluster correlation among incidences of events¹⁴ (see Appendix 2).

Analysis

Analysis was performed in intention-to-treat. For the primary analysis, we used the Kaplan–Meier method to estimate the delay before getting a specialist’s opinion in order to begin treatment. We evaluated between-group comparisons using a Cox mixed-effects model, taking into account clustering of GPs and identities of dermatologists who took care of patients as random effects. Missing data were managed using multiple imputation procedures. Predictors in the models included sex, age, and identities of both GP and dermatologist. The final inference was combined from 50 sets of imputed data.

For secondary outcomes, we compared patients’ satisfaction between groups using logistic models adjusted for clustering of GPs and identities of dermatologists. We used Fishers’ exact tests to compare physicians’ satisfaction between groups. Missing data regarding patients and/or physicians’ satisfactions were replaced so that the analysis did not favour the intervention. Patients and physicians with missing information in the intervention group were considered as “very unsatisfied”, whereas in the control group they were considered as “very satisfied”. P -values < 0.05 were considered significant.

We performed all analyses using R version 3.1.2. This trial is registered on ClinicalTrials.gov, identifier NCT02122432.

Results

Characteristics of participants

A total of 39 GPs (20 GPs in the teledermatology group and 19 in the control group) were included in the study, and 26 included at least one patient (13 GPs in the teledermatology group and 13 in the control group).

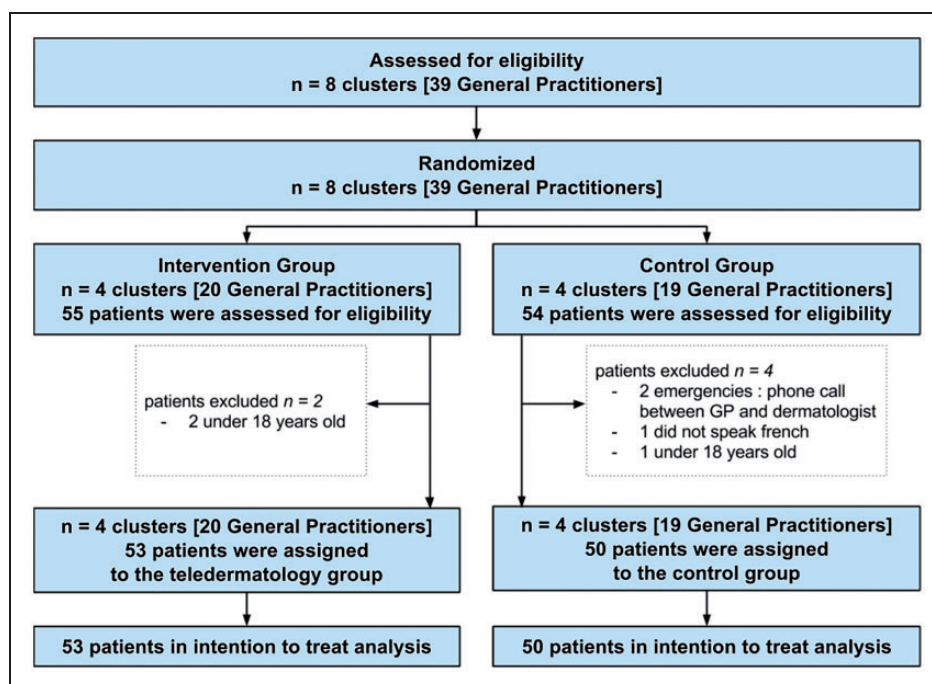


Figure 1. Flow diagram.

In total, 109 patients were assessed for eligibility from February to July 2014. Six patients were excluded: two patients were considered emergencies and needed

Table 1. Patient characteristics ($n = 103$).

	Teledermatology arm $n = 53$	Control arm $n = 50$
Age – mean [min; max]	44 [19–81]	43.5 [19–78]
Male sex – N (%)	16 (30.2%)	25 (50%)
Amount of time it took GPs to process referral before sending (minutes) – mean [min; max]	25.1 [10–60]	10.4 [3–20]
<i>Final diagnosis from the dermatologist – N (%)</i>		
Mycotic infection	3 (5.7%)	1 (2%)
Viral infection	1 (1.9%)	2 (4%)
Bacterial infection	3 (5.7%)	1 (2%)
Atopic dermatitis	11 (20.7%)	1 (2%)
Benign or malignant tumours	4 (7.5%)	2 (4%)
Rosacea/acne	1 (1.9%)	1 (2%)
Psoriasis	0 (0%)	1 (2%)
Inflammatory condition*	6 (11.3%)	0 (0%)
Other**	8 (15.1%)	3 (6%)
Missing information or unknown	16 (30.2%)	38 (76%)

*All erythema nodosum were included in this category.

**Other includes: pityriasisrosea, seborrheic keratosis, medication side effects, androgenetic alopecia, polymorphous light eruption, and post trauma lesions.

immediate attention from a dermatologist, one patient did not speak French, and three patients were under 18 years old. Therefore, 103 patients were randomized: 53 in the teledermatology group and 50 in the control group (Figure 1). Patients' mean age was 43.7 (range 19–81) years and 39 (37.8%) were males. (Table 1).

In the intervention group, dermatologists reached a conclusion and elaborated a treatment plan for 39 patients (73.5%) using transmitted photographs. Among these patients, they deemed unnecessary a follow-up specialist consultation for 25 patients (47%). For the 14 remaining patients (26.5%), they could not decide a clinical follow-up solely using the photographs and asked to see the patient in consultation.

Primary outcome

The median delay between the initial GP's consultation and the dermatologist's reply in order to begin care was four days in the intervention group and 40 days in the control group. For the primary outcome, we found an unadjusted HR of 3.77 and an HR of 2.55 adjusting for clustering of GPs and identities of dermatologists; $p = 0.011$ (Figure 2). The intra-cluster correlation among incidences of events was 0.08, thus yielding a power analysis of 93% and 76% for a HR = 3.77 and HR = 2.56, respectively (Appendix 2). For patients in the intervention arm for whom dermatologists could not have reached a diagnosis and/or treatment plan using solely the pictures sent, median time before consultation was 27 days. These results suggest that dermatologists used the available information to triage patients.

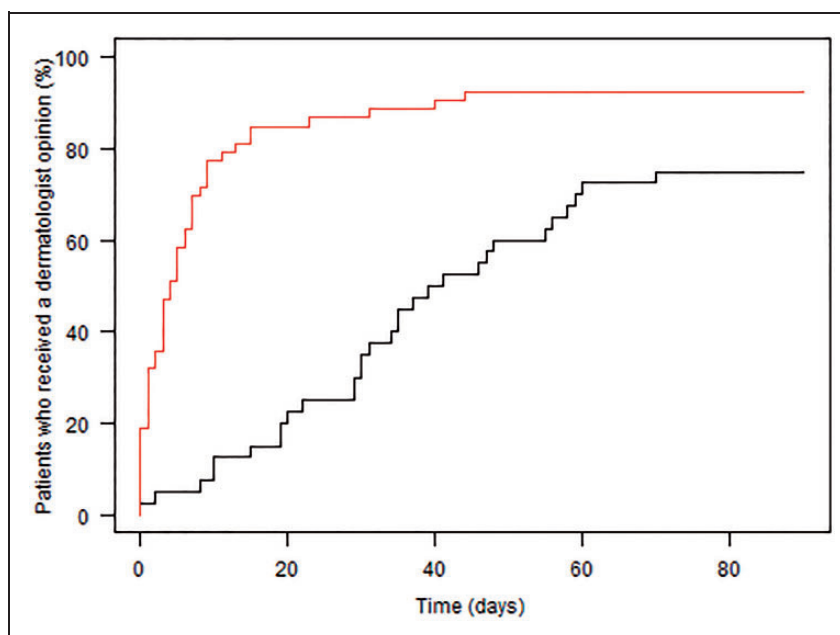


Figure 2. Kaplan–Meier Estimates of patients who obtained a dermatologist opinion allowing beginning care (red line corresponds to the intervention group; black line corresponds to the control group).

After 15 days, 45 (85%) and five (10%) patients obtained a dermatologist's opinion allowing GPs to begin care in the intervention group and the control group, respectively. A total of four (7.5%) and 10 (20%) patients did not obtain a dermatologist's opinion allowing GPs to begin care after 90 days in the intervention group and the control group, respectively (Table 2).

Secondary outcomes

Number of prevented dermatology consultations. In the intervention group, 25 requests (47.2%) did not require a face-to-face consultation between the patient and the dermatologist. Diagnosis was possible without seeing the patient "live" for 24 (45.3%) teledermatology requests. One request did not need a consultation despite the absence of a precise diagnosis.

Patient's satisfaction. For global satisfaction, 45 patients (84.9%) in the intervention group were satisfied or very satisfied versus 47 patients (94%) in the control group ($p=0.99$). For satisfaction about the time to treatment, 38 patients (71.7%) considered that the time to treatment was short or very short in the intervention group, versus 23 patients (46%) in the control group ($p=0.20$) (Table 3).

Table 2. Number of patients who obtained a reply from the dermatologist allowing the GP to begin care ($n=103$) after 15, 30, 60, and 90 days.

	Intervention arm $n=53$	Control arm $n=50$
At 15 days – N (%) [*]	45 (84.9)	5 (10)
At 30 days – N (%) [*]	46 (86.8)	13 (26)
At 60 days – N (%) [*]	49 (92.5)	29 (58)
At 90 days – N (%) [*]	49 (92.5)	30 (60)
Censored – N (%) [*]	4 (7.5)	10 (20)
Missing data – N (%) [*]	0	10 (20)

^{*}Proportion of patients in the given arm.

Table 3. Patients' satisfaction between the two arms ($n=103$).

	Teledermatology arm ($n=53$)	Control arm ($n=50$)	p -value
Patients' global satisfaction			
Very satisfied or satisfied	45 (84.9%)	47 (94%)	0.99
Unsatisfied or very unsatisfied	8 (15.1%)	3 (6%)	
Patients' satisfaction about the delay before care			
Very satisfied or satisfied	38 (71.7%)	13 (26%)	0.20
Unsatisfied or very unsatisfied	15 (28.3%)	37 (74%)	

GPs' satisfaction. For global satisfaction, nine GPs (69.2%) in the intervention group were satisfied or very satisfied versus nine GPs (69.2%) in the control group ($p=1$). For the time-to-treatment satisfaction, 10 GPs (76.9%) in the intervention group considered that the time to treatment was short or very short, versus seven GPs (53.9%) in the control group ($p=0.41$) (hndix 3).

Number of unusable photographs. The quality of photographs was insufficient for dermatologists to diagnose or treat for 11 (20.75%) patients. Among these patients, solely based on the standardized electronic message, dermatologists were able to decide that six (54.5%) patients required and two (18.2%) did not require a face-to-face consultation with the dermatologist.

Discussion

Summary

This pragmatic study showed that a simple store-and-forward teledermatology intervention could significantly reduce the delay to get a dermatologist's opinion allowing GPs to begin care in ambulatory settings in France. We showed an increase in the number of patients that received a diagnosis and management plan during the study period and a decrease in the median delay before obtaining a dermatologist's opinion. This is important, as these factors (simply receiving a diagnosis or treatment plan and the delay in receiving this information) have been shown to influence patients' quality of life.¹⁵

Patients and GPs' satisfactions were not significantly different between the two groups. This was not surprising considering that most patients trust their GPs and do not consider the delay in obtaining a specialist's opinion as a major component of their satisfaction with their treatment.

Strengths and limitations

The main strength of this study was its pragmatic approach. Our research protocol aimed to mimic the process of real care for patients. In the intervention group, we showed that dermatologists did not need to see all patients who were believed to need a specialist opinion in face-to-face consultations. As a result, this process could save time for both specialists and patients. In addition, our store-and-forward teledermatology protocol used: 1) a free pre-existing secured email box (MS-Santé), for which every physician in France has access; and 2) the GPs' mobile phones or cameras to take the photographs. Thus, besides the time required for training the GPs, our intervention had very low set-up costs.¹⁶

This study is not without limitations. First, patients and GPs' satisfactions were collected using simple Likert scales, which were not validated, and we cannot ascertain the reliability of these measures. Second, we did not assess patient health outcomes because we aimed to have a

minimal data collection process to closely reflect the actual clinical practice of clinicians. Of note, a recent trial assessing the impact of a teledermatology intervention similar to ours did not show an improvement of quality of life for patients in primary care.¹¹ Third, because dermatologists were part of this study, delay before their responses might have been better than in routine practice. Fourth, this study had a small sample size. Although we achieved an acceptable power of analysis, estimates for the delay before receiving a dermatologist's opinion to begin care may be inaccurate. Nevertheless, this study could easily be integrated into systematic reviews and meta-analyses and contribute to the building of evidence.¹⁷

Comparison with existing literature

Several store-and-forward teledermatology protocols have been evaluated in previous trials,⁸ mainly in the US. These studies showed that teledermatology 1) was acceptable for patients and physicians; 2) was comparable with face-to-face consultations for diagnosis or treatment^{11,18}; and 3) could improve triage of patients by dermatologists. In our study, the proportion of consultations that could be avoided using the teledermatology intervention was slightly superior to previous results in the literature (with 18% to 38% of consultations avoided).^{6,19} These results could reflect the improvement of techniques and the quality of images. However, conclusions should be cautious as the settings and organization of care in these studies were different. In this study, we showed that a simple store-and-forward teledermatology intervention using GPs' own phones was feasible in France and that it could significantly reduce time before treatment for patients.

Implications for research and/or practice

Teledermatology has the power to offer GPs a new and accessible method to get specialists' opinions. However, several key points should be considered before generalizing these practices to larger populations. First, teledermatology depends on the quality of pictures taken by GPs. In our study, 20% of photographs were unusable in the intervention group, thus increasing the need for dermatologist consultations. However, most of the unusable photographs came from a single cluster. The exclusion of this cluster from analyses showed that 6.9% of the photographs were unusable. Teledermatology may improve quality of care, but in order to do so, it is important for GPs to take enough time to meet the technical guidelines.

In our study, although every GP had a two-hour training session and we used a simple protocol, GPs' understanding seemed to be the most important factor for successful implementation in daily practice. Finally, the teledermatology intervention required significantly more time for physicians to refer patients than standard letters. In a situation where GPs already have a limited time to do everything they should do (taking care of the acute problems, performing preventive care, managing chronic

conditions, etc.), it is necessary to rethink how interventions using new technologies can be implemented so that patients can benefit from them.

Conclusion

A simple, low-cost store-and-forward teledermatology intervention significantly reduced the delay in obtaining a dermatologist's opinion allowing GPs to begin care, as compared to usual care in France.

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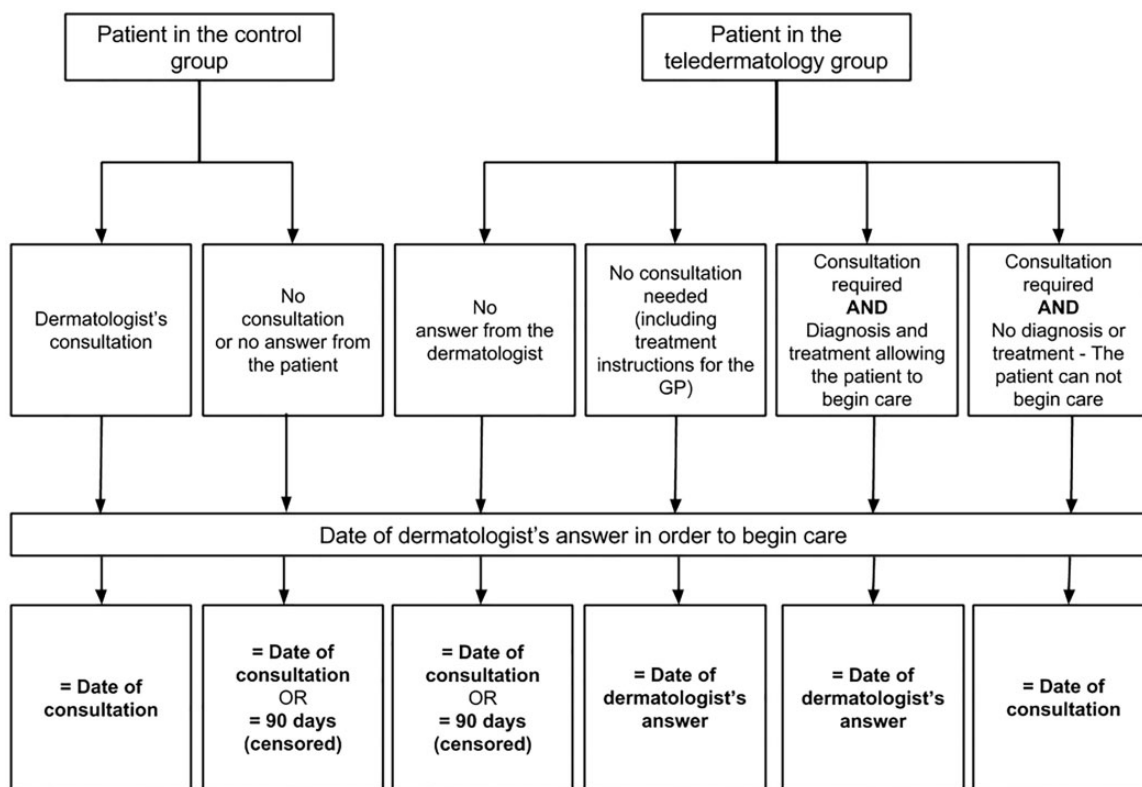
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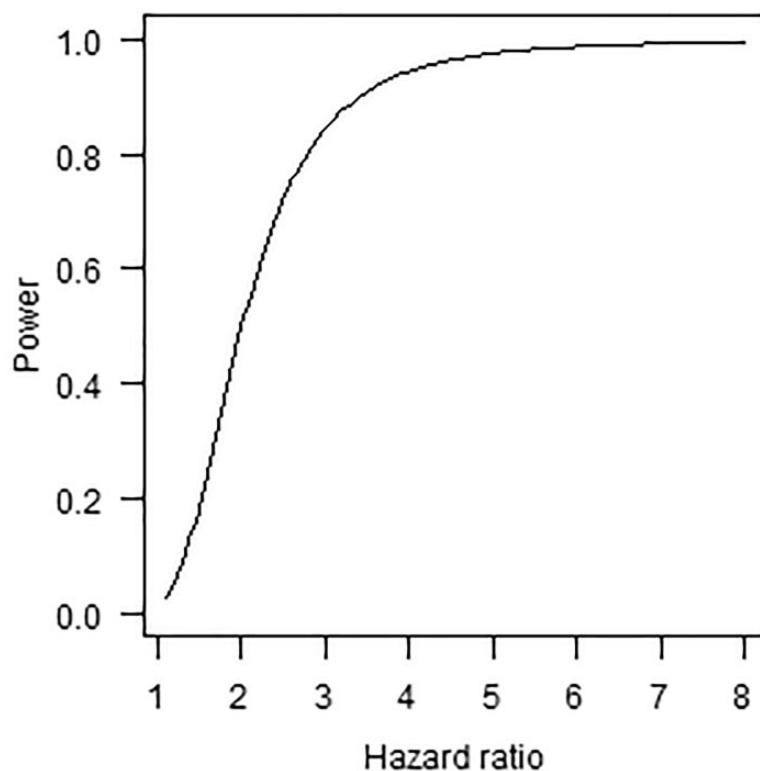
Appendix I

Algorithm for classification of dates used in analyses



Appendix 2

Power curve for estimation of power of analysis as a function of estimated hazard ratio, taking into account the: 1) total number of events in each arm; 2) ratio of randomization allocation; and 3) intra-cluster correlation among incidences of events



Appendix 3

General practitioners' satisfaction ($n = 26$)

	Teledermatology arm ($n = 13$)	Control arm ($n = 13$)	p -value
Physicians' global satisfaction			
Very satisfied or satisfied	9 (69.2%)	9 (69.2%)	1
Unsatisfied or very unsatisfied	4 (30.8%)	4 (30.8%)	
Physicians' satisfaction about the delay before care			
Very satisfied or satisfied	10 (76.9%)	7 (53.9%)	0.41
Unsatisfied or very unsatisfied	3 (23.1%)	6 (46.1%)	