

Research design in TeleCare Nord

Telecare North NCT01984840 on www.clinicaltrials.gov

General information

The purpose of the research segment of TeleCare Nord is to provide evidence of the effects of large-scale telemedicine implementation and to generate qualitative and quantitative scientific knowledge relevant to the future application of telemedicine.

From a scientific perspective, the effect of implementing telemedicine can only be obtained through a randomised and controlled research design.

Scientific evidence of the effect of telemedicine is in demand both in Denmark and abroad. This means that the implementation of a randomised and controlled large-scale experiment under the auspices of TeleCare Nord would generate crucial knowledge concerning the health-related, economic and patient-related effects of telemedicine. This knowledge is expected to be of great significance to the future care pathways of patients with chronic disorders.

Another objective of the research is to provide greater knowledge about management and organisational challenges related to telemedicine innovations in interorganizational networks. Additionally, knowledge about how a pilot innovation is transformed to a large-scale project in a cross-sectorial setting. The longitudinal qualitative casestudy is used as research methodology to obtain knowledge about these management and organizational implications of telemedicine in large-scale, and the process from pilot to large-scale. Different qualitative methods are used to investigate these perspectives.

Background: TeleCare Nord as the concluding link in the research pipeline for developing and testing telemedicine

The TeleCare Nord project – which initially works to achieve full-scale telemedicine implementation in the area of chronic obstructive pulmonary disease (COPD) – is the result of a process which progresses in stages:

The first stage has comprised small telemedical trials in both North Jutland and other locations. The Electronic Plaster (at Vendsyssel Hospital) and small telemedical trials, conducted as part of Digital North Jutland, made up the first stage, but did not include randomised and controlled studies.

The second stage – specifically involving pulmonary patients (the first group of patients in the TeleCare Nord project) – was the recently concluded TeleKat project. TeleKat involved a limited controlled experiment showing that telemedicine had the potential to have a positive financial and clinical impact on pulmonary patients.

The third stage is TeleCare Nord, whose purpose is initially to benefit COPD patients by demonstrating that telemedicine can have a positive impact on healthcare quality, welfare economy and the individual patient on a large scale in an operational situation.

Purpose

The purposes of the research project associated with TeleCare Nord are 1) to test the effects of telemedicine on patients with severe or moderate COPD in relation to the existing patient care pathway without telemedicine and to apply the results obtain in a wider context; and 2) to identify and analyse specific organisational and management challenges inherent in the intersectoral collaboration in TeleCare Nord. The effects of telemedicine are specified on the basis of health-related, economic, patient-related and organisational goals corresponding with the project goals incorporated into the business case approved for TeleCare Nord (described on pages 4 and 5 of Business Case, v. 1.0, February 2012):

Project goals

1. Empower patients by making data and knowledge available to patients, boosting the patients' self-care skills and giving the patient more influence on his/her own state of health.
2. Increase patients' peace of mind and satisfaction, as well as improving their quality of life (measured by means of quality adjusted life years (QALY)).
3. Integrate the efforts into the treatment of COPD patients in an interplay with the patient and healthcare professionals to maximise the duration of the patient's self-care in his/her own home.
4. Reduce the number of hospitalisation days to 70% of the level for traditional treatment.
5. Reduce the number of readmissions to hospital to 70% of the level for traditional treatment.
6. Reduce the number of outpatient visits to 70% of the level for traditional treatment.
7. Free up time of clinical staff.
8. Free up time of municipal care staff.
9. Use active research to document the lessons learnt which make it possible to carry out similar initiatives targeting patients with other chronic disorders.
10. Improve the quality and efficiency of intersectoral collaboration and reduce unintentional incidents in intersectoral transitions.

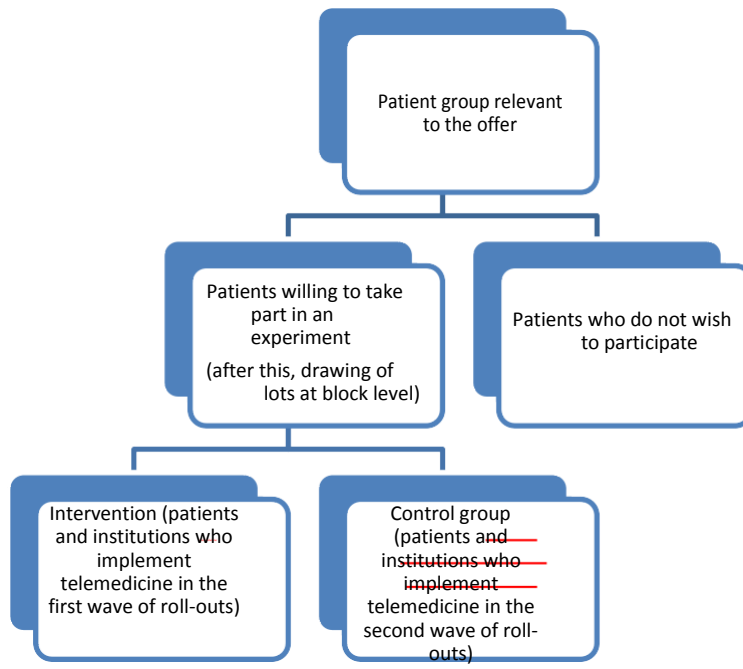
Randomised study: methodology and expected results

The research design of the project is subject to the policy decisions affecting of TeleCare Nord's roll-out, and the research project will be planned to conform to the municipalities' budgeted expenditures and gains.

The research design of the project will closely conform to the business case in that it will be possible for the research aspect to "document" the achievement (or partial achievement) of the effects expected from implementing telemedicine.

Methodology

The design of the research project is also planned and organised so as to coordinate the data collection process with other evaluation projects according to external grants and the needs of other external partners (National Board of Social Services, University of Southern Denmark). This will involve particularly close relations with the evaluation effort associated with the Clinically Integrated Home Monitoring project (KIH), supported by the Danish Public Welfare Technology Fund, to ensure uniform methodology, the reuse of evaluation concepts and supplementary evaluation and research effort



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The research project is a randomised (in clusters) and controlled study where *controlled* means that it must be possible to compare patients who receive a given telemedicine technology (intervention group) with patients who do not receive this technology (control group). In a way, data from the control group corresponds to what is referred to in non-randomised and non-controlled studies as the project's reference-point analysis. Patients who do not receive the technology (control group) will also be offered telemedicine later on, in phase 2 of the implementation of TeleCare Nord. Groups will be divided at a level constituting the home-care districts areas, or possibly at municipal level in those municipalities where it is not possible to subdivide to a lower level.

Randomised means that a draw of lots will determine whether a given patient or group of patients is assigned to the intervention group or the control group. In TeleCare Nord, cluster-randomisation will naturally be used where the home-care districts (or the municipalities) are grouped into fairly comparable pairs (e.g., in Aalborg, the West Elderly Area can be paired with the South-West Elderly Area), after which lots will be drawn to determine which of the two home-care districts will take part in phase 1 of the implementation (and thus which district must wait until phase 2).

In both groups (e.g. West Elderly Area and South-West Elderly Area), patients suitable for the offer have to be selected before lots are drawn to determine which will be the intervention group and control group respectively. The selection of patients will take place under the auspices of TeleCare Nord based on a range of healthcare criteria in a work flow involving the region's GPs. Based on a series of data sources and registry information concerning medicine use and diagnosis, including from the Clinical Department of Epidemiology, a complete list of suitable COPD patients will be drawn up. A healthcare professional affiliated with the project is expected to qualify the list before GPs select suitable patients from the list (i.e. unsuitable patients will be excluded on the basis of the exclusion criteria laid down in the project beforehand). It should be noted that the structure for dividing up patients into the paired blocks, which must be randomised (and which could comprise home-care districts) will be agreed with the individual municipalities.

The patients in the intervention group will receive the offer first. The patients in the control group will receive the offer later on. This conforms to the business case, as the roll-out of telemedicine will take more than two years. The period of time between the roll-out for the intervention group and the control group is planned to be one year. In other words, the research design exploits the fact that, due to restricted capacity during actual implementation, not all patients can be offered the technology at the same time; the fact that some patients do not receive access to the technology until later on is exploited in the meantime by using these waiting patients as the control group for the group of patients who start receiving the technology first.

It should be noted that much of the data collected in the project will be included in both the research process described and in the other evaluation projects mentioned above.

Expected Results

The evidence will be divided into financial, healthcare/clinical and patient-oriented consequences. The project's outcome measurements will correspond with the project goals listed in the business case.

Primary health-related/clinical goals:

In the study, the EuroQol (EQ-5D) and the Short Form-36 Health Survey will be used for describing the self-reported physical and mental health status and health related quality of life. The patients will fill in the questionnaires upon inclusion in the study and again after 12months.

The study will also measure whether telemedicine can reduce the number of admissions to hospital of COPD patients and reduce the duration of (re-)hospitalisation. Furthermore, a number of clinical targets for the patients' diseases and progression of the disease will be included in the study.¹

Primary health economics goals:

The primary outcome measure for the health economics studies will be to determine the incremental cost-effectiveness ratio (ICER), i.e. 'value for money' and 'budget impact'. Hospitalisation expenditure in particular constitutes a high percentage of total health costs for COPD patients, and previous studies have rendered probable that telemedicine could reduce the incidence of hospitalisation. In addition to hospitalisation costs, the differences between the patients in the intervention group and the control group will be specified in terms of other hospital costs (e.g. outpatient visits), costs for public health insurance (medicine, GP, etc.), municipal expenditure for home-care, home-care nursing, rehabilitation, etc., (including the number of hours worked by clinical and care staff) and transfer incomes.

Primary patient-related goals:

The primary patient-related goals are empowerment, self-care skills, peace of mind and satisfaction. Data for the primary health-related and clinical goals are obtained through questionnaires, interviews, clinical and administrative registers and by means of extra clinical analyses.

Case Study: frame of reference, methodology and focus

Innovation networks are a relatively new research concept. However, the concept is used in several research disciplines, and hence used in different paradigms and referring to different levels and forms. According to Royer and Bijman (2009), it is possible to differentiate between 1) co-innovation between the departments and divisions of a single organisation; 2) co-innovation between organisations (horizontally and vertically) including between public and private enterprises; and 3) co-innovation at meso and macro levels such as development processes in innovation systems in business clusters, regions, sectors and nations.

TeleCare Nord focuses on the second type of innovation network; co-innovation between organisations. Tidd and Bessant (2009) identify nine different types of innovation network in this area alone, even without covering all the types described in the literature. The network in TeleCare Nord can be characterized as a systemic innovation network with different mutually dependent participants with complementary capabilities, working together on a shared task in an interorganizational field (Gustafsson & Seemann, 1985; Alter & Hage, 1993; Rogers & Whetten, 1982; Gray, 1989; Gage & Mandell, 1990; Kickert et al., 1997; Seemann, 1996, 1999, 2001, 2010; Seemann & Antoft, 2002; Axelsson & Axelsson, 2007; Gustafsson 2007).

An example of a shared task is the patient care pathways of TeleCare Nord. Systemic networks for public-sector participants often contain inherent contradictions arising from inconsistent mandates, laws and rules. The participants have different goals and tasks, different core skill-sets and technologies, different organisational cultures, different structures and systems and different contexts in the form of parent

¹ It should be further considered whether special clinical analyses of patients, e.g. by a home-care nurse, should be carried out as a baseline and a later point in time during the study. This type of (extra) clinical analysis could support the medical assessment of the impact of telemedicine, but costs money. Also, determining the impact of telemedicine (in terms of cost-cutting potential) could be impaired if analyses of all patients are carried out initially (i.e. in addition to the general care pathway), analyses which in themselves could prompt treatment. This entails a risk of underestimating the impact of telemedicine because control-group patients receive extra analyses (and derivative offers/options) which they would not receive otherwise.

organisations, interest groups and other network relationships (Gustafsson & Seemann, 1985).

TeleCare Nord exemplifies a complex systemic network with multiple participants from different organisations, sectors and political levels. The core network consists of public health care organisations involved in the treatment and rehabilitation of COPD patients.. The context is made up of the participants' parent organisations, interest groups, and participants involved in innovation and development projects which influence, or are capable of influencing, the development processes in TeleCare Nord.

From the research literature we know, that top-down innovation strategies are politically-influenced hierarchical processes with weak interorganisational management. The networks are characterized by fluctuations with shifting patterns of dominance, adaptation and influence between the participants, each of whom are held in dilemmas and cross-pressures. The public-sector actors in the network are held in dilemmas and cross-pressures between the shifting, and sometimes contradicting demands, of the innovation network and their parent organisations and other network collaborations, e.g. with colleagues in professional groups at other hospitals or municipalities. Private-sector participants have to balance between network demands and their own market conditions and overall business strategies. Therefore, it is very difficult to consolidate interdisciplinary innovation at the network level. Often silo innovation within the organizations own domain will become dominating in such networks, resulting in insufficient interdisciplinary coordination (Seemann & Gustafsson, 1985; Seemann, 1996, 2010; Seemann, Dinesen & Gustafsson, 2012 a, b).

We also know that bottom-up strategies in systemic networks can bring about highly dynamic innovation in the pilot phases, but the transition phase from development project to large-scale operation is very difficult in systemic networks with public-sector participants. Many projects fade away at the completion of the development phase as there are no driving forces to lead the innovations into an actual operating situation (Seemann, Dinesen & Gustafsson, 2012b).

There are many indications that success and failure in systemic innovation processes largely depend on whether the following two key challenges are successfully dealt with: 1) organising, facilitating and managing network processes and respective relationships with one's own base; and 2) transitioning from development to operation. However, we know too little about how to handle these critical challenges from a management perspective. TeleCare Nord prompts and enables the exploration and generation of empirical knowledge/results in these two areas in the (continued) interorganisational innovation process.

A longitudinal study which uses qualitative methods to study the TeleCare Nord process will be based on the following empirical focal points:

- identifying and mobilising the participants;
- organising and setting up rules of interaction in the network;
- facilitating creativity, knowledge-sharing, combining knowledge and interorganisational learning processes;
- interorganisational treatment concepts.
- organisational development
 - development of the technologies, skill-sets, processes, systems, structures and strategies of the individual participants;
 - development of the network's processes, systems and structures, including the participants' interrelationships and communication, as well as striking a balance between benefits, risks and interests;
- dealing with strategic dilemmas and cross-pressures for public and private participants;

- handling conflicts and processes which are going awry.

The goal is to develop models and strategies for developing and implementing large-scale interorganisational projects such as TeleCare Nord. Such an analysis, which involves complex factors in the network's context with several levels and several sectors' interaction, would be comprehensive. Therefore, the project is envisioned to be capable of analysing aspects of this problem, depending on how the process develops and other factors.

Planned PhD processes

The criterion for determining which research activities are eligible for 50% funding by TeleCare Nord will be an assessment of whether the research can be directly applied to a retrospective evaluation and/or prospective evaluation of the impact in relation to the project goals set out in the approved business case (in this case, the retrospective evaluation analyses the results achieved in the project, whereas a prospective evaluation focuses on analysing the results that are likely to arise by continuing and expanding the project). The remaining 50% of the funding will be applied for from Aalborg University where there is precedence for such co-funding.

Three PhD processes are recommended for assessing the effects obtained in the project: a health-economics PhD scholarship (PhD 1); a health-related/patient-oriented PhD scholarship (PhD 2); and an organisational-theory PhD scholarship (PhD 3). The health-economics PhD process will be affiliated with the Danish Centre for Healthcare Improvements, Aalborg University; the health-related/patient-oriented PhD process will be affiliated with the Department of Health Science and Technology, Aalborg University; and the organisational-oriented PhD scholarship will be affiliated with the Centre for Organization, Management and Administration, Aalborg University.

The table below outlines how the three PhD processes will address the project goals set out in the business case:

	PhD 1	PhD 2	PhD 3
Patient empowerment		XXX	
Increased patient peace of mind and satisfaction		XXX	
Integration of treatment intervention for self-care in the patient's own home		XXX	X
Reducing the number of hospitalisation days	XX	XXX	
Reducing the number of readmissions to hospital	XX	XXX	XX
Reducing the number of outpatient visits	XX	XXX	XX
Freeing up the time of clinical staff	XXX		xx
Freeing up the time of municipal care staff	XXX		xx
Applying the results in a wider context for patients with other chronic	X	X	XX
Reducing unintentional incidents in intersectoral transitions	X	XX	XXX

Qualitative and quantitative scientific knowledge relevant to the future use of telemedicine could be generated by follow-up research, which could naturally be conducted under the auspices of TeleCare Nord. This could include research conducted in the fields of nursing, occupational therapy, physiotherapy and other humanistic and technical professions. Follow-up research could naturally be organised into separate PhD processes and, to ensure the interdisciplinary aspect, it would be natural to build up a network for communicating and coordinating research activities affiliated with TeleCare Nord. Aalborg University (represented by Ole Hejlesen, Janne Seemann and Lars Ehlers) will be responsible for this type of coordination.

All PhD processes which are funded wholly or partly by TeleCare Nord will be structured to allow for prompt publication of the results. This could be achieved by having PhD dissertations made up of three or four scientific articles which are published on an ongoing basis concurrent with the finalisation of results. Even though the final results for PhD 1 and 2 cannot be expected to be published until the end of phase 2, some partial results could be expected to be published after the end of phase 1. The PhD dissertations published at the end of PhD projects 1 and 2 would comprise these three or four articles supplemented with an introduction, outline, discussion, etc. For PhD 3, the publishing of empirical results in scientific articles would mostly take place during the last part of the project period and in continuation of this. Prompt feedback could take the shape of working notes typical of action research and verbal feedback on preliminary results.

Putting the project into a wider context

The present research design provides a natural framework for future implementation of new telemedicine initiatives and provisions for new patient categories: first, the project will test and demonstrate on a small scale how telemedicine can be used for a given patient group; after this a controlled small-scale study will show that there is an effect; and finally the new initiative must be tested in a large-scale experiment. This will involve "elimination processes" where only the best and most promising initiatives will qualify for the large-scale process.

As large-scale testing is very costly, it is crucial to qualify and test new ideas during the far less costly first two phases.

In addition to the internal communication and coordination within the project, it will also be possible to use the TeleCare Nord network to ensure that the general public in North Jutland and the rest of Denmark gain access to quality-assured information about the results of introducing telemedicine and the scientific insights gained through this.