A pragmatic randomized control trial comparing telehealth with standard clinical care in the follow-up of patients with chronic conditions within the primary care setting

Short title: Pragmatic RCT of telehealth vs standard care in follow-up of patients with chronic conditions

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Protocol synopsis

Title of the study	A pragmatic randomized control trial comparing telehealth with standard clinical care in the follow-up of patients with chronic conditions
Short title	Pragmatic RCT of telehealth vs standard care in follow-up of patients with chronic conditions
Treatment	
Control treatment	Standard clinical care
Study centers planned	The following six municipalities are included in the study: Oslo, Eid, Kristiansand (recruiting from the Agder counties), Ullensaker (in cooperation with Gjerdrum), Larvik and Bodø
Study period	First patient recruited: February 19th, 2019 Anticipated recruitment period: February 1st, 2019 to June 30th, 2020 Estimated date of last patient completed: June 30th, 2021
Treatment duration	Patients in the intervention group will be followed up using telehealth solutions for 12 – 18 months Patients in the control group receive standard clinical care throughout the study period
Study objectives	Primary: 1. To assess whether patients who are followed up using telehealth experience an improved health state (or lower reduction in health state for patients with deteriorating health) compared to patients receiving standard clinical care. 2. To assess whether patients who are followed up using telehealth are more satisfied with the health care services than patients receiving standard clinical care. 3. To assess whether patients who are followed up using telehealth utilize less healthcare resources than patients receiving standard clinical care Exploratory: 1. To evaluate the organization of the service 2. To evaluate the cost-effectiveness of telehealth compared to standard clinical care
Study endpoints	Primary endpoints: • Health related quality of life (EQ-5D) • Overall satisfaction with treatment and follow-up • Health and care cost per person Secondary endpoints: • Physical functioning • Sleep • Coping

	• Satisfaction with the telehealth technology (only in the intervention group) • Satisfaction with health care personnel • Patient involvement • Perceived benefits • Use of health and care services Exploratory endpoints: • Describe and evaluate the service: organization, cooperation between health and care providers, user involvement, technological solutions • Summarize costs and benefits of the intervention and comparator strategy • Evaluate cost-effectiveness • Compare cost-effectiveness across local projects
Study design and description	A randomized, open, controlled, multicenter, pragmatic comparative study
Study population	Norwegian adult male and female patients (aged >=18 years) with chronic conditions, with medium to high risk of worsening of their condition, hospitalization or increased need for health and care services. Although the inclusion criteria do not restrict to specific diseases or conditions, examples of relevant patient groups include; patients with chronic conditions, mental illness, physical disabilities, and cancer patients.
Main inclusion criteria	• >18 years of age • The patient has a considerable disease burden and comprehensive medical needs • The patient has a chronic disease • The patient has medium to high risk of worsening of their condition, hospitalization or increased need for health and care services • The patient has a high consumption of healthcare services • The patient has a reduced level of function • The patient is motivated to use telehealth solutions • The patient is likely to benefit from the use of telehealth solutions
Main exclusion criteria	• Patients who are not competent to consent • Patients who are unable to handle the tablet and the measuring equipment to be used • Patients with substance abuse
Sample size	600 patients are planned to be recruited. The sample size was decided by the Norwegian Directorate of Health.
Randomization procedure	Eligible patients are allocated in a 1:1 ratio between telehealth and standard clinical care, using sealed paper-based envelopes with a note that states either “intervention group” or “control group”.
Efficacy assessments	Efficacy variables include health related quality of life, assessments of patient’s own physical and mental health, coping, user experience, resource use
Safety assessments	Physical examination and vital signs, record of adverse events, user experience
Other assessments	Resource utilization and cost-benefit assessments
Dara analysis	The main analysis in planned when all patients have concluded the study, and all data have been collected. Preliminary analyses will be conducted, and results presented in two midterm reports during the period of the trial.

Content

List of abbreviations and definition of terms

Term	Explanation
	"Telehealth includes those activities/actions that allow the patient, outside the traditional arenas where patients face healthcare professionals, to acquire, record and share clinically relevant information about their health status electronically, with the purpose of providing information or guidance to the patient's self-management, and/or provide decision support for diagnosis, treatment or follow-up for health professionals." (Scottish Center for Telehealth & Telecare, 2016)
Telehealth	Technological solutions allow the health and care service to monitor and follow-up the patient remotely. Users of telehealth can answer simple questions about their health condition and/or perform agreed measurements related to their health (e.g., blood pressure, blood sugar, oxygen saturation, weight) via a tablet or a similar device. The results are transferred from the measuring devices to the tablet so that users can easily see them and track their own results over time. The results are transmitted digitally to a follow-up service. The follow-up service contacts the patient in case of signs of deterioration or when measurements lie outside what is normal values for the individual. The follow-up service provides medical support and guidance based on the patient's needs and plan for follow-up, and will, in consultation with the patient, assess whether this should contact their GP/emergency room.
Follow-up service	The follow-up service is the center that receives and follows the measurements from the patients who receive telehealth. The municipalities are free to organize the follow-up service according to local needs, but it is required that the employees have nursing competence. The follow-up service may be co-located with other municipal services such as home nursing or the emergency room service. In municipalities that have multidisciplinary care teams, the nurse in the multidisciplinary care team may follow-up the patients using telehealth.
User	A user is a patient who receives telehealth.
Participant	A participant is a patient who is included in the clinical trial of telehealth - either in the intervention group or the control group.
Trial	Trial refers to the research-based evaluation and pragmatic randomized-controlled trial comparing telehealth with standard clinical care, initiated by the Norwegian Directorate of Health in 2018. The trial is carried out at six local centers.
Project	Project refers to one of the six local trials of telehealth. The projects receive co-financing from the Norwegian Directorate of Health in order to carry out the trial of telehealth in line with the Directorate of Health's guidelines.
Evaluation	Evaluation refers to the research-based evaluation of the trial. The Directorate of Health has commissioned an evaluation of the trial. The evaluation constellation includes researchers from the Institute of Health and Society at the University of Oslo, Oslo Economics and the Norwegian Centre for Rural Medicine (NCRM) at UiT - the Arctic University of Norway, Tromsø. The purpose

	of the evaluation is to estimate the effects of telehealth within a primary care setting on the users' health status, the user's experience with the service and healthcare resource utilization. The aim of the evaluation is to inform the decision about whether and how to implement telehealth as part of primary care services in Norway.

1. Introduction

The Norwegian health authorities has initiated a three-year trial of telehealth as part of the treatment of patients with chronic illness in the period 2018-2021 (Helsedirektoratet, 2018). Within the trial, telehealth indicates that patients (or 'users of healthcare', herein referred to as 'users') are followed-up outside health-care facilities using information and communication technologies (ICTs), so-called "welfare technological solutions". Users receiving telehealth can answer questions about their own health and/or perform measurements related to their health (e.g. blood pressure, blood glucose, oxygen measurement, weight) via a tablet according to a personalized schedule. The measurement values are transferred from the measuring devices to a tablet so that the users can easily see them and track their results over time. The results are also transmitted digitally to a follow-up service, a healthcare center with nurses, who contacts the patient when needed. The follow-up service provides medical support and guidance based on the patient's needs and planned follow-up, and will, in consultation with the user, evaluate whether the user should contact the GP or emergency room.

The study population of the trial includes users with comprehensive medical needs, with medium to high risk of worsening of their condition, hospitalization or increased need for health and care services.

A consortium of researchers from the Institute of Health and Society at the University of Oslo, Oslo Economics and the Norwegian Centre for Rural Medicine (NCRM) at UiT - the Arctic University of Norway has been engaged by the Norwegian Directorate of Health to evaluate the effects of the trial.

The evaluation includes three main parts: 1) An effect evaluation, 2) a cost-benefit analysis, and 3) a process evaluation which aims to provide recommendations for how to organize and implement telehealth in clinical practice. The main effect outcomes include physical and mental health, patient experience and use of health services.

1.1 Previous evidence on the use of telehealth

There is a large literature that studies the effects of telehealth on patient outcomes. One challenge related to this literature is the extent of variation in the existing studies. Studies vary in the type and design of telehealth solution, in the study population, in the endpoints studied, in the design and quality of the study, among other things. This makes comparisons and generalizations of studies and findings challenging.

The evidence on clinical outcomes are mixed, but some general patterns emerge. Numerous studies, systematic reviews and reviews of reviews suggest that there are positive effects on clinical outcomes in treatment of chronic diseases. For example, an evidence mapping prepared for the U.S. Department of Health and Human Services (Totten, et al., 2016), found that a large body of research found positive patient outcomes for remote patient monitoring for several chronic conditions. The most consistent finding of this evidence mapping was the effectiveness of telehealth when used for communication and counseling or remote monitoring for chronic conditions such as cardiovascular disease and respiratory disease, showing improvements in i.e., mortality and quality of life and reductions in hospital admissions.

The evidence related to costs and resource utilization is even more mixed. There are several potential explanations for this. One is that costs may be more easily affected by the type of telehealth intervention, by the organization and financing of the health service. This also provides extra challenges for researchers who are to conduct systematic reviews, resulting in fewer systematic reviews of the cost-effectiveness of telehealth. The evidence mapping mentioned above found fewer positive results for cost and utilization of health care services. 15 of 32 systematic reviews that reported on cost/utilization found a benefit or a potential benefit from telehealth. Most of these focused on remote patient monitoring. For other types of telehealth, the no or limited evidence of reductions in cost of utilization of health services.

A more extensive literature review on the effects of telehealth in the primary care service on patient outcomes will be delivered by the Norwegian Institute of Public Health to the NDH by the end of 2019.

1.2 Background for the study

Norway has an ageing population, and the need for health and care services will likely increase in the coming years. There is a need for innovation to face these challenges. Technology is one of the pillars of the future health

and care service, and the evaluation of telehealth will help inform how technology can be used as a tool for follow-up in patient trajectories.

During the period 2016-2018, the Norwegian Directorate of Health conducted an initial trial of welfare technology solutions for telehealth (Intro International, 2018). A total of 822 people in seven projects in four municipalities participated in the trial. The study population included people with chronic conditions, and primarily people with COPD, diabetes and heart failure. The study showed that the users were satisfied with the intervention. However, due to the lack of a control group in the trial, it was not possible to draw conclusions about health effects and costs. Although the trial provided useful insight to the potential value of telehealth, the study did not provide enough evidence on the effects to inform national recommendations. Thus, there is a need for more knowledge about the effects and consequences of telehealth for all the actors involved, i.e. both patients and service providers.

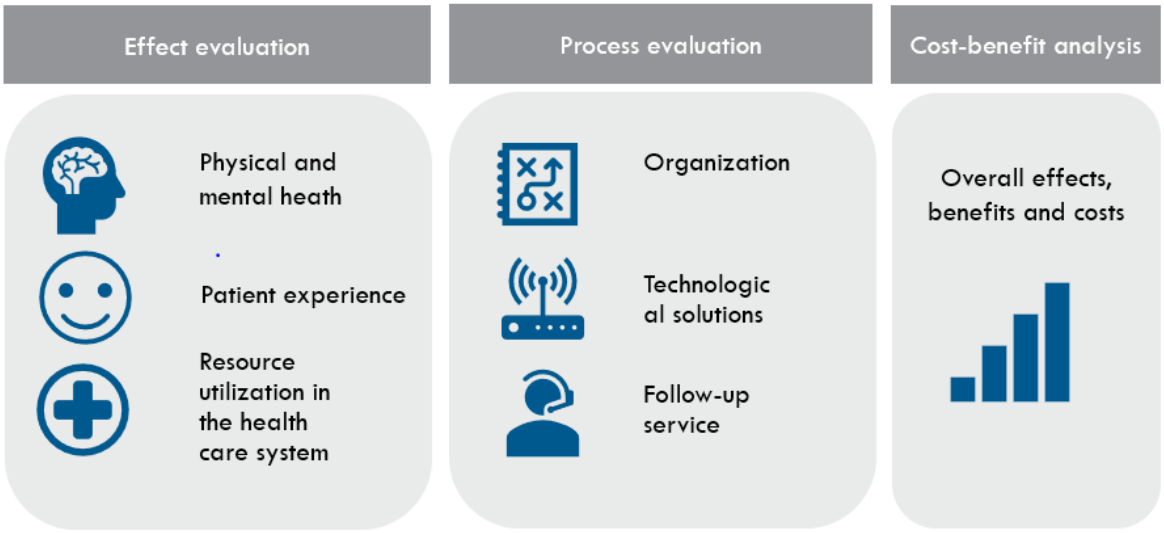
The Norwegian Directorate of Health has therefore initiated a new trial, conducted as a pragmatic randomized control trial, of telehealth for people with chronic disease. The trial is carried out in the period 2018 - 2021 and is part of the National Welfare Technology Program (Nasjonalt Velferdsteknologiprogram). 2018 involved recruitment of local centers to participate in the trial as well as planning and study design. The first patients are recruited to the trial in 2019. The purpose for the new trial, as defined by the Norwegian Directorate of Health, is to obtain knowledge about the effects of telehealth that can inform recommendations for national implementation. The intervention is described in more detail in Section 4.

1.3 Evaluation of the telehealth trial

On behalf of the Norwegian Directorate of Health, the research consortium will evaluate the telehealth trial using a mixed-methods approach, with three main evaluation components: 1) effect evaluation, aimed at measuring the effect of telehealth on the users' health status, patient experience and resource utilization in the healthcare system; 2) process evaluation, aimed at evaluating the organization of the service, collaboration and interaction between different actors; and 3) cost-benefit analysis, aimed at comparing health benefits and costs of telehealth compared to standard clinical care (Figure 1).

The evaluation is based on a wide range of data sources, including repeated surveys and interviews with patients and health personnel in various parts of the health service. Registry data will also be obtained on the use of health services within both the municipal health and care service, the GP service and the specialist health service. In addition, data from the follow-up service will be analyzed if available.

Figure 1: Evaluation of trial of telehealth



1.4 Organization of the trial

The Norwegian Directorate of Health has initiated the trial and is responsible for its implementation. The Norwegian Directorate of Health has designed the scope of the trial, including central elements of the intervention, such as main features of the intervention, study population, inclusion and exclusion criteria, organization of the service, overall outcome measures, study duration and number of participants. When designing the scope of the trial, the Norwegian Directorate of Health has involved participants in the previous trial, as well as representatives for various stake holders, such as patient associations and health care providers and municipalities. The Norwegian Directorate of Health is also responsible for recruiting the participating municipalities, and for providing guidance to these local projects regarding practical implementation of the telehealth.

The Norwegian Directorate of Health is also the principal for the evaluation. The evaluation is carried out by a constellation of researchers at the University of Oslo, Oslo Economics and the National Center for District Medicine (hereafter referred to as the research consortium). The researchers are responsible for the development of the evaluation design within the scope of the trial set by the Norwegian Directorate of Health, data collection and management and statistical method and data analysis. The Norwegian Directorate of Health will not have access to the raw data material but will receive summarized reports with results along the way and after the trial has ended.

1.5 Participating municipalities and scope of the trial

The trial of telehealth is conducted at a total of six local centers. The participating centers are situated in the municipalities of Eid, Bodø, Larvik, Oslo (in the districts of Sagene, Grünerløkka, Gamle Oslo, St. Hanshaugen), Ullensaker (in cooperation with Gjerdrum) and Kristiansand. Kristiansand municipality is leading a local center recruiting patients from 30 municipalities in the Agder county.

Eid municipality, as well as a general practitioner office in Kristiansand and one in the Sagene district also participate in the pilot study of multidisciplinary care teams within primary care. The Norwegian Directorate of Health has asked the research consortium to evaluate synergies between the two trials. However, the telehealth trial is not designed to explicitly examine the effect of participating in both studies, as this was not possible within the frames given by the Norwegian Directorate of Health. Instead, synergies will be investigated through interviews.

The local centers carry out the trial in line with the guidelines from the Norwegian Directorate of Health. The centers also undertake to follow the study protocol for the trial. It is the centers' responsibility to recruit participants to the trial.

2. Study objectives and related endpoints

As described above, the evaluation of telehealth consists of three main parts: 1) an effect evaluation, 2) a process evaluation, and 3) a cost-benefit analysis. The effect study is designed as a randomized, non-blinded, controlled study conducted at six local centers in Norway. The telehealth trial and the related evaluation will provide more knowledge about effects, benefits and costs, as well as highlight how telehealth can contribute to fulfilling national goals for the primary health service as stated in Report No. 26 (2014-2015) to the Storting (Meld. St. 26, 2014–2015) and the Government report Omsorg 2020 [Care 2020] (Helse- og omsorgsdepartementet, 2015). The results from the evaluation will inform recommendations on the national implementation of telehealth.

Table 1: Study objectives and related endpoints

	Objectives	Outcomes	Assessments
Primary	To assess whether patients who are followed up using telehealth experience an improved health state (or lower reduction in health state for patients with deteriorating health)	Primary • Health related quality of life (EQ-5D) Secondary • Physical functioning • Sleep	Section 6.1

	compared to patients receiving standard clinical care.	• Coping	
Primary	To assess whether patients who are followed up using telehealth are more satisfied with the health care services than patients receiving standard clinical care.	Primary • Overall satisfaction with treatment and follow-up Secondary • Satisfaction with the telehealth technology (only in the intervention group) • Satisfaction with health care personnel • Patient involvement • Perceived benefits	Section 6.2
Primary	To assess whether patients who are followed up using telehealth utilize less healthcare resources than patients receiving standard clinical care	Primary • Health and care cost per person Secondary • Use of health and care services	Section 6.3
Explanatory	To evaluate the organization of the service	• Describe and evaluate the service: organization, cooperation between health and care providers, user involvement, technological solutions	Section 6.4
Explanatory	To evaluate the cost-effectiveness of telehealth compared to standard clinical care	• Summarize costs and benefits of the intervention and comparator strategy • Evaluate cost-effectiveness • Compare cost-effectiveness across local projects	Section 6.5

3. Study population and study period

The target population includes people with chronic diseases, with a medium to high risk of worsening their condition, re-admission to hospital or an increased need for health and care services. The inclusion criteria are set by the Norwegian Directorate of Health. Patients who meet the inclusion criteria and who consent to participation are randomized 1:1 in accordance with the procedure described in Section 5. Patients in the intervention group receives follow-up using telehealth (which is described in more detail in Chapter 4), while patients in the control group receive standard clinical care.

Testing Period:

- Date for inclusion of first patient: February 2019
- Expected recruitment period: February 2019 to June 2020
- Expected closing date for follow-up of last patient June 2021

Follow-up period: 12 to 18 months

3.1 Inclusion criteria

The primary inclusion criterion is that the individual has a considerable disease burden and comprehensive medical needs. Thus, the target population for the trial is patients with chronic diseases, with medium to high risk of worsening of their condition, hospitalization or increased need for health and care services. These patients are characterized by a high consumption of healthcare services (such as hospital services, regular medical services, and home services, or a combination of these) and are largely composed of patients with non-infectious chronic diseases such as diabetes, COPD, cardiovascular disease, mental illness and cancer. These patients often have comorbidities and comprehensive medical needs. Only adults, aged 18 or older, can be included in the trial.

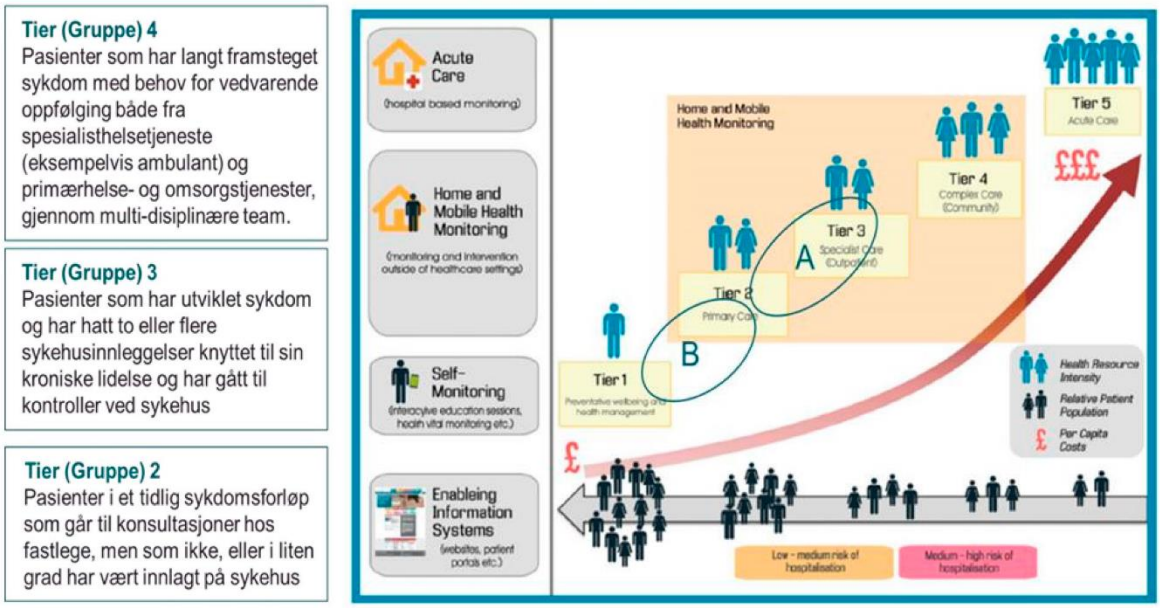
Specific inclusion criteria include:

- >18 years of age
- The patient has a considerable disease burden and comprehensive medical needs
- The patient has a chronic disease
- The patient has medium to high risk of worsening of their condition, hospitalization or increased need for health and care services
- The patient has a high consumption of healthcare services
- The patient has a reduced level of function
- The patient is motivated to use telehealth solutions
- The patient is likely to benefit from the use of telehealth solutions

For each potential participant, the patient's GP evaluates whether these criteria are met.

Figure 2 illustrates groups of the population with different needs for health and care services, and the figure can be used to illustrate which groups should be included in the trial. The previous trial focused on patients categorized into groups 2 to 4. This trial will focus on patients categorized into groups 3 and 4. In group 4, however, most patients are expected to have such comprehensive need for healthcare services that they are less likely to benefit from telehealth compared to patients in group 3. At the same time, some patients in this group can probably benefit greatly from telehealth because it provides better control of their own health situation and reduced risk of deterioration.

Figure 2: National model for telehealth in Scotland



Source: Scottish Centre for Telehealth & Telecare (2017, s. 20), modified in The Norwegian Directorate of Health (2017, s. 10)

3.2 Exclusion criteria

Patients who are not competent to consent are excluded from participating in the trial. This means that patients who participate in the trial must be able to make their own decisions and understand the consequences of their

own choices. A person who is competent to consent can reason and evaluate alternatives, can express credible choices and understand the consequences of their own choices.

Other exclusion criteria include:

- Patients who are unable to handle the tablet and the measuring equipment to be used
- Patients with substance abuse; this patient group is often unstable, and telehealth is likely more applicable for patients who are likely to use the tablet and any measuring devices regularly and as intended.

3.3 The number of participants

The Norwegian Directorate of Health has defined a target number of participants at a minimum of 600 patients.

3.4 Recruitment of patients

Anybody, including health and care personnel, the patients themselves and their relatives can suggest patients for participation in the trial. In most cases, health personnel recruit patients. Suggestions are made to the project administration, which consists of municipality employees.

The Norwegian Directorate of Health has stressed that it is important that the participating municipalities focus on recruiting patients. All participating municipalities have written plans for recruitment that are regularly evaluated and updated. Among actions that are undertaken to promote recruitment of patients are information meeting at hospitals and GP offices, newspaper articles and the like.

4. Treatment – telehealth vs. standard clinical care

4.1 Telehealth

Organization and responsibilities

The Norwegian Directorate of Health has outlined guidelines on how to organize telehealth in clinical practice, yet the participating municipalities may adapt the service according to local needs (within the guidelines). The local centers are responsible for facilitating cooperation between the general practitioner scheme, the follow-up service and the municipalities' other health and care services. The centers are also responsible for equipment, technological solutions and telehealth software. This includes the procurement, logistics, training in the use of equipment and user support. Four different suppliers of technological solutions are involved in the trial, and consequently, technological solutions may vary across the municipalities. In addition, the centers may differ in their target population (with respect to main diagnoses), main recruitment channels, and the design of the service itself. For example, the follow-up service may have different opening hours or different physical location (e.g. at the emergency room or at the home nursing care unit).

Patient follow-up

Once it has been decided that a patient will receive telehealth, the GP should, together with the patient, nurse and possibly other health personnel, prepare a follow-up plan based on the patient's goals, disease burden and risk of deterioration. The Norwegian Directorate of Health, in collaboration with the participating centers are currently developing standardized follow-up plans.

Once the follow-up plan has been outlined, the user receives a tablet and potentially measuring instruments. The user is offered training in how to use the equipment. The tablet is used to answer simple questions about the patient's own health and/or perform measurements related to health status (such as blood pressure, blood sugar, oxygen saturation, weight). The registered results are automatically transferred from the measuring devices to the tablet so that user can see them and track their own results over time. The results are also automatically transmitted digitally to the follow-up service, which contacts the user in case of abnormal results.

Patients receiving telehealth will receive follow-up from a nurse[1] at the follow-up service. The nurse monitors the user's measurements and provide medical support and guidance based on the user's needs. The nurse will respond

[1] Centers involved in the pilot study with multidisciplinary care teams may engage the same nurses in follow-up of patients receiving care from both multidisciplinary care teams and telehealth follow-up.

to abnormal results, and will, in consultation with the patient, consider whether the user should contact the GP or the emergency room.

The health personnel will, in consultation with the user, determine how often the user should carry out the measurements. For most user's, the frequency of the measurements will be gradually reduced over time. Different health conditions and diagnoses will require different follow-up; thus, the frequency of measurements will vary across users. The frequency of measurements will be recorded.

The technological solutions will inform the patient and the follow-up center when the measurement results deviate from the normal values for the user. The threshold values for when measurements are considered abnormal are dynamic and defined in consultation between the health personnel and the user. The notifications are illustrated by red, yellow or green, and the employees in the follow-up service act based on previous measurements from the user, threshold values and / or the user's perception of their own health that day. If a user does not perform the scheduled measurements, this can also cause the follow-up service to contact the user.

4.2 Standard clinical care

Patients who are assigned to the control group will receive standard clinical care. Exactly what kind of care they will receive depends om their illness and their needs.

5. Recruitment of study participants

Potential participants are first proposed by health personnel at hospitals or in municipal health and care services, by GPs, by patients themselves or their relatives, either directly to the patient's GP or to the project administration (possibly via the municipal allocation office[2]) (step 1 in Figure 3). Participation proposals are forwarded from the project administration to the GP. Then, the GP, who has the medical responsibility for the patients on their patient list (i.e., within the GP scheme), is responsible for deciding whether the patient is eligible for receiving telehealth (step 2). In cases where the GP receives proposals directly, the GP makes this assessment immediately. If a patient is considered eligible, the patient is invited to an information meeting with a project employee where the patient is offered the opportunity to participate in the trial (step 3). If the patient gives her consent to participate in the trial, the patient is randomized into an intervention or a control group (step 4). Randomization takes place in connection with the information meeting, and the project administration is responsible for the randomization. Thereafter, the patient receives further follow-up depending on which group they are allocated to (step 5).

Figure 3: Recruitment in the randomized control trial of telehealth

5.1 Step 1: Potential participants are proposed for the trial

Both patients themselves, relatives, general practitioners and health care personnel at hospitals or in the municipal health and care service may propose relevant patients for the trial of telehealth. If the patient himself proposes to participate, the procedure will be adapted depending on where the patient first approaches his / her desire for participation (see below). Patients who are proposed as study participants will be informed that the trial of telehealth is carried out as a randomized-controlled trial.

Recruitment via health personnel in hospitals or in municipal health and care services

Health personnel (of any type) in the specialist health service or in the municipal health and care service may propose patients for the trial. Health personnel who recruit patients should be familiar with the inclusion criteria. The health personnel may conduct an informal, introductory conversation with relevant patients and inform about

[2] By municipal allocation office, we mean the unit in the municipality that makes decisions about which municipal services are to be granted.

telehealth and the related trial (including the recruitment process and follow-up). The conversation will form the basis for an assessment of the patient's interest and motivation for participating in the trial, as well as the prerequisites for using simple technology. The patient must (orally) consent to being proposed for participation in the trial. Health personnel make an overall assessment of eligibility based on the conversation with the patient and, if deemed eligible, send a proposal for participation in the trial. The proposal is sent to the patient's GP or the center's administration (depending on how the local organization of the service). Such a notification constitutes an important part of the decision-making basis for the GP who decides whether the patient is suitable for participation in the trial. The message should be concise and contain information about the patient's state of health, suitability for telehealth, and motivation, as well as confirmation that the patient is informed about the trial. The centers prepare routines for how the message is transmitted from health personnel to the GP, to ensure the patient's safety and privacy.

Recruitment via the general practitioner

GPs who participate in the trial assess which patients on their list can benefit from the use of telehealth, based on their own knowledge of the patients. In the face of patients who are suitable for telehealth, the GP can discuss the items as described above (in the section "Recruitment via health professionals in hospitals or in municipal health and care services") with the patient and then report the patient to the project administration.

Self-recruitment or recruitment through relatives / acquaintances

Patients and their relatives may suggest themselves as participants in the trial. This may occur if the patient for example hears about medical distance monitoring via acquaintances, reads about it in the newspaper or the like. These patients can contact the GP, the health personnel in the municipality or the specialist health service to get in touch with the project administration.

5.2 Step 2: The GP assesses eligibility

The Norwegian Directorate of Health has planned that approximately 100 GPs will participate in the trial. The centers have signed letters of intent with GPs who are committed to recruiting patients for the trial. The GP has the medical responsibility for the patients on their list and should therefore assess the patient's eligibility for telehealth (i.e., whether the patient meets the inclusion criteria) based on their knowledge of the patient, patient records and the information in the proposal message from the project administration or other health personnel.

Practitioners who are not informed about the trial

Some patients, who are recruited from hospitals, home care services or others, may have a GP who is not involved in the trial (and thus did not sign a letter of intent). These GPs may not be familiar with the trial. In these cases, the project administration will inform the GPs about the trial. These GPs can recruit patients to the trial on the same basis as GPs who have been involved from the start of the trial.

5.3 Step 3: Patients are invited to participate in the trial

Patients who have been deemed eligible for participation by the GP will be contacted by the project administration and invited to an individual meeting where the patient is invited to participate in the trial. The information meeting can be held at the project employee's workplace, or at the patient's home if necessary due to the patient's health condition. At the information meeting, the project employee will inform the patient about the trial and about telehealth. The meeting will include:

- Information about the trial and what participation means for the patient. The Norwegian Directorate of Health and the centers have prepared information material (a brochure and an information film) that can be used as a basis for the discussion.
- Obtaining consent for participation (see details below)
- Completion of a questionnaire about her physical and mental health, follow-up from and experiences with the health and care service, and background information, including demographics, marital status, place of residence and housing, scope of informal care from family and friends, use of other types of welfare technology (security alarm, self-help tools, etc.).
- Randomization into intervention or control group (see section 5.4)
- Information on further follow-up (see section 5.5)

Obtaining consent for participation

After the project employee has informed the patient about the trial and what the participation entails, the patient is asked whether he / she agrees to participate in the trial. If the patient agrees to participate in the trial, the patient signs the consent form. A requirement for participation is that the patient is competent for consent. Relatives cannot consent on behalf of the patient. The patient cannot receive telehealth without the consent to participate in the trial.

If the patient does not agree to participate in the trial, the meeting ends, and the patient is followed up further by the healthcare service according to standard clinical care. In this case, the patient will not be able to receive telehealth, and patient information is not recorded as part of the trial. However, anonymous information is registered to inform the analysis of loss-to-follow-up (see section 9.5). If the patient does not agree to participate in the trial, the randomization envelope is not opened, and the project employee brings the unopened envelope back to the office and place it back in the stack of envelopes.

If the patient needs more time before he / she decides whether to participate or not, the patient may have a reflection period of a maximum of two weeks. Equipment for the use of telehealth cannot be delivered to the patient before the patient has signed the consent statement for participation in research.

5.4 Step 4: Consenting patients are randomized

Patients who agree to participate in the trial sign the consent form before the randomization process. Once the patient has signed the consent form and completed the baseline questionnaire, the patient and the project employee open the randomization envelope together. The project employee informs the patient about the outcome of the randomization and explains how the follow-up will be organized (described in more detail in chapter 5.5). The meeting ends, and the project employee ensures that the patient is followed up in accordance with the protocol according to assigned treatment group (i.e., intervention / control).

Participants in the control group may, after the end of the follow-up period, receive a new assessment of the use of telehealth. Participants who withdraw their consent will be able to receive a new assessment no earlier than one year after the consent is first signed.

5.5 Step 5: Assessments of participants

Assessments the intervention group

How telehealth will be delivered will vary between both centers and individual patients. During the information meeting, the patients are informed of what is expected from them in connection with the evaluation of the trial (Table 2). Participants in the intervention group will be asked to complete a questionnaire every six months during the follow-up period, which lasts up to18 months. The first questionnaire is completed at the information meeting. The questionnaires are distributed by mail.

Some users (and their relatives) will be requested to be interviewed one or two times during the project period. In addition to questionnaires and interviews, we collect information about the patients from various administrative registries, including the use of health and care services within municipal health and care services, the fixed-care service and the specialist health service. Details of the registry data are described in Table 3.

Table 2: Assessments of participants in the trial

	Intervention group	Control group
Questionnaire	• Survey every six months for 18 months • The collection of survey information is terminated in June 2021	• Survey every 6th month for 18 months • The collection of survey information is terminated in June 2021
Interviews	• Selected participants are interviewed once or twice during the follow-up period	• None
Registry data	• Registry data are collected for the period 2017-2022	• Registry data are collected for the period 2017-2022

Patient data from the follow-up service	• Data on measurements are collected if the patient uses telehealth • The collection of information is terminated in June 2021	• None

Assessments in the control group

Patients included in the control group receive regular follow-up from the health service. They are informed that they are expected to participate in the trial by completing a questionnaire every six months during the follow-up period, which lasts for up to 18 months or until the patient withdraws their consent for participation. The first questionnaire is filled out at the information meeting. The following questionnaire is distributed by mail. We will collect registry data for the participants in the control group (corresponding register data for the participants in the intervention group). After the follow-up period, participants in the control group may receive a new assessment related to telehealth.

5.6 After the follow-up period

After completing the 18-month follow-up period, the participants can have a new the assessment of eligibility for the use of telehealth if the municipality continues the service. If a patient in the intervention group still receives telehealth, we will continue to record information from the follow-up service unless the patient does not consent to this. We will collect this information until June 30, 2021.

We will obtain registry data information covering all participants in the period 2017-2022. We collect data after the follow-up period to allow potential analyses of longer-term effects.

5.7 Withdrawal from the intervention and/or the trial

Patients may withdraw from receiving telehealth at any time during the study period, without reasoning, by contacting the local project administration. Study participants may withdraw from the trial with or without withdrawing their consent to participate. If a participant withdraws from the trial and withdraws the consent, collected information about the patient will be deleted and no additional information will be collected. If the patient withdraws without withdrawing their consent, collected information will be stored and used in the evaluation. The patient will be asked if he/she is willing to participate in the evaluation through questionnaires or interviews. The patient will also be asked if registry data can be collected until the end of the project period.

The municipality is responsible for following up patients who are withdrawing from the trial.

Trial discontinuation

The randomized control trial may be discontinued in the event of any of the following

- Occurrence of adverse events unknown to date with respect to their nature, severity and duration
- Medical or ethical reasons affecting the continued performance of the trial
- Difficulties in the recruitment of patients
- Continued financing of the trial is not prioritized by the Parliament

5.8 Exceptions from the study procedure: patients enrolled in the previous trial who wishes to continue receiving telehealth

Patients who already receive telehealth within the previous trial of telehealth at the start of the new trial continue to receive telehealth and will not be included in the current trial.

5.9 Linkage to other registers

In addition to variables collected in the trial, patients are asked to give consent to collection of data from registries such as the Norwegian Prescription Database, The Norwegian Health Economics Administration and the Norwegian Patient Register. This allows certain outcomes to potentially be obtained through linkage to national medical or public registers and databases to answer research question related to health economics.

6. Assessments

6.1 Physical and mental health

One of the three main goals of the effect evaluation is to investigate the effect of telehealth on the users' health status, including physical and mental health, and associated health-related quality of life.

The study population consists of relatively old and ill patients with chronical illnesses. Previous experiences suggest that comorbidity is common in this group. The hypothesis is that the use of telehealth will improve the physical and mental health of the intervention group relative to the control group. Given the medical condition of the study population, a relative improvement in the physical health does not necessarily correspond to an absolute improvement. Rather, it is expected that the use of telehealth can lead to a stable development or a slower decline in physical health compared to the control group.

Health-related quality of life (EQ-5D)

We focus on self-reported health status using the validated questionnaire EuroQol 5 Dimensions 5 Levels (EQ-5D-5L) which is used to measure health status and associated health-related quality of life. The form contains five dimensions of health, including walking, personal care, ability to perform common tasks, pain / discomfort and anxiety / depression. For each of these dimensions, the patients indicate a level of 1-5, which describes the degree of health problems within each dimension (no problems, some problems, moderate problems, severe problems, extreme problems). The response combination of level within each dimension allows a total of 3125 different health conditions. Research-based methods have been developed to assign a quality of life value between zero and 1.0 to each of the 3125 combinations.

We will measure patients' EQ-5D scores during follow-up. Changes in EQ-5D scores for patients in the intervention group will be compared with changes in EQ-5D scores in the control group. Telehealth is considered to improve health-related quality of life if patients in the intervention group experience a statistically significant improvement (at a 95 % confidence level), or a lower deterioration, in health-related quality of life during follow-up compared with patients in the control group.

Physical functioning (IPLOS functioning score)

A relative improvement in physical functioning is measured as the difference in the IPLOS functioning score between the intervention and control group.

Sleep quality

Participants are asked "Hvis du tenker på de siste 7 dagene, i hvilken grad har du... A) Hatt problemer med å sove om natten B) Hatt problemer med å sove for mye?" (If you think about the last 7 days, to what extent have you experienced the following a) had problems sleeping at night b) had problems sleeping too much?) Answers on a four-point scale ranging from "Not at all" to "To a very large extent".

Coping with one's disease

Participants are asked several questions about their coping with their medical conditions and how they are managing their everyday lives.

- I hvilken grad opplever du at du har kontroll over helsesituasjonen din? (To what extent do you feel that you have control over your health situation?)
- I hvilken grad opplever du at helsetilstanden din gjør det vanskelig å planlegge hverdagen? (To what extent do you feel that your health condition makes it difficult to plan everyday life?)
- I hvilken grad opplever du at du forstår din kropps signaler og symptomer? (To what extent do you feel that you understand your body's signals and symptoms?)
- I hvilken grad opplever du at helsetilstanden din gjør det vanskelig å realisere dine evner og mål? (To what extent do you find that your health condition makes it difficult to realize your abilities and goals?)

Answers on a four-point scale ranging from "Not at all" to "To a very large extent".

Qualitative assessments

The quantitative assessments described above are supplemented with insights from interviews on the themes listed above. Interviews are conducted with a sample of patients, relatives, and GPs and other health personnel. An overview of the interviews to be conducted is found in Table 5.

6.2 Patient experience

Overall satisfaction with treatment and follow-up

Patients are asked "I hvilken grad er du fornøyd med oppfølgingen av din helse?" (To what extent are you satisfied with the follow-up of your health?). Answers on a four-point scale ranging from "Not satisfied at all" to "Very satisfied"

Satisfaction with involvement of the GP

Patients are asked "I hvilken grad opplever du at din fastlege er tilstrekkelig involvert i oppfølgingen av din helse?" (To what extent do you experience your GP is sufficiently involved in the follow-up of your health?) Answers are reported on a four-point scale ranging from "Not at all" to "To a very large extent".

User involvement

Patients are asked "I hvilken grad opplever du at du har mulighet til å medvirke til din egen behandling?" (To what extent do you experience that you have opportunity to contribute to your own treatment?) Answers are reported on a four-point scale: "Not at all" to "To a very large extent"

Qualitative assessments

The quantitative assessments described above are supplemented with insights from interviews on the themes listed above. Interviews are conducted with a sample of patients, relatives, and GPs and other health personnel. An overview of the interviews to be conducted is found in Table 5.

6.3 Use of health and care services

The use of health and care services is analyzed using information from various national registers. Health and care services include all kinds of services from primary and specialist health care providers. The use of health and care services is registered for all participants in the period 2017-2022. Thus, the use of health and care services can be followed at least two years before and up to three years after recruitment.

Use and costs are calculated on a yearly basis from recruitment.

The following outcomes are analyzed:

- The number of consultations with the GP
- Contact with the follow-up service
- Number of visits to the home service
- Scope and composition of home-based care services
- Number and scope of municipal emergency unit (KAD) stays
- Number of contacts with emergency services
- Number and composition of outpatient consultations and day treatments
- Number, scope and composition of hospital admissions and bedtime
- Number of emergency admissions due to complication of chronic disease
- Number and composition of consultations with private specialists
- Scope and composition of drug use

Total health and care cost per person

Total costs for health and care services per person are calculated on a yearly basis using publicly available statistics of cost related to the use of health and care services and actual use of health and care services. Total costs are also split between different parts of the health service (primary and specialist health care services).

6.4 Process evaluation

We will evaluate the process, that is, examine how the service is developed and implemented within the local context. In this exploratory analysis, we will mainly rely on in-depth interviews with key actors in the different health care contexts, supplemented with survey data. Examples of topics are:

- Organization of the service in the municipality
- Involvement of other health care providers: the GP, home nursing, specialist health care
- Extent of follow-up
- Technological solutions
- Involvement of users and their relatives
- Patient's own treatment plan
- Inclusion and exclusion criteria
- Financing of the service
- Telehealth in municipalities with primary health care teams

The process evaluation will rely om insight from interviews.

6.5 Cost-benefit analysis

In Norway, cost-benefit analyses are used to inform decision making and prioritization across all sectors of the economy. The purpose of this cost-benefit analysis is to assess the overall benefits and costs of the use of telehealth. This analysis will also elucidate distributional effects and an assess the societal value of telehealth (including an assessment of which factors are essential in ensuring the value of telehealth).

The analysis will use data obtained in the effectiveness study and in the process evaluation, supplemented with separate collection of national statistics, interviews with key stakeholders and findings in the research literature. The analyses are carried out in accordance with the steps in the guide for socioeconomic analyses from the Directorate for Financial Management (Direktoratet for økonomistyring, 2018) and the specific guidelines for analyses from the Norwegian Directorate of Health (Helsedirektoratet, 2012). In accordance with the framework, the analysis includes all types of effects, both monetized and non-monetized effects, as well as intended and unintended effects.

According to the current guidelines for conducting cost-benefit analyses in Norway (Direktoratet for økonomistyring, 2018), the consequences of telehealth will be measured against the zero alternative, which in this case involved standard clinical care.

Other pilot projects that may be partly overlapping with this study (for example, multidisciplinary care teams within primary care (Helsedirektoratet, 2018) and structured interdisciplinary follow-up teams (Helsedirektoratet, 2018)) have also been implemented in this same period. We will assess whether the various interventions "cannibalize" or "accelerate" the beneficial effects when interacting (decreasing vs. increasing marginal benefit).

We will assess the societal value based on the monetized effects, and then consider to what extent non-monetized effects contribute to the societal value. After an assessment of key uncertainties and distributional effects, the value of introducing telehealth can be compared with standard clinical care. The analysis of distributional effects will shed light on how benefits and costs are distributed between primary and specialist health services, as well as in the general population and for general practitioners, municipalities and health enterprises.

7. Safety monitoring and reporting

The local centers are responsible for the detection and documentation of adverse events.

8. Data Management and monitoring

8.1 Case report forms (eCRF)

Staff at the local centers enter the data required by the protocol into the electronic Case report forms (eCRF) and are responsible for assuring that data entered the eCRF is complete, accurate, and that entry is performed in a timely manner. If any assessments are omitted, the reason for such omissions should be noted in the eCRFs. Corrections and the reason for these will also be recorded.

The case report forms are developed in Microsoft Excel.

8.2 Source data

The following data are recorded directly into the eCRF by the project administration:

- Health-related information: diagnoses (main diagnosis, other diagnoses) use of other types of welfare technology (safety alarm, self-help tools, etc.)
- Information related to recruitment to the trial: consent, intervention / control group, recruitment channel, important dates (first inquiry, information meeting, signed consent, start-up, termination), equipment provided, cause of any interruption
- In addition, simple anonymous registration of gender, age (in categories), and recruitment channel (hospital, municipal health and care service, GP, self-recruitment), main diagnosis, as well as the reason for the drop-out of those who are invited to participate but who do not want to participate.

8.2.1 Data from national administrative health registers

Data will be used at the individual level from various health registers and administrative registers, and these will be linked at the individual level. Data will also, after consent, be linked to information from surveys and from the follow-up service. Register data is obtained for all participants in the trial in the period 2017-2022.

An overview of the different registries and variables is provided in Table 3.

Table 3: National administrative health registers

Data source	Type of variables
The Norwegian Health Economics Administration Database (KUHR)	Use of GP and emergency room services.
General practitioner register (Fastlegeregisteret)	Information about patient's GP
Municipal patient and user register (KPR)	Use of municipality health and care services
Norwegian Patient Register (NPR)	Use of somatic and psychiatric hospital services (in-patient and out-patient)
Norwegian Prescription Database (Reseptregisteret)	Use of pharmaceuticals
The participating municipalities' EHR systems	Use of municipality health and care services
Municipality-State-Reporting (KOSTRA)	Resource use at municipal level

8.2.2 Data from surveys

As part of the evaluation, we will carry out three different surveys: to users, to general practitioners and to employees in the follow-up service. The surveys are used to obtain both quantitative and qualitative data. Quantitative data is obtained in areas where register data does not extend, e.g. in areas such as health status, quality of life, patient experience, as well as time spent and quantitative assessments of telehealth. The

questionnaires are also used to obtain information of a more qualitative nature, typically in the form of open questions about i.e., patient experience, or health personnel's assessments of recruitment, organization, benefits and challenges. The surveys are a useful supplement to interviews as they reach a larger number of respondents, thus providing more breadth than a limited range of interviews. Insights from the surveys can often be followed up in interviews and in this way the various data sources complement each other. An overview of the surveys is presented in Table 4.

Table 4: Overview of surveys

Recipients	Time	Distribution	Number of recipients	Themes	Control	Questionnaire
Participants (intervention and control group)	At recruitment, and thereafter every six months. Max. 4 times.	Postal	600	Health related quality of life (EQ-5D), valuation of own health, sleep quality, physical activities, mental health, coping, user experience in the health and care service, demographics	Randomized control group	Appendix B – Participant questionnaire
General practitioners	Fall 2019, Spring 2021	Electronic	All who have patients in the trial	Recruitment, inclusion and exclusion criteria, follow-up of participants, cooperation with other health and care providers, experiences with telehealth	None	Appendix C – GP questionnaire
Follow-up service	Fall 2019, Spring 2021	Electronic	All employees in the follow-up service	Recruitment, inclusion and exclusion criteria, follow-up of participants, cooperation with other health and care providers, experiences with telehealth, time-use	None	Appendix D – Follow-up service questionnaire

8.2.3 Interviews

During the project period, interviews will be conducted with several different stakeholders: patients, relatives, GPs, employees in the follow-up service, the local center administration, municipal administration, employees in the municipal health and care services and the specialist health service.

There are two purposes of the interviews:

1. Provide input for the process evaluation by shedding light on issues, such as recruitment, participation and organization of the telehealth service. The target group is typically users and relatives, as well as employees in the health service with close association with the trial.
2. The second purpose of the interviews is to obtain information for the cost-benefit analysis. For this purpose, we also interview persons with managerial responsibility in municipal administration, municipal health and care services, and in the specialist health service.

An overview of planned interviews is shown in Table 5.

Table 5: Overview of interviews

Target group	Time	No. of respondents	Themes	Type of interview
Users of telehealth solutions	2019, 2021	2-5 per center	Patient experience, safety, coping, health status, recruitment	Individual

Participant in the control group	2019, 2021	1-2 per center	Patient experience, safety, coping, health status, experiences in the control group	Individual
Relatives	2019, 2021	2-3 per center	Experience with telehealth, time-use, coping, security, shift of responsibility and work tasks	Group (together with user of telehealth)
General practitioners	2019, 2021	2-3 per center	The local and national context, Recruitment, inclusion- and exclusion criteria, follow-up of telehealth patients, collaboration with other health care providers, costs and benefits (for patient, doctor, society), follow-up of patients in the control group.	Individual
Employees in the follow-up service	2019, 2021	At least one per center, preferably all	Success criteria for good medical follow-up, how to succeed in practice, costs and benefits (for patient and society), organization of follow-up service, collaboration	Group
Local center administration	2018, 2019, 2020, 2021	All	Collaboration with other health care providers, organization, national context, costs and benefits (patient, health and care services and society), challenges, shifting of tasks and responsibilities, follow-up of patients in the control group	Group
Representatives from the municipality health and care services	2019, 2021	1-5 per center	Local and national context, recruitment (inclusion / exclusion criteria), collaboration and interaction, costs and benefits (patient, health and care services and society), challenges, shifting of tasks and responsibilities	Group
Representatives from the specialist health care services	2019, 2021	1-5 per center	Local and national context, recruitment (inclusion / exclusion criteria), collaboration and interaction, costs and benefits (patient, health and care services and society), challenges, shifting of tasks and responsibilities	Group

8.2.4 Data from the follow-up service

The researchers are investigating the possibilities of obtaining data from the follow-up service. Two types of data are required from the follow-up service:

- Patient registrations (answers to questions related to patients physical and mental health and measurements transferred to the follow-up service via the tablet)
- Contacts with the follow-up service

Patient measurements

As part of the medical distance follow-up, users answer simple questions about their own health and day-care. Some carry out simple measurements, i.e. weight, temperature, blood pressure or oxygen measurement. This data is sent to and registered with the follow-up service. By linking data from the follow-up service to other health registers, we will be able to form a more comprehensive picture of the patients' health status and their development. Tabell 6 gives an overview of the most important types of data. These data are naturally only available for patients in the intervention group.

Tabell 6: Overview of patient registrations (non-comprehensive)

Type of data	Outcome measure
Questions related to physical and mental health	• Assessment of current health status • Breathing • Mood
Measurements	• Blood glucose • Long-term blood sugar (HbA1c) • Blood Pressure • Weight • Temperature • Oxygen measurement / spirometry? • Pulse

Contacts with the follow-up service

If possible, we would like to have access to aggregated data on inquiries to the follow-up service at project and monthly level. Information on the use of the follow-up service will constitute an important part of the data basis for the socio-economic analysis.

It will be relevant to analyze the following types of information: number of users (new, active, completed), number of users with additional need for training, number of measurements, number of contacts (electronic and telephone), number of deviations on equipment, number of maintenance tasks, number of contacts with GP and other health personnel, courses for employees, etc. Exactly what information can be delivered depends on the service provider. This type of information will not be linked to individual users.

8.3 Study monitoring

The researchers will on a regular basis check the following:

- Informed consent process
- Reporting of adverse events and other safety data
- Adherence to protocol
- Maintenance of required regulatory documents
- Data completion of the CRFs

8.4 Confidentiality

The municipalities are responsible for the secure retention of the patient identification and the code list. The eCRFs are linked with other source data by the Norwegian Prescription Database, who will replace the social security number with an anonymous personal identifier. The linked data material is delivered to the researchers without the social security number, but with the anonymous personal identifier.

8.5 Database management

A data management plan will be developed describing the quality control of the CRF, data entering procedures, coding and security. Patient files shall be kept for the maximum period permitted by each municipality. The study documentation shall be retained and stored during the study and two years after study closure. All information concerning the study will be kept in a safe place inaccessible to unauthorized personnel.

8.6 Collection and storage of data

Different types of source data will be collected in the study, and strict data retention requirements are set. It will include data processing agreements between the researchers and all participating municipalities, as well as with the suppliers of the technological solutions if they supply data to the project, and other third parties involved in the study.

Services for Sensitive Data (TSD) at the University of Oslo will be responsible for storing linked data in the project. Only authorized project members will have access to data from this server.

The register data is collected up to and including 31.12.2022. Then, data is stored for up to two years before they are deleted (31.12.2024).

The research consortium is together responsible for all data collected in the study. However, main responsibility for the different sources are distributed as follows:

- University of Oslo has the main responsibility for the collection and storage of the registry data
- Oslo Economics has the main responsibility for the collection and storage of the survey and interview data

9. Statistical method and data analysis

9.1 Determination of sample size

The Norwegian Directorate of Health decided that 600 participants should be included in the trial, and the participating centers have committed to recruit patients according to this goal. This should not be regarded as a ceiling for how many patients can be recruited, and the centers have stated that they hope to recruit a larger number of participants. The sample size was decided by the Norwegian Directorate of Health prior to involvement from the research consortium, and power calculations were not used to calculate how many patients should be included in the trial.

The power calculations in Table 7, are based on the results of the previous trial of telehealth that was carried out by the NDH in 2016-2018 (Intro International, 2018). The trial investigated of the same endpoints, for a similar population. However, in the previous trial there was a greater spread in the degree of morbidity, but somewhat less spread in terms of diagnosis compared with the trial that is now being carried out. The number of users was also lower in the previous trial than we expected in this trial. Thus, there is some uncertainty associated with the reported standard deviations, and followingly, the calculations may overestimate the required sample size.

In Table 7, we focus on four outcome measures: self-assessed health status (VAS) from the EQ-5D questionnaire, number of regular GP consultations, number of outpatient consultations and number of bed-days in hospitals..

From the previous trial, we know that after 5 to 9 months of telehealth follow-up, users reported self-rated health state at 0.612 (on a scale of 0 to 1), and this decreased by an average of 0.105 units from start-up. Thus, the users of medical distance monitoring experienced a decrease in self-assessed health status, but our hypothesis is that a control group would experience an even greater decline. In panel A, we show the required sample size to identify a statistically significant effect at a 5 % level with strength of 80 % for three different outcomes: that the action group reports 0.05, 0.08 or 0.105 lower reduction in self-assessed health status during the follow-up period compared to with the control group. In panel B, the desired sample size is calculated based on the number of GP consultations per year. In the previous trial, the participants experienced an average reduction of 2 visits per year compared to an average of 14.66 regular visits per year. We assume that the control group will be able to experience unchanged or increased number of GP consultations, and therefore calculate strength based on scenarios with a difference of 2-4 doctor visits. In panels C and D, the same calculations are repeated for the number of outpatient consultations and emergency days. The same reasoning applies.

Our assessment is that a sample size of 600 is enough to estimate significant effects of telehealth, but that a larger sample is preferable. The NDH and the participating municipalities are informed about this and work to increase the number of participants.

Table 7: Power calculations

	Mean, *intervention* (st. dev.)	Difference from control	N intervention	N control	N total
		0,050	356	356	712
A. Visual analog scale (VAS)	0,612 (0,238)	0,080	139	139	278
		0,105	87	87	174
		-2	908	908	1816
B. No. of consultation with GP	14,66 (15,21)	-3	404	404	808
		-4	227	227	454
		-0,5	1081	1081	2162
C. No. of outpatient consultations	2,34 (4,15)	-1	270	270	540
		-1,50	120	120	240
		-1,33	1371	1371	2742
D. No. of emergency inpatient days	4,14 (12,43)	-2,00	606	606	1212
		-2,50	388	388	776

9.2 Randomization

Patients who agree to participate in the trial are randomized 1: 1 to the intervention and control group. The treatment allocation is non-blinded in that both providers and patients will know the outcome of the treatment allocation. The actual randomization is carried out by a project employee in the local centers. The project administration stores sealed randomization envelopes in their office.[3] Each sealed envelope contains a sheet marked with either "tiltak" (intervention) or "kontroll" (control), which determines which group the patient is placed in. For each GP in the trial, there is a separate stack of six envelopes: three " intervention " and three "control". Each time a patient on GP's X's list is invited to an information meeting, the project employee takes the top envelope from GP's stack of envelopes. If more than six patients are recruited on the GP's patient list, the project employee will receive a new stack of six envelopes for this GP. Thus, we can ensure that there will be approximately equal distribution of intervention and control patients from each GP. Oslo Economics distributes the stacks of opaque envelopes to the projects.

If a patient is invited to an information meeting and the patient's GP has not previously been involved in the trial, a separate stack of envelopes for this GP should be obtained prior to the meeting so that the patient can be randomized into the trial.

For each information meeting (chapter 8.3), the project employee takes an envelope from the appropriate GP's stack *without opening it*. The envelope is opened together with the patient after the consent form is signed, and the questionnaire is filled out. If the patient does not agree to participate in the trial, the envelope remains sealed. The project employee brings the sealed envelope back to the office and puts it back in the proper stack of envelopes.

[3] This randomization technique was considered the best practically implementable technique given the practical implementation of the study.

9.3 Sample for analysis

We will study the following range of patients:

- Intention to treat (ITT) population: this is the sample of randomized patients, regardless of whether they are followed up using telehealth or not
- Per-protocol (PP) population: this is the sub-sample of the ITT population that follows the study protocol during the entire follow-up period (12-18 months)
- Safety population: this is the subset of the ITT population that begins follow-up (uses telehealth), and either completes follow-up or withdraws from the study.

The analysis will mainly be carried out using the ITT population. The reason for this is that loss-to-follow-up is likely to bias the results so that we estimate a greater effect of the use of telehealth than what is estimated by focusing on the PP population. Thus, an analysis of the ITT population is a more conservative estimate.

In addition, we will carry out analyses where we compare the outcome of the intervention group with one or more registry-based control groups. The control groups can be selected based on discretionary assessments and / or by means of statistical methods, e.g. propensity score matching. It will be possible to base the choice of control group on variables such as gender, age, diagnosis and municipality of residence. The results of such an analysis will have to be interpreted with caution but will constitute an interesting supplement to the rest of the analysis.

9.4 Statistical analysis

The aim of the trial is to estimate the effects of telehealth on the three outcomes of health status, patient experience and resource use in the health service. The choice of statistical method for analyzing the data will be adapted to the characteristics of the outcome variables in question.

Non-parametric methods

For several variables, both from registers and from the surveys, we will use non-parametric tests such as Wilcoxon signed ranks test or McNemar test. In these tests, each of the collected variables is examined separately, and the null hypothesis is that there is no difference between the intervention and control group. This null hypothesis could be rejected if the individual test's test observer is above critical limit. We will use the conventional significance level of 5% in the statistical analyses. For the analyses of variables where we utilize the randomization of intervention and control group, statistically significant differences between the groups could have interpretation as causal effects.

For parts of the data material, information will only be available for the participants in the intervention group. This applies to information that is directly related to receiving telehealth. In these cases, we will investigate whether there are changes in outcomes over time. The choice of statistical method could be the same as for other analyses. Significant changes will usually be interpreted as significant associations, but care will be taken to interpret any findings as causal effects.

Parametric methods

For some (groups of) variables, it will be relevant to use different types of regression models to study the effect of telehealth. Both difference-in-difference models and structural equation models will be applied. The use of structural equation models allows to study how telehealth affects a group of variables simultaneously. For example, it will be examined whether telehealth affects a group of health variables, a group of user satisfaction variables, or a group of resource use variables simultaneously. Where necessary, we will use structural equation models that consider that the outcome variables are binary / categorical and that the data material has so-called multi-level structure, since the material consists of repeated observations of the same individuals within the same municipality, over time.

Explanation variables and sensitivity analysis

There is considerable variation in the study. This applies to both the variation in the study population and the organization of the service. Sensitivity analyses will be carried out through inclusion of control variables and subsample analyses, but the extent of such analyses is limited by the relatively small sample size.

9.5 Analysis of loss-to-follow-up

We expect loss-to-follow-up among the participants in the ITT population, and it is important to document this in order to be able to interpret the results. Patients can drop out either before or after consent is given.

We will register anonymous information about patients who drop out before consent is given. This includes gender, age (in intervals), main diagnosis, recruitment channel, reason for non-participation.

Drop-out that occur after the consent has been obtained will be analyzed to ensure that drop-out does not drive the results. Characteristics of those who drop out will be compared to those who complete the follow-up.

Drop out will also be highlighted through interviews with GPs and other health personnel, as well as with the project administration.

10. Study management

10.1 The Norwegian Directorate of Health

The Norwegian Directorate of Health is responsible for the practical implementation of the trial, and will:

- Define the scope of the trial
- Recruit participating municipalities
- Assist the participating municipalities in designing and setting up the service
- Follow the implementation of the project (incl. recruitment targets)
- Partially finance the local projects
- Establish a reference group for the trial

10.2 The researchers

The University of Oslo, Oslo Economics and the Norwegian Centre for Rural Medicine (NCRM) have joint responsibility for developing and implementing the study design. The University of Oslo and Oslo Economics have joint responsibility for data processing. The University of Oslo, Oslo Economics and the Norwegian Centre for Rural Medicine (NCRM) will:

- Develop the research design
- Apply for necessary approval from ethical committees and data protection services
- Draw up data processor agreements with participating municipalities and third parties involved in the study
- Conduct the evaluation as described in this study protocol
- Present results in three reports

10.3 The participating municipalities

- Develop the service
- Implement and run the service according to protocol
- Recruit participants
- Conduct study initiation meetings
- Facilitate data collection

10.4 Study amendments

If it is necessary for the study protocol to be amended, the amendment and/or the new version of the study protocol must be notified to and approved by the management at the University of Oslo and Oslo Economics and the Norwegian Centre for Research data (NSD) according to EU and national regulations.

10.5 Audit and inspections

Authorized representatives of the Data Protection Authority may visit the centers to perform inspections. Likewise, representatives from the Norwegian Directorate of Health may visit the municipalities to perform audits. The purpose of an inspection is to systematically and independently examine study-related activities and documents to determine whether these activities were conducted, and data were recorded, analyzed and accurately reported according to the protocol, and any applicable regulatory requirements.

11. Risk assessment

There are several risks connected with the telehealth trial. Risks are closely monitored by the NDH and the researchers. The following are among the most central risks identified:

Recruitment of participants

There is a worry that the recruitment target will not be reached within June 30, 2020. However, the NDH and the local centers have detailed plans for recruitment and follow the development closely. At the same time, the centers have signalized that they aim at recruiting more patients than they originally signaled.

In December 2019, the NDH will evaluate the recruitment process. If recruitment is insufficient, one option is to terminate the trial.

Spillover of treatment to control group

A drawback of the randomization strategy is that there is a risk that the intervention spills over to the control group. The knowledge of the intervention might affect both the type and extent of the care that the control group receives. The health and care personnel are made aware of this issue. The patients in the study have a need for health care services, and the protocol is that they receive "standard clinical care". In practice, what this means, depends om the patient's medical condition and needs.

It is important for the interpretation of the results of the study, that the actual treatment that the control group receives is studied. This is done in many ways. First, we collect information on the use of health and care services for the intervention and control group from national health registers. Second, we will interview health and care personnel about the follow-up of patients in the control group. Third, we will conduct interviews with patients in the control group about their experiences. Fourth, we plan to compare the outcomes of the treatment and the control group in the study to a register-based control group containing patients with similar characteristics in non-participating municipalities. Thus, we will have an additional control group that is not affected by the trial. This comparison is performed using data from the related evaluation of primary health teams.

If the patients in the control group receive more comprehensive follow-up than they would in the absence of the reform, the effects of the intervention are likely *underestimated*, rather than overestimated.

Heterogeneity in the trial

This telehealth trial is less rigorously designed that many conventional randomized control trials. There is variation in the delivery of the intervention (telehealth), in the follow-up of the control group, and in the study population. This poses some challenges in the analysis of the data, and effects must be interpreted as averages over different types of interventions and groups of patients.

Data management

The data management of the study is challenging. Data are collected and linked from several sources, at several point in time. This requires good procedures for data collection and management. A data management plan har been developed.

12. Ethical and regulatory requirements

12.1 Privacy Policy

It is the joint responsibility of the University of Oslo and Oslo Economics to conduct a Data Protection Impact Assessment (DPIA). A DPIA was conducted together with the Norwegian Centre for Research data (NSD) in

January 2019. The DPIA concludes that the data collection and storage within the project is conducted in accordance with the GDPR.

12.2 Informed consent procedure

The research group and/or the project administration is responsible for giving the patients full and adequate verbal and written information about the nature, purpose, risk and benefits of the trial. They are informed about the strict confidentiality of their patient data, but that their medical records may be reviewed by the researchers for evaluation purposes.

It is emphasized that the participation is voluntary and that the patient can refuse further participation in the trial whenever she/he wants. This will not prejudice the patient's subsequent care. Participants who withdraw their consent may request that all information collected be deleted, unless they are included in publications or articles.

Patients who have not signed the written consent form cannot obtain equipment from the municipality, and consent is thus a prerequisite for participation in the trial. The consent form is enclosed in Appendix A.

A copy of the signed consent statement is given to the patient. Signed consent statements are collected in a suitable folder by the project administration and will also be scanned and stored electronically at the project administration.

Written consent will be also obtained from participants in the evaluation other than those in the intervention and control group. This includes interviewees, such as GPs, employees and the follow-up service, other representatives from the health and care service and relatives.

12.3 Patient Identification

The project administration keeps a record of everyone who has signed consent. This overview includes name, date of birth, and birth number and address. The personal information is stored in a separate password-protected document.

Each participant gets a unique serial number that acts as a link between different data sources. The researchers will not have access to directly identifiable information about the patients.

12.4 Confidentiality

Healthcare professionals participating in the trial have a duty of confidentiality towards the patients. In interviews with health personnel, there will be no questions about individual patients.

12.5 Ethical committee approval

The Regional committees for medical and health research ethics (REK) has assessed the study protocol. In the decision from 26.11.2018, REK stated that the trial falls outside REK's area of responsibility as it was deemed as health services research and not medical research.

12.6 Other regulatory approvals

The protocol will be registered in www.clinicaltrials.gov in summer 2019.

13. Trial sponsorship and financing

The trial is financed by the Norwegian Directorate of Health and the participating municipalities. The evaluation of the trial is fully financed by the Norwegian Directorate of Health.

14. Publication Policy

The results of the trial will be published in two midterm reports and a final report which will be submitted to the Norwegian Directorate of Health (see chapter 15).

We will also consider submitting the results for publication in international peer-reviewed journals.

15. Overall progress plan

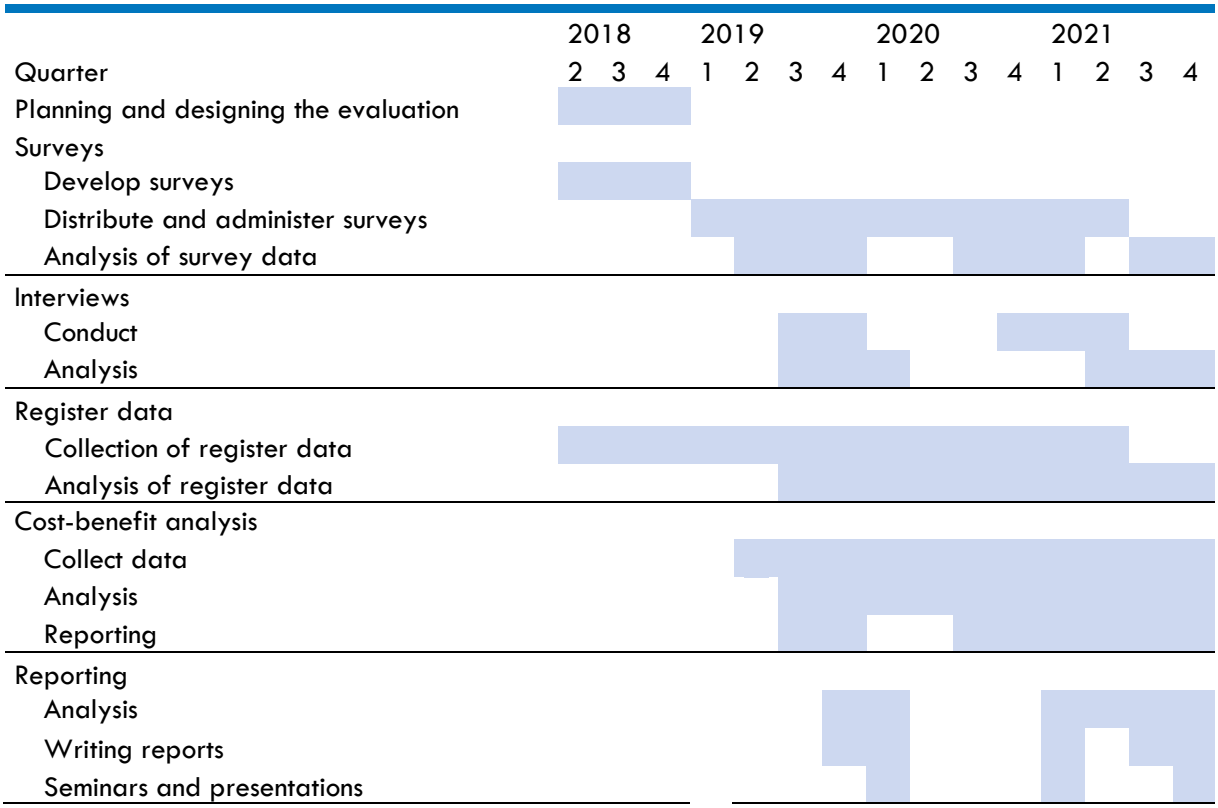
The participating municipalities were recruited in the spring of 2018. The summer and autumn of 2018 were devoted to service development and evaluation design. Recruitment of users and evaluation of the measure started in February 2019. The follow up period ends in the summer of 2021. The exact end date depends on the contract between the Directorate of Health and the individual municipalities.

Table 8 shows important milestones in the evaluation, and Table 9 contains an overview of the progress of the evaluation.

Table 8: Important milestones

Milestone	Date
Recruitment starts	01.02.2019
First midterm report	01.03.2020
Second midterm report	01.03.2021
Recruitment ends	30.06.2020
Final report	01.11.2021
Last survey is posted	30.06.2021
Final report to the NDH	01.12.2021
Register data collection terminated	31.12.2022
Project ends	31.12.2022
Data is deleted	31.12.2024

Table 9: Overall progress plan



Project administration
- Project meetings
- Meetings with sponsor and stake holders
- Project administration n.e.c.

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Appendix A: Participant consent form

This Statement is for your consent to participate in a trial of medical distance follow-up. The purpose of the trial is to find out how telehealth affects health, experience of the health service and consumption of health services. Participation is voluntary. You can withdraw your consent at any time. Below you can read more about the trial and what participation means to you and give your consent if you accept the invitation to participate.

What does participation mean to you?

- As a participant in the trial, you will be asked to complete a short questionnaire up to four times over 18 months, regardless of whether you are part of the group that receives follow-up using telehealth solutions or the control group. Your questionnaire responses are recorded electronically or on paper. In addition, some users will be asked to be interviewed by the researchers. It will take approximately one hour, and audio recordings and notes will be taken from the interviews.
- We will collect and record information about you from various local and national registers. All data will be de-identified, and results will be presented at group level. This means that you will not be able to recognize data that is being analyzed or presented. Table 1 (p. 4) gives an overview of what types of information are collected about you and from which registers.
- The purpose of the data collection is to investigate whether your state of health, experience and use of health services has changed during the trial period. This knowledge will help to further develop and improve the Norwegian health service.

More about the testing

The Directorate of Health has been commissioned by the Ministry of Health and Care Services to
conduct a trial of medical distance monitoring in the period 2018-2021. The University of Oslo, Oslo Economics and the National Center for District Medicine are responsible for the research.
In practice, distance monitoring means that you as a user answer health-related questions on a tablet and/or record measurements related to your health (e.g. blood pressure, blood sugar, oxygen measurement). The information is sent electronically to a follow-up service, where health professionals monitor the measurements and follow you up in accordance with a treatment plan that your GP has prepared in consultation with you. The equipment is easy to use, and you get training at startup.
The purpose of the trial is to find out how distance follow-up affects the physical and mental health of users, user experience and use of resources in the health service. We will also examine how the service is delivered, and assess the costs and benefits of distance follow-up, both for the users, the health service and society as a whole. The Directorate of Health will

use the results of the research as the basis for national recommendations on distance follow-up.
In order to establish knowledge about the effect of distance follow-up compared to current practice, the test is conducted as a randomized controlled trial in selected municipalities. This means that half of those who agree to participate in the trial receive distance follow-up (so-called 'action group') while the other half receive regular follow-up from the health service (so-called 'control group'). It is a coincidence which group you end up in (is determined by lottery). To investigate the effect of distance monitoring on participants' consumption of health services in both the short and long term, we will collect and record information about you from various local and national registries in the period from 2017 to 2022.
If your municipality continues the offer with distance follow-up after the end of the follow-up period (18 months), participants in both the action and control group will have the opportunity to be considered for distance follow-up.

What happens to the information about you?

The information recorded about you will be used as described above. You have the right to access the information that is registered about you and the right to correct any errors in the information that is registered. All information will be processed without name and birth number or any other directly recognizable information. A code links you to your information through a link key. Information obtained is stored on a secure data server. Audio recordings are stored in a locked safe, and notes are stored in a workbook that only the research group has access to on the Oslo Economics network. The project is scheduled to end on 31 December 2024, and audio recordings and information collected will be deleted within three years of the end of the project (by 31 December 2027). Information recorded about you by the employees in your municipality can be used for internal quality assurance in the municipality.

Your rights

As long as you can be identified in the data material, you are entitled to:

- insight into what personal information is registered about you,
- obtaining personal information about you,
- to delete personal information about you,
- obtain a copy of your personal data (data portability), and
- to submit a complaint to the Privacy Ombudsman or the Data Inspectorate regarding the processing of your personal data.

Approval of the test

We process information about you based on your consent.
On behalf of the Department of Health and Society at UiO and Oslo Economics, NSD - Norwegian Center for Research Data AS has considered that the processing of personal data in this project complies with the privacy regulations.

Voluntary participation and opportunity to consent

Participation in the trial is voluntary. If you wish to participate, sign the Declaration of Consent at the bottom of this page. You may withdraw your consent at any time and without giving any reason and may require that information collected about you be deleted. This will not have any impact on your continued use of the public health services. If you later want to retire or have questions about the project, you can contact:
Susanna Sten-Gahmberg, project manager at Oslo Economics, on mobile:
451 34 135, or by e-mail: ssg@osloeconomics.no. Alternatively, you can contact the Privacy Ombudsman at UiO by email: personvernombud@uio.no.

With best regards,

Tor Iversen
Project Manager
Professor at UiO

Consent Statement

I have received and understood information about the project Proof of medical distance follow-up and have been given the opportunity to ask questions. I agree to:

- ☐ Obtaining register information about me as described above (compulsory for participation in the trial)
- ☐ To participate in a survey (compulsory for participation in the test)
- ☐ To participate in an interview
- ☐ That my personal data is stored after the end of the project for research purposes
- ☐ That my relatives can be interviewed about my participation in the trial

I agree that my information will be processed until the project is completed and will be deleted by 31 December 2027.

(Signed by participant, date)

Table 10: Overview of information obtained from local and national registers

Type of information	Variables	Source
General information about you	Age, gender, education, marital status, living situation and place of residence, main source of living (own income, pension, social security, other), household income (at intervals), extent of informal care, use of other types of welfare technology (security alarm, self-help tools, etc.)	Municipal registration and questionnaire
Your use of the GP services	Number of consultations and contacts, selected tariffs and measurements, number of kroner in the form of reimbursement and free cards	The Norwegian Health Economics Administration Database (KUHR), Municipal Patient and User Register (CPR), General practitioner register
Your use of the emergency room service, appointment specialists and physiotherapists with an operating agreement	Number of consultations and contacts, selected tariffs and measurements, number of kroner in the form of reimbursement and free cards	The Norwegian Health Economics Administration Database (KUHR), Municipal Patient and User Register (KPR)
Your use of municipal health and care services	Number of visits and time spent on home services and practical assistance, municipal emergency 24-hour service, short-term stays	Municipal Patient and User Register (KPR), electronic patient record
Your use of specialist health services	Information on outpatient consultations, bed days, admissions including procedures and diagnoses	Norwegian Patient Register (NPR)
Your use of telehealth	Date of start-up and eventual termination, recruitment channel, status, diagnoses, assigned technology	Municipal registration
Your measurements and other records from the follow-up service	Answers to questions about your health, measurements of weight, blood sugar, blood pressure, oxygen measurement, heart rate, spirometry, temperature and other measurements from the test	Follow-up service / municipality / technical solution provider
Your use of medicines	Use of medicines; number, types and doses	Norwegian Prescription Database (NorPD)

Appendix B: Participant questionnaire

ANONYMOUS IDENTIFIER * x x x x *

Telehealth trial: Questionnaire for participants

You receive this questionnaire because you have agreed to participate in a trial of telehealth.

As part of the trial, you will receive a questionnaire about every six months. You will receive a total of four questionnaires during the follow-up period. If you do not return the questionnaire within one week, you will first receive a reminder by mail, and then a reminder by phone. Norsk Gallup manage the survey on behalf of the researchers.

The questionnaire is about your physical and mental health, your experience and satisfaction with the follow-up of your health, as well as background information about you.

Your answers are of great importance, and we appreciate your participation!

If you have any questions related to the survey, please contact Hanna Løyland, project member at Oslo Economics, by email at hil@osloeconomics.no.

Physical and mental health

1. **How often do you engage in physical activity of such intensity that you become somewhat breathless and/or sweaty?**
   - ☐ Every day
   - ☐ 4-6 times per week
   - ☐ 2-3 times per week
   - ☐ Once a week
   - ☐ 1-3 times per month
   - ☐ Less than once a month
   - ☐ Never
2. **To what extent do you engage in physical everyday activities such as gardening, gardening, walking or cycling as a transport?**
   a. To a small extent
   b. To some extent
   c. To a large extent
   d. Do not know

3. **To what extent do you feel that you have a healthy diet that meets your energy and nutritional needs?**
    a. To a small extent
    b. To some extent
    c. To a large extent
    d. Do not know

4. **How often do you participate in social activities?**
    a. Rarely
    b. Occasionally
    c. Often
    d. Do not know

5. **Think about how you have been feeling the past 7 days. To what extent did you feel…?**

    Note: Only choose one option for each line

	Not at all	To a small extent	To some extent	To a large extent	Do not know
Happy					
Enthusiastic					
Calm and relaxed					
Worried					
Depressed or sad					
Irritated					
Lonely					
Concerned					

6. **Think about the past 7 days, to what extent did you…**
   Note: Only choose one option for each line

	Not at all	To a small extent	To some extent	To a large extent	Do not know
Have trouble sleeping at night?					
Have trouble with oversleeping?					
Feel weak, with low energy?					
Experience a loss of appetite?					
Eat too much?					
Feel faint or dizzy?					

7. **All in all, how would you rate your health?**
   - ☐ Very good
   - ☐ Good
   - ☐ Neither good nor poor
   - ☐ Poor
   - ☐ Very poor
   - ☐ Do not know

8. **All in all, how happy are you with your life?**
   a. Not happy at all
   b. Dissatisfied
   c. Neither dissatisfied nor satisfied
   d. Satisfied
   e. Do not know

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

- I have no problems in walking about ❑
- I have slight problems in walking about ❑
- I have moderate problems in walking about ❑
- I have severe problems in walking about ❑
- I am unable to walk about ❑

SELF-CARE

- I have no problems washing or dressing myself ❑
- I have slight problems washing or dressing myself ❑
- I have moderate problems washing or dressing myself ❑
- I have severe problems washing or dressing myself ❑
- I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

- I have no problems doing my usual activities ❑
- I have slight problems doing my usual activities ❑
- I have moderate problems doing my usual activities ❑
- I have severe problems doing my usual activities ❑
- I am unable to do my usual activities ❑

PAIN / DISCOMFORT

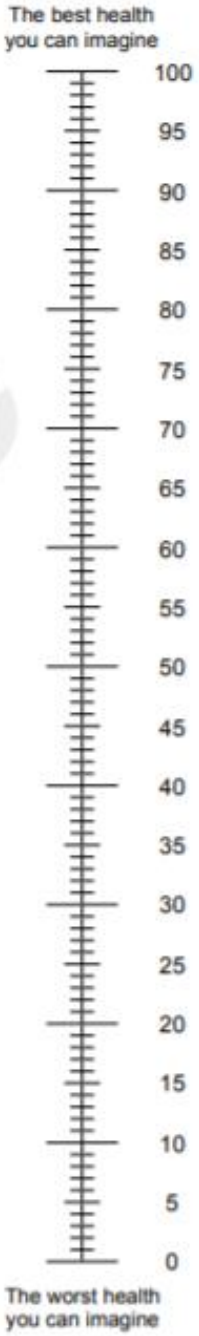
- I have no pain or discomfort ❑
- I have slight pain or discomfort ❑
- I have moderate pain or discomfort ❑
- I have severe pain or discomfort ❑
- I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

- I am not anxious or depressed ❑
- I am slightly anxious or depressed ❑
- I am moderately anxious or depressed ❑
- I am severely anxious or depressed ❑
- I am extremely anxious or depressed ❑

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



Monitoring of own healtg

9. How do you perceive the following?

Note: Only choose one option for each line

	Not at all	To a small extent	To some extent	To a large extent	Do not know
To what extent do you feel in control of your own health?					
To what extent do you feel that your current state of health makes it difficult to plan your everyday life?					
To what extent do you feel that you understand your body's signals and symptoms?					
To what extent do you feel that your current state of health makes it difficult to realize your goals and abilities?					
To what extent do you feel satisfied with the follow-up of your health?					
To what extent do you feel that your regular general practitioner (GP) is adequately involved in following up your health?					
To what extent do you feel that you have the					

opportunity to contribute to your own treatment?					

10. **On average, during the past month, how did you regsiter measurements and/or answer the questionaire on your tablet?**
    a. **More than once a day**
    b. Once a day
    c. **4-6 times per week**
    d. 2-3 times per week
    e. Once a week
    f. Less than once a week

11. **What type of technology do you use in connection with the follow-up on your tablet?** *Choose more than one option if neccessary*
    a. **Tablet**
    b. Scale
    c. Blood glucose monitor
    d. Blood pressure monitor
    e. Pulse Oximeter
    f. Spirometer
    g. Thermometer
    h. Capnograph
    i. Other

12. Consider the following statements.

Note: Only choose one option for each line

	Disagree	Neither agree nor disagree	Agree	Do not know
Registrations via the tablet are difficult to carry out				
Registrations via the tablet gives me ***too much*** responsibility for my own health				

The registrations via the tablet make me feel safer in everyday life				
Follow-up via the tablet does ***not*** fit my health condition				
Follow-up via the tablet does ***not*** affect my health				
Overall, the follow-up via the tablet is of good quality				

13. To what extent are the following aspects of the follow-up of your health via the tablet (telehealth monitoring) important to you?
Note: Only choose one option for each line

	Not at all	To a small extent	To some extent	To a large extent	Do not know/ not relevant
That health care professionals monitor my measurements/ answers my questions					
Being able to monitor my own measurements					
That I can contact the follow-up service if needed					

That the follow-up service sends me tips and advice related to my *health*					

Background information

14. What is your gender?

a. Male
b. Female
c. Do not want to answer

15. What is your mother tounge?

a. Norwegian
b. Swedish, Danish eller Finnish
c. Other
d. Do not want to answer

16. In what year were you born?

---

17. What is your highest level of completed education?

a. Elementary school
b. Primary and lower secondary school
c. Upper secondary education
d. Higher education
e. Do not want to answer

18. What is your marital status?

a. Unmarried
b. Married/ cohabitant/ registered partner
c. Widow/widower
d. Divorced
e. Separated
f. Do not want to answer

19. What is your current living situation?

a. **Live alone**
b. **Live with children**
c. **Live with spouse/ cohabitant/ registered partner**
d. **Live with parents/siblings/other**
e. **Live in residential care home, nursing home, house-share etc.**
f. **Do not want to answer**

20. Do you regularly get help or care from someone who does not receive a salary to help you?
(F*or instance help with personal hygiene, cooking, house cleaning, or to keep track of appointments*.)

a. **Spouse/ cohabitant/ registered partner**
b. **Parents**
c. **Children**
d. **Neighbour**
e. **Friends/ acquaintances**
f. **Other family**
g. **Other**
h. **No, no I do not get help → Go to question 22**
i. **Do not want to answer → Go to question 22**

21. How often do you get help or care from someone who does not receive a salary to help you?

a. **Never**
b. **Once a month**
c. **2-3 times per month**
d. **1 day per week**
e. **2-3 days per week**
f. **4-5 days per week**
g. **6-7 days per week**
h. **Do not want to answer**

22. Do you use any of the following technological aids?

a. **Safety alarm**
b. **Medication Dispenser**
c. **I do not use any of the technological aids mentioned above**
d. **Do not want to answer**

23. What is your main source of income?

a. **Own income**
b. **Pension**
c. **Social insurance**
d. **Other**
e. **Do not want to answer**

24. What is your household's annual income before tax (salary, pension, sickness benefit, social insurance etc.)?

a. **0-200 000 NOK**
b. **200 000-400 000 NOK**
c. **400 000-600 000 NOK**
d. **600 000-800 000 NOK**
e. **800 000-1 000 000 NOK**
f. **1-1.2 million NOK**
g. **1.2-1.5 million NOK**
h. **1.5-2 million NOK**
i. **More than 2 million NOK**

25. Is there anything else you would like to share about the measurements/registrations, the tablet, the follow-up and the use of the technology?

Open answer

Thank you for your participation!

Appendix C: GP questionnaire

Telehealth trial: Questionnaire for GPs with patients who are participating in the trial

Definition of telehealth monitoring

Telehealth monitoring is a broad concept that lacks a clear definition. When we refer to "telehealth monitoring" in this survey, we refer to telehealth monitoring provided within the framework of the test conducted by the Directorate of Health and your municipality. Below is a brief description:

Telehealth monitoring means that the patient can be followed up remotely by the health and care service using technological solutions. Users of remote monitoring can answer simple questions about their health status via a tablet, and take measurements related to their health status (eg blood pressure, weight, O2 saturation). The results are transferred from the measuring devices to the tablet so that the patient can easily see them and monitor their own results over time. The results are also transmitted digitally to a follow-up service. The response service / follow-up service contacts the patient in case of signs of deterioration and measurements beyond what are normal values for the individual. They provide medical professional support and guidance based on the patient's needs and plan for follow-up, and will, in consultation with the patient, consider whether they should contact their GP / emergency room.

Telehealth monitoring can provide better health and better patient experience through targeted use of health care resources. The distance follow-up initiative can come from a general practitioner, a hospital, the patient himself or another health professional. It is the GP who, in consultation with the patient, assesses whether distance follow-up may be appropriate and professionally justified for the individual. The GP will, together with the patient, nurse and any other relevant health personnel, prepare a plan for follow-up based on the patient's goals, symptom picture and risk of deterioration. This plan forms the basis for the follow-up content, frequency and contact point for the individual.

Buy "follow-up service", we mean the unit that monitors the registrations the users send via their tablets. The follow-up service has different names in different municipalities, including the follow-up service, the telemedicine center and the health guard

Inclusion and exclusion criteria:

The target group of the telehealth trial is patients with chronic diseases, with medium or high risk of worsening of one's condition, risk of re-hospitalization or increased need for health and care service. These patients have a high consumption of health care services and the target group consists largely of patients with non-communicable chronic diseases such as diabetes, colic, cardiovascular disease, mental disorders and cancer. This group often has several diagnoses, complex and large needs, and are in need of follow-up of their diseases.

Patients who are not competent to consent, patients who cannot use the tablet or the measuring devices, and patients with substance use disorders, shall not be included in the trial.

In this part of the questionnaire we ask how you experience these inclusion and exclusion criteria.

1. To what extent are you familiar with the inclusion and exclusion criteria for participation in the telehealth trial (other than they are described above)?
    - ☐ Not at all
    - ☐ To a small extent
    - ☐ To some extent
    - ☐ To a large extent
    - ☐ Do not know

2. To what extent do you feel that the inclusion criteria for participation in the trial are suitable?
    - ☐ Not at all
    - ☐ To a small extent
    - ☐ To some extent
    - ☐ To a large extent
    - ☐ Do not know

3. You have stated that you do not at all or to a small extent feel that the inclusion criteria for participation in the telehealth trial are suitable. Can you elaborate?

4. What proportion of patients on your patient list do you estimate meet the inclusion criteria for telehealth?
    - ☐ No one
    - ☐ 1-4%
    - ☐ 5-9%
    - ☐ 10-14%
    - ☐ 15-19%
    - ☐ More than 20%

5. How many patients have you considered for telehealth (by recruiting them yourself or receiving a request from the project administration)?

6. How many of these did you consider not suited for participation?

7. What was the reason you considered these people not suited for participation? (More than one answer is possible)
    - ☐ The patient's health
    - ☐ The patient's ability to use technology
    - ☐ Lack of time for follow-up of patient using telehealth
    - ☐ Lack of time to consider and understand what telehealth is
    - ☐ Other

8. You have stated that there was another reason why you considered one or more people not suited. Can you elaborate?

9. Do you have any other comments related to the inclusion and exclusion criteria for telehealth monitoring?

The GP's assessment of the patient's suitability for participation in the trial of telehealth monitoring

In the examination of telehealth monitoring, the Directorate of Health has decided that the general practitioner, who is responsible for the patients on his list, must assess whether each patient proposed is suitable to participate in the trial. In this section we ask about your opinions on this.

10. Do you think it is right that you as a GP should be involved in the assessment of the patient's suitability for telehealth monitoring?

- Yes
- No

11. You stated that you do not think it is appropriate that you as a GP should evaluate the patient's suitability for telehealth monitoring. Can you elaborate?

Recruitment to medical distance monitoring

In this section we ask questions related to the recruitment to telehealth monitoring.

12. To what extent do you feel your patients are interested in receiving telehealth monitoring (disregarding that the trial is conducted as a randomized controlled trial)?
    - Not at all
    - To a small extent
    - To some extent
    - To a large extent
    - Do not know

13. Have you identified and recruited patients on your list?
    - Yes
    - No

14. How many patients have you recruited?

15. Have you systematically reviewed your patient list to identify patients who may be eligible for telehealth monitoring?

16. In what way did you go through your patient list (eg using Medrave)?

17. To what extent has the recruitment of patients for telehealth monitoring been time-consuming?
    - Not at all
    - To a small extent
    - To some extent
    - To a large extent
    - Do not know

18. Do you have any other comments related to the recruitment of patients for the trial of telehealth monitoring?

19. How many patients on your list are currently participating in the telehealth monitoring trial (and are included in the intervention group)?

20. How much time do you spend in an average month on telehealth monitoring (both recruitment and follow-up of patients receiving distance monitoring)?
    - Less than half an hour
    - Between half an hour and one hour
    - Between one and two hours
    - Between three and five hours
    - More than five hours

21. Do you experience any change in the total amount of time you spend (the number of consultations and the time per consultation) on an average patient using telehealth monitoring?
    - Time spent is significantly reduced
    - Time spent is somewhat reduced
    - No noticeable change in time spent
    - Time spent is somewhat increased

- ☐ Time spent is significantly increased

22. Do you have access to your patients' measurements?
    - ☐ Yes, I have direct access via journal system or similar
    - ☐ Yes, but only if the patient brings their tablet
    - ☐ No

23. To what extent is it useful for you to have access to your patients' measurements?
    - ☐ Not at all
    - ☐ To a small extent
    - ☐ To some extent
    - ☐ To a large extent
    - ☐ Do not know

Collaboration and interaction

The goals of telehealth monitoring are better patient experience, better (or more stable) physical and mental health, and lower costs for the health care services. One way to achieve these goals is by better collaboration and collaboration between different parts of the health care services.

In this section, we ask how you feel that the collaboration with other health care services related to telehealth monitoring works.

24. How often do you contact the follow-up service in the following situations?
    - Recruitment of patient / user for the trial
        - ☐ Never
        - ☐ Less than once per month
        - ☐ 1-2 times per month
        - ☐ 3-4 times per month
        - ☐ More than 4 times a month
    - Design of follow-up plan for patient / user participating in the trial
        - ☐ Never
        - ☐ Less than once per month
        - ☐ 1-2 times per month
        - ☐ 3-4 times per month
        - ☐ More than 4 times a month
    - Follow-up of patient / user participating in the trial
        - ☐ Never
        - ☐ Less than once per month
        - ☐ 1-2 times per month
        - ☐ 3-4 times per month
        - ☐ More than 4 times a month

25. How does telehealth monitoring affect your interaction with:?
    - Home nursing care unit
        - ☐ Much worse interaction
        - ☐ Somewhat worse interaction
        - ☐ No change in interaction
        - ☐ Some better interaction
        - ☐ Much better interaction
    - Specialist health service

- Much worse interaction
- Somewhat worse interaction
- No change in interaction
- Some better interaction
- Much better interaction

26. How do you feel that telehealth monitoring affects the coordination and consistency of the service provision of the individual patient?
    - I find that the degree of coordination and coherence is reduced
    - I find that there is no change in the degree of coordination and context
    - I find that the degree of coordination and coherence is increasing

27. Do you have any other comments related to the interaction with other healthcare providers?

Satisfaction with and benefits of telehealth monitoring for patients/users

In this section, we ask about how you perceive that telehealth monitoring affects the users.

28. To what extent do you feel that the users are satisfied with telehealth monitoring?
    - Not at all
    - To a small extent
    - To some extent
    - To a large extent
    - Do not know

29. To what extent do you feel that telehealth monitoring contributes positively to users ...?
    - Physical health
        - Not at all
        - To a small extent
        - To some extent
        - To a large extent
        - Do not know
    - Mental health
        - Not at all
        - To a small extent
        - To some extent
        - To a large extent
        - Do not know
    - Security
        - Not at all
        - To a small extent
        - To some extent
        - To a large extent
        - Do not know
    - Coping with own illness
        - Not at all
        - To a small extent
        - To some extent
        - To a large extent
        - Do not know

30. To what extent do you feel that telehealth monitoring helps patients / users become more involved in the follow-up of their own illness?
    - ☐ Not at all
    - ☐ To a small extent
    - ☐ To some extent
    - ☐ To a large extent
    - ☐ Do not know

31. Do you experience a change in the proportion of immediate help appointments among patients receiving telehealth monitoring?
    - ☐ I experience a reduction in the proportion of immediate help appointments
    - ☐ I do not experience any change
    - ☐ I experience an increase in the proportion of immediate help appointments

Claims related to telehealth monitoring

32. Consider the following claims regarding telehealth monitoring.
    - Telehealth monitoring can contribute to unnecessary disease focus among some users
        - ☐ Strongly disagree
        - ☐ Disagree
        - ☐ Neither agree nor disagree
        - ☐ Agree
        - ☐ Strongly agree
    - Telehealth monitoring can contribute to increased security for relatives
        - ☐ Strongly disagree
        - ☐ Disagree
        - ☐ Neither agree nor disagree
        - ☐ Agree
        - ☐ Strongly agree
    - Telehealth monitoring can help to more accurately assess users' needs for health care
        - ☐ Strongly disagree
        - ☐ Disagree
        - ☐ Neither agree nor disagree
        - ☐ Agree
        - ☐ Strongly agree
    - Telehealth monitoring can help to identify the need for health care that the user would otherwise not require
        - ☐ Strongly disagree
        - ☐ Disagree
        - ☐ Neither agree nor disagree
        - ☐ Agree
        - ☐ Strongly agree
    - Telehealth monitoring can help save resources for the GP services
        - ☐ Strongly disagree
        - ☐ Disagree
        - ☐ Neither agree nor disagree
        - ☐ Agree
        - ☐ Strongly agree

33. What do you think are the biggest challenges for implementing telehealth monitoring as a national measure in the future?

34. Do you have any other comments related to telehealth monitoring?

Background information

35. In which municipality do you work?
    - ☐ Bodø
    - ☐ Eid
    - ☐ Kristiansand
    - ☐ Larvik
    - ☐ Oslo
    - ☐ Ullensaker
    - ☐ Gjerdrum
    - ☐ Other municipality in Agder
    - ☐ Other municipality

36. In which urban district do you work?
    - ☐ Alna
    - ☐ Bjerke
    - ☐ Frogner
    - ☐ Gamle Oslo
    - ☐ Grorud
    - ☐ Grünerløkka
    - ☐ Nordre Aker
    - ☐ Nordstrand
    - ☐ Sagene
    - ☐ St. Hanshaugen
    - ☐ Søndre Nordstrand
    - ☐ Ullern
    - ☐ Vestre Aker
    - ☐ Østensjø

37. Do you participate as a GP in the trial of primary health care teams?
    - ☐ Yes
    - ☐ No

38. What is your gender?
    - ☐ Male
    - ☐ Female

39. How old are you?
    - ☐ Younger than 30 years
    - ☐ 30-39 years
    - ☐ 40-49 years
    - ☐ 50-59 years
    - ☐ 60 years or older

40. How many years have you worked as a GP?
    - ☐ Less than 1 year
    - ☐ 1-2 years

- 3-4 years
- 5-9 years
- 10 years or more

41. What is your highest level of completed education?
    - Cand. Med.
    - Authorized physician LIS1
    - Specialist in general medicine
    - Specialist in other domain

42. Do you have any comments related to this survey?

Appendix D: Follow-up service questionnaire

Telehealth trial: Questionnaire for employees in the follow-up service

Inclusion and exclusion criteria:

The target group of the telehealth trial is patients with chronic diseases, with medium or high risk of worsening of one's condition, risk of re-hospitalization or increased need for health and care service. These patients have a high consumption of health care services and the target group consist largely of patients with non-communicable chronic diseases such as diabetes, colic, cardiovascular disease, mental disorders and cancer. This group often has several diagnoses, complex and large needs, and in need of follow-up of their diseases.

Patients who are not competent to consent, patients who cannot use the tablet or the measuring devices, together with patients with substance use disorders, shall not be included in the trial.

In this part of the questionnaire we ask how you experience these inclusion and exclusion criteria.

1. To what extent do you experience that the inclusion and exclusion criteria are well suited for telehealth monitoring?
   - ☐ Not at all
   - ☐ To a small extent
   - ☐ To some extent
   - ☐ To a large extent
   - ☐ To a very large extent

2. You have stated that you do not at all, or to a small extent, feel that the inclusion criteria for participation in the telehealth trial are suitable. Can you elaborate?

3. Do you have any comments related to the inclusion and exclusion criteria for the telehealth trial?

The general practitioner's assessment of the patient's suitability for participation in the trial of medical distance follow-up:

In the telehealth trial the Directorate of Health has decided that the general practitioner, as a medical professional responsible for the patients on his/her list, must assess whether each proposed patient is suited to participate in the trial. In this section we ask about your opinions on this.

4. Do you think it is right that it is mandatory that the GP participates in the assessment of the patient's suitability for telehealth monitoring?
   - ☐ Yes
   - ☐ No

5. You answered that you do not think it is right that it is mandatory that the GP participates in the assessment of the patient's suitability for telehealth monitoring. Can you elaborate?

Your time spent:

In this part we ask about we ask you how you allocate your working time to different tasks. Think of an average work week.

6. How large is your overall job percentage related to telehealth follow-up?

- ☐ 0-20
- ☐ 21-40
- ☐ 41-60
- ☐ 61-80
- ☐ 81-100

7. Indicate (approximately) the percentage of your total working time spent on the following tasks related to telehealth monitoring? [indicate one number per line]
   - Recruiting new patients (including information meetings, training/instruction, ancillary working and interdisciplinary work with the patients plan for follow-up)
   - Phone calls with patients
   - Assessment of measurements / results
   - Communication with the GP (not interdisciplinary meetings in connection to starting the patient up with telehealth monitoring), other primary health care or specialist health care
   - Other

Collaboration and interaction

The goals of telehealth monitoring are improved patient experience, improved (or more stable) physical and mental health, and lower costs for the health care services. One way to achieve these goals is by improved collaboration and collaboration between different parts of the health care services.

In this section, we ask how you feel that the collaboration with other health care services related to telehealth monitoring works.

8. How does interaction with the following actors work related to the organization of telehealth monitoring in your municipality:

	Very poorly	Poorly	Neither poorly nor well	Well	Very well
Home care services (home nursing, BPA, everyday rehabilitation etc.)					
The GP service					
Specialist health service					

9. You have answered that the interaction with one or more actors works poorly or very poorly. Can you elaborate?

10. How does interaction with the following actors work related telehealth monitoring of each individual patient:

	Very poorly	Poorly	Neither poorly nor well	Well	Very well
Home care services (home nursing, BPA, everyday rehabilitation etc.)					
The GP service					
Specialist health service					

11. You have answered that the interaction with one or more actors works poorly or very poorly. Can you elaborate?

12. How do you feel that telehealth monitoring affects the coordination and consistency of the service provision of each individual patient?

    - I find that the degree of coordination and coherence is reduced
    - I find that there is no change in the degree of coordination and context
    - I find that the degree of coordination and coherence is increasing

13. Do you have any further comments related to the interaction with other actors in the health service?

Satisfaction with and benefits of telehealth monitoring for patients/users

In this section, we ask about how you perceive that telehealth monitoring affects the users.

14. To what extent do you feel your patients are interested in receiving telehealth monitoring (disregarding that the trial is conducted as a randomized controlled trial)?
    - ☐ Not at all
    - ☐ To a small extent
    - ☐ To some extent
    - ☐ To a large extent
    - ☐ Do not know

15. To what extent do you feel that the users are satisfied with telehealth monitoring?
    - ☐ Not at all
    - ☐ To a small extent
    - ☐ To some extent
    - ☐ To a large extent
    - ☐ Do not know

16. To what extent do you feel that telehealth monitoring contributes positively to users ...?
    - Physical health

- ☐ Not at all
- ☐ To a small extent
- ☐ To some extent
- ☐ To a large extent
- ☐ Do not know

- Mental health
  - ☐ Not at all
  - ☐ To a small extent
  - ☐ To some extent
  - ☐ To a large extent
  - ☐ Do not know
- Security
  - ☐ Not at all
  - ☐ To a small extent
  - ☐ To some extent
  - ☐ To a large extent
  - ☐ Do not know
- Coping with own illness
  - ☐ Not at all
  - ☐ To a small extent
  - ☐ To some extent
  - ☐ To a large extent
  - ☐ Do not know

17. To what extent do you feel that telehealth monitoring helps patients / users become more involved in the follow-up of their own illness?
    - ☐ Not at all
    - ☐ To a small extent
    - ☐ To some extent
    - ☐ To a large extent
    - ☐ Do not know

Claims related to telehealth monitoring

18. Consider the following claims regarding telehealth monitoring.
    - Telehealth monitoring can contribute to unnecessary disease focus among some users
      - ☐ Strongly disagree
      - ☐ Disagree
      - ☐ Neither agree nor disagree
      - ☐ Agree
      - ☐ Strongly agree
    - Telehealth monitoring can contribute to increased security for relatives
      - ☐ Strongly disagree
      - ☐ Disagree
      - ☐ Neither agree nor disagree
      - ☐ Agree
      - ☐ Strongly agree
    - Telehealth monitoring can help to more accurately assess users' needs for health care
      - ☐ Strongly disagree
      - ☐ Disagree
      - ☐ Neither agree nor disagree

- Agree
- Strongly agree

- Telehealth monitoring can help to identify the need for health care that the user would otherwise not require
  - Strongly disagree
  - Disagree
  - Neither agree nor disagree
  - Agree
  - Strongly agree

19. What do you think are the biggest challenges for a national implementation of telehealth monitoring in the future?

20. Do you have any other comments related to telehealth monitoring?

Background information

In this section we ask a few background questions for use in the statistical analysis

21. In which municipality do you work?
    - Bodø
    - Eid
    - Kristiansand
    - Larvik
    - Oslo
    - Ullensaker
    - Gjerdrum
    - Other municipality in Agder
    - Other municipality

22. What is your gender?
    - Male
    - Female

23. How old are you?
    - Younger than 30 years
    - 30-39 years
    - 40-49 years
    - 50-59 years
    - 60 years or older

24. What is your highest level of completed education?
    - Licenced practical nurse
    - Bachelor's in nursing
    - Master's in nursing
    - Other

25. Do you have any comments related to this survey?