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Telemedicine in France: A review of registered clinical trials from 2000 to 2015

Télémédecine en France : revue des essais cliniques enregistrés entre 2000 et 2015

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Summary
Introduction. — Telemedicine activity is increasing in France. The assessment of telemedicine research, however, including registered clinical trials, has yet to be published. Using an international open access database (ClinicalTrials.gov), a study was conducted to identify registered telemedicine clinical trials in France from 2000 to 2015.
Materials and methods. — The data extracted on 6th August 2015 led to the retrieval of a total of 41 studies, of which 39 were included.
Results. — The first registered telemedicine clinical trial was received in 2006 and the latest in 2015. The studies were primarily conducted by public hospitals (66.7%), followed by private companies (20.5%). The objectives of the studies were primarily treatment based with all having efficacy and/or safety endpoints. Sixteen trials were in the recruiting phase, 12 were completed and four were terminated before the date of completion. The main telemedicine activities in the studies involved telemonitoring ($n = 28$), teleconsultation ($n = 7$) and tele-expertise ($n = 3$). Ten medical specialties were represented in the trials with a key focus on cardiology, endocrinology and pulmonology.

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Discussion and conclusions. — Telemedicine clinical trials have increased in France most evidently since 2011. The use of an open clinical trials database enabled characteristics to be described. A telemedicine registry may be necessary to improve future research as well as to enhance evidence-informed health policies regarding telemedicine activities in France.

MOTS CLÉS
Télémédecine ;
Télésanté ;
Politique de télémédecine ;
Registre d'essais cliniques ;
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Résumé
Introduction. — Les activités de télémédecine augmentent en France. L'évaluation de la recherche en télémédecine, cependant, y compris les essais cliniques enregistrés, n'a pas encore été publiée. En utilisant une base de données internationale ouverte (ClinicalTrials.gov), une étude a été menée afin d'identifier les essais cliniques en télémédecine enregistrés en France entre 2000 et 2015.
Matériels et méthodes. — Les données extraites le 6 août 2015 ont permis d'identifier un total de 41 études, dont 39 ont été incluses.
Résultats. — Le premier essai clinique en télémédecine enregistré a été reçu en 2006 et le plus récent l'a été en 2015. Les études ont été menées principalement par des hôpitaux publics (66,7 %), et par des entreprises privées (20,5 %). L'objectif de ces études était principalement l'évaluation du traitement avec comme critère de jugement l'efficacité et/ou la sécurité des interventions de télémédecine. Seize essais étaient en phase de recrutement, 12 étaient achevés et quatre étaient terminés avant la date d'achèvement. Les principales activités de télémédecine dans les études étaient la télésurveillance ($n = 28$), la téléconsultation ($n = 7$) et la télé-expertise ($n = 3$). Dix spécialités médicales étaient représentées dans les essais avec une part importante en cardiologie, endocrinologie et pneumologie.
Discussion et conclusions. — Cette étude a permis de décrire les caractéristiques et les tendances des essais cliniques réalisés en France au cours des 15 dernières années en matière de télémédecine, montrant une augmentation depuis 2011. Un registre de télémédecine pourrait être ainsi nécessaire pour améliorer la recherche future en télémédecine, ainsi que pour améliorer les politiques de santé basées sur les données probantes concernant les activités de télémédecine en France.

Introduction

Telemedicine activity is increasing in France. A survey conducted by the French Ministry of Health estimated a total of 331 telemedicine projects and activities in 2013 [1]. With the revision of the health legislation in 2009 and the launch of the National Telemedicine Deployment Strategy in 2011, this number has increased by almost 30% compared to the previous year's total of 256 projects and activities [2—4].

Regarding research in telemedicine, however, information such as characteristics and trends have not been assessed nor published in France, to date. Access to evidence in research and an understanding of current research trends, particularly in developing fields such as telemedicine, is of importance to enhance the quality and pertinence of evidence-informed national health policies [5].

Characteristics of clinical trials may be accessed from several clinical trial registry databases available online. Since 2005, registration of clinical trials has been required by the International Committee of Medical Journal Editors (ICMJE) as a requisite for the publication of results generated by a clinical trial. The main international clinical trial registry, ClinicalTrials.gov, is run by the National Institute of Health in the United States of America [6]. One of the registry objectives is to allow and promote an efficient allocation of research funds through the access of current and past trials.

The aim of this study was to provide a review of registered clinical trials in telemedicine in France from 2000 to 2015. The review aimed to provide a description of the characteristics and trends of these trials for the improvement of evidence-informed health policies in the future.

Method

There are currently no registries existing in France concerning telemedicine to date. An open access database, ClinicalTrials.gov, run by the US National Institute of Health was explored as a proxy for data collection on registered telemedicine clinical trials conducted in France. A research query was performed on the 6th of August, 2015 and data

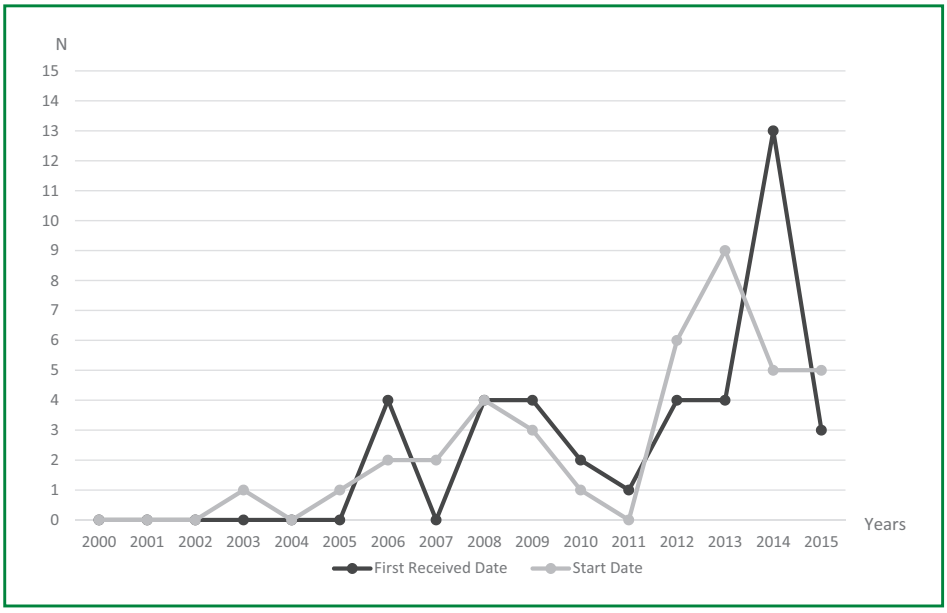

Figure 1. Registered telemedicine clinical trials in France: first received and starting dates per year, from 2000 to 2015.
Essais cliniques en télémédecine enregistrés en France : dates du premier enregistrement et du début de l'essai par année, 2000 à 2015.

was directly extracted and downloaded from the registry on that date.

The research query used was ''telemedicine OR teleconsultation OR telemonitoring OR teleexpertise OR telecardiology OR telesurgery''. All probable key words were tested to improve the number of trials retrieved, however it did not increase the number of results obtained. The variables of interest used were: promoter, medical specialty, disease, status of the study, type of study, endpoint, study design, primary purpose, age of patients included, first received date, start date and number of patients enrolled.

The 'first received date' was the date of the first trial registered. The 'start date' was the effective date of the trial beginning. If the registration occurred after the start date of a trial then the 'first received date' of a trial may have taken place after the 'start date' (the definition of variables are found online on the ClinicalTrials.gov website [7]).

The type of telemedicine activity was defined according to the regulatory definition of telemedicine activity in France as stated in the decree No. 2010-1229 [8]. Clinical trials that did not match these definitions were excluded from the study.

Results

The results from the research query found 41 studies. Two studies were excluded as they did not match the legal regulatory definition of telemedicine activities in France. The study, therefore, investigated a total of 39 registered clinical trials (Table 1). The first registered clinical trial was received in 2006 and the most recent was received in 2015. The first registered clinical trial started in 2003 and the most recent in 2015. The maximum number of trials registered in a year was in 2014 with a total of 13 trials (33%). The maximum number of trials started in a year was in 2013 with a total of 9 clinical trials (27.3%). The majority of trials in the past 15 years started between 2012 and 2015 with a total of 25 trials (64.1%) (Fig. 1).

The trials were primarily conducted by public hospitals ($n = 26$, 66.7%) followed by private companies ($n = 8$, 20.5%), and other institutions. The majority of public hospitals conducting registered telemedicine clinical trials were based in university hospitals ($n = 22$). The three main university hospitals were Assistance publique—Hôpitaux de Paris ($n = 6$), Grenoble University Hospital ($n = 6$) and Toulouse University Hospital ($n = 4$).

The main companies that privately funded telemedicine clinical trials in France as promoters of the trials were Biotronik SE & Co. KG ($n = 4$), ResMed ($n = 2$), Alere ($n = 1$), and Initiative pour la santé ($n = 1$). Other institutions involved included the French Centre for Studies and Research on the Intensification of Diabetes Treatment (*Centre d'études et de recherche pour l'intensification du traitement du diabète* [CERITD]) ($n = 2$), the French Federation of Pulmonology ($n = 2$) and Paris 7 Public University ($n = 1$). Novo Nordisk A/S and Sanofi were collaborators of CERITD in the TELEDIAB-2 trial and the TELESAGE trial respectively (Table 2).

The majority of trials were in the recruiting phase ($n = 16$ trials; 41%) and started between February 2013 and January 2015. Twelve trials (30.8%) were in the completed phase and four trials were terminated (10.3%). Among the terminated trials, one was terminated due to ethical reasons of inefficacy and one trial was terminated due to insufficient recruitment. Three trials were currently active and not recruiting, three trials were not yet recruiting and one clinical trial was suspended because a criterion to end the study prematurely was fulfilled.

There were 32 interventional trials and 7 observational studies. Among the interventional trials, there were 31 randomized clinical trials in open label and one single blind. All trial endpoints were efficacy or efficacy and/or safety. The purpose of the trials were treatment ($n = 14$), supportive

Table 1 Names of telemedicine registered clinical trials in France, 2000 to 2015.
Noms des essais cliniques enregistrés en France, 2000 à 2015.

ID	Acronym	Name
1	TRUST-tPA	Therapeutic trial evaluating efficacy of telemedicine (TELESTROKE) in the management of patient with acute stroke within 3-hour after their symptom onset who are admitted to a remote hospital with no stroke unit facility
2		Robot-based tele-echography II — a comparative study using two echographic modalities for diagnosis of thoraco-abdominal injuries at the Trauma Center of the Grenoble University Hospital
3		Web-based follow-up using cellular phone in type 1 diabetic patients under insulin pump therapy: the PumpNet Study
4	Home CARE	Home CARE — Home Monitoring in CArdiac REsynchronisation therapy
5	EVATEL	Evaluation of the ''tele-follow-up'' for the follow-up of implantable defibrillators
6	TELEDIAB	Multicenter assessment of the PDA-FIT system in type 1 diabetic patients with chronic failure of intensive insulin therapy and conventional care. The TELEDIAB-1 study
7	TELFIT	Reinforcement of the impact of a functional insulin therapy-training course by telemonitoring with a PDA-phone in type 1 diabetic patients. The TELFIT study
8	effecT	Clinical effecT of heart failure management via home monitoring with a focus on atrial fibrillation (effecT)
9	READ	Cardiac rehabilitation of heart failure patients by telemedicine: a randomized multicentre study
10	SEDIC	Impact of clinical follow-up and therapeutic education by telemedicine in chronic heart failure: a randomized multicentre study
11	TELEDIAB-2	Multicentric evaluation of two telematics systems in type 2 diabetic patients in failure of oral treatment and having to start treatment by basal insulin
12	ECOST	Effectiveness and cost of ICD follow-up schedule with telecardiology
13	SETAM	Investigation on early detection and active management of supraventricular arrhythmia with telecardiology
14	TELESAS	Usefulness of a telemedicine system for OSA patients follow-up with high cardiovascular risk
15	TELEDIAB-3	Prospective assessment of MEOS telemedicine E-portal on ambulatory care of type 1 diabetic patients
16	OPTISAS2	Blood pressure reduction induced by continuous positive airway pressure (CPAP) in sleep apnoea patients at high cardiovascular risk: a randomized controlled trial comparing usual CPAP Care versus a multidisciplinary and coordinated follow-up based on a telemonitoring web platform
17	CARESS_PREMI	Contribution of computerized real time analyses of cardiorespiratory signals to the diagnosis of infection in preterm infants
18	TELEGRAFT	Randomized open label study evaluating the coverage by teleconsultation versus standard follow-up of renal transplant patients according to a risk score of early graft failure (KTFS)
19	BIOMIC	Home-based assessment of plasma volume, serum potassium and renal function variations in patients with heart failure and low left ventricular ejection fraction: pilot study BIOMIC. Biomarkers and therapeutic modelisation in heart failure
20	OPTISAS1	Multidisciplinary and coordinated follow-up based on a telemonitoring web platform for improving continuous positive airway pressure (CPAP) compliance in low cardiovascular risk sleep apnea patients
21	AIRPEDIA	Medico-economical assessment of telemedicine during chronic diabetes-related foot wound management
22	Respir@dom	A telemedicine system for the follow-up of patients with SAS
23	EDUC@DOM	Effectiveness and cost-effectiveness analysis of a telemonitoring program on lifestyle for people with type 2 diabetes at home. Study based on a health network in diabetology
24	OSICAT	Optimization of the ambulatory monitoring for patients with heart failure by telecardiology
25	TELE-VAD	Installation of noninvasive ventilation at home using telemedicine: a pilot study on feasibility and impact on ventilation compliance
26	HELP	Heart failure educational and follow-up platform

Table 1 (*Continued*)

ID	Acronym	Name
27	TELEDERMATO	Teledermatology versus usual care on delay before diagnosis and treatment of dermatologic conditions
28		Clinical and medico-economic assessment of conventional care plus the ''Autonom@Dom'' telemonitoring system versus a conventional care package alone, for people with heart failure in several French structures
29	e-COBHALT	Elderly chronic diseases online biometric analysis home living technology
30	Dite-ROP	Effectiveness and cost-effectiveness of tele-expertise for the screening examination of premature infants for retinopathy of prematurity
31	TLM-EVLINE	Assessment of teleconsulting in nursing homes
32	TLM-TM91	Assessment of teleconsulting in nursing homes to avoid transportations to the emergency units
33	eCOPD001	Pilot study evaluating feasibility and benefits of telemonitored NIV treatment on COPD patients
34	TELESAGE	Evaluation of the DIABEO system in poorly controlled DM1 or DM2 patients treated with a basal-bolus insulin regimen
35	TLM-Inmates	Evaluation of tele-expertise for inmates with a dermatological lesion
36	RESPECT	Mobility assessment & follow-up in frail elderly: clinic-technical validation of a smart insole in real life
37	FACE	French cohort study of chronic heart failure patients with central sleep apnoea eligible for adaptive servo-ventilation (PaceWave, AutoSet CS, AirCurve 10 CS): predictive factors of poor compliance
38	Telemalrare	Rationalization of the treatment pathway of patient suffering from rare skin disease with telemedicine
39	DETECT	Dementia in long-term care facilities: telemedicine for the management of neuropsychiatric symptoms

Table 2 Investigators of registered telemedicine clinical trials in France, 2000 to 2015.
Investigateurs des essais cliniques en télémédecine enregistrés en France, 2000 à 2015.

Investigator	*n*	%
Public hospital	26	66.7
Assistance publique—Hôpitaux de Paris	6	
University Hospital, Grenoble	6	
University Hospital, Toulouse	4	
University Hospital, Rennes	2	
University Hospital, Caen	2	
University Hospital, Limoges	1	
University Hospital, Nantes	1	
Other	4	
Private company	8	20.5
Biotronik SE & Co. KG	4	
ResMed	2	
Alere e-Santé	1	
Initiative Pour la Santé	1	
Other institutions	5	12.8
Centre d'études et de recherche pour l'intensification du traitement du diabète	2	
Fédération française de pneumologie	2	
Université Paris 7 — Denis Diderot	1	
Total	39	100

care ($n = 7$), prevention ($n = 4$), diagnosis ($n = 2$) and research in health services ($n = 2$).

The study population of the trials were mostly adults ($n = 35$) in three age categories; over the age of 18 ($n = 28$), over the age of 60 ($n = 1$) and over the age of 65 ($n = 4$). Specific age targeted populations such as elderly persons were included in 2 trials as well as 2 trials including premature babies aged under 32 weeks. The average number of patients per study was 357 (range: 18; 1501).

Telemonitoring ($n = 28$), teleconsultation ($n = 7$) and tele-expertise ($n = 3$) were the three main telemedicine activities used in the studies. The principal medical specialty in the studies was cardiology, followed by endocrinology and pulmonology. Other medical specialities that were represented were geriatrics, dermatology, neurology, infectiology, nephrology, ophthalmology and radiology.

Regarding available data, the clinical trials comprised of 13 varying diseases with the majority targeted at chronic heart failure ($n = 8$) and diabetes ($n = 8$). Obstructive sleep apnoea ($n = 4$) and arrhythmia ($n = 4$) were also studied (Table 3).

Discussion

For the first time, characteristics and trends of registered clinical trials in telemedicine in France were described. Covering a 15-year period from 2000 to 2015, an evident trend was observed, showing an increase in telemedicine research in France. Most specifically, this increase was observed in the last few years since 2011.

Table 3 Diseases studied in registered telemedicine trials in France, 2000 to 2015.
Maladies étudiées lors des essais cliniques en télémédecine enregistrés en France, 2000 à 2015.

Disease	*n*	%
Chronic heart failure	8	24.3
Diabetes	8	24.3
Obstructive sleep apnoea	4	12.2
Arrhythmia	4	12.2
Chronic respiratory failure	1	3
Chronic obstructive pulmonary disease	1	3
Dementia	1	3
Healthcare associated infections	1	3
Rare diseases	1	3
Renal transplant	1	3
Retinopathy of prematurity	1	3
Stroke	1	3
Trauma	1	3
Total	33	100

The majority of registered clinical trials in France were publicly established highlighting the role and potential importance of publicly funded research in telemedicine. Although the majority of registered clinical trials were based in public university hospitals, the distribution of research were located in three cities: Paris, Grenoble and Toulouse. Research in telemedicine was therefore not equally distributed geographically in France. Lack of capacity or expertise to conduct telemedicine clinical trials in public university hospitals may have been a reason for the unequal distribution.

The extensive activity in telemedicine conducted in the Île-de-France region partly due to the ORTIF platform [9,10] may explain the number of studies conducted in Paris. The focus of the Grenoble University Hospital's diabetes unit on applied and innovative technologies for diabetes care [11,12] may explain the high level of telemedicine research activity in Grenoble. The pioneering telemedicine implementation in the Midi-Pyrénées region [13,14] may explain the importance of telemedicine research conducted in Toulouse. The 2013 Ministry of Health report regarding telemedicine activities in France showed that the Île-de-France and Midi-Pyrénées were regions with the highest telemedicine activities declared as shown in this study.

Private companies participated in telemedicine research in France. The necessity to provide efficacy, safety and medico-economic data for approved reimbursement of telemedicine devices and/or applications may be the motivation of private company participation. Biotronik SE & Co. KG, a medical device company, funded research to demonstrate the efficacy and safety of the remote follow-up of implantable cardioverter defibrillators [15]. Alere e-Santé funded research on optimization of ambulatory monitoring of patients with heart failure using telecardiology [16]. ResMed conducted research to evaluate the benefits of telemonitoring noninvasive ventilation long-term treatment efficacy for patients with chronic obstructive pulmonary disease (COPD).

The TELESAGE trial was implemented by CERITD with Sanofi as a collaborator. The objective of the trial was to generate data on the cost effectiveness as well as impact of the DIABEO system as an organizational care model for the reimbursement from health authorities [17]. The involvement of Sanofi in telemedicine may be explained by the recent evolution of the pharmaceutical industry's business model to provide complimentary services to their products [18].

Regarding the purpose of the clinical trials, studies were mostly aimed at validating the treatment efficacy of telemedicine interventions. Telemonitoring of non-communicable chronic diseases was the primary telemedicine intervention involved in the studies conducted. In 2015, the French Ministry of Health emphasized telemonitoring of non-communicable chronic diseases as the target for telemedicine deployment in France for 2016 and 2017. This focus was defined in two health policy documents: '*Pacte Territoire Santé 2*' (Territorial Health Agreement 2) (engagement 9) [19] and '*GT 33 CSIS-CSF : permettre l'émergence d'une stratégie industrielle en matière de e-santé, en soutien de la politique de santé publique, en associant les industriels. Lever les freins au déploiement de la télémédecine*' (GT 33 CSIS-CSF: enabling the emergence of an industrial strategy in terms of e-Health, by supporting public health policy, with an association with manufacturers. Removing barriers to the deployment of telemedicine) [20].

In the Ministry of Health report regarding telemedicine in 2013, it was shown that teleconsultation and tele-expertise were the contributing telemedicine activities in France (78%). Additionally, the report stated telemonitoring as contributing to 22% of telemedicine activity in France. In the registered clinical trials collected however, telemonitoring showed to be the most prevalent and teleconsultation and tele-expertise were the least contributing telemedicine activities. This may show that implemented activities are not linked with the research studies conducted or that the main activity in research is not yet implemented into activities.

Stroke and chronic kidney failure were the most prevalent diseases reported in France by the Ministry of Health, however, only one clinical trial was registered for each disease. This may be due to the public support for the implementation of regional telestroke and tele-dialysis programs without specific research funds associated. Concerning chronic wound management, 19 activities were reported by the Ministry of Health. However, no clinical trials were registered despite a national experiment being conducted on this topic since 2014 [21]. Eventually, chronic heart failure was one of the main topics reported by the Ministry of Health and was also the main research topic of registered trials (Table 4).

The international registry database was an applicable tool to collect information and analyse data as it supported several variables to be studied in relation to telemedicine clinical trials conducted in France. One limitation using ClinicalTrials.gov was the possible underestimation of any trials not registered to the database. The limitation of underestimation however, was not possible to assess as there was no registry in telemedicine in France. Other limitations using ClinicalTrials.gov included the quality of data that may have potentially been misled in the data analysis and the risk

Table 4 Diseases concerned by telemedicine activities reported by the Ministry of Health in 2013 in France. *Maladies concernées par des activités de télémédecine reportées par le ministère de la Santé en 2013 en France.*

Disease	*n*	%
Stroke	30	9
Chronic kidney failure	30	9
Chronic heart failure	24	7.3
Chronic wounds	19	5.7
Other	228	68.9
Total	331	100

that the research performed did not capture all registered trials [22—24]. The assessment of published results using bibliometric data for clinical trials in telemedicine could have been suitable [25], however, limitations from potential publication bias of non-published results may have arisen [26—28].

In this study, an open database allowed research on telemedicine to be conducted. Readily available data from open database registries may support public health research in developing fields such as telemedicine in the future. Improvement of metadata, however, may be necessary to increase the quality and value of research [29—31].

A telemedicine registry in France may be useful in supporting telemedicine implementation by providing a response to national health authorities on the application of policy legislation to early detection of new trends in telemedicine [32]. The initiation of a registry may require more work than the 2013 survey conducted by the Ministry of Health. However, the quality of results may be improved. Associating a research registry to an ongoing activities registry may further be of use for the evaluation of telemedicine implementation and effectiveness on enhancing quality improvement of activities and policies [33,34].

Conclusion

The development of an open access registry for telemedicine research and activity in France would be a beneficial tool to improve research on telemedicine outcomes and impact on the French health system as well as enhance evidence-informed telemedicine policies.

Disclosure of interest

The authors declare that they have no competing interest.

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