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Effectiveness and organizational conditions of effectiveness of telemedicine in nursing homes. A study protocol of a comparative prospective cohort (EFFORT study)

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Abstract

Introduction: The profile of nursing home (NH) residents has changed over the past decade with more dependency, more severe chronic diseases and more treatments prescribed. For residents, the major consequence is the higher risk of unplanned hospitalization. French guidelines recommend the development of interactive telemedicine (**InT**) in NHs in order to improve access to care, and to decrease the rate of avoidable unplanned hospitalizations.
Methods and analysis: The aim of this study is to analyze the impact of an **InT** protocol delivered in NHs on the rate of unplanned hospitalizations, and on the quality of life at work and the organizational conditions of effectiveness of telemedicine in NHs. We will perform a mixed methods study combining a cluster non-randomized controlled trial in two matched parallel arms (telemedicine group and control group) and qualitative analysis of the evolution of organizational and professional contexts in NHs.
Ethics and dissemination: The study protocol was approved and sponsored by the French Ministry of Health. The study received ethical approval from the Bordeaux University Hospital Institutional Review Board. We will communicate the final results to the public via conferences and results will also be submitted for publication in international peer-reviewed scientific journals.
Trial registration number NCT03486977

Keywords

Telemedicine, geriatrics, multimorbidity, qualitative research, quantitative

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Introduction

More than 700,000 people in France live in nursing homes (NHs).[1] The profile of NH residents has changed over the past decade with more dependency, more severe chronic diseases and more treatments prescribed.[2] For example, it is important to note the sharp increase in the prevalence of neurocognitive disorders (51.8%) and psycho-behavioral disorders (43.2%) in older adults currently living in French NHs.[2] For care professionals, the changing profile of nursing home residents means they must provide a higher

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level of care. This may negatively affect their quality of life at work, which is defined as the perception of their working conditions, their ability to express themselves and act, and the content of their work. Indeed, despite the growing needs of NH residents, the number of nursing staff has not increased, and we observe low social performance indicators: an average absenteeism rate 1.3 times higher than the average in the health sector and an accident frequency index twice the national average.[3]

For residents, the major consequence is a higher risk of hospitalization. Indeed, the annual rate of hospitalization has increased and concerns about 25% of NH residents in France. More generally, 40% of NH residents are hospitalized at least once a year including emergency department transfers.[2,4–6]

Generally, unplanned hospitalizations, defined as admission via the emergency department, are catastrophic for the oldest patients. We talk about real "*iatrogenic hospital*", which implies higher risks of complications secondary to treatments. In fact, the mortality rate is greater than 10% during such hospitalizations, with a higher risk of morbidities like functional decline, falls, and iatrogenic complications related to inappropriate use of drugs.[7–9]

It is of course essential to refer older adult patients to the hospital emergency room when their state of health requires it, but it is surprising to note that literature data shows that more than half of these hospitalizations are potentially avoidable. Indeed, it is reported that 31 to 67% of unplanned hospitalizations could have been avoided by correctly taking care of patients in NHs.[10–14] The French Health Authority (HAS) recently reported predictive criteria for avoidable hospitalizations, such as hospitalization in the previous 6 months, a recent admission to a NH, older age, absence of palliative care programs or advance directives organized in NHs, absence of an emergency liaison file in NHs, and clinical practices that are considered to be risky in NHs including physical restraints, enteral feeding and the presence of a catheter.[2]

The French Health Authority (HAS) has published recommendations in order to reduce unplanned hospitalizations for NH residents. These guidelines recommend in particular the development of telemedicine in order to improve access to care, especially for old, dependent and multi-morbid patients living in NHs.[2] The French government has set the deployment of telemedicine in all NHs in France as a priority.[15]

In the French Decree on telemedicine, published on October 19, 2010, telemedicine is defined as the use of information and communication technologies to improve patient outcomes by increasing access to care and medical expertise.[16] Telemedicine is classified into three main categories[15–18]: remote patient monitoring, store-and-forward, and interactive telemedicine (InT). InT allows physicians and patients to communicate in real time. Such sessions can be conducted in NHs and include the use of video conferencing software that complies with data security. These sessions will be used and analyzed in the present protocol study and may represent a real opportunity for patients living in NHs: 1) to improve access to care for dependent older adults living in NHs, allowing a quick and easy access to specialist consultations irrespective of the geographical location of the NH and the local care offered; 2) to optimize the quality of care by taking into account the resident's overall geriatric evaluation data (difficult to perform in emergency wards); and 3) to allow dissemination of good geriatric practices through exchanges during video conferencing with healthcare professionals working in NHs. These exchanges favor the development of health professionals' skills, and improve their professional practices through the gradual sharing of professional cultures.

In 2014, the Regional Health Agency of Aquitaine developed a regional project for the deployment of telemedicine with the acquisition of a centralized telemedicine platform and the expansion of the telemedicine program in about 50 nursing homes in Gironde. The Regional Health Agency also carried out a survey of telemedicine needs in NHs among 352 NH coordinator physicians. The results made it possible to define several thematic areas for telemedicine in NHs, including complex chronic wounds; psycho-behavioral disorders associated to Alzheimer's and related diseases as defined by the HAS in 2009[19]; psychiatric diseases; complex palliative situations; and situations of acquired deforming hypertonia and contractures.

Recent published data from our team showed that InT helped to optimize the management of residents, taking into account the results of standardized geriatric evaluation data, which can be difficult in traditional "face-to-face" consultations or during unplanned hospitalizations.[20]

Even if this feedback from InT experiments shows feasibility in NHs, no information is currently available about the impact of this new technology on residents' care pathways, particularly in terms of unplanned hospitalizations. Data on the impact of telemedicine on quality of life at work is also lacking, i.e., perception of working conditions, physical and mental charge, job strain, job recognition, sense of work. As shown in recent data from our team, it is also strategically important to understand what the facilitating factors are, as well as the working contexts favorable to the use of telemedicine. It is also important to identify the determinants of action regarding the development of telemedicine in NHs.[21] This data is still lacking, while

the use of InT in NHs varies greatly, as does the mobilization of healthcare teams.

Hypothesis of the study

We hypothesize that InT in NHs is a strategy to improve residents' care pathways, particularly in terms of unplanned hospitalizations. We also expect that a multidimensional analysis of the conditions of effectiveness of telemedicine will identify the key factors in optimizing its use. We assume that equipping NHs to use telemedicine has a direct effect on the rate of unplanned hospitalization by the monitoring of residents but also more widely, by the dissemination of geriatric best practices in NHs. We hypothesize that the successful use of telemedicine in NHs depends on a positive ownership by all actors in the chain of care and by managers of institutions. This full ownership is based on managerial, technical, and professional dimensions that are conducive to improving quality of life at work and quality of care.

Objectives of the study

The primary aim of this study will be to analyze the impact of InT strategy delivered in NHs on the rate of unplanned hospitalizations.

The secondary aims of the study will be to analyze the impact of telemedicine acts: 1) on the rate of potentially avoidable hospitalizations; 2) on the average length of hospital stay; 3) on the quality of life at work (job-demand-resources); 4) on the organizational conditions of effectiveness of telemedicine in NHs: socio-organizational factors of appropriation (adherence and acceptance) by professionals towards the technological change of the care relationship via telemedicine.

Research design

The EFFORT study is registered on ClinicalTrials.gov since 1 June 2016 (ClinicalTrials.gov ID: NCT03486977). The protocol version is V.8, 28 June 2017.

Study design

We will conduct a mixed methods study combining a cluster non-randomized controlled trial in two matched parallel arms (telemedicine group and control group) and qualitative analysis of the evolution of organizational and professional contexts in NHs.

Design of the quantitative study. The study will be a cluster non-randomized controlled trial in two matched parallel arms. The clusters are the NHs. Each group of NHs will be followed for 12 months.

- **"Telemedicine group":** NHs are already equipped for InT as part of the regional deployment project of the telemedicine device of the Health Regional Agency (Aquitaine, France). The InT procedure was organized in accordance with the French Decree of October 19, 2010 related to telemedicine,[18] and included:
  - o the consent of the resident or the resident's legal representative and the consent of his attending GP;
  - o a request sent by the NH staff on a secured regional platform called TELEmedicine Aquitaine (TELEA) including a file containing: patient characteristics, i.e., sociodemographic data, level of autonomy, comorbidities and severity, and treatments; and the reasons of telemedicine request;
  - o a connection through TELEA platform between the expert team of the department of Clinical Gerontology and the included NHs;
  - o a report sent by the expert team to the GP and the NH staff via a secured messaging system.

- **"Control group":** NHs without telemedicine equipment. These NHs will be identified after matching for each "telemedicine group" on the number of residents, the GMP (average weighted GIR: "Groupes Iso Ressources" = score to reflect the average level of dependency of residents of a residential care facility for older adults), the PMP (weighted average PATHOS: an evaluation system set up by the National Union of Clinical Gerontology and the Medical Service of the National Fund for Health Insurance for Salaried Workers which identify indicators in medical and technical care for a given population living in NHs[22]), and the distance to an hospital with an ED.

Design of the qualitative study. In parallel, a qualitative study will be conducted in the "Telemedicine group" of NHs. Four NHs will be selected according to their degree of use of telemedicine (ratio number of InT per month/number of beds), i.e., two strong users NH, and two low users NHs. The Regional Health Agency of Aquitaine has set a target of two InT acts per month for 100 beds. Four NHs will be identified according to the following two degrees of telemedicine use: two strong user NHs (more than 2% monthly), and two low user NHs (less than 2% monthly). The qualitative study will aim to collect the expectations and representations of NHs' health professionals and managers, the characteristics of work organization, the history of the implementation of telemedicine, the

professional relationships (cooperation, alliance, conflict) and implementation strategies, organizational factors of appropriation by professionals and impacts on care practices.

Participants and enrolment strategy

Patient recruitment. For the quantitative study, all NH's residents, men or women, aged 65 years and over, and likely to be eligible for InT because of one of the chronic conditions identified as a reason for InT by the Regional Health Agency, will be included in the study in both NH groups. Eligible residents will be included during a short period of 3 months.

In this study, we have chosen to exclude NH residents who do not suffer from chronic conditions related to the thematic defined for telemedicine by the Regional Health Agency; and residents or their legal representatives who have expressed their opposition to participate to the study.

NH's health professional recruitment for the quantitative and qualitative study. Health care teams will be included in the quantitative study of the quality of life at work, i.e., nurses, and caregivers.

NH Residents' General practitioners, NH physician's coordinator, NH nurse's coordinator, nurses and caregivers, who have a professional activity in selected NHs and agree to participate in the study will be included in the qualitative study.

Outcomes

Primary outcome. The main evaluation criterion will be the occurrence of unplanned hospitalizations in both studied groups. We make the hypothesis that telemedicine could reduce this rate by at least 45% (reaching 22% of unplanned hospitalizations in the study group). Unplanned hospitalizations will be defined in this project as hospitalizations preceded by residents' visits to emergency departments.

Secondary outcomes. Quantitative secondary outcomes will be as follows:

- The occurrence of potentially avoidable hospitalizations;
- The average length of hospital stay for all the hospitalized residents;
- The quality of life at work and positive organizational contexts, which will be analyzed using the 8 scores of the job-demand-resources scale of Huguenotte et al.[23] which will measure a possible link between organizational contexts and the effectiveness of telemedicine, and will be sent to all the NH professionals.

Qualitative secondary outcomes will be as follows:

- Data concerning the context, implementation and use of InT in the selected NHs
- Data related to the organizations, practices, and professional routines of the health professionals in the selected NHs
- Issues concerning the financing of telemedicine and the costs involved
- Technical issues related to the implementation of telemedicine in the NHs
- Data related to ethical, legal, telemedicine-induced changes

Intervention

Organization of InT acts

The presence of a clinical situation related to one of the telemedicine themes defined by the Regional Health Agency of Aquitaine, will start the request of an InT act. The NH team will need to obtain the resident's written consent or that of their legal representative.[16] Telemedicine acts will be organized via the Aquitaine regional telemedicine platform TELEA, which is a secure platform allowing scheduling of telemedicine appointments via collaborative information tools and also aggregating, within a tele-file, all of a patient's medical data. Depending on the type of NH request, the secretary of the required center plans an InT act meeting within 72 hours with a required specialist: psychiatrist, geriatrician, dermatologist, functional rehabilitator specialist or palliative care specialist.

In the NH side, telemedicine sessions usually take place with the resident's attending general practitioner, the coordinator physician, the healthcare team, and the patient. Telemedicine sessions are organized by videoconference either in a dedicated room using a fixed station, or in the resident's room using a mobile cart. The equipment is designed to minimize the interactions between the computer and the caregivers in order to allow them to focus only on performing the act: no action on the equipment is necessary during the consultation, just start the computer and wait for the call from the required expert specialist. The screens are equipped with a high definition camera remotely controllable by the required center team. During InT acts, all the professionals have to disclose their identity as stipulated in the telemedicine decree of 2010.[16] The role of the NH team is to explain the resident's clinical situation and the reasons for requesting expert advice, and to assist the resident if necessary. For example, the team may have to "translate" or repeat the words of the required specialist to the resident.

On telemedicine center side, InT sessions take place with a different specialist depending on the reason for the request. All the transmitted clinical data (*via* the regional TELEA platform) are studied by the specialist prior to the beginning of the InT act. The session takes place in a dedicated telemedicine room, which is equipped with a fixed telemedicine station. First, the specialist introduces themselves to the resident and the NH team. Then, the resident's geriatric assessment is completed using data transmitted during the videoconference by the NH team, and a report is written in accordance with the telemedicine decree of 2010[16] and sent via secure messaging to the requesting NH and the attending physician.

Organization of care in the control group

In the control group, usual care will be realized, i.e., medical follow-up and prescriptions set up by resident's general practitioners.

Data collection

Rate of unplanned hospitalizations

The occurrence of one or more hospitalizations will be collected every two months in both studied groups, by a clinical study coordinator via visits to NHs.

Predictive factors of unplanned hospitalizations

Predictors of unplanned hospitalizations will be collected at inclusion and every two months. These data will include:

- The presence of predictive factors of unplanned hospitalizations are collected during inclusion visits. These are: the rate of hospitalizations in the last 6 months, and the presence of diseases such as chronic heart failure, respiratory difficulties, urinary problems, infections, and pressure ulcers;
- Clinical practices that are considered to prevent hospitalizations are also collected during inclusion visits, i.e., the presence of advanced directives, the presence of an emergency liaison file (i.e., useful information filled by resident's GP as recommended by HAS in 2015[24]), the presence of mobile palliative care teams, and the presence of home hospitalization teams.
- The severity of chronic diseases and the dependency: resident's autonomy is assessed, i.e., activities of daily living (Katz ADL score[25]), the cumulative illness rating scale geriatric score (CIRS-G[26]) is collected, and the list of drugs in progress are collected every two months;
- The presence of risky care practices such as the utilization of restraints, enteral nutrition or the use of catheters, or recent use of new drugs are collected every two months.

Rate of avoidable hospitalizations

The selection of potentially avoidable hospitalizations will be done using the Weissman's classification,[27] which will identify potentially preventable causes of hospitalization, based on the primary diagnosis, coded by the International Classification of Diseases 10th Revision data (ICD10). Secondarily, an expert committee composed by geriatricians, and pharmacists will classify these hospitalizations into avoidable or non-preventable hospitalizations, on the basis of a consensus. This analysis will be based on additional clinical information: i.e., resident's clinical data before the period of hospitalization, and clinical data during hospitalization.

Impact of telemedicine acts on the quality of life at work

During inclusion visits and at the end-of-study visit (M12), scores of the job-demand-resources scales of Huguenotte et al.[23] will be collected. This questionnaire contains four main parts, i.e., questions about work contexts based on perception of perceived stress balance between work demands and resources; questions about the effectiveness and perceived quality of care; and questions about the perception of effectiveness of telemedicine in NHs. We collected some complementary data at the level of NHs — the number of telemedicine monthly acts, the size of settings, sociodemographic characteristics of professionals, dependency average level of the residents, and the status of the institution.

Impact of telemedicine acts on the organizational conditions of effectiveness of telemedicine in NHs

In situ observations and semi-directive interviews within four selected NHs will be carried out with NH professionals by the same sociology research staff:

- Observations will focus on the day-to-day work, InT situations, and requests, during 15 days in each selected NH using a previously established observation guide. The research staff will follow the professionals in their daily professional activity and will take note of all the elements (verbal and non-verbal) at work during the interactions between research staff and the professionals. Based on the information collected, a report will be produced

for each NH. The observations will be "neutral", without intervention of the researcher.
- Thirty-six semi-directive interviews will also be carried out with nurses, nursing assistants, psychologists, coordinator nurses, coordinator physicians, managers and general practitioners to collect their expectations, representations and difficulties about telemedicine.

Statistical analysis

Sample size calculation

It is assumed that the rate of unplanned hospitalizations in the control group would be 40%, and that telemedicine could reduce this rate by at least 45% (reaching 22% of unplanned hospitalizations in the study group).With a risk α of 5% and a power of 80%, it is necessary to include a total of 206 patients (Chi^2 test). Taking into account the cluster effect, with an intra-cluster coefficient of 5% and an average number of 14 residents per NH, the number of patients to be included is 340 or a total of 24 NHs (12 with telemedicine and 12 controls).

Analysis

All analyses will be performed with intent-to-treat (the group variable used is whether or not telemedicine was used) in the main analysis; and under treatment (the group variable used is whether or not telemedicine was used) in the sensitivity analysis.

Analyzes will be performed with SAS® software (versions 9.4 or later) and R software.

The occurrence of unplanned hospitalizations as well as avoidable hospitalizations will be studied with joint nested frailty models allowing us to take into account: recurring events of interest, nested random effects (patients and facility), possible truncation by a terminal event (death).

Concerning the analysis of the effect of telemedicine on the quality of life at work, the 8 scores of the job-demands-resources questionnaire were analyzed independently. The multiplicity of tests will be therefore taken into account by adjusting the p-value using the False Discovery Rate (Benjamini and Hochberg).

Data from each of the semi-structured interviews (anonymized) will be collected through data recording, transcribed and coded using NVivo software. Data analysis will be performed using the comparative method in a deductive (from the interview guide) and inductive analytical approach (the Grounded Theory of Glaser and Strauss).

Patient and public involvement. Patients and public will not be actively involved in the study design. The results of the study will be disseminated to health professional participants through several meetings and email exchanges.

Discussion

Regarding the care pathway of residents in NHs, in 2015 the French Health Authority (HAS) insisted on *"the development of telemedicine in NHs to reduce the unplanned hospitalization of residents"*.[3] Little scientific evidence has been provided in NHs about the impact of a telemedicine strategy in improving residents' care pathways.

Some published data has shown positive results in terms of quality of care and in terms of reducing unplanned hospitalizations.[28–31] The work of Grabowski et al. evaluated the effectiveness of telemedicine in NHs including InT acts during off hours.[32] This randomized controlled trial (which compared InT with a medical physician's telephone call) included 11 American long-term care units and showed an 11.3% reduction in the hospitalization rate in the "telemedicine" group.

Even if there is little scientific evidence of the impact of InT in NHs, descriptive results of previous studies reported by our team[21] identified interesting benefits of InT for NH residents and health care teams; i.e., InT optimizes the organization of care, by avoiding treatment delays and complications linked to chronic diseases; by decreasing trips to and from the hospital (sources of complications including loss of autonomy, iatrogenic, depression, falls), by decreasing journeys and by enhancing the possibility for patients in NHs to receive specialized care in their place of residence. InT will enhance the professional exchanges between NH teams and specialists for better application and better diffusion of geriatric good practices within the NH. InT is also considered an answer to the isolation of nursing and medical teams working in NHs; it increases the possibility of strengthening interprofessional collaborations and acquiring new knowledge.[20] Telemedicine makes it possible to have this valuable communication time with NH caregivers and physicians, exchanges that are often non-existent in specialized face-to-face consultation or day hospitalization in health facilities. These discussions favor the professional development of health workers and improve their practices by the progressive sharing of professional culture.

Finally, expected benefits of InT include the reduction of health system expenditures by preventing complications for patients with chronic diseases, by avoiding or shortening hospitalizations, and by

reducing logistics costs such as transport. We expect that it will lead to a more effective use of resources by limiting unplanned hospitalizations.

However, there is a lack of data concerning the determinants of organizational effectiveness with regard to telemedicine in NHs. In order to optimize the effectiveness of telemedicine in NHs, it is necessary to strengthen the analysis of the obstacles and contributing factors so that we can identify the most favorable contexts for the use of telemedicine

The EFFORT study will be one of the first comparative prospective studies with the objective to demonstrate that InT is a relevant strategy to improve residents' care pathways, particularly in terms of unplanned hospitalizations. For the first time, we will also be able to assess the beneficial effects of InT on quality of life at work in NHs and the impact of InT on the organizational conditions of effectiveness of telemedicine in NHs. The design of this protocol, in particular the procedures for setting up the control group and cluster inclusion, will allow us to demonstrate our hypothesis. The pairing of NHs will allow us to strengthen the comparability of both groups on major variables associated with the main outcome measure. The "telemedicine group" and the "control group" will therefore be comparable in terms of residents' dependency and chronic diseases, which are major factors influencing hospitalizations.[23] The groups will also be comparable in terms of distance (km) from the NH to a hospital with an ED. Practices and organization of care within NHs can be modified according to the local offer of care, in particular determined by the presence and the proximity of a health establishment. The implementation of telemedicine is organized by involving the whole of the NH. The inclusion in clusters will avoid contamination bias, take into account organizational constraints for the implementation of telemedicine into the NH, and take into account the specificities of residents' care within the NHs. Our psycho-sociological and organizational approach highlights the appropriation of telemedicine and its integration into care practices. The quantitative approach will help to determine the nature and the intensity of the link between an innovative practice such as InT and its impact on the context of care and quality of work life, in terms of better communication between the professionals or in terms of reducing the mental load of care. The qualitative analysis, as close as possible to the daily realities of the field, will provide an original approach for better deployment and functioning of the device. The evaluation of the overall quality of care in terms of effectiveness and quality of life at work is also integral to the innovative nature of this project.

In CONCLUSION, in order to identify the determinants of action and facilitate the development of telemedicine in NHs, it is strategically important to describe and understand the facilitating factors and the working contexts that favor the use of telemedicine.

Strengths and limitations of this study

1. Is the first comparative prospective study with the objective to prove that the use of InT is a relevant strategy to improve residents' care pathways, particularly in terms of unplanned hospitalizations
2. Uses non-randomized controlled design in two matched parallel arms. The clusters are the NHs.
3. Constitutes an original axis for evaluation of the overall quality of care in terms of goodness and quality of life at work in NHs
4. Uses design by pairing of NHs, which makes it possible to strengthen the comparability of both groups on major variables associated with the main outcome measure.

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